

PCV13 and SDM, Best Diets 2020, Genetic Testing Fraud

From the ACIP and the CDC

1) Shared Decision Making (SDM) for PCV13 Vaccine in Adults \geq 65

In 2014, the Advisory Committee on Immunization Practices (ACIP) recommended a routine PCV13 (“Pneumovax 13”) vaccination starting at age 65 followed by a PPSV23 (“Pneumovax 23”). This was based primarily on a large but limited study, the CAPiTA trial, that demonstrated a reduction in pneumococcal pneumonia and invasive pneumococcal disease (meningitis, sepsis) with this regimen. After the recommendation, there were updates from the ACIP about the timing of the vaccines (because the ACIP recommended catch-up vaccination for those that had already received PPSV23) resulting in some lingering confusion. At the time of the initial approval, the ACIP had determined they would re-examine this recommendation because the ongoing routine vaccination of children with PCV13 would be expected to reduce the overall burden of disease over time.

At their June 2019 meeting, the ACIP reviewed the previous three years of epidemiologic data on pneumococcal disease and decided to convert the PCV13 recommendation to a “shared-decision making” recommendation for immunocompetent adults \geq 65. All adults with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), CSF leak or cochlear implants (regardless of age) should still receive a PCV13 as previously indicated. The “shared-decision making” terminology replaces the old “provisional” or “B” recommendation from the ACIP and is distinguished from the routine (or “general” or “A”) recommendations.

The ACIP has finally released some guidance about how clinicians and patients should decide together on the advisability of the PCV13 vaccine after age 65. They recommend the following points for discussion:

- PCV13 is safe and effective in older adults.
- The risk of PCV13-type disease in older adults is related to exposure to PCV13 type pneumococcal disease and their underlying medical conditions.
- Older adults who should consider routine PCV13 vaccination include those;
 - 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
 - with 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.

If the patient and clinician agree that vaccination with PCV13 is a good idea, the same rules apply to timing of vaccination as applied before the June recommendation. See the ACIP’s Adult Immunization Schedule or the vaccination apps available from the CDC (“CDC Vaccine Schedules”) or STFM/AAFP (“Shots Immunizations”) for guidance.

John's Comment:

Unfortunately, pneumococcal vaccination for older adults has gotten harder, not easier. The nursing home and travel-based recommendations seem logical to me. I don't know many areas in the US that will have low pediatric uptake of PCV13, but in this era of vaccine hesitancy, it's possible. The chronic disease part of the recommendation is based on the most indirect evidence, so this might be the best area of discussion with your patient – based on their overall health and interest in vaccine-based prevention.

As for the timing of the doses, I recommend really poring over this recommendation in the schedule or apps once, making your own notes, and talking about it with your clinical staff to get everyone on board. Also note that the CDC use of “shared decision making” is not consistent with the model being written about in the literature, including the lack of algorithms and statistics to guide the dialogue. Their approach seems more like “shared dialogue with advice.”

Reference:

- Matanock A et al. Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Updated Recommendations of the ACIP. MMWR 2019;68(46):1069-1075. [Link](#)
-

From the US News and World Report and Follow-up**2) Best Diet Rankings for 2020**

U.S. News recently released its annual assessment of the best diets, offering extensive data and information on 35 popular diet plans. The rankings were established by a panel of experts, including nutritionists, dieticians and physicians. They evaluated and scored the diets in seven areas, including: how easy it is to follow; likelihood of losing significant weight in the first 12 months; likelihood of losing significant weight for 2 years or more; how well it helps prevent and manage cardiovascular disease; how well it helps prevent and manage diabetes; nutritional completeness; and safety.

For the third consecutive year, the Mediterranean Diet ranks as the No. 1 Best Diet Overall. The Mediterranean Diet also rated best in multiple other categories; best plant-based diet, easiest diet to follow, best diet for healthy eating (tie), best diet for diabetes, and ranked 2nd for best diet for heart health. The DASH Diet and the Flexitarian Diet (a plant-based plan, with meat in moderation) were tied for 2nd best overall diet. The WW (Weight Watchers) diet was 4th.

WW (Weight Watchers) was the top-rated Best Weight-Loss Diet and Best Commercial Diet. Jenny Craig was the 2nd Best Commercial Diet, followed by the Nutritarian Diet.

It is important to note that there isn't "a" Mediterranean diet. The cultural lifestyle of people in countries bordering the Mediterranean Sea shares common principles, including an active lifestyle, weight control, and a diet high in produce, nuts and healthy oils and low in red meat, sugar, and saturated fat. A Mediterranean diet pyramid has been developed to help guide those desiring to follow this nutritional approach (see References).

The DASH Diet (Dietary Approaches to Stop Hypertension) is promoted by the NHLBI to stop or prevent HTN. It emphasizes vegetables, fruits, whole grains, lean protein and low-fat dairy. DASH also discourages foods that are high in saturated fat, such as fatty meats, full-fat dairy foods and tropical oils, as well as sugar-sweetened beverages and sweets and sodium. The NHLBI publishes free guides on the plan (See references).

Mark's Comment:

It is notable that diet plans that ranked the lowest included Atkins, Keto, Whole 30, and Dukan diets. Most of these include a limitation of carbs and an emphasis on protein and the long-term maintenance of ketosis. While these diets have become quite popular (and have been shown to be potentially effective with short-term weight loss), their long-term health impact continues to be concerning.

I asked Beth Polk, MD, one of our FM colleagues who is board certified in Lifestyle Medicine and faculty for the AAFP Family Physician Health and Well-being Conference (and will be speaking at the upcoming VAFP Wintergreen Conference) to provide commentary. Beth replied, *“What stands out for me is that there is a growing consensus that a diet that consists of predominantly plants is the healthiest overall and addresses most of the chronic diseases we see every day. Increasing fruits, vegetables, beans, nuts and seeds, decreasing meat intake and eliminating processed foods is the common thread in the top diets mentioned. The best advice we are able to give our patients is still ‘eat food, mostly plants, and not too much.’”*

This is the approach I follow personally. I've named it the “Pollanian diet” after the author Michael Pollan, who described this approach in his books [In Defense of Food](#).

References:

- U.S. News Best Diets Rankings for 2019. January 2, 2020. [News Release](#) Full List: [Link](#)
 - Oldways Mediterranean Diet: [Link](#) and Diet Pyramid: [Pyramid Link](#)
 - DASH Information long version: [Link](#) and short version: [Link](#)
-

From the OIS and Question from a Colleague: Cave Ergo Medicus

3) Genetic Testing Fraud – Let the Doctor (and Patient) Beware

Question: I've been receiving forms from “genetic testing companies” that contain patient information requesting that I “approve” the patient's request for genetic testing through the company. Are these requests legitimate?

Answer: When used correctly, genetic testing may offer opportunities to reshape the way healthcare is delivered and can potentially lead to substantial improvements in population health and individual health outcomes. Currently, most genetic tests are only applicable in specific circumstances and all genetic tests are generally only needed one time, as the results would typically not be expected to change in the absence of a new disease process.

The U.S. Department of Health and Human Services Office of Inspector General (OIS) has alerted the public about a fraud scheme involving genetic testing. Genetic testing fraud occurs when Medicare is billed for a test or screening that was not medically necessary and/or was not ordered by a Medicare beneficiary's treating physician.

Scammers are offering Medicare beneficiaries "free" screenings or cheek swabs for genetic testing to obtain their Medicare information for identity theft or fraudulent billing purposes. Fraudsters are targeting beneficiaries through telemarketing calls, booths at public events, health fairs, and door-to-door visits. Beneficiaries who agree to genetic testing or verify personal or Medicare information may receive a cheek swab, an in-person screening or a testing kit in the mail, even if it is not ordered by a physician or medically necessary. If Medicare denies the claim, the beneficiary could be responsible for the entire cost of the test, which could be thousands of dollars.

Additionally, some of these companies are obtaining patient data and then reaching out to physicians to have them sign a form indicating approval. The Healthcare Fraud Prevention Partnership (HFPP) described existing problems with the use of genetic testing that are not related to actual or potential medical diagnoses, overuse of genetic testing where the tests have no clinical value (possibly related to an actual or potential medical diagnosis, but not germane to treatment decisions), and repeated genetic testing of the same person. HFPP also has noted that direct-to-consumer marketing is increasing patient demand for potentially unnecessary genetic testing. In some instances, physicians are obliging by ordering the unnecessary test.

Mark's Comment:

The potential for fraud around genetic testing is stunning and this will likely only get worse. In the September, the OIG brought charges and CMS took adverse administrative action against CGx testing companies and providers who filed more than \$1.7 billion in claims to Medicare as part of an apparent \$2.1 billion fraud scheme. My encouragement is for all of us to be on the lookout for these requests, and to not "approve" any requests that you did on initiate as part of a legitimate work-up.

References:

Healthcare Fraud Prevention Partnership: White Paper - Examining Clinical Laboratory Services. May 2018. [Paper](#)

HHS Office of the Inspector General: Fraud Alert – Genetic Testing Scam. September 27, 2019. [Link](#)

Follow-up:

Thanks to the many readers who had comments regarding the Pointer on "Fasting for Health" from the 12/23/19 edition of Take 3. How timely that the NEJM published an article on intermittent fasting in the December 26 edition! It is a very well-written article for those who are new to this topic (and even for those who are more well-versed).

Reference:

de Cabo R and Mattson M. Effects of Intermittent Fasting on Health, Aging, and Disease. N Engl J Med 26 December 2019; 381:2541-2551. [Abstract](#)

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

Mark and John

Carilion Clinic Department of Family and Community Medicine