Pneumococcal Vaccination Update FAQs for NM Health Care Professionals

(3/10/2022)

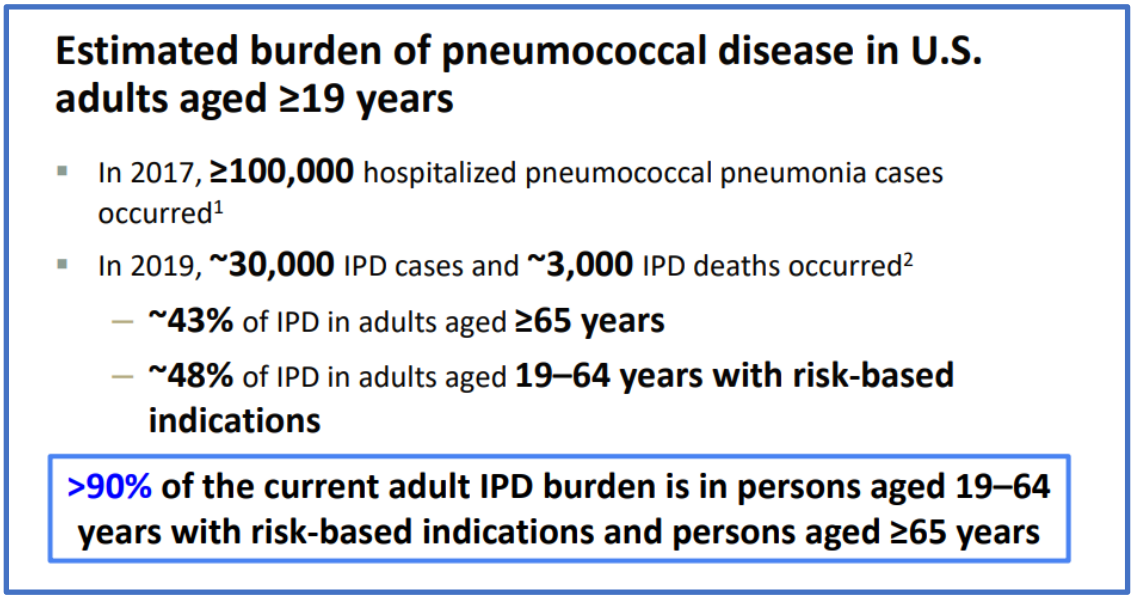
What's new about pneumococcal vaccination in the US?

In October, 2021, the Advisory Committee on Immunization Practices (ACIP) approved either PCV20 (Prevnar 20) alone or the combination of PCV15 (Vaxneuvance) + PPSV23 (Pneumovax) to replace PCV13 (Prevnar 13) + PPSV23 for adults 19 years and older who qualify for pneumococcal vaccination.[1] The ACIP is the committee within the US Centers for Disease Control and Prevention (CDC) that reviews and recommends vaccination schedules for US adults and children.

What is the burden in the US of pneumococcal disease among adults?

Streptococcus pneumoniae is the leading cause of bacterial pneumonia worldwide and results in serious morbidity and mortality due to invasive pneumococcal disease (IPD), which includes those with pneumococcal meningitis and/or bacteremic pneumonia.

Fig. 1 Estimated burden of pneumococcal disease in U.S. adults aged 19 years and older[1,2]



What is the pneumococcal vaccination strategy for NM in 2022?

1. PCV 20 is added to the inpatient and outpatient NM formulary. In early 2022, NMH Antimicrobial Subcommittee and the Executive Pharmacy and Therapeutics Committee selected PCV20 for the inpatient and outpatient formulary based on its efficacy, safety and simplicity of vaccination schedule. This will be the stand-alone pneumococcal vaccination of adults 19 years and older. This formulary change has been approved by NM System Executive P and T and is likely to be adopted throughout the NM System this spring. The use of PCV20 represents an expansion of coverage for conjugate vaccination. Previously, several groups of adults ages 19-64 years with chronic medical conditions received PPSV23 but did not receive PCV13.

2. PCV 13 will remain on formulary for pediatric patients. PCV 20 is not approved for use in children below the age of 19 years.
3. PPSV23 will remain on formulary for adults for series completion and for select pediatric patients.

Who qualifies to receive PCV20 vaccine?[3]

1. Adults between 19 years and 64 years with certain chronic diseases who have not previously received a conjugated pneumococcal vaccine or whose previous vaccination history is unknown should receive a single dose of PCV20. The listed chronic medical conditions include the following:
   alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking, chronic renal failure, nephrotic syndrome, congenital or acquired immunodeficiency, iatrogenic immunosuppression (including long-term systemic corticosteroids and radiation therapy), generalized malignancy, human immunodeficiency virus infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies, nephrotic syndrome, CSF leak, or cochlear implant.
2. Adults 65 years and above who have not received a previous conjugated pneumococcal vaccination or whose previous pneumococcal vaccination history is unknown should receive a single dose of PCV20.
3. Those adults who previously received only PPSV23 should receive a PCV20 vaccine. Note the recommended timing of PCV20: this vaccine should be administered at least 1 year after a patient's latest PPSV23 dose.
4. Adults who received PCV20 between age 19 and 64 years should not receive a second PCV20 at age 65.
5. Should select patients who previously received PCV13 as an adult with or without PPSV23 receive PCV20? The ACIP has not include a clear recommendation of this topic. The Work Group is in favor of "providing an opportunity to administer [PCV20]," but the full evaluation of safety, efficacy, and cost-effectiveness have not been performed. This category of patients includes those over 65 years old and those who are significantly immunodeficient.

In what settings should adults receive PCV20?

1. Outpatient: A vaccine that is administered once during adulthood should be administered early in the time period that a patient qualifies; the greatest number of missed opportunities for pneumococcal vaccination are in the outpatient setting. Thus, expanding the availability for receiving vaccinations at outpatient primary care and subspecialty clinics is advantageous.
2. Inpatient: Many patients, however, are without primary outpatient physicians or outpatient specialty care homes and thus would benefit from receiving PCV20 while hospitalized. In general, the ACIP recognizes that it is acceptable to administer vaccinations during hospitalization or at discharge if a patient is not moderately or severely acutely ill.

What is happening to PPSV23 at NM?

1. PPSV23 is available for children younger than 19 years old with certain chronic conditions, cochlear implants or immunocompromising conditions.
2. At this point, PPSV23 is available for adults for series completion for those patients who have already received PCV13 or PCV15 as adults but have not yet received PPSV23. The time interval between PCV13 or PCV15 and the subsequent PPSV23 dose depends upon the indication for adult pneumococcal vaccination. For adults with chronic medical conditions, one dose of PPSV23 should be administered 1 or more years after PCV13 or PCV15. Adults with immunocompromising conditions, cochlear implant or CSF leak may benefit from shorter interval, as early as 8 weeks after PCV13 or PCV15.[3]

Are there changes in Pediatric Pneumococcal Vaccination Schedules and what changes can be expected?

Presently there are no changes in the pneumococcal vaccination schedules for children. The ACIP Work Group tentatively plans to evaluate PCV15 for children later in 2022. The pediatric studies of PCV20 are underway.

Routinely, children receive four doses of PCV13 between ages 2 months and 15 months and thus are protected throughout childhood. There is a specific catch-up PCV13 schedule for children <5 years old those who missed the recommended doses.

Children 2-18 years old with underlying conditions such as diabetes mellitus, chronic lung disease including asthma with high-dose oral glucocorticoids, and chronic heart disease receive 1 dose of PPSV23; if PCV13 catch-up is needed, the latter vaccine is given at least 8 weeks prior to the PPSV23. For additional immunocompromised conditions, patients receive additional doses of PCV13 and PPSV23. Conditions include sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma.

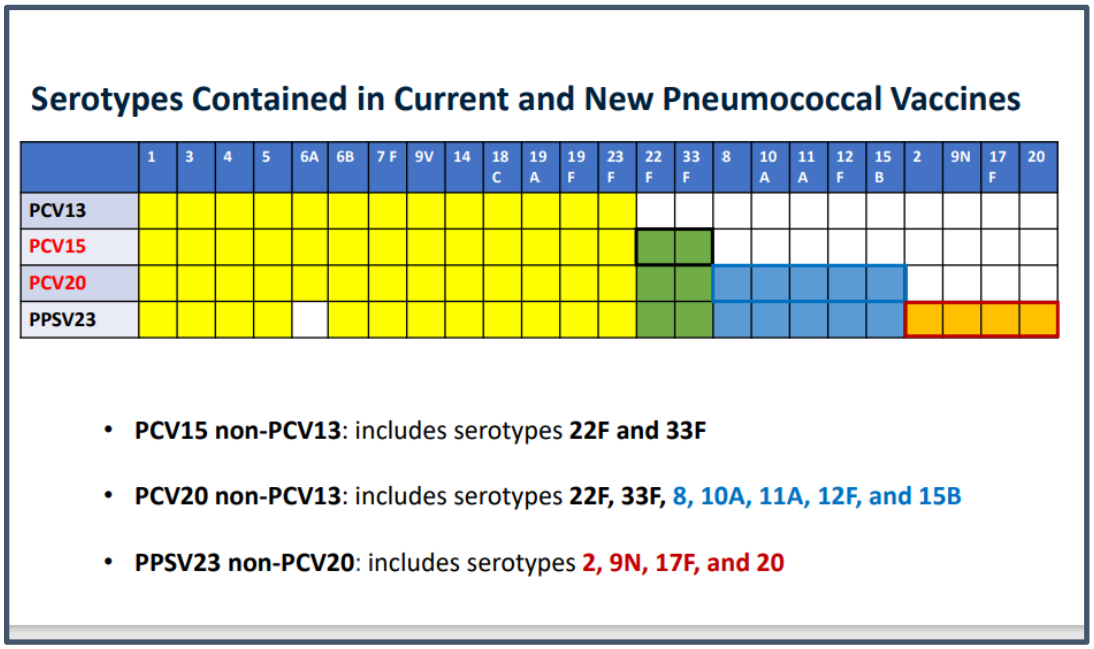
For those ages 6-18 years with chronic liver disease or alcoholism with no history of PPSV23 should receive one dose of this vaccine.

How does PCV20 work and what does it contain?

There are approximately 100 serotypes of *Streptococcus pneumoniae*; each serotype represents a different sugar making up the outermost layer, the capsule, of encapsulated strains. In nature, the sugar of the capsule is the major virulence factor of *S. pneumoniae*; non-encapsulated strains are, in most cases, non-virulent. The PCV20 vaccine contains the polysaccharides of 20 serotypes of *S. pneumoniae.* These serotypes provide increased protection for many but not all serotypes associated with adult human invasive pneumococcal disease. Conjugation of the polysaccharide to the carrier protein results in long-lasting T-cell memory and provides T-cell help.

PCV 20 contains saccharides of the following *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F. Also, the vaccine contains the protein carrier (diphtheria toxoid protein), polysorbate 80, succinate buffer, sodium chloride, and aluminum as aluminum phosphate adjuvant.

Figure 2. Comparing Spectrum of 4 pneumococcal vaccines[1]



In what situations is PCV20 contraindicated?

PCV20 should not be administered to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any component of PCV20 or to diphtheria toxoid. Note that there is no egg component in this vaccine and the pre-filled syringe is latex-free.

How is PCV 20 administered?

PCV20 comes in single-use pre-filled syringes that must be shaken vigorously until the liquid is a homogenously suspended. Administer 0.5 mL IM x1 in the deltoid.

What are common side effects PCV20?

Like other pneumococcal vaccinations, side effects include pain at injection site, muscle pain, fatigue, headache, joint pain. Swelling at the injection site may occur. Fever is rare (<1%).

May PCV20 be safely administered to patients at the same time as a flu shot?

Yes. Both vaccines have been found to be effective when administered at the same visit.

REFERENCES

1. Kobayashi, M. Advisory Committee on Immunization Practices, ACIP Meeting, Considerations for Age-based and Risk-based Use of PCV15 and PCV20 among U.S. Adults and Proposed Policy Options. October 20, 2021.
2. Centers for Disease Control and Prevention. 2018. Active Bacterial Core Surveillance Report, Emerging Infections Program Network, Group B *Streptococcus*, 2018.
3. Kobayashi, M., JL Farrar, R Gierke, et al. Use of 15-valent pneumococcal conjugate vaccine and 20-valent pneumococcal conjugate vaccine among U.S. adults: updated recommendations of the advisory committee on immunization practices – United states, 2022 Morb Mortal Wkly Rep 2022 Jan 28. 71(4):109-117.