Take 3 – Practical Practice Pointers© February 24, 2020 Edition

Continuous Glucose Monitoring, Adult Immunizations, GI Cocktails

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From the Guidelines

1) Continuous Glucose Monitoring (CGM) Update

Glucose monitoring is key for the achievement of glycemic targets for many people with diabetes. Glycemic management is primarily assessed with the A1C test, the primary measure studied in clinical trials demonstrating the benefits of improved glycemic control. Self-monitoring of blood glucose (SMBG) may help with self-management and medication adjustment, particularly in individuals taking insulin.

Continuous glucose monitoring (CGM) has emerged as a complementary method for the assessment of glucose levels. CMG has an important role in assessing the effectiveness and safety of treatment in many patients with type 1 diabetes (T1D), and limited data suggest it may also be helpful in selected patients with T2D, such as those on intensive insulin regimens.

Currently available CGMs can show trends as glucose levels rise or fall and can display graphs showing glucose levels over specified periods of time. Most CGMs check glucose approximately every 1-5 minutes, display readings, and alert patients when glucose levels are higher or lower than preset thresholds. The *FreeStyle Libre* systems are a little different. They don't alert patients to highs and lows. Readings are only captured when patients scan for them. Additionally, most CGMs still require fingerstick glucose readings in order to make treatment decisions. Only the *Dexcom G5 Mobile*, *Dexcom G6*, and *FreeStyle Libre* systems are approved to be used alone (without fingerstick glucose readings) to adjust meds and make treatment decisions.

Many endocrinology experts believe CGM should be available to <u>all patients using insulin</u> regardless of diabetes type. Most of the data supporting the use of CGM are in patients with T1D. CGM may be appropriate for the following patients with T2D:

- Patients at risk from hypoglycemia (athletes, elderly, renal impairment)
- Patients with hypoglycemia unawareness (except Freestyle Libre)
- Patients with severe or frequent hypoglycemia
- Patients unable to reach A1C goals because of hypoglycemia
- Patients using multiple insulin injections

According to the 2020 ADA Standards of care for patients with DM:

- When used properly, real-time and intermittently scanned CGM in conjunction with insulin therapy are useful tools to lower A1C and/or reduce hypoglycemia in adults with T2D who are not meeting glycemic targets. **B**
- Time in range (TIR) is associated with the risk of micro-vascular complications and should be an acceptable end point for clinical trials and can be used for assessment of glycemic control. Additionally, time below target (70 and 54) and time above target (180) are useful parameters for reevaluation of the treatment regimen. **E**

TIR of 70% correlates with an A1C of 7%, while TIR of 50% correlates with an A1C of about 8%. In general, it is recommended to avoid blood glucose values less than 54 and aim for less than one hour per day with blood glucose values <70.

The patient's specific needs and goals should dictate SMBG frequency and timing or the consideration of CGM use.

My Comment:
Most endocrinology experts believe CGM should be available to all patients using insulin regardless of diabetes type. I respectfully disagree. Most patients with T2D, even those on stable doses of long-acting insulin, likely do not need nor will benefit from this technology.

I reached out to Randi Earls, PharmD, who is one of our FM residency faculty and a Certified Diabetic Educator, for her thoughts: "Since monitoring is more art than science I think a good rule of thumb is to ask patients to check their blood sugar levels only if the results will be important to making treatment adjustments. If a person with T2D is on multiple daily insulin injections we know that those patients should routinely monitor glucose. However, the evidence is unclear about whether multiple daily checks (either by CGM or finger stick) can improve blood sugar readings/A1c or reduce hypoglycemic episodes in other patients wth T2DM such as those on oral therapy or basal insulin. However, if you have a very astute patient who would like insight on the impact of meds and lifestyle choices then perhaps increased monitoring with a CGM can help. However, so can regular finger sticks with a lot less cost and know how."

Wise words, Randi. As has been covered in past Take 3 editions (and is part of the Choosing Wisely recommendations), most patients with T2D do not require or benefit from self-monitoring of glucose levels at all, and in particular once stabilized on their medication or if adjustments are not being regularly performed based on the measurements.

References:

- ADA Standards for Medical Care in Diabetes – 2020: Abridged for Primary Care Providers. Clinical Diabetes published ahead of print December 20, 2019. Link
- ADA Standards of Care 2020: Diabetes Care. January 1, 2020; volume 43 issue Supplement 1. Link
- Clinical Resource**,** *Continuous Glucose Monitoring FAQs. Pharmacist's Letter/Prescriber's Letter.* September 2019. By subscription.

From the Centers for Disease and Prevention (CDC)

2) New 2020 Immunization Schedules for Adults

Every year, in the first week of February, the CDC and the Advisory Committee on Immunization Practices (ACIP) releases the updated schedule of immunization recommendations for adults.***** The ACIP meets three times a year, and makes recommendations that become official upon their publication in the MMWR – usually 1-2 months later. However, this yearly event serves as a good time to review the last year's recommendation major changes.

HPV – The FDA approved HPV vaccine through age 45 for both sexes in 2018. The ACIP has now recommended universal vaccination through age 26. The vaccine works better at younger ages – so much so that if two vaccines are given at least 5 months apart under age 15, a third dose is not needed. If given after age 15, the full three-dose schedule is required, but only three doses. There is no benefit to giving more than three lifetime doses of HPV vaccine. Between ages 27 and 45, the ACIP has recommended a "shared decision making" conversation about vaccination. This conversation should emphasize the ongoing risk of HPV acquisition (related to new sexual partners), the improved effectiveness with early vaccination and vaccination before exposure to specific subtypes, the lack of a clinical test of immunity, and the inability of the vaccine to prevent complications from an existing infection.

Td and TdaP – The ACIP recommends using either vaccine to complete the every-10-year recommendation for tetanus booster after the adolescent Tdap vaccine (usually age 11-12).

PCV13 – This was covered in Take 3 #313, but basically, PCV13 is recommended after age 65 for everyone with immune compromising conditions (including splenectomy, immune-suppressing medication use, a cerebrospinal fluid leak, or a cochlear implant), but a shared decision-making conversation is recommended for immunocompetent patients age 65 or older. Considerations for shared decision making for immunocompetent adults include: residing in nursing homes or other long-term care facilities, living in areas with low pediatric uptake of PCV13 vaccination, travelling to areas with low PCV13 vaccination rates, and having one of the following medical conditions: chronic heart disease (CHF and cardiomyopathies), lung disease (COPD and asthma), liver disease (cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, transaminase elevation greater than twice upper limit of normal), diabetes, alcoholism, and/or smoking.

MenB – A "blue box" – signifying a shared decision-making recommendation – is added to the schedule to emphasize the previous recommendation about shared decision-making for this vaccine for low-risk individuals ages 16-23 (but only noted as 19-23 here, because it's the adult table).

HepA – A yellow box was added to the schedule to reflect the new general recommendation for Hepatitis A vaccine for adults living with HIV at any CD4 level. Hepatitis A vaccination continues to be recommended as part of protection against an outbreak, for chronic liver disease, for homeless adults, for men who have sex with men, as prevention against travel exposure, and for certain healthcare workers.

John's Comments:
The ACIP continues to try to make the schedule more useful and readable – concentrating on formatting and trying to reduce the word count in the Notes section. You should be able to find most of the clinical information about vaccines just using the graphical schedule and notes. I find it very helpful to post the schedule (using the mailed copies from the AAFP and the downloadable schedules available online at the reference below) near my desk and refer to them often.

> ***Disclaimer** – I am a member of the Adult Immunizations Workgroup for the ACIP, which advises on the production of the schedule every year.

Reference:
CDC Recommended Adult Immunization Schedule for ages 19 years or older, United States, 2020. Link

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From the Literature, Question from a Colleague, and FCM-CAPS

3) The Use of the "GI Cocktail" – A Brief Reminder

Question: "What is the correct composition for a GI Cocktail for patients who present with atypical chest pain?"

Answer: Differentiating acute chest pain caused by myocardial ischemia from other, potentially more benign causes of chest pain is a frequent diagnostic challenge faced in the clinical setting. Even in the emergency department, only 30% of patients presenting with chest pain will have a cardiac origin for the pain, and gastroesophageal disorders are one of the common sources of non-cardiac chest pain, yet remain clinically difficult to differentiate from cardiac pain.

A systematic review of the use of the "GI Cocktail" to help differentiate cardiac from gastroesophageal chest pain was published in 2014. The authors concluded: *"The use of a GI cocktail compared with standard diagnostic protocols (serial ECG and biomarkers and provocative testing or imaging) is not proven to improve accuracy of diagnosis, and cannot reliably exclude myocardial ischemia."* There has been nothing published since that would refute this conclusion.

Mark's Comments:
This may be another example of "old habits (which are usually based on when and where we trained) die hard." This topic was reviewed by our FCM Quality Committee as well as our management team and departmental executive committee, and the decision based on the evidence was to remove the many assorted "GI Cocktails" from our office formulary list. Mylanta and Maalox were retained.

Jonathan Stewart, MD, who serves as co-chair for our departmental Clinical Advance and Patient Safety (FCM-CAPS) committee concluded the following: *"Since there is no standard for the use of this approach and available literature has found no role for its use, I believe we should discourage use of this concoction rather than trying to 'standardize' the components."*

Reference:
Chan S, et al. The use of GI cocktail for differentiating GERD and ACS in the ED: a systematic review. Heart Lung Circ 2014 Oct;23(10):913-23. Article

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

Mark and John

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