Immunization Pharmacy Protocol

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1. What’s new

PCV20 has been approved by the FDA for children 7 years through 18 years of age who have a high risk condition.

Added shared clinical decision-making for adults 65 years of age or older who previously received both PCV13 and PPSV23.
2. Oregon model immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

B. Screen clients for contraindications.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client’s permanent health record.

E. Verify needle length for IM injection into the vastus lateralis or deltoid. PPSV23 may also be given by SQ injection into the fatty tissue over the triceps with a 5/8” needle.3

F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.12

G. Pneumococcal vaccines:

1) Give 0.5 mL PCV20 vaccine (Prevnar 20), PCV15 (VAXNEUVANCE), or PCV13 (Prevnar 13) intramuscularly (IM) to eligible clients. See Section 5. A–C; OR

2) Give 0.5 mL PPSV23 vaccine (Pneumovax 23) IM, or subcutaneously (SC) to eligible clients. See Section 5. C-E.

H. Pneumococcal conjugate vaccines and PPSV23 should not be given at the same time. Either vaccine type may be given simultaneously with influenza and most other ACIP-recommended child and adult vaccinations.6

I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.13

I have read, understand, and agree to participate by the terms of this protocol.

Pharmacist Signature ___________________________ Date ___________________________
3. Vaccine schedule for pneumococcal vaccines

**Vaccine Schedule: Pneumococcal Conjugate Vaccine (PCV13, PCV15, or PCV20)**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
<th>No. of Doses</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥7 years</td>
<td>0.5 mL</td>
<td>Varies by age</td>
<td>Intramuscular</td>
</tr>
</tbody>
</table>

**Vaccine Schedule: Pneumococcal Conjugate Vaccine (PCV20)**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
<th>No. of Doses</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥19 years</td>
<td>0.5 mL</td>
<td>1</td>
<td>Intramuscular</td>
</tr>
</tbody>
</table>

**Vaccine Schedule: Pneumococcal Polysaccharide Vaccine (PPSV23)**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Dose</th>
<th>No. of Doses</th>
<th>Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥7 years</td>
<td>0.5 mL</td>
<td>Varies by age</td>
<td>Intramuscular or Subcutaneous</td>
</tr>
</tbody>
</table>

4. Licensed pneumococcal vaccines

**Pneumococcal Conjugate Vaccines**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Presentation</th>
<th>Acceptable Age Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevnar 20™</td>
<td>0.5-mL prefilled syringes</td>
<td>≥7 years</td>
</tr>
<tr>
<td>VAXNEUVANCE™</td>
<td>0.5-mL prefilled syringes</td>
<td>≥7 years</td>
</tr>
<tr>
<td>Prevnar 13®</td>
<td>0.5-mL prefilled syringes</td>
<td>≥7 years</td>
</tr>
</tbody>
</table>

**Pneumococcal Polysaccharide Vaccine (PPSV23)**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Presentation</th>
<th>Acceptable Age Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumovax 23®</td>
<td>0.5-mL single-dose vials</td>
<td>≥7 years</td>
</tr>
<tr>
<td></td>
<td>0.5-mL prefilled syringes</td>
<td></td>
</tr>
</tbody>
</table>

5. Recommendations for use

A. Persons with Special Indications

**Pneumococcal Vaccine (PCV15 or PCV20 and PPSV) for Persons 7–18 Years of Age with High Risk Conditions**

<table>
<thead>
<tr>
<th>Age</th>
<th>Previous PCV Vaccination History</th>
<th>Previous PPSV Vaccination History</th>
<th>Due Now (≥8 weeks since last pneumo)</th>
<th>Due Next</th>
</tr>
</thead>
</table>
### B. Routine Schedule for PCV20 or PCV15

All persons ≥65 years of age should receive a single dose of PCV20 or doses of PCV15 and PPSV in series.\(^6,7\)

<table>
<thead>
<tr>
<th>Age</th>
<th>PCV20 or PCV15</th>
<th>PPSV*</th>
<th>Minimum Spacing</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥65 years</td>
<td>PCV20 or PCV15</td>
<td>≥1 year after PCV15</td>
<td>≥8 weeks after PCV15</td>
</tr>
</tbody>
</table>

*Indicated only for persons who received PCV15, and not for those who received PCV20. If PPSV is not available, one dose of PCV20 may be used.

### C. Persons with Special Indications for PCV20 or PCV15\(^6\)

<table>
<thead>
<tr>
<th>Age</th>
<th>Previous PCV or PPSV Vaccination History</th>
<th>Recommended Regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>19–64 years</td>
<td>PPSV only</td>
<td>1 dose of PCV20 or PCV15</td>
</tr>
<tr>
<td>PCV13 only</td>
<td>PPSV, if indicated</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>PCV13 and PPSV</td>
<td>No additional doses</td>
<td></td>
</tr>
<tr>
<td>Unknown Vaccination History</td>
<td>1 dose of PCV20; or PCV15 followed by PPSV</td>
<td></td>
</tr>
</tbody>
</table>

*Alcoholism; chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy); cigarette smoking; diabetes mellitus; CSF leak; cochlear implant; sickle cell disease and other hemoglobinopathies; asplenia; HIV infection; chronic renal failure; nephrotic syndrome; immunodeficiency; diseases treated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma.

D. Shared clinical decision-making for patients 65 years of age or older:

Patients who have previously received both PCV13 and PPSV23 may also receive PCV20 ≥5 years or more since the last dose of pneumococcal vaccine based on shared clinical decision-making.

PCV20 is not routinely recommended, however certain patients are at increased risk of exposure or increased risk of serious disease, including:

- Seniors living in nursing homes or other long-term care facilities;
- Seniors living in areas with low pediatric pneumococcal conjugate vaccine uptake;
- Seniors with immunocompromising conditions;
- Seniors with cochlear implants;
- Seniors with cerebrospinal fluid leak;
- More than one of these chronic medical conditions: alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes.

6. Contraindications

PCV20\(^1\), PCV15\(^2\), or PCV13\(^4\)

Persons who experienced an anaphylactic reaction to a previous dose of any pneumococcal conjugate vaccine, any vaccine component, or any diphtheria toxoid-containing vaccine.

PCV13\(^4\)

Allergy to soy peptones.
PPSV23
Persons who experienced an anaphylactic reaction to a previous dose of pneumococcal vaccine or a vaccine component.

7. Warnings and precautions
Persons with acute, moderate, or severe illness with or without fever may choose to delay immunization until symptoms have improved.13

PPSV23
Care should be exercised when administering to patients with severely compromised cardiovascular or pulmonary function in whom a systemic reaction would pose a significant risk.3

8. Other considerations
A. Adults with previous PPSV23 only: Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.6

B. Adults with previous PCV13: The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series.6 One dose of PCV20 may replace the PPSV if PPSV is not available.

C. Adverse Events: Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.13

D. Lactation: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing.1-4

E. Pregnancy: Pneumococcal vaccine should be considered for persons at increased risk.13

F. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See sections 5, recommendations for use, for the necessary minimum interval between doses.6,8

G. May give influenza and zoster vaccines at same visit as PPSV23.7

H. Splenectomy, immunocompromising therapy, or cochlear implant:
   For children ≤18 years of age: When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If pneumococcal vaccine is not administered before
surgery, it should be administered ≥2 weeks after surgery. If the patient is unlikely to return, vaccine can be administered in the immediate post-operative period.\textsuperscript{10}

**For adults ≥19 years of age:** When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, pneumococcal vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If PCV vaccine is not administered before surgery, it should be administered ≥2 weeks after surgery. If the patient is unlikely to return, vaccine can be administered in the immediate post-operative period.\textsuperscript{10}

I. Immunization should precede the initiation of immunocompromising therapy by at least two weeks.\textsuperscript{10}

J. Children who have experienced invasive pneumococcal disease should receive all recommended doses of a pneumococcal conjugate vaccine as appropriate for their age and underlying condition. The full series of scheduled doses should be completed even if the series is interrupted by an episode of invasive pneumococcal disease.\textsuperscript{10}

K. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.\textsuperscript{1-4}

L. **Recipients of Hematopoietic Cell Transplants (HCT):**

   **For children ≤18 years of age:** ACIP recommends that patients be revaccinated with three sequential doses of PCV20 vaccine beginning 3–6 months after HCT transplant. A fourth dose of PCV20 is recommended at least 6 months after the third PCV20 dose, or at least 12 months after HSCT, whichever is later.\textsuperscript{13}

   **If PCV20 is not available,** three doses of PCV15, followed by a dose of PPSV23 at least 12 months after HSCT may be given. For patients with chronic graft-versus-host disease who are receiving PCV15, a fourth dose PCV15 dose can be given in place of PPSV23.\textsuperscript{13}

   **For adults ≥19 years of age:** ACIP recommends that patients be revaccinated with three, sequential doses of PCV vaccine beginning 3–6 months after HCT transplant. A dose of PPSV should be administered ≥8 weeks after the last dose of PCV.\textsuperscript{13}

9. **Side effects and adverse reactions**

   | PCV13\textsuperscript{4}, PCV15\textsuperscript{2}, PCV20\textsuperscript{1} |
10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4832).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Discard</th>
<th>Latex</th>
<th>Temp</th>
<th>Storage Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevnar 20¹</td>
<td></td>
<td></td>
<td></td>
<td>Store syringes horizontally to minimize resuspension time. Do not freeze.</td>
</tr>
<tr>
<td>VAXNEUVANCE²</td>
<td>N/A</td>
<td>No</td>
<td>2°-8°C</td>
<td>Do not freeze. Protect from light.</td>
</tr>
<tr>
<td>Prevnar 13³</td>
<td></td>
<td></td>
<td></td>
<td>Vaccine is stable at temperatures up to 25°C for up to 4 days—not recommended for storage or shipping</td>
</tr>
</tbody>
</table>
11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html

<table>
<thead>
<tr>
<th>Event and interval from vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Shoulder Injury Related to Vaccine Administration (7 days)</td>
</tr>
<tr>
<td>B. Vasovagal syncope (7 days)</td>
</tr>
<tr>
<td>C. Any acute complication or sequelae (including death) of above events (interval—not applicable)</td>
</tr>
<tr>
<td>D. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval—see package insert).</td>
</tr>
</tbody>
</table>

12. References


