Take 3 – Practical Practice Pointers[®] November 18, 2019 Edition <u>Tetanus and Medicare</u>, <u>Colon CA Screening</u>, <u>SAD</u>

An Immunization Question from a Colleague and Follow-up

1) Why Doesn't Medicare Cover Tetanus Shots!?

Question: With the new ACIP recommendations that Tdap can be used for all tetanus shots instead of Td, I'm still not clear why Medicare does not cover either of these?"

Answer: To help answer this question, I reached out to one of our colleagues, Roger Hofford, MD, who has been involved in many policy initiatives over the years and is my "go to" colleague for all things legislative.

Roger answered: Even though ACIP/CDC recommend either one, it does not mean Medicare covers Tdap. Congress would have to change the law since they consider it preventive and not medically indicated except for an injury. Several years ago, I met with one of our Congressman asking them to consider placing legislation after there was an outbreak of pertussis in Roanoke and Floyd County and was turned down.

Additional research found that if a Medicare patient steps on a rusty nail (injury), then the Td booster would be covered under Part B (but <u>not</u> Tdap). Otherwise, the shot falls under a Part D coverage which won't reimburse this in the office. Influenza, Pneumovax, and Hepatitis B are all covered under Part B. In our region, since our Pharmacies don't carry the Td, Medicare patients who want this vaccination could get it at the Health Department. The Shingles vaccine is covered by Part D with great variability in reimbursement but can be obtained (with cost depending on a patient's Part D details) at pharmacies.

My Comment:

Variable insurance coverage has impacted why many ambulatory clinics (including those in Carilion Family Medicine) have chosen to not stock vaccines, including the zoster (Shingrix) vaccination. This becomes even more of a problem if a patient fails to sign an Advance Beneficiary Notice of Noncoverage (*ABN*) Form and then receives an unexpected bill. In many cases, present insurance reimbursement is less than the cost of the vaccination for our clinics. Medicare part D covers flu and pneumovax/prevnar but requires members go to the pharmacy for other vaccines. Some health systems set up for billing as a pharmacy to be able to administer and bill other vaccinations. Carilion has not historically done this.

Reference:

Medicare Learning Network - Payment for Part D Vaccines under the Medicare Drug Benefit: Link

From the Literature and the American College of Physicians (ACP)

2) Screening for Colorectal Cancer – New Guidance

The American College of Physicians (ACP) recently published a "guidance statement" regarding colorectal cancer screening by synthesizing evidence from recent guidelines, including those from the US Preventive Services Task Force, the American Cancer Society, the American College of Radiology, the Canadian Task Force on Preventive Health Care, the Scottish Intercollegiate Guidelines Network, and the US Multi-Society Task Force on Colorectal Cancer. The quality of the guidelines was assessed using the AGREE II (Appraisal of Guidelines for Research and Evaluation II) instrument with priority given to recommendations on the basis of direct evidence from research studies over modeling data. Recommendations include:

- Screen for colorectal cancer in average-risk adults between the ages of 50 75.
- Select the screening test with the patient on the basis of a discussion of benefits, harms, costs, availability, frequency, and patient preferences. Suggested screening tests and intervals are fecal immunochemical testing (FIT) or high-sensitivity guaiacbased fecal occult blood (HS-FOBT) testing every 2 years, colonoscopy every 10 years, or flexible sigmoidoscopy every 10 years plus fecal immunochemical testing every 2 years.
- Discontinue screening in average-risk adults older than 75 years or in adults with a life expectancy of 10 years or less.
- These recommendations do not apply to patients with a personal or FH of CRC, previous diagnosis of adenomatous polyps, or symptoms compatible with CRC.

The guidance specifically states that more research beyond diagnostic accuracy assessment is needed to evaluate the clinical benefits and harms of FIT plus sDNA (Cologuard) and CT colonography. Until then, it notes other screening methods have stronger direct and indirect evidence of clinical effectiveness in reducing CRC mortality. With regard to the potential harms of Cologuard, the authors specifically state, "Data on harms are limited because most information comes from a single diagnostic accuracy study in which the authors had potentially important conflicts of interest. Additional harms unique to FIT plus sDNA (vs. HSgFOBT or FIT) arise from the sDNA component of the test, which lowers its specificity for CRC screening (more "false positives"). A positive result despite negative findings on colonoscopy may be due to neoplastic changes not visible on colonoscopy or the presence of noncolonic aerodigestive or supracolonic neoplasms. Patients with positive sDNA results and negative findings on a follow-up colonoscopy may have more aggressive short-term surveillance because of heightened concerns related to unresolved false-positive findings."

An accompanying editorial notes the controversy regarding screening intervals, as most guidelines recommend FIT or HS-FOBT yearly (rather than every 2 years) if these are used for screening.

My Comment:

When viewed through a population health lens, the greatest challenge with CRC screening is the large number of patients who have never had any initial screening. Given the many choices available, some which are very inexpensive, this is a tragedy. Cologuard is by far the most aggressively marketed test, but as noted above, this does not make it necessarily the preferred choice. The authors acknowledge there are areas of insufficient evidence; specifically, trials that directly compare the efficacy and risks of different screening methods, as well as trials that address race, ethnic, and sex differences in screening and mortality.

References:

- Qaseem A, et al. Screening for Colorectal Cancer in Asymptomatic Average-Risk Adults: A Guidance Statement From the American College of Physicians. Ann Intern Med. 5 November 2019;171(9):643-654. <u>Link</u>
- Pignone M. Accompanying Editorial: Link

From the Literature and Timely Topic Review

3) Seasonal Affective Disorder (SAD)

Seasonal affective disorder (SAD) is a seasonal pattern of major depressive episodes associated with either bipolar or recurrent major depressive disorder. It occurs more often in women than men and usually in January and February. It appears to be cause by seasonal changes in daylight.

The best metaphor for SAD is hibernation, which may be thought of as the biologic correlate of wintertime SAD. Unlike people with classical depression, who typically eat less and sleep less, people with SAD eat more and sleep more, much like animals hibernating for the winter. People with SAD are not actually sad; mainly, they just feel tired and less interested in things (ie, anhedonic) and because of this often don't realize they have depression.

In *DSM-5*, SAD is now known as depressive disorder with seasonal pattern, for which the diagnostic criteria are as follows:

- A regular temporal relation between the onset of major depressive episodes and a particular time of year
- Full remissions that also occur at a characteristic time of year
- No episodes of depression during the time of year when the individual experiences a normal mood
- Seasonal major depressive episodes substantially outnumber the nonseasonal major depressive episodes that may have occurred over the individual's lifetime

It is important to note there can be an association with bipolar disorder, and for those who experience spring/summer mania as part of their pattern, treating this is important as part of the care plan.

No large studies have found any one treatment to be superior. Daily light therapy of at least 5,000 lumens for 30 minutes in the morning has been shown to be helpful as has dawn light simulation. This time should be adjusted based on response. The cost of these devices is now as low as \$60. Response can be within 1-2 weeks.

Antidepressants such as bupropion, fluoxetine, sertraline may improve symptoms of SAD. There is weak evidence for the benefits of melatonin, tryptophan, and vitamin D supplementation. Often the combination of medications and light therapy is necessary. A randomized trial showed that cognitive behavioral therapy (CBT-SAD) and light therapy are comparably effective for SAD during an acute episode, and both may be considered as treatment options. A Cochrane review found that the evidence was limited regarding using light therapy or CBT as a preventive measure. Additionally, a randomized, placebo-controlled trial suggests that bright light treatment, both as

monotherapy and in combination with fluoxetine, was efficacious and well tolerated in the treatment of adults with <u>nonseasonal</u> MDD, with the combination treatment having most consistent effects.

Other recommended interventions to help with both treatment and prevention include sleep hygiene, daily walks outside, even on cloudy days, aerobic exercise, enhanced indoor lighting with regular lamps and fixtures, and a special kind of light therapy called dawn simulation.

Many people experience fall/winter symptoms that are below the full syndrome threshold for a clinical depressive episode. These are the individuals for whom the term *winter blues* was coined. The interventions in the previous paragraph are recommended for this as well.

My Comment:

It is exciting that we continue to understand more about circadian rhythms and the impact of light on our mental health. Be on the lookout for these symptoms in your patients over the next 3 months and be sure to get some regular outdoor "light therapy" of your own!

References:

- Rohan KJ, et al. Randomized Trial of Cognitive-Behavioral Therapy Versus Light Therapy for Seasonal Affective Disorder: Acute Outcomes. Am J Psychiatry. September 2015; 172(9):862-9. <u>Link</u>
- Lam RW, et al. Efficacy of Bright Light Treatment, Fluoxetine, and the Combination in Patients With Nonseasonal Major Depressive Disorder JAMA Psychiatry. Published online November 18, 2015. Link
- Cochrane Reviews Light therapy and psychological therapies for prevention of winter depression. March 18, 2019. <u>Link</u> and May 24, 2019. <u>Link</u>

Feel free to forward Take 3 to your colleagues. Glad to add them to the distribution list.

Mark

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