Updates from the Pneumococcal Vaccines Work Group

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Advisory Committee on Immunization Practices

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October 2021 ACIP Vote on Use of PCV15/PCV20

Adults aged ≥65 years

- Adults aged ≥65 years **who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown** should receive a dose of pneumococcal conjugate vaccine (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23.

Adults aged 19–64 years with certain underlying medical conditions or other risk factors

- Adults aged 19–64 years with certain underlying medical conditions or other risk factors* **who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown** should receive a dose of pneumococcal conjugate vaccine (either PCV20 or PCV15). When PCV15 is used, it should be followed by a dose of PPSV23.

*Alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking, chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, 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, CSF leak, or cochlear implant

Clinical Guidance on the PCV15–PPSV23 Interval

- *When PCV15 is used, the recommended interval between PCV15 and PPSV23 is ≥1 year. A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition*, cochlear implant, or cerebrospinal fluid leak to minimize the risk for IPD caused by serotypes unique to PPSV23 in these vulnerable groups.*

*chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, 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, CSF leak, or cochlear implant

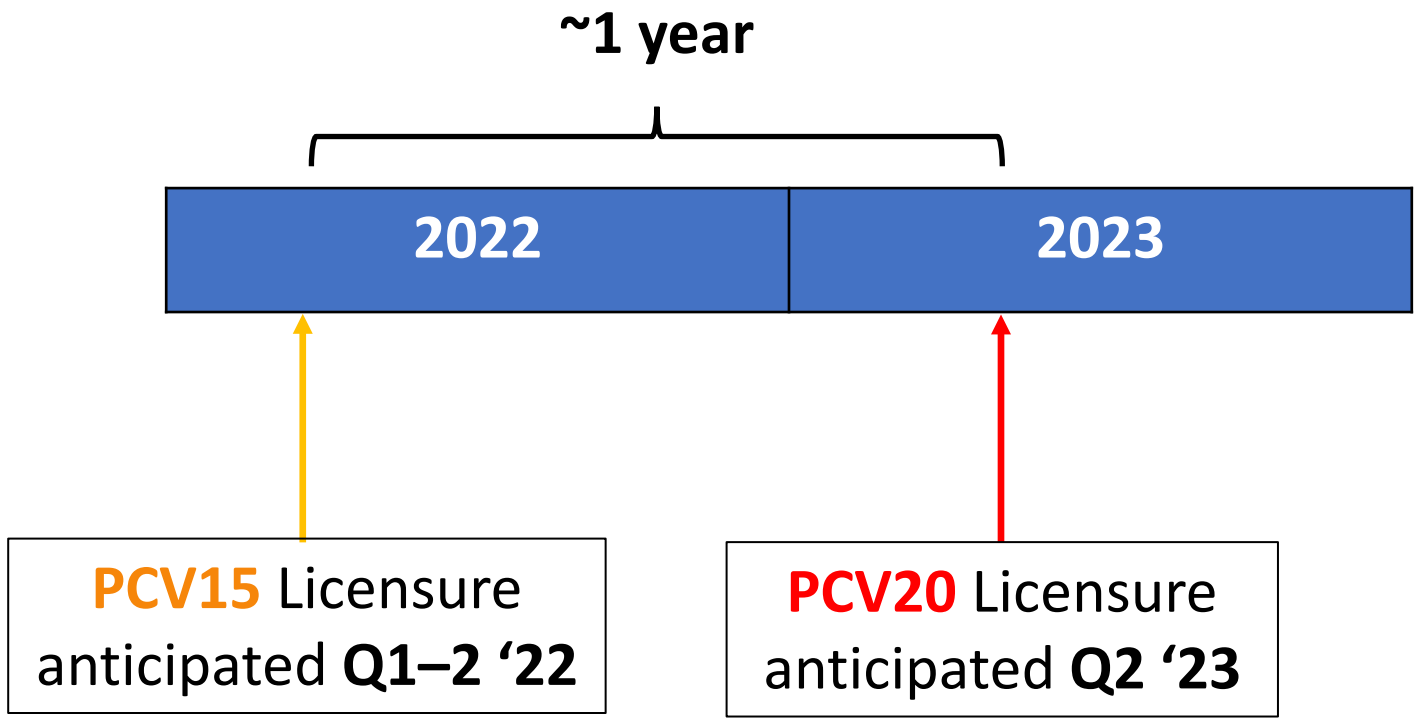
Clinical Guidance for Those Who Previously Received PPSV23 Only

- *Adults who have only received PPSV23 may receive a pneumococcal conjugate vaccine (either PCV20 or PCV15) at least 1 year after their last PPSV23 dose.*

Clinical Guidance for Those Who Previously Received PCV13 (with/without PPSV23)

- The Work Group is in favor of providing an opportunity to administer higher-valent PCVs to those who have already received PCV13 (with/without PPSV23).
- 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 by the ACIP.
- MMWR policy note expected to be published on January 28th, 2022 does not include a recommendation on PCV15/PCV20 use in adults who previously received PCV13 (with/without PPSV23).

Anticipated Timeline of PCV15 and PCV20 Licensure in Children



Current PCV13 Recommendations for Children

- **Routine** administration for all children aged <2 years
  - 4 dose series at 2, 4, 6, and 12–15 months
- **Catch-up** vaccination for children aged <5 years who missed their recommended doses
- Children aged 2–18 years with **certain medical conditions** in series with PPSV23

MMWR 2010 (59); RR-11
MMWR 2013 (62); 521–524

Proposed Policy Question

- Should PCV15 be recommended as an option for U.S. children who are recommended to receive PCV13?

Evidence to be Reviewed by the Work Group

- Immunogenicity and safety on PCV15 use in children (Phase 2/3 studies)
- Epidemiology of pneumococcal disease and vaccine-preventable disease burden for
  - Invasive pneumococcal disease
  - Non-invasive pneumococcal pneumonia
- Expected public health impact and cost-effectiveness of PCV15 use
  - Estimated direct/indirect effects in children
  - Impact on health equity
- Use of GRADE and EtR framework

Proposed Timeline of ACIP Presentations (Tentative)

Jan 2022 ACIP

- Work Group Announcement

Feb 2022 ACIP

Presentation on:

- Pediatric Pneumococcal disease epi
- Phase II/III PCV15 studies in children
- EtR (part 1)/GRADE

June ‘22 ACIP

Presentation on:

- Cost-effectiveness analysis
- EtR (part 2)

Vote after vaccine licensure and when deemed appropriate by ACIP