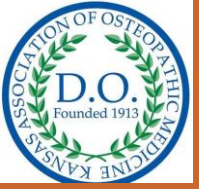




MAKING PNEUMOCOCCAL VACCINES “MORE” UNDERSTANDABLE

- Stan Grogg, DO, FACOP, FAAP
 - Professor Emeritus – OK State Univ-CHS
 - AOA’s liaison representative for the CDC’s
 - Advisory Committee on Immunization Practices
(ACIP)



CONFLICTS OF INTEREST

- Consultant for Pfizer: PCV-20 Vaccine
- Consultant for Dynavax: Hep B Vaccinee
- Consultant for Takedo for Dengue Vaccine

The Kansas Osteopathic Medical Association Representatives have mitigated and approved the presentation



OBJECTIVES: AFTER THE PRESENTATION, THE PARTICIPANT SHOULD BE ABLE:

- 1. Understand which pneumococcal vaccines are recommended by the CDC's Advisory Committee on Immunization Practices (ACIP)
- 2. Incorporate into a private practice the use of pneumococcal vaccines
- 3. Acknowledged the difference between a polysaccharide vaccine from a conjugated vaccines



REFERENCES

1. CDC's webpage Pneumococcal Vaccination:
<https://www.cdc.gov/vaccines/vpd/pneumo/index.html> (Accessed 2/28/23)
2. ACIP's slides for Feb. 2023 discussion pneumococcal vaccination:
<https://www.cdc.gov/vaccines/acip/meetings/slides-2023-02-22-24.html>.
(Accessed 2/28/23)
2. Storage, handling, and administration:
[//prevnar20.pfizerpro.com/administration?gclid=3afd3a71519d19df980c598f5ed6ff23&gclsrc=3p.ds&](https://prevnar20.pfizerpro.com/administration?gclid=3afd3a71519d19df980c598f5ed6ff23&gclsrc=3p.ds&) (Accessed 2/28/23)



OUR NON-PROFIT, POWER OF A NICKEL, TAKE MEDICAL TEAMS INTERNATIONALLY TO MEDICALLY UNDERSERVED AREAS

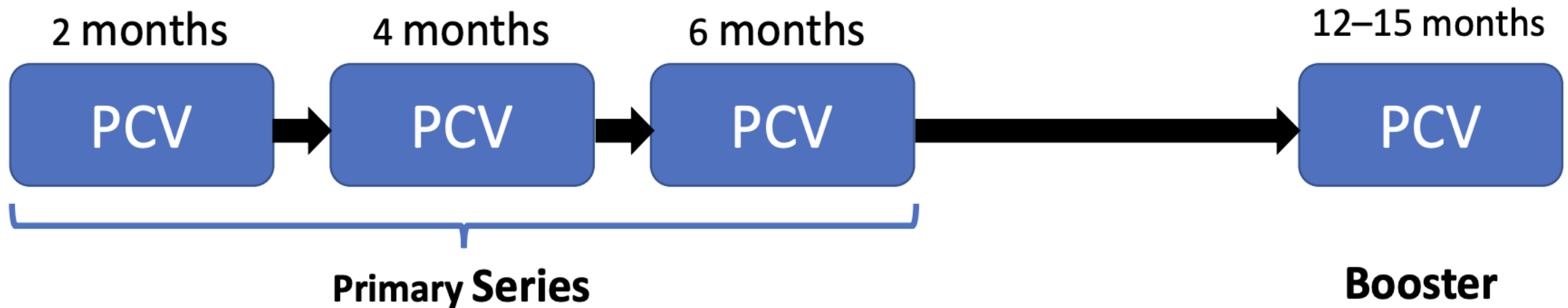
- We recently took a team of of 17 to Saigon, Vietnam.
- Evaluated and treated 350 patients over 4 days of clinics in three orphanages and one village
- Applied protective covering over 300 patients' teeth



Interested, check out our website at www.powerofanickel.org
Or google power of a nickel

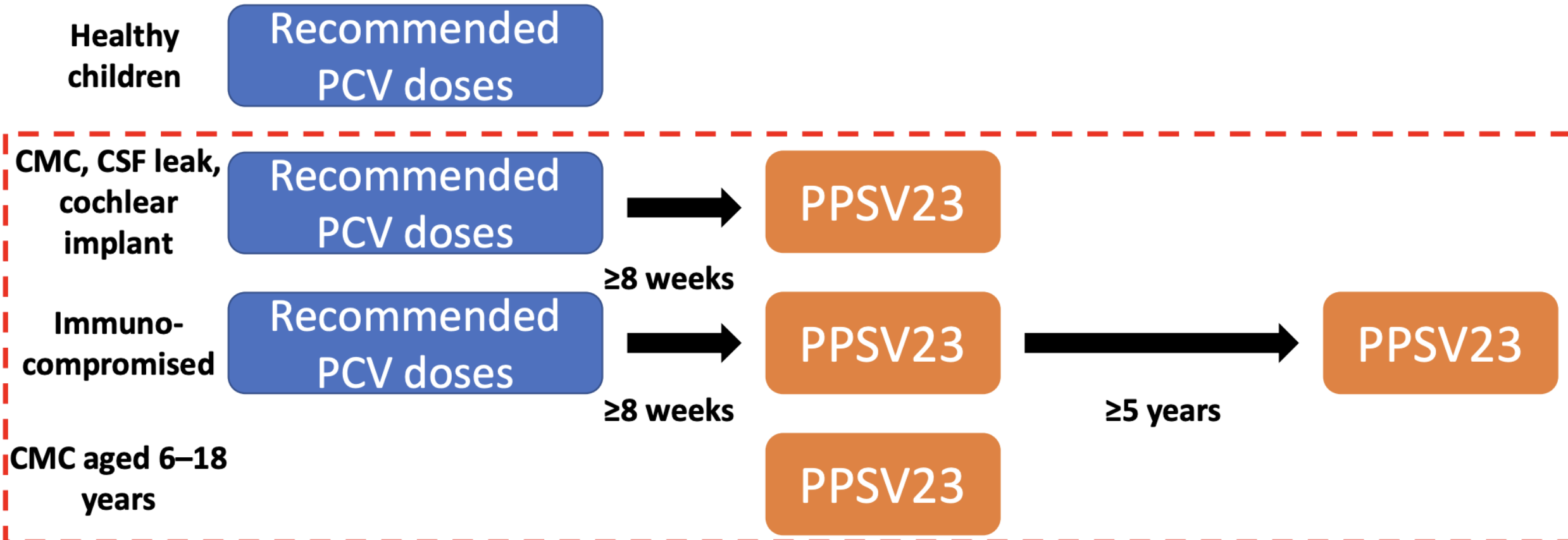
All children under age 2 years have the same pneumococcal vaccine recommendations

- 3 primary series and a booster="3+1" schedule



Either **PCV13** or **PCV15** can be used for U.S. children.

Children with certain underlying conditions are recommended to **receive PPSV23** in addition to the recommended PCV doses



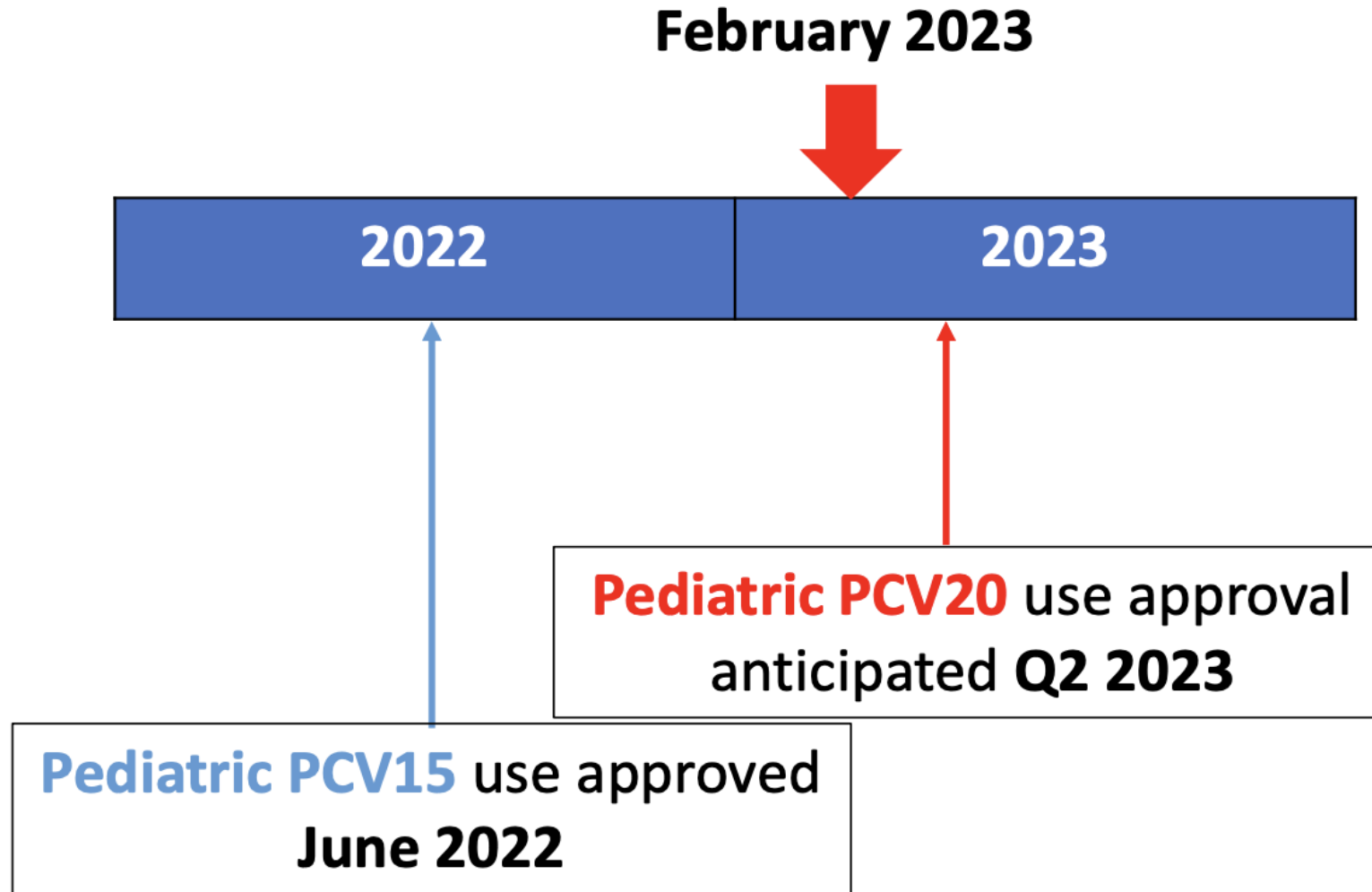
Note: Excludes catch-up vaccination schedules.

CMC=chronic medical conditions, including chronic heart disease, chronic lung disease, diabetes mellitus

CSF=cerebrospinal fluid

[Use of 15-Valent Pneumococcal Conjugate Vaccine Among U.S. Children: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022 | MMWR \(cdc.gov\)](#)

Approval of PCV20 use among Children Anticipated in 2023



[U.S. FDA Accepts for Priority Review the Supplemental Biologics License Application for Pfizer's 20-Valent Pneumococcal Conjugate Vaccine in Infants and Children | Pfizer](#)



QUESTIONS UNDER DISCUSSION BY ACIP

- Should **PCV20** be recommended as an option for pneumococcal conjugate vaccination **according to currently recommended dosing and schedules, for U.S. children aged <2 years?**
- Should **PCV20 without PPSV23** be recommended as an option for pneumococcal vaccination **for U.S. children aged 2–18 years with underlying medical conditions that increase the risk of pneumococcal disease?**

Pneumococcal carriage is precursor to pneumococcal disease

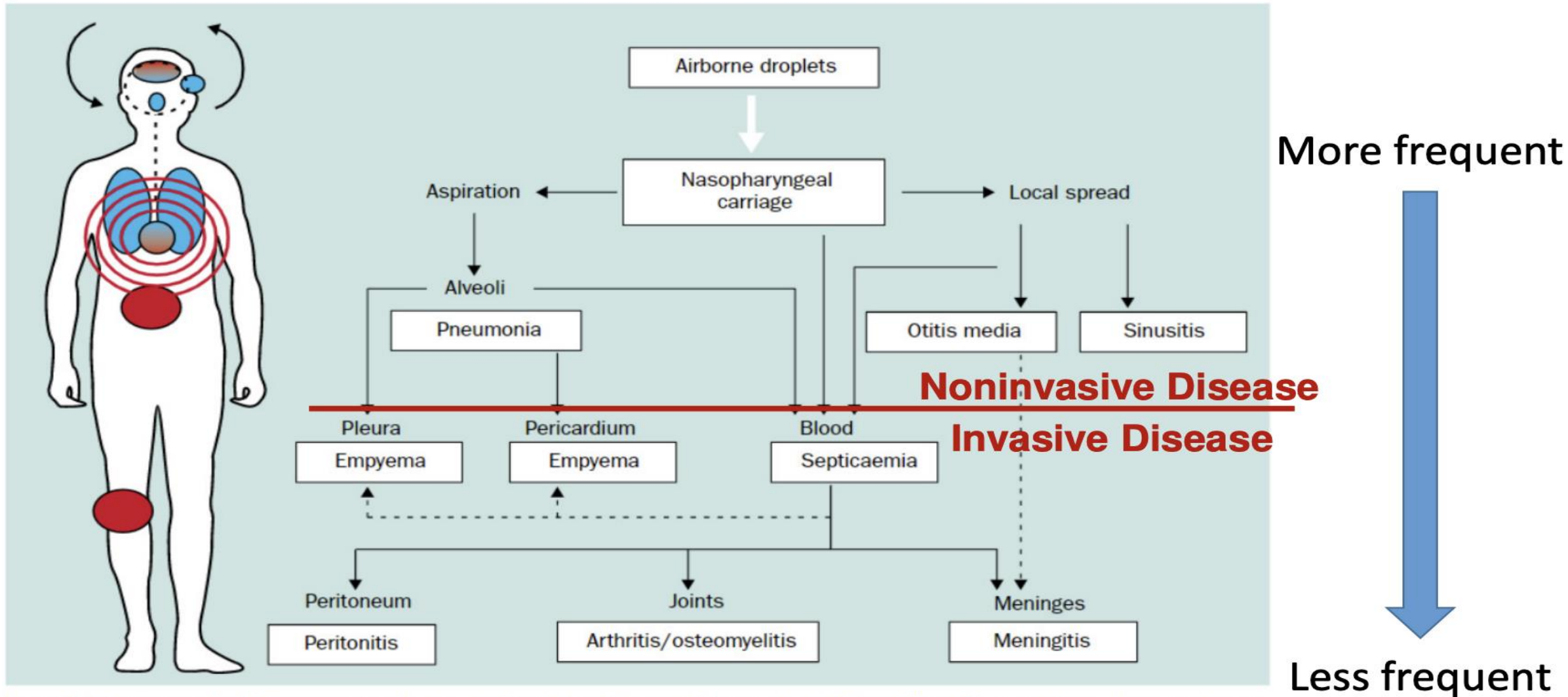
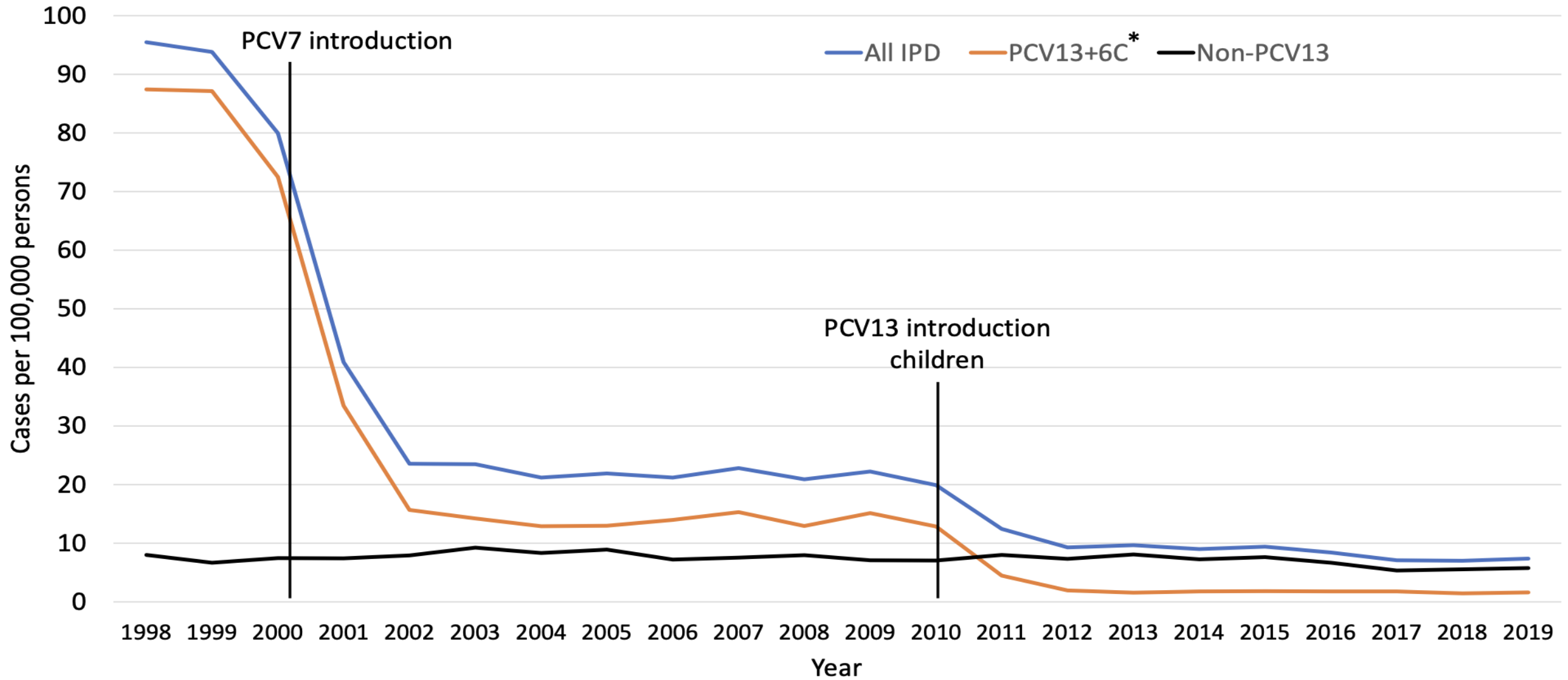
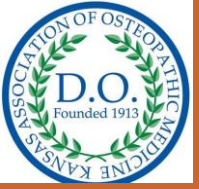


Figure 1. Pathogenic route for *S. pneumoniae* infection. Redrawn from reference 2. Organs infected through the airborne and haematogenic routes are depicted in blue and red, respectively.

Incidence rates of invasive pneumococcal disease (IPD) among children < 5 years old, 1998–2019



Serotype 6C was grouped with PCV13 serotypes due to cross protection from 6A antigen in the vaccine



Conclusions

- Use of PCVs (PCV7, PCV13) significantly decreased the incidence of pneumococcal disease in U.S. children
- Risk of disease remains higher in children with immunocompromising conditions compared to children without
- In 2018–2019, the proportion of IPD caused by vaccine serotypes was:
 - PCV20, non-PCV13: ~30% of IPD
 - PCV15, non-PCV13: ~15% of IPD



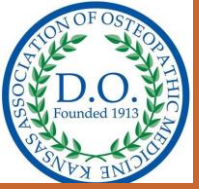
Summary of pneumococcal disease epidemiology in children

- Use of PCVs (PCV7, PCV13) significantly decreased the incidence of pneumococcal disease in U.S. children.
 - Outpatient ARIs caused by pneumococcus, such as AOM, sinusitis, and pneumonia, are common causes of outpatient visits and antibiotic prescribing.
 - Risk of disease remains high in children with underlying conditions that increase the risk of pneumococcal disease.
-
- The estimated incidence of pediatric outpatient visits and antibiotic prescriptions attributable to PCV20-13 serotypes is 4 – 5 times the incidence attributable to PCV15-13 serotypes.



INCIDENCE OF PNEUMOCOCCAL DISEASE IN ADULTS; SURVEILLANCE

- Invasive pneumococcal disease is a reportable condition in all states, with cases immediately reported to the appropriate health department
- CDC tracks invasive pneumococcal disease through two systems: National Notifiable Diseases Surveillance System (NNDSS) and Active Bacterial Core surveillance (ABCs)
- CDC does not track non-invasive pneumococcal disease, like ear and sinus infections, through either surveillance system



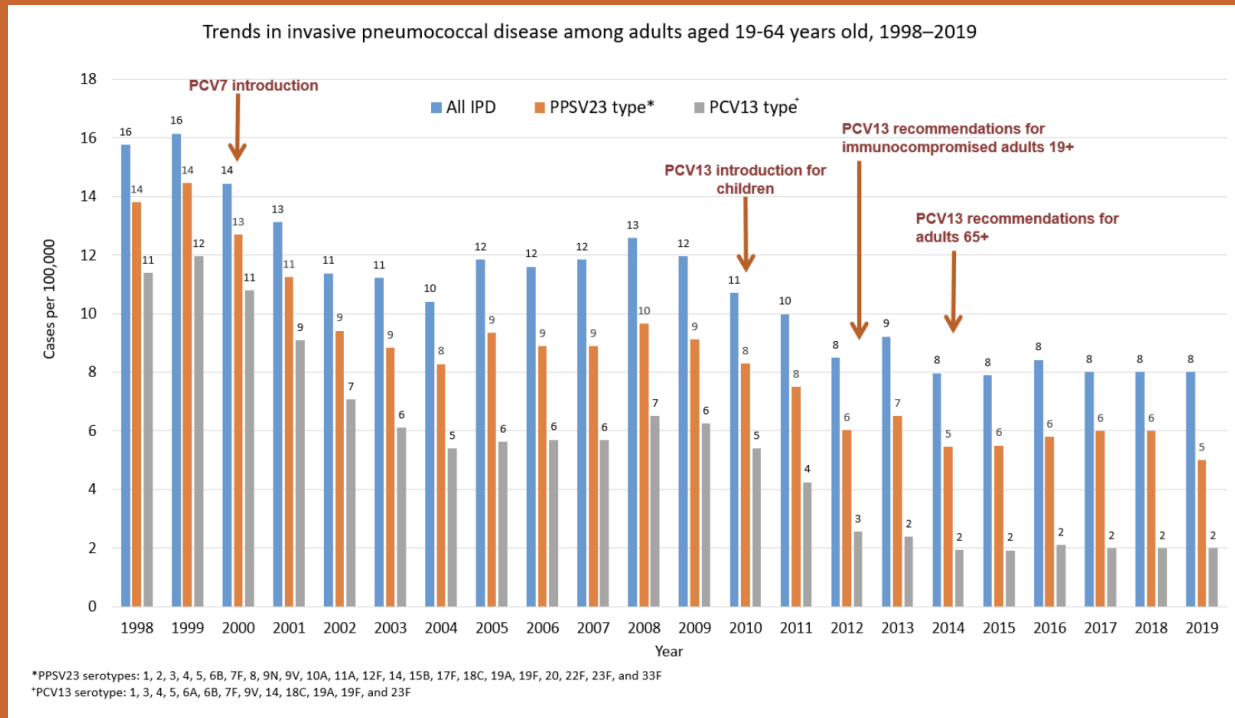
TRENDS

- Invasive pneumococcal disease dramatically declined in both children and adults following the introduction of pneumococcal conjugate vaccines in the United States (see figures below)
- CDC first recommended PCV7 in 2000 and PCV13 in 2010



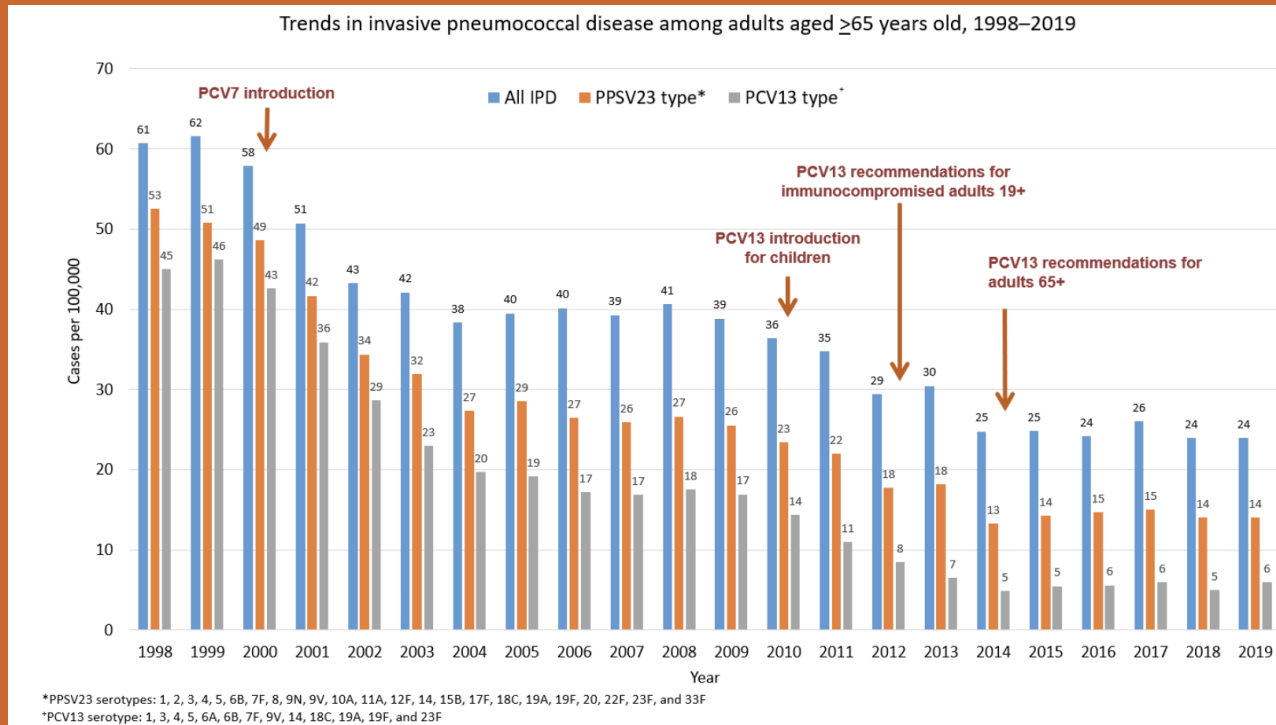
INCIDENCE OF INVASIVE PNEUMOCOCCAL DISEASE (IPD) AMONG ADULTS 19 THROUGH 64 YEARS OF AGE FROM 1998 THROUGH 2019

- Blue bars overall IPD incidence
- Orange included in the 23-valent pneumococcal polysaccharide vaccine (PPSV23)
- Grey serotypes included in the 13-valent pneumococcal conjugate vaccine
- **IPD incidence declined from 16 cases per 100,000 in 1998 to 8 cases per 100,000 in 2019**





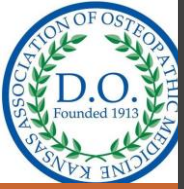
TRENDS 65 AND OLD PNEUMOCOCCAL DISEASE 1998-2019



- Blue bars represent overall IPD incidence
- Orange bars included in 23-valent pneumococcal polysaccharide vaccine (PPSV23)
- Grey bars included in the 13-valent pneumococcal conjugate vaccine (PCV13)
- **Overall IPD incidence declined from 61 cases per 100,000 in 1998 to 24 cases per 100,000 in 2019**

Pneumococcal vaccines currently recommended for use in the United States

	Recommended for children	Recommended for adults
Pneumococcal conjugate vaccines		
PCV13	<input checked="" type="checkbox"/>	
PCV15	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
PCV20		<input checked="" type="checkbox"/>
Pneumococcal polysaccharide vaccine		
PPSV23	Risk-based recommendations	If previously received PCV13 or PCV15



SUMMARY OF PNEUMOCOCCAL VACCINES

New conjugated vaccines

PCV-20 by Pfizer (Prevnar 20)

PCV-15 by Merck
(VAXNEUVANCE)

- Previous polysaccharide Vaccine
- PPSV-23 by Merck (Pneumovax)
- Previous Conjugated Vaccine
 - PCV-13 by Pfizer (Prevnar 13)
 - No longer recommended for adults

Serotypes Contained in Current and New Pneumococcal Vaccines

	1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F	22F	33F	8	10A	11A	12F	15B	2	9N	17F	20	
PCV13	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	White	White	White	White	White	White	White	White	White	White	White	White
PCV15	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green	White	White	White	White	White	White	White	White	White	White
PCV20	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green	Blue	Blue	Blue	Blue	Blue	Blue	White	White	White	White
PPSV23	Yellow	Yellow	Yellow	Yellow	White	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green	Blue	Blue	Blue	Blue	Blue	Blue	Yellow	Yellow	Yellow	Yellow

Serotypes contained in current and new pneumococcal vaccines

	1	3	4	5	6A	6B	7 F	9V	14	18 C	19 A	19 F	23 F	22 F	33 F	8	10 A	11 A	12 F	15 B	2	9N	17 F	20	
PCV13	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow												
PCV15	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green										
PCV20	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green	Green	Green	Green	Green	Green	Green				
PPSV23	Yellow	Yellow	Yellow	Yellow	White	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Green	Green	Green	Green	Green	Green	Green	Green	Orange	Orange	Orange	Orange

For analysis purposes:

- **PCV13+6C:** includes serotype **6C** with PCV13 types due to cross protection from 6A antigen
- **PCV15 non-PCV13:** includes serotypes **22F** and **33F**
- **PCV20 non-PCV15:** includes serotypes **8, 10A, 11A, 12F, and 15B**
- **PPSV23 non-PCV20:** includes serotypes **2, 9N, 17F, and 20**

Clinical Impact: Potential IPD Cases by Vaccine Serotype

- Currently, no studies comparing the efficacy of Prevnar 20™ to 15-valent pneumococcal conjugate vaccine

Adults ≥ 65 Years

13 Serotypes 27%

15 Serotypes 41%

20 Serotypes 55%

Adults 19-64 Years

13 Serotypes 30%

15 Serotypes 43%

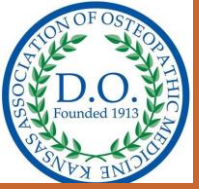
20 Serotypes 62%

0 10 20 30 40 50 60 70 80 90 100




PNEUMOCOCCAL VACCINE RECOMMENDATIONS FOR ADULTS OLDER THAN 65: RELATIVELY NEW

- For those who have **never received any pneumococcal conjugate vaccine**, CDC recommends **PCV15 or PCV20** for adults 65 years or older
- If PCV15 is used, this should be followed by a dose of **PPSV23** in 12 months



CASE 1: 65-YEAR-OLD WITH NO PNEUMOCOCCAL VACCINES

- What are the suggested pneumococcal vaccines?
- A. Give only PPSV23
- B. Give PCV15 now and follow in 12 months with PPSV23
- C. Give PCV20 now and pneumococcal vaccines are complete
- D. Both B and C are correct 
- E. None of the above or PCV20



CAN YOU GIVE THE PATIENT ABOVE OTHER VACCINES WITH PCV15 AND PCV 20

- Yes
- If not up to date with influenza and/or COVID19 vaccines, then the patient can be up-dated
- Other vaccines can be given if needed (i.e. Tdap, MMR, etc)
- Don't miss opportunities



CASE 2
65-YEAR-OLD WHO HAS RECEIVED PCV13
AND PPSV23 AFTER 65

What vaccine, if any, should you recommend?

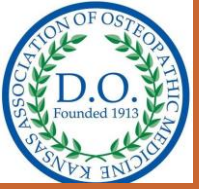
- A. PCV 15
- B. Give another PPSV23 in 5 years after last PPSV23
- C. PCV 20
- D. Patient and healthcare provider can use **shared clinical decision** making to decide if patient should receive PCV20
- D. None of the above are needed





WHAT IS SHARED CLINICAL DECISION MAKING

- **Key component of patient-centered health care**
- A process in which clinicians and patients work together to make decisions and select tests, treatments and care plans based on clinical evidence that balances risks and expected outcomes with patient preferences and values



CASE 2 CONT.

- Adults 65 years or older have the option to get **PCV20** if they have already received
 - PCV13 (but not PCV15 or PCV20) at any age
- And
- PPSV23 at or after the age of 65 years old
- Shared clinical decision is recommended

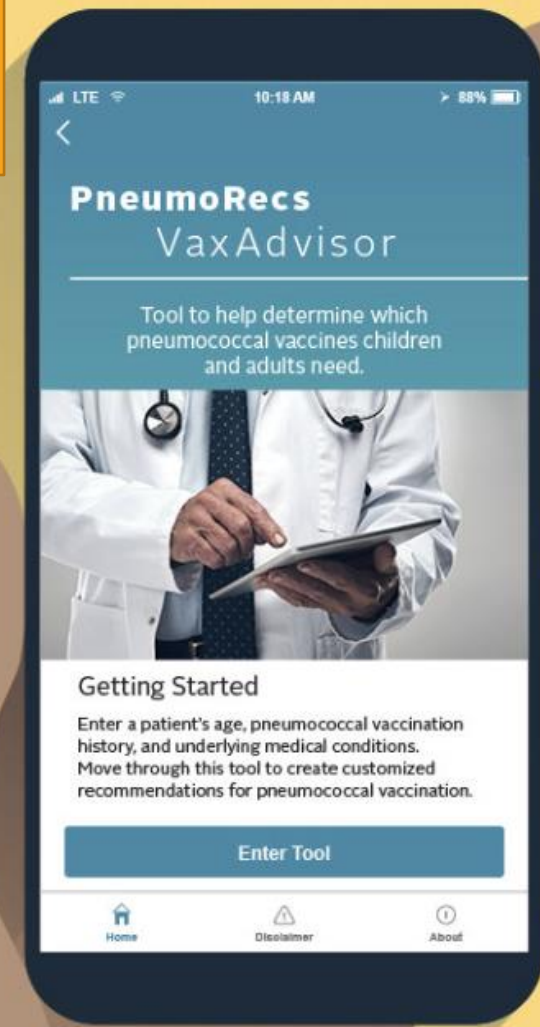


Here is my gift: an APP that answers the questions for pneumococcal vaccine use

PNEUMORECS VAXADVISOR MOBILE APP FOR VACCINE PROVIDERS

<https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html>

The *PneumoRecs VaxAdvisor* mobile app helps vaccination providers quickly and easily determine which pneumococcal vaccines a patient needs and when. The app incorporates recommendations for all ages so internists, family physicians, pediatricians, and pharmacists alike will find the tool beneficial.



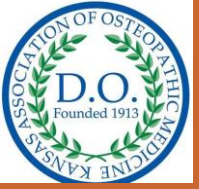
PneumoRecs VaxAdvisor is available for download on iOS and Android mobile devices.



PRACTICE CASE: USE YOUR NEW DOWNLOADED PNEUMORECS VAXADVISOR

- **68 yo woman with a history of COPD and chronic kidney disease presents to your office for a Medicare Wellness Visit**
 - She reports receiving a single Pneumovax 23 vaccine 5 years prior and remembers she was supposed to get “another pneumonia vaccine”.

- Enter a patients' age
- Note if patient has specific underlying medial condition
- Answer questions about the patient’s pneumococcal vaccination history
- The APP provides patient specific guidance per ACIP



ACIP RECOMMENDATIONS FOR THIS PATIENT:

- You may give one dose of PCV15 or PCV20 at least 1 year after their last dose of PPSV23
- Regardless of which vaccine is used (PCV15 or PCV20), their pneumococcal vaccinations are complete
- All on board?



WHAT ARE THE DIFFERENCE BETWEEN A POLYSACCHARIDE AND CONJUGATE VACCINES

Polysaccharide

- Polysaccharide (sugar moiety) stimulates immune response
- T-cell independent response and no B cell memory
- Not immunogenic in elderly and young children
- Reduces invasive disease, but no effect on carriage

Conjugate

- Polysaccharide attached to a protein
- T-cell dependent response and B-cell memory
- Enhanced immunogenic response
- Reduces invasive disease and carriage



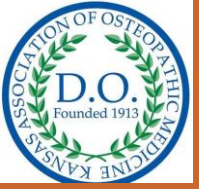
SIMPLIFIED PNEUMOCOCCAL VACCINE ACIP RECOMMENDATIONS

- **The ACIP recommends pneumococcal vaccine for:**
 - Those aged 65 years and older
 - Those aged 19-64 years with certain medical and immunocompromising conditions



WHAT ARE RISK FACTORS FOR PNEUMOCOCCAL INFECTIONS FOR 19-64 YEARS OF AGE?

- **Advanced Age**
- **Viral Infections**
- **Alcohol and Cigarette Use**
- **COPD and other pulmonary disorders**
- **CSF leak and cochlear implant**
- **Comorbidities**
 - Immunocompromised state, including asplenia, HIV
 - Diabetes
 - Kidney disease
 - Lymphoma or other malignancy
 - Organ transplant



FYI

Adults aged 19–64 years with immunocompromising conditions have 9–18 times the risk of pneumococcal disease compared with healthy adults.



NEW SIMPLIFIED PNEUMOCOCCAL RECOMMENDATIONS FOR 19 AND OLDER HIGH- RISK POPULATION AND 65 AND OLDER

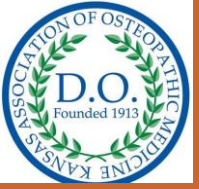
Option 1: Two (2) Vaccine “combo”

- **PCV15 (Vaxneuvance) then PPSV23 (Pneumovax 23)**
 - Give PCV15 first, then
 - >1 yr later (minimum 8 weeks for immunocompromised), give PPSV23

Option 2: Single (1) Vaccine


- **PCV20 (Prevnar20)**

IF PCV20 is given from 19 years of age and older, pneumococcal vaccinations are complete



CASE 3:


A 69 Y/O FEMALE SMOKER HAS ONLY RECEIVED A PCV7 AT 19 YEARS OF AGE AND NO OTHER PNEUMOCOCCAL VACCINES, WHAT IS THE CDC'S RECOMMENDATION?

- A. Give one dose of PCV 20
- B. Give 1 dose of PCV15 followed in one year with a PPSV23
- C. Patient does not need any further pneumococcal vaccinations
- D. Either A or B above 
- E. None of the above



CASE 4: A 23 Y/O SMOKER (OR ALCOHOLIC,
ASTHMATIC) HAS RECEIVED A PPSV23
VACCINE AT AGE 19


What pneumococcal vaccination is/are recommended?

- A. Give 1 dose of PCV15 or PCV20 at least 1 year after the last dose of PPSV23 - pneumococcal vaccination is complete 
- B. Repeat the PPSV23 every 5 years
- C. Give a PCV 15 every 5 years
- D. Give a PCV 20 every 5 years
- E. None of the above



**CASE 5: A 36 Y/O ASTHMA PATIENT HAS
ONLY RECEIVED HER PCV 13;
ASTHMA PATIENTS ARE HIGH RISK FOR IPD**


What are your options recommended for this patient?

- A. Give 1 dose of PCV20 at least 1 year after PCV13
- B. Give two additional doses of PPSV23 with the 2nd dose at least 5 years after the first dose of PPSV23
- D. Give a 3rd dose of PPSV23 at age 65 years or older (minimum interval 5 years since the second dose of PPSV23)
- E. If a patient is age 65 years or older when the second dose is given, then a third dose is not indicated
- F. All of the above are options 

But the best for compliance and costs is A



CASE 6: AN ALCOHOLIC TURNS 65 YEARS AND HAS ONLY RECEIVED ONE PPSV23 IN THE PAST; ALCOHOLICS ARE HIGH RISK FOR IPD

- What pneumococcal vaccination is recommended?
- A. Give 1 dose of PCV20, if at least 1 year since last dose of PPSV23 vaccination, no additional doses of PPSV23 are necessary
- B. Give give one dose of PCV15 if at least 1 year since recent PPSV23 vaccination; no additional PPSV23 is needed since they had already received a dose
- C. All of the above 
- D. None of the above



PNEUMOCOCCAL VACCINE SAFETY

▪ Most common side effects

- Fatigue
- Loss of appetite
- Sore or swollen arm from the shot
- Fever
- Headache
- ***Very rarely: severe (anaphylactic) allergic reactions may occur after vaccination***
- ***Rates of serious adverse events (SAEs) within 6 months of vaccination were 2.5% among PCV15 recipients and 2.4% among PCV13 recipients. No SAEs or deaths were considered to be related to the study vaccines***



COSTS OF PNEUMOCOCCAL VACCINES

- ❑ PCV13 \$257.99^a
 - ❑ PCV15 \$246.20^a
 - ❑ PCV20 \$283.72^a
 - ❑ PPSV23 \$133.47^a
 - ❑ Administration+Time cost: \$56.73^b
-
- $$\$246.20 + 133.47 = \$379.67$$



FUTURE PNEUMOCOCCAL VACCINES ARE ON THE HORIZON BY GSK AND MERCK

	1	3	4	5	6 A	6 B	7 F	9 V	1 4	1 8 C	1 9 A	1 9 F	2 3 F	2 2 F	3 3 F	8	1 0 A	1 1 A	1 2 F	1 5 B	2	9 N	1 7 F	2 0	2 0 B	1 5 A	1 5 C	1 6 F	2 3 A	2 3 B	2 4 F	3 1	3 5 B				
PCV13																																					
PCV15																																					
PCV20																																					
PPSV23																																					
AFX3772																																					
V116																																					

24-valent pneumococcal vaccine

AFX3772, GSK

- Completed phase 1/2 study for adults¹

21-valent pneumococcal conjugate vaccine

V116, Merck

- Completed phase 1/2 study for adults²
- Phase 3 immunobridging studies in adults are currently ongoing

1. Chichili et al. Vaccine 2022; 2. Platt et al. Lancet ID 2022.



QUESTIONS/COMMENTS/CONCERNS



- Contact information
 - Stanley.grogg@okstate.edu
- Or
- www.powerofanickel.org for international medical mission trips