Take 3 – Practical Practice Pointers© July 29, 2019 Edition

HPV and PCV13, "Shared Decision-Making", Discontinuing Meds

From the Advisory Committee on Immunization Practices (ACIP)

1) New Recommendations for HPV and PCV13 Vaccinations

The CDC's Advisory Committee on Immunization Practices (ACIP) recently voted to update its recommendations for use of the nine-valent HPV (Gardasil 9) and 13-valent pneumococcal conjugate (PSV13/Prevnar) vaccines.

HPV: The HPV vaccination is approved by the FDA for use up to age 45 in both men and women, but up to now had not received a recommendation for this.

- The committee voted to recommend that HPV vaccination be offered to adults between the ages of 27-45 who have not been adequately vaccinated based on shared clinical decision-making.
- The committee voted to recommend harmonizing the upper age for catch-up HPV vaccination across genders; now, all males ages 21-26 are recommended for catch-up HPV vaccination regardless of risk factors. The age was previously 21.

PCV13: Previously, the recommendation has been to immunize all those over the age of 65 with the PCV13 followed by the pneumococcal polysaccharide vaccine (PPSV23 or Pneumovax23) at least 1 year later.

- The committee voted to recommend shared clinical decision-making for administration of the PCV13 vaccine for people 65 and older who aren't immunocompromised and who haven't previously received it.
- All those 65 and older are still recommended to receive a dose of PPSV23.
- The PPSV23 should still be given alone for persons age 19-64 who are at increased risk for pneumococcal infection and/or serious complications of pneumococcal infection. This would include:
    - Current cigarette smoking
    - Chronic heart disease, including CHF and cardiomyopathy (but not HTN)
    - Chronic lung disease, including asthma and COPD
    - Diabetes mellitus
    - Alcohol use disorder
    - Chronic liver disease, including cirrhosis
- BOTH PCV13 and PPSV23 should still be given to adults of any age who have the underlying conditions listed below (not all inclusive). It is preferred that the PCV13 should be given first, followed by PPSV23; the recommended interval between the vaccines is $\geq$ 8 weeks.
    - Congenital or acquired immunodeficiency HIV infection
    - Generalized malignancy
    - Hematologic malignancy
    - Iatrogenic immunosuppression, including long-term systemic glucocorticoids or radiation
    - Chronic renal failure

- Functional or anatomic asplenia, including sickle cell disease, other hemoglobinopathies, congenital asplenia, and acquired asplenia

My Comment:
Though these recommendations have not yet been finalized by the CDC, there is no reason to think that they won't be. A few important things to note:
1) HPV vaccination for adults older than 26 should be based on risk.
2) The PCV13 changes will further complicate that which in my observation is already a very confusing process.
3) Remember, patients who received 1 or 2 doses of PPSV23 for any indication at age 64 years or younger should receive an additional dose of PPSV23 vaccine at age 65 years or older if at least 5 years have elapsed since their previous PPSV23 dose.
4) The process of "Shared Decision-Making" continues to be used as a "catch-all phrase" that both the literature and the practicalities of clinical medicine would indicate is more aspirational than based in reality. We're presently left without guidance by the ACIP as to what data would be presented to a patient to even begin the process of such shared decision-making if they are at low risk. In the case of both HPV and PCV13, it would be wonderful (and perhaps should be required in any guideline or recommendation that includes shared decision-making) that they also provide the tools to engage in such a conversation! See Pointer 2 for more thoughts on this.

Reference:
Helio Infectious Disease News: 26 June, 2019. Link

From the Art of Medicine

2) Engaging in "Shared Decision-Making"

My Comment:
As is pointed out in Pointer 1, I continue to be concerned about how the term "shared decision-making" is being utilized by all groups, as they appear to imply this is a globally understood and easily accomplished process. It is not.

Shared decision-making (between clinician and patient and, in some cases, family members) appears to be an excellent strategy for making health care decisions when there is more than one medically reasonable option. The purpose of shared decision making is to ensure patients:

- understand their diagnosis;
- understand that they have a choice about their care;
- understand the risk/benefit tradeoffs involved in each of the choices; and
- come to a decision that is in keeping with their values and preferences.

Framed in this way, theoretically "shared decision-making" should be used for the majority of medical decisions, since, except in emergencies, there is usually more than one reasonable path. Understood in this way, however, there are many challenges to this process. What does it mean for a patient to "understand" a diagnosis? Can most patients truly understand the nuances of possible benefits and risks of different paths when these are often hard to quantify for a population, let alone for an individual patient,

and where we in medicine often can't even agree (e.g.: HTN guidelines, PCa screening, T2D goals, breast cancer screening, cancer treatment, etc.)? What if their values are in conflict with sound medical practice or societal values (opioids, antibiotics, etc.)?

Additionally, true "academically-defined" shared decision-making **takes time** – sometimes a lot of time depending on the decision. See the referenced "Ottawa Personal Decision Guide Aid" to appreciate just how detailed "true" shared decision-making could be! And what about all the data indicating that most people (and many clinicians) do not truly grasp probability, often greatly overestimating potential benefit and underestimating potential harm, and the influence we clinicians can have on how they view this?

Finally, though understandable, there is great danger in carving out a process of "shared decision-making" to a few more highly controversial or emotionally charged diagnoses or interventions, as many healthcare decisions are potentially "life-altering" over time.

Instead, acknowledging the limitations and uncertainty involved in patient care, let's use the 4 steps above as an "aspirational" general guide rather than a hard-and-fast rule for all patients in most circumstances, doing our best to ensure that they are routinely informed about and included in decisions about their care. That just seems like the right thing to do.

References:
AHRQ – The SHARE Approach to Shared Decision-Making: SHARE Approach
Ottawa Personal Decision Guide Aid: https://decisionaid.ohri.ca/docs/das/OPDG.pdf

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Question From a Colleague Reprise

3) Discontinuing Medications for Patients Who Don't Follow-Up

Question:
What should be the process for managing patients who are on ACE-I, ARBs, thiazide diuretics or digoxin who have not had a BMP/drug level in the past 12 months and have not followed-up despite requests to do so?

Answer:
It was recently brought to my attention that there are still many questions regarding this, so I am repeating a Pointer that was initially published in February of 2018. The clinical dilemma in the case of BP meds is that stopping/not refilling them could cause a patient to have uncontrolled HTN, but not stopping the medication could mean that their kidney function or serum electrolytes could be abnormal without our being aware of it. Both are potential safety issues.

Guidance from our Carilion Clinic A-CAPS committee (Ambulatory Clinical Advance and Patient Safety) includes the following:

- There should be a consistent approach across all clinicians/clinics/departments.
- We should be deliberate about educating our patients regarding follow-up and laboratory monitoring expectations at the initiation of treatment and/or when a refill

request is made and should document this in their health record (a dot-phrase in the EHR is the easiest way to do this).

- For patients on the particular medications noted above, a BMP blood test and drug levels when appropriate should be performed at least yearly or more frequently at the discretion of their clinician in the context of their overall health.
- If the patient requests a refill and is due for a follow-up and/or lab testing (13-15 months at most – 13 months if they have been given a "1 month + 12 refill" or 15 months if given a "90 days + 4 refill"), a phone call should be made and the patient informed that it is past time for a follow-up visit and lab study.
- At that time, they should be given a 1 month refill, instructed to follow-up within the month, and told if they don't follow-up in this time period, their medication will not be refilled until they do so. This conversation should also explore if there are particular barriers to the patient following-up, and an attempt made to address these barriers. Documentation of this conversation should be made in the chart, preferably with a smartphrase. A phone call is preferable to a letter to insure the patient received the message, but could be accompanied by a follow-up letter as well if desired.
- If the patient doesn't follow-up during this time period, the medication should not be refilled and should be removed from their active medication list.
- Once the patient does follow-up (if they do so), consideration should be given to placing them on a medication that does not require laboratory monitoring. Even so, the medication should not be continued beyond the period of time their clinician feels is safe without monitoring.
- Patients who don't follow-up should **not** be dismissed from the practice, in line with our present Carilion dismissal policy.
- A similar approach should be considered for other medications.

My Comment:
Being consistent as to how we navigate these patient care "dynamic tensions" is important from both a quality/safety and risk/legal perspective. How the use of the MyChart tool in our EHR fits into this process is unclear. The committee discussion also exposed the fact that there is not good science (nor clinical practice consistency) as to how we determine follow-up frequency for patients, and often this is guided by the need for laboratory monitoring and/or by "expert opinion."

This question also brings to light two other "Pointers" for your consideration: 1) Using the 90 days plus 4 refills approach to refill management (90+4) for many chronic medications, and 2) The importance of regular medication reconciliation within our patient's health record.

Reference:
Carilion Clinic Ambulatory Quality and Patient Safety Committee (A-CAPS):
Inside Carilion Link

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

Mark

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