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Pneumococcal Vaccine Guidance 2022

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PNEUMOCOCCAL DISEASE BURDEN

Pneumococcal pneumonia is by far the most common presentation of pneumococcal disease.[1] In the outpatient setting, Streptococcus pneumoniae is the number one pathogen to cause pneumonia. Streptococcal pneumonia accounts for 35% of outpatient pneumonia cases, with some reports of upwards of 60% when extensive diagnostic testing is performed.[2] In 2019, pneumonia killed more than 700,000 children under the age of 5 years old, which accounted for 14% of all deaths in that age group.[3] Streptococcus pneumoniae was the leading cause of morbidity and mortality in lower respiratory infections worldwide and contributed to 1,189,937 deaths in 2016[4]. Pneumococcal diseases also include meningitis and bacteremia, with upwards of 3000 deaths yearly and a fatality ratio of 14% and 12% respectively.[5]

Available Formulations

- Polysaccharide – PPSV23
- Conjugate – PCV13, PCV15, PCV20

VACCINE SPECTRUM OF ACTIVITY

There are currently four available pneumococcal vaccines in the United States: Pneumococcal conjugate vaccines (PCV13, PCV15, and PCV20) and Pneumococcal polysaccharide vaccine (PPSV23). Each vaccine has its own unique spectrum of streptococcus pneumoniae serotype coverage thereby emphasizing the importance of appropriate use and administration of these vaccines[6]. Prior to the development of the PCV20 vaccine, patients were administered the PCV13 or PCV15 followed by the PPSV23 to achieve full coverage against all S. Pneumoniae serotypes. The PCV20 now offers similar coverage to the PCV13 or PCV15/PPSV23 series in a single dose. Unlike the other pneumococcal vaccines (PCV13, PCV15 and PPSV23), PCV20 is only indicated in adults ≥18 years of age. However, expansion of the PCV20 indications and its respective age-related recommendations are pending and may be expanded to infants and children within the upcoming months.

- **PCV 13:** indicated for active immunization of infants ≥6 weeks of age and children <6 years of age for the prevention of otitis media caused by S. pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F

- **PPSV23:** indicated for active immunization of children ≥2 years and persons ≥50 years who are at increased risk for pneumococcal disease caused by S. pneumoniae serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 20, 22F, 23F, and 33F

- **PCV15:** indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in patients ≥6 weeks of age

- **PCV20:** indicated for active immunization of persons ≥18 years of age for the prevention of pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33FConjugate vaccines, such as the PCV13, PCV15 and PCV20, are vaccines which combine a weak antigen with a strong antigen as a carrier. The weak antigen induces a stronger immune response thereby granting active immunity to recipients.

Pneumococcal vaccination is both safe and effective against preventing S. Pneumoniae infection and incidence of serious adverse effects is very low. The most common side effect of these vaccines are injection site reactions. Guillain-Barre syndrome (GBS) is a rare acute flaccid paralysis syndrome which commonly manifests as early symptoms of upper respiratory tract infection or diarrhea within 3 months of the insulting factor. GBS results from the stimulation of autoimmunity where auto-immune antibodies attack the host's myelin sheath of the nerves in the peripheral nervous system. Incidence of GBS have been reported and associated with the pneumococcal vaccine with very low incidence. Despite this, the overall benefit of preventing life-threatening infections greatly outweighs the risks of pneumococcal vaccination.

Fainting or syncope remains to be a common concern for many individuals, especially adolescents. Fainting is most commonly reported after three specific vaccines given to adolescents, which include HPV, MCV4, and Tdap. However, since the ingredients for the aforementioned vaccines are different, it has been hypothesized that fainting is more directly correlated with the vaccination process and not due to the vaccines themselves. Despite this, precautions to mitigate falls and their associated risks should be taken to avoid harm from related falls or other accidents most notably head injuries. Giving patients a beverage, a snack, or some reassurance has been shown to prevent some fainting. In addition to this, having the patient sit or lie down can also greatly reduce the risks associated with fainting. Furthermore, patients should be observed for at least 15 minutes after vaccination to ensure safety post-administration.

Target Populations

- Children
- Adults
- Elderly

PEDIATRIC DOSING SCHEDULE

In pediatric patients, the CDC recommends pneumococcal vaccination as part of routine childhood vaccination and additional doses for patients with high-risk conditions[7]. In patients eligible to receive both pneumococcal conjugate (PCV13) and pneumococcal polysaccharide (PPSV23) immunizations, PCV13 should be administered first. High-risk conditions include immunocompromised, HIV, diabetes, kidney failure, end stage renal disease, dialysis, heart disease, chronic lung disease, CSF leak, cochlear implant, asplenia, persistent complement component deficiencies, and chronic liver disease

Table 1. For pediatric patients without high-risk conditions:

1st Dose	2nd Dose	3rd Dose	4th Dose
PCV13	PCV13	PCV13	PCV13
2 months old	4 months old	6 months old	12-15 months old

In children ages 24-59 months with incomplete PCV13 series, 1 catch-up dose is recommended

Table 2. For pediatric patients with chronic heart disease, chronic lung disease, or diabetes:

Incomplete PCV13 Series* (ages 2-5)		**Complete PCV13 Series and No History of PPSV23** (ages 2-18)
≥ 3 PCV13 Doses	< 3 PCV13 Doses	
1 dose PCV13	2 doses PCV13 (8 weeks apart)	1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)

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Table 3. For pediatric patients with cerebrospinal fluid leak or cochlear implants:

Ages 2-5		
Incomplete PCV13 Series* (ages 2-5)		**Complete PCV13 Series and No History of PPSV23** (ages 2-18)
≥ 3 PCV13 Doses	< 3 PCV13 Doses	
1 dose PCV13	2 doses PCV13 (8 weeks apart)	1 dose PPSV23 (at least 8 weeks after completing all recommended PCV13 doses)
Ages 6-18		
No History of PCV13 or PPSV23	**Any Number of PCV13 Doses and No History of PPSV23**	**PPSV23 and No PCV13 Doses**
1 dose PCV13, 1 dose PPSV23 8 weeks later	1 dose PPSV23 (at least 8 weeks after most recent PCV13 dose)	1 dose PCV13 (at least 8 weeks after PPSV23)

Table 4. For pediatric patients with sickle cell disease, asplenia, immunodeficiency, HIV, chronic renal failure, malignancy, or solid organ transplant:

Ages 2-5		
Incomplete PCV13 Series* (ages 2-5)		**Complete PCV13 Series and No History of PPSV23** (ages 2-18)
≥ 3 PCV13 Doses	< 3 PCV13 Doses	
1 dose PCV13	2 doses PCV13 (8 weeks apart)	2 doses PPSV23 (first at least 8 weeks after completing all recommended PCV13 doses; second 5 years later)
Ages 6-18		
No History of PCV13 or PPSV23	**Any Number of PCV13 Doses and No History of PPSV23**	**PPSV23 and No PCV13 Doses**
1 dose PCV13, 2 doses PPSV23 (first 8 weeks later, second 5 years later)	2 doses PPSV23 (first at least 8 weeks after most recent PCV13 dose; second 5 years later)	1 dose PCV13 (at least 8 weeks after PPSV23) 1 dose PPSV23 (5 years after first PPSV23 dose and 8 weeks after PCV13 dose)

Table 5. For pediatric patients with chronic liver disease or alcoholism:

Ages 6-18
No History of PPSV23
1 dose PPSV23 (at least 8 weeks after any prior PCV13 doses)

* Patients who have not received all doses in the recommended series or catch-up series are defined as having an incomplete series

ADULT DOSING SCHEDULE

In adult patients, the CDC recommends pneumococcal vaccination for all adults over 65 years old and adults 19 through 65 years old with certain underlying medical conditions or risk factors.

High-risk conditions include alcoholism, cerebrospinal fluid leak, chronic heart disease, chronic liver disease, chronic lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, congenital or acquired immunodeficiencies, diabetes, generalized malignancy, HIV, Hodgkin disease, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, sickle cell disease or other hemoglobinopathies, and solid organ transplants.

For all adults over 65 years old:

PCV 13	→	PPSV23
(any age)	(at least 1 year)	(age ≥ 65)

The CDC recommends that all adult patients over 65 years old receive 1 dose of PCV13 at any age, then 1 dose of PPSV23 at least 1 year later.

EFFICACY

Pneumococcal vaccines provide protection against some strains of streptococcus pneumoniae, a type of bacteria that can cause pneumococcal disease.

The CAPITA trial evaluated the efficacy of the PCV13 vaccine and found 46% protection against vaccine-type pneumococcal pneumonia, 45% protection against vaccine-type non-bacteremia pneumococcal pneumonia, and 75% protection against vaccine-type invasive pneumococcal disease.[8]

The PCV20 vaccine was derived from the existing PCV13 vaccine and was found to be noninferior to the PCV13 vaccine. Efficacy for the PCV20 vaccine is based on real-world effectiveness studies, which show approximately a 73% reduction in vaccine-type pneumonia hospitalizations in vaccinated patients. In a phase 3 trial evaluating the safety and efficacy of PCV20, the vaccine was found to be safe and well tolerated with similar effectiveness to the PCV13 vaccine.[9]

The PPSV23 vaccine is about 60-70% effective in protecting against invasive pneumonia, with variable efficacy in elderly and immunocompromised patients.[10]

For adults over 19 years old with underlying medical conditions or risk factors (except cerebrospinal fluid leaks or cochlear implants):

PCV13	→	PPSV23	→	PPSV23	→	PPSV23
(any age)	(at least 8 weeks)	(age < 65)	(at least 5 years)	(age ≥ 65)	(at least 5 years)	age ≥ 65

The CDC recommends that all adult patients over 19 years old with underlying medical conditions or risk factors receive 1 dose of PCV13, then 1 dose of PPSV23 after 8 weeks, followed by 1 dose of PPSV23 5 years later, and then an additional dose of PPSV23 after age 65 (separated by at least 5 years from previous PPSV23 dose).

For adults over 19 years old with cerebrospinal fluid leaks or cochlear implants:

PCV13	→	PPSV23	→	PPSV23
(any age)	(at least 8 weeks)	(age < 65)	(at least 5 years)	(age ≥ 65)

The CDC recommends that all adult patients with cerebrospinal fluid leaks or cochlear implants receive 1 dose of PCV13, then 1 dose of PPSV23 after 8 weeks, followed by 1 dose of PPSV23 after age 65 (separated by at least 5 years from previous PPSV23 dose).

For all adult patients over 65 years old or over 19 years old with underlying medical conditions or risk factors who have never received a pneumococcal vaccine or have unknown immunization history:

The CDC recommends 1 dose of either PCV15 or PCV20. If PCV15 is used, the patient should receive 1 dose of PPSV23 at least 1 year later.

For patients who have previously received PPSV23 but not PCV13, PCV15, or PCV20:

The CDC recommends 1 dose of either PCV15 or PCV20 at least 1 year from the PPSV23 dose

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COMMON SIDE EFFECTS

The most reported adverse drug reaction is local erythema, induration and/or soreness at the injection site. More uncommon but severe adverse drug reactions include anaphylaxis and syncope. Anaphylactoid/hypersensitivity reactions may occur; as a result, immediate treatment (including epinephrine 1mg/mL) for anaphylactoid and/or hypersensitivity reactions should be readily available upon administration of the vaccine. In addition to this, syncope has also been reported and may result in serious injuries such as skull fracture and cerebral hemorrhage. Procedures should be in place to avoid injuries.

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