Introduction of the Pneumococcal Work Group

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Pneumococcal Vaccines Work Group Chair
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Advisory Committee on Immunization Practices

October 28, 2020

Pneumococcal Vaccines Work Group

- ACIP Members

- Katherine Poehling (Chair)
- Keipp Talbot

- Ex Officio Members

- Jeffrey Kelman (CMS)
- Lucia Lee (FDA)
- Tina Mongeau (FDA)
- Thomas Weiser (IHS)
- Kristina Lu (NIH)

- CDC Lead

- Miwako Kobayashi (NCRID)

- Liaison Representatives and Consultants

- Nina Ahmad (AAFP)
- Mark Sawyer (AAP/COID)
- Jason Goldman (ACP)
- David Nace (AGS/AMDA)
- Jane Zucker (AIM)
- Oliver Baclic(NACI)
- Carol Baker (IDSA)
- William Schaffner (NFID)
- TBD (NMA)
- Nancy Bennett (U. of Rochester)
- Monica Farley (VAMC/Emory)
- Keith Klugman (BMGF)
- Sarah Long (Drexel University)
- Arthur Reingold (UC Berkley)
- Lorry Rubin (CCMC)
- Cynthia Whitney (Emory)
- Richard Zimmerman (U. of Pittsburgh)

Pneumococcal Vaccines Work Group

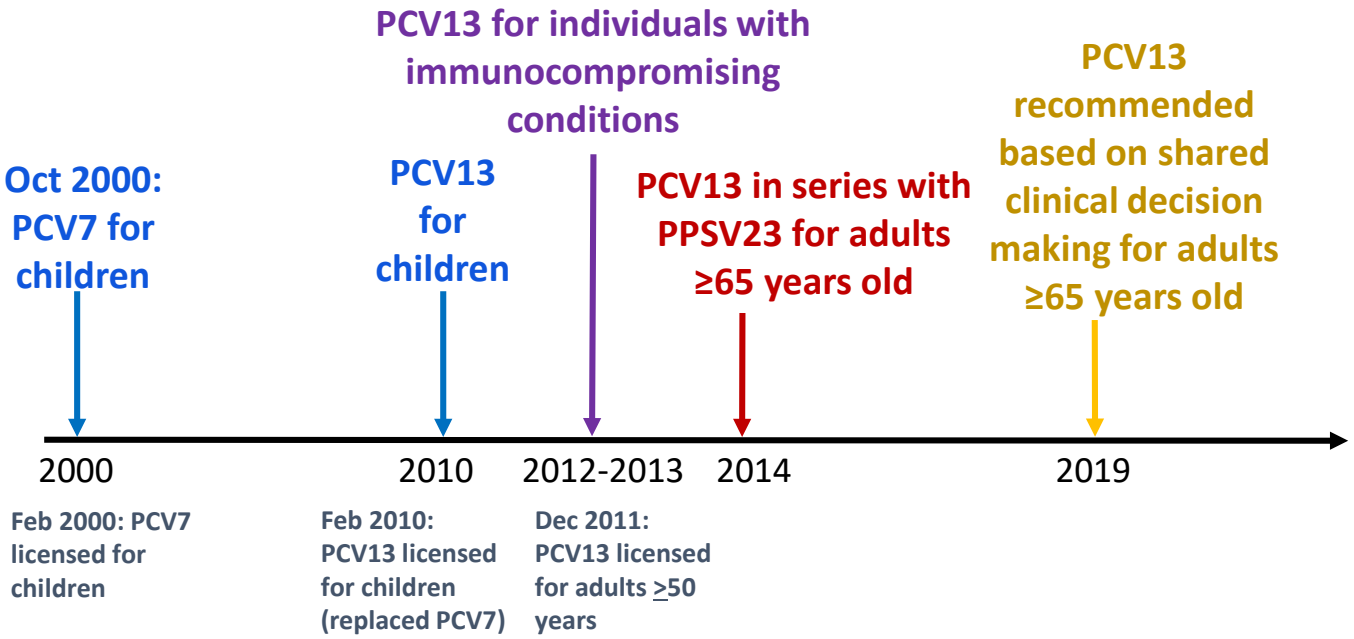
- CDC Contributors

- Tamara Pilishvili (Respiratory Diseases Branch)
- Penina Haber, Pedro Moro (Immunization Safety Office)
- Sarah Schillie (Immunization Services Division)

Pneumococcal Work Group Terms of Reference: Purpose

- Review current data including efficacy, effectiveness, immunogenicity, epidemiology, and cost-effectiveness of pneumococcal conjugate and polysaccharide vaccines and assess the strength of the evidence
- Review current recommendations considering up-to-date evidence
- Revise or update recommendations for pneumococcal vaccine use as needed

ACIP PCV Recommendations



Conclusions from the EtR leading to ACIP vote in 2019

Element	Favoring Continued PCV13 Use	Favoring No Longer using PCV13
Burden of Disease	• PCV13-type disease reduced, but not eliminated through indirect effects from pediatric PCV use	• Indirect effects from pediatric PCV use have reduced the burden of PCV13-type disease to historic lows
Benefits	• PCV13 effective in preventing PCV13-type pneumococcal disease	• **Impact from PCV13 use in older adults observed to date is minimal; no impact on IPD and inconsistent findings across studies for impact on pneumonia** • **Benefits from continued PCV13 use are expected to be minimal**
Acceptability	• **Frequent changes in recommendations may negatively impact the perceived importance of future adult vaccine recommendations**	• Credibility comes from evidence-based recommendations
Resources Used	• A recommendation change would incur a cost to update electronic medical records, decision support tools, etc.	• Economic analyses results do not favor continued PCV13 use
Feasibility	• **Universal prevention strategies are easier to implement effectively than risk-based ones** • **Frequent changes in recommendations present implementation challenges**	• Simplifies the recommendations—current recommendations have been confusing and difficult to implement

New PCV Products on the Horizon

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

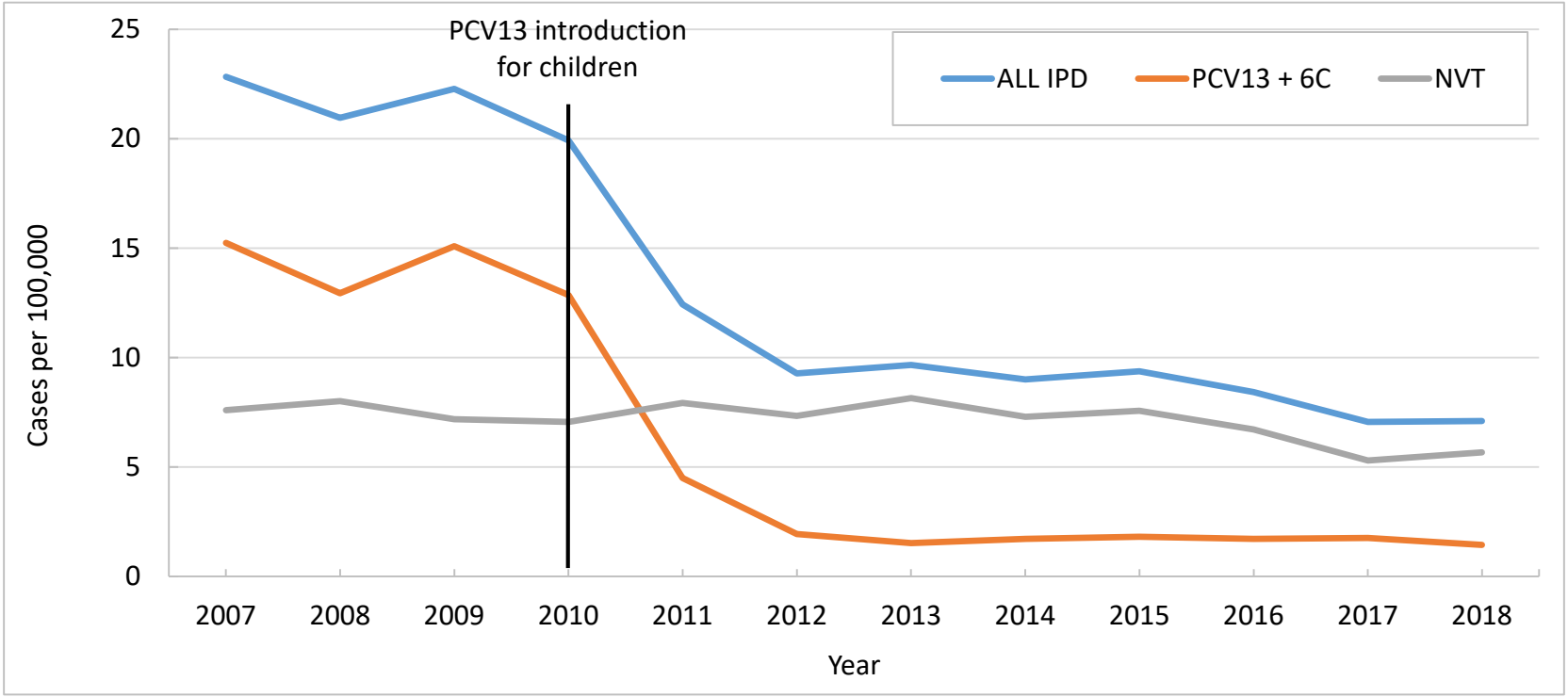
- Merck: PCV15 (PCV13 serotypes + serotypes **22F and 33F**)
  - Licensure anticipated Q3–4 2021

- Pfizer: PCV20 (PCV13 serotypes + serotypes 8, 10A, 11A, 12F, 15B, **22F, and 33F**)
  - Licensure anticipated in June 2021

Pneumococcal WG ToR, 2020–2021

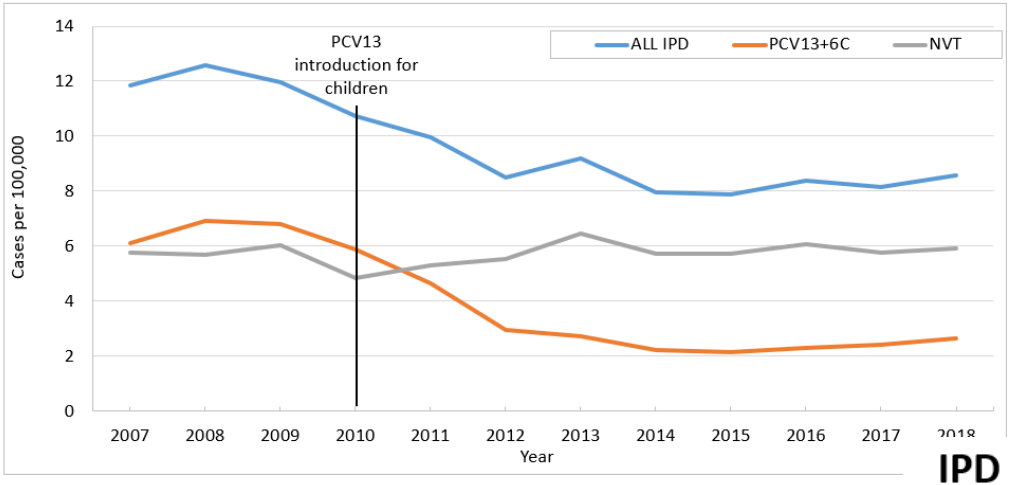
- Review considerations for and evidence supporting the use of higher valent pneumococcal conjugate vaccines in the general population of US adults.
- Review considerations for and evidence supporting the use of higher valent pneumococcal conjugate vaccines for adults with certain underlying conditions.
- Present policy options for ACIP vote.

IPD Rates among Children <5 Years Old, 2007–2018



CDC, Active Bacterial Core surveillance

IPD Rates among Adults 19–64 Years Old, 2007–2018

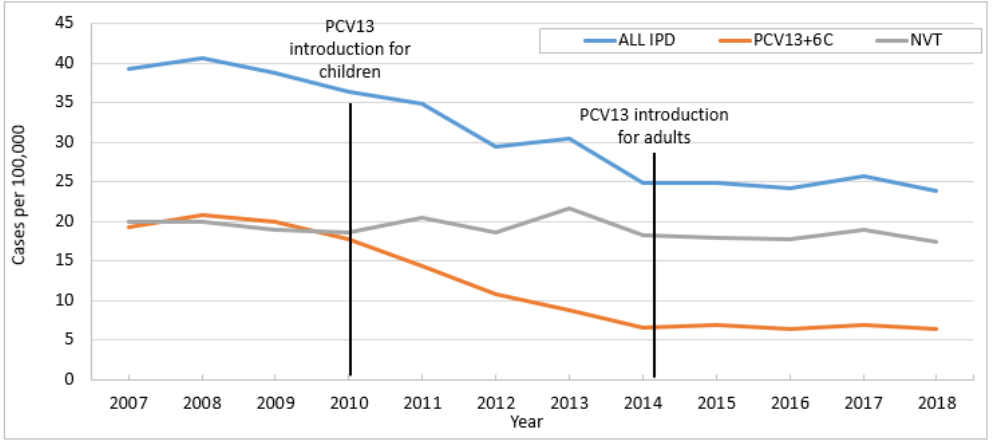


Key Points:

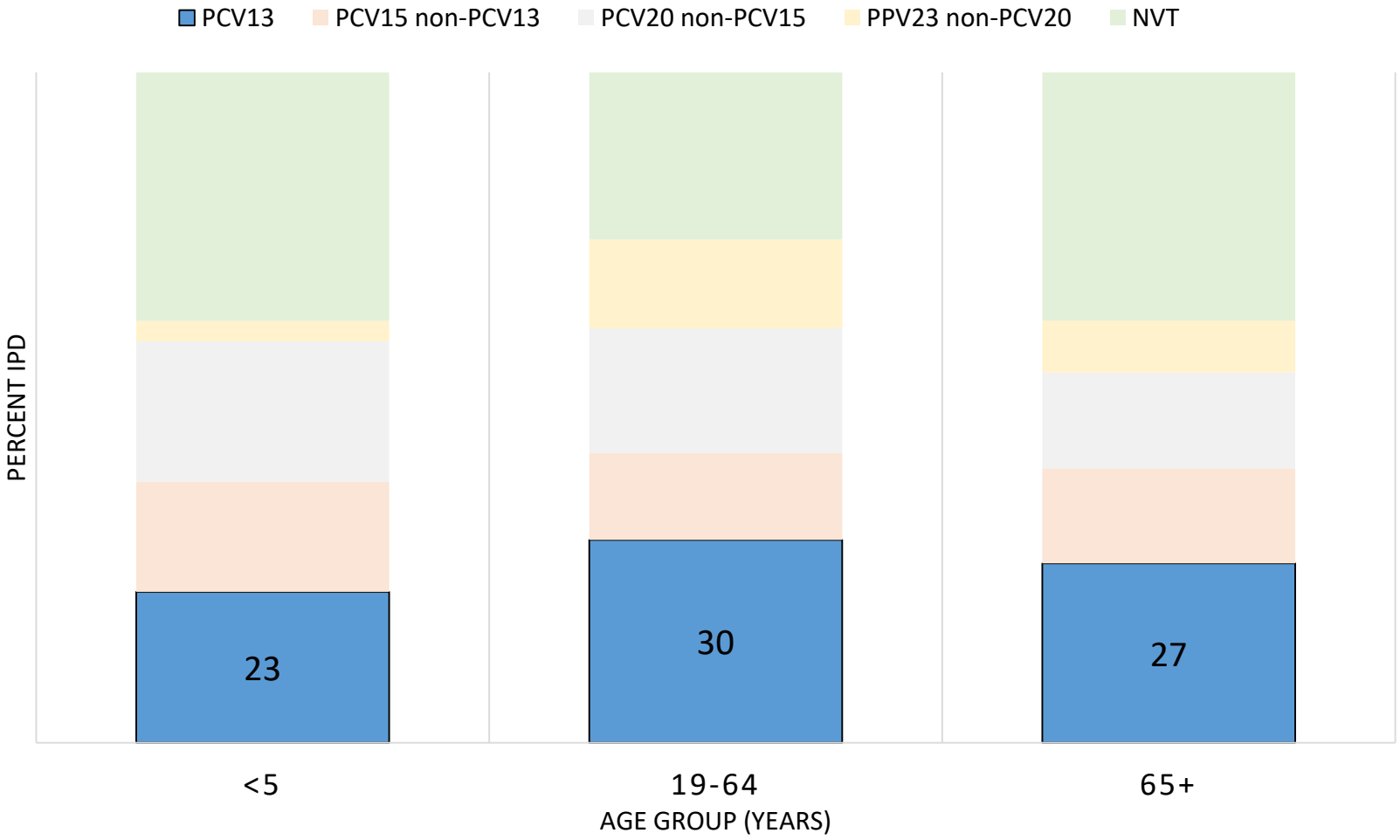
- PCV13-type IPD incidence declined in adults, likely due to indirect effects from PCV13 use in children.
- Since 2014, no population level impact was observed on PCV13-type IPD in adults ≥65 years.

CDC, Active Bacterial Core surveillance

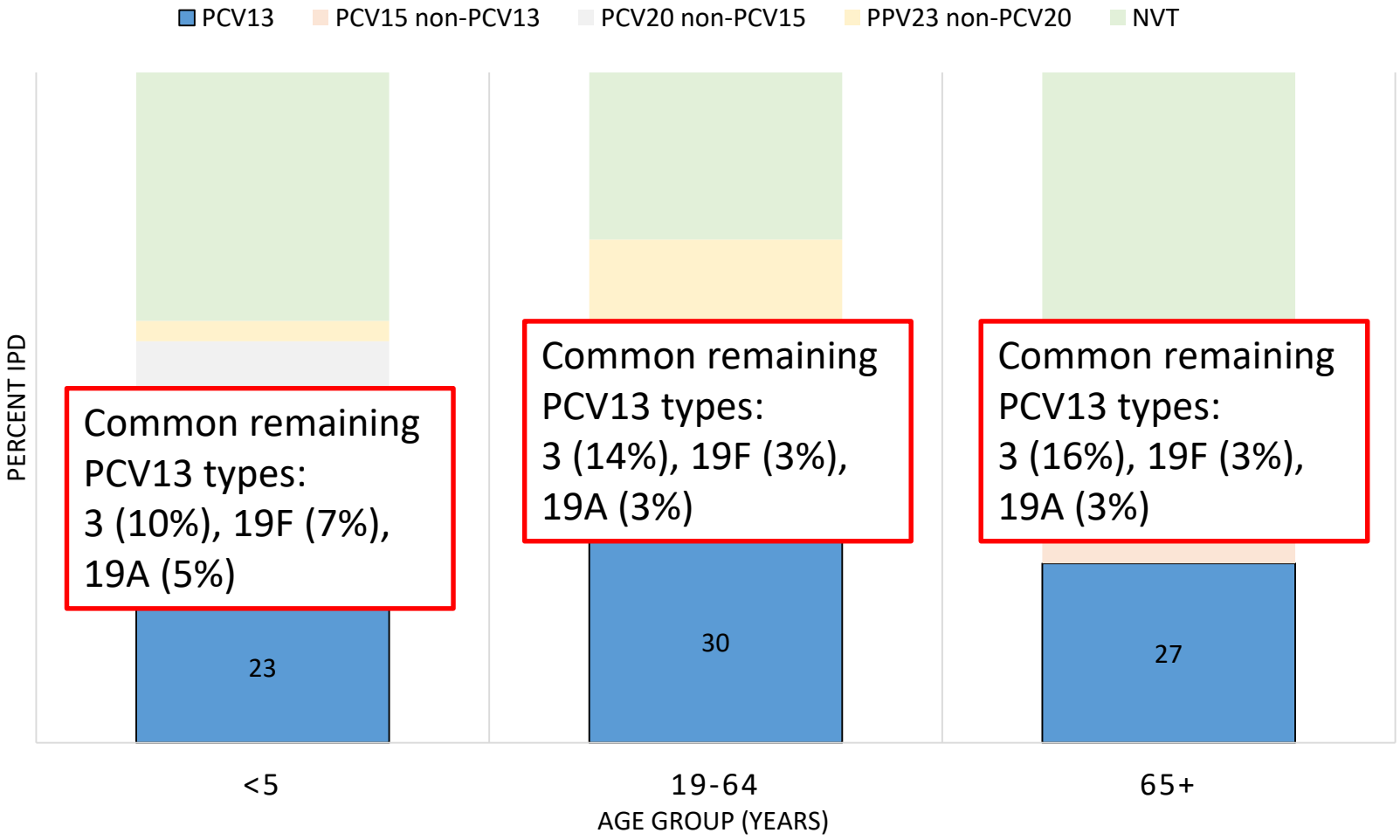
IPD Rates among Adults ≥65 Years Old, 2007–2018



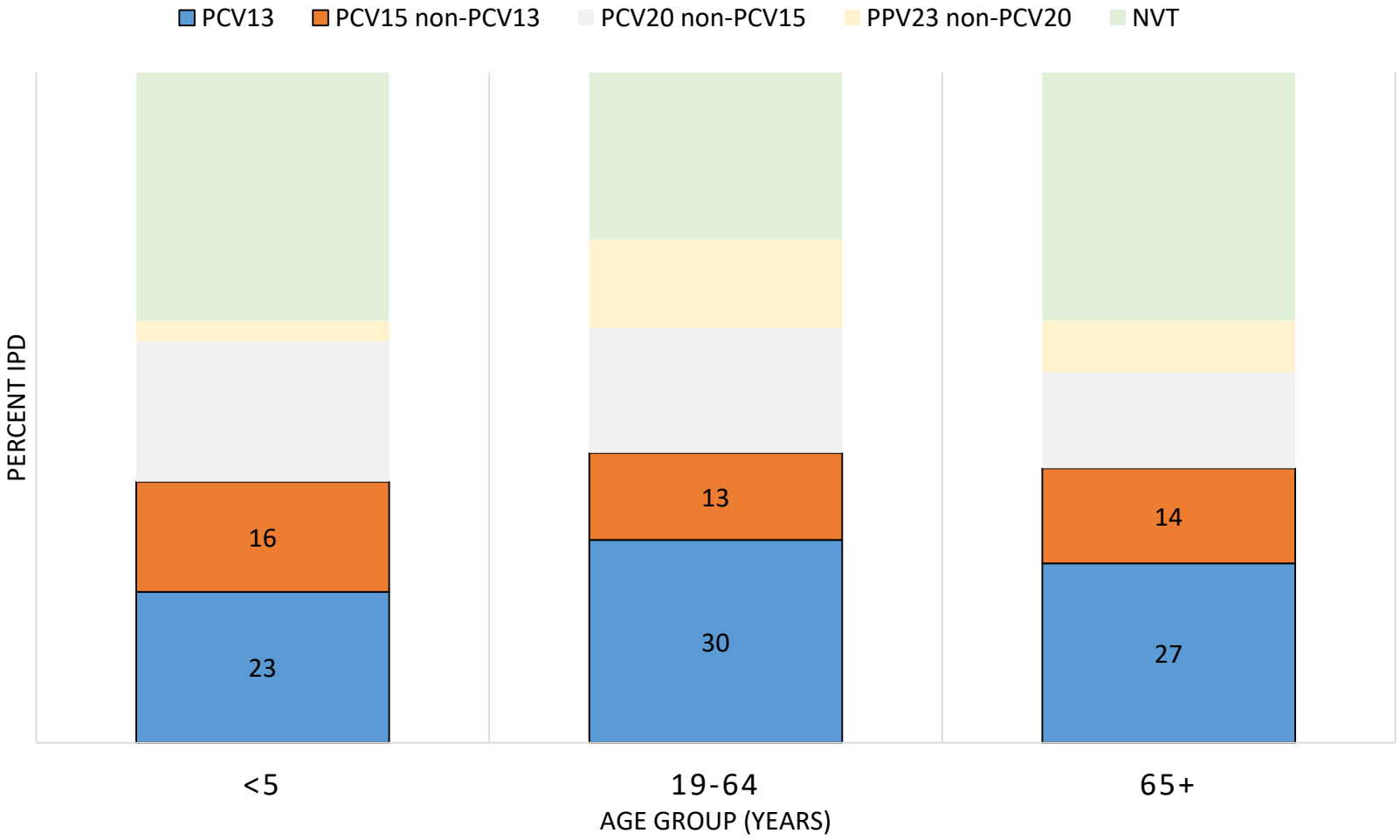
Proportion of PCV13-Type IPD by Age Group, 2017–2018



Remaining PCV13-Type IPD by Age Group, 2017–2018



IPD Serotype Proportion by Vaccine-Type, 2017–2018



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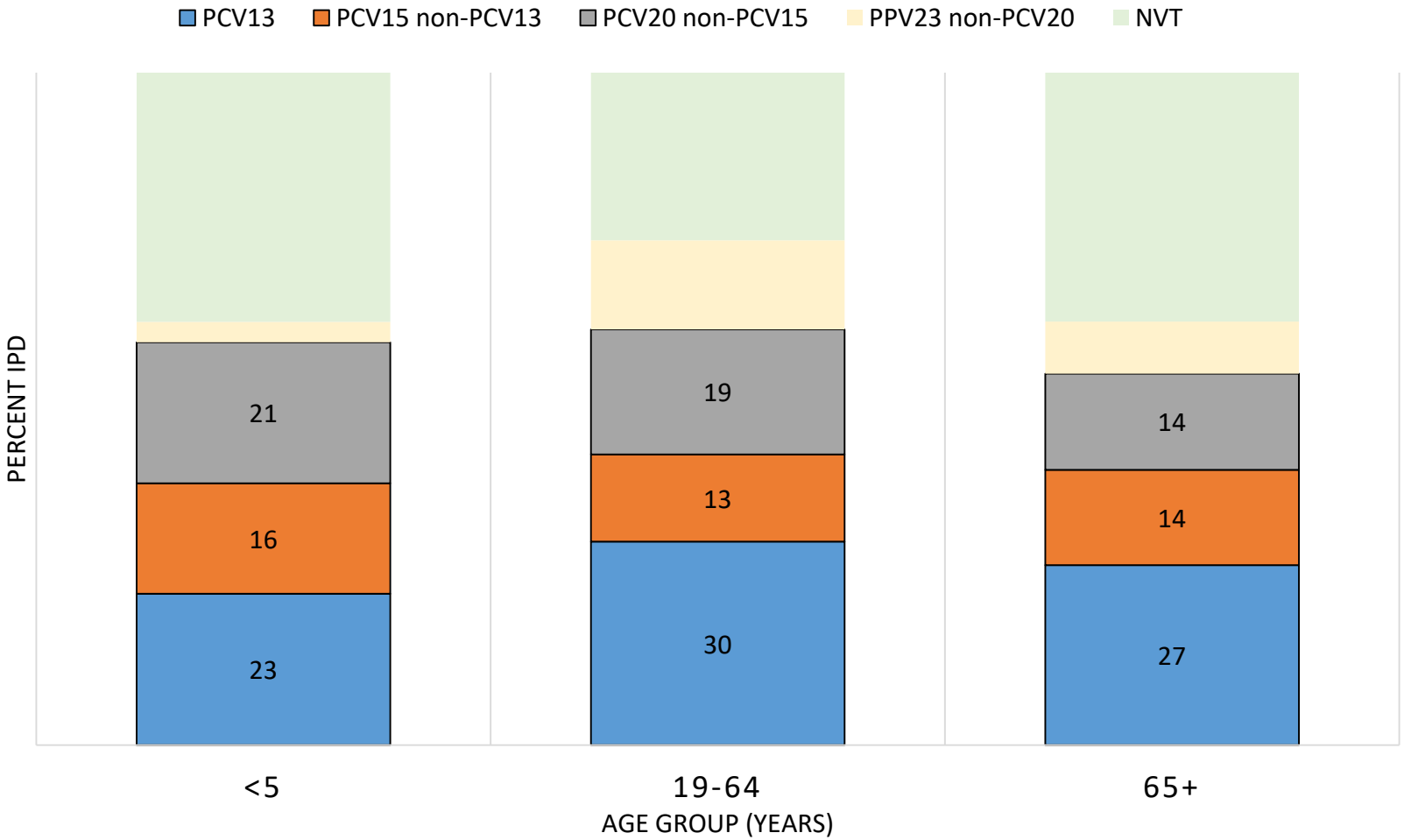
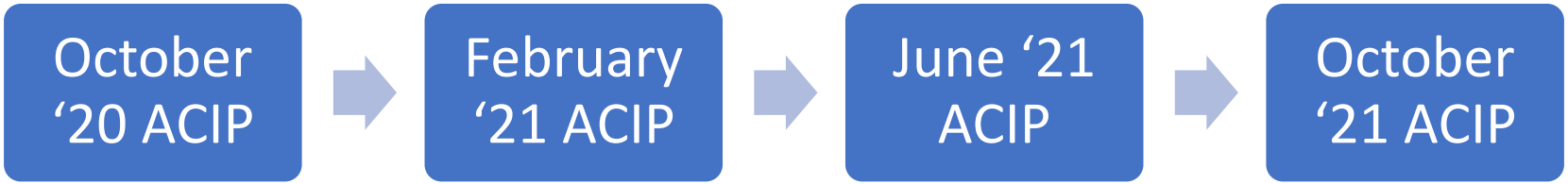


Anticipated Timeline for Licensure of New Adult PCV Products



Pfizer (PCV20)	**Filed to FDA (Oct '20)**		**Licensure anticipated (June '21)**		
Merck (PCV15)		**Filing planned (Q4 2020)**		**Licensure anticipated* (Q3 2021)**	**Licensure anticipated* (Q4 2021)**

*Q3 2021 approval is assuming US standard review. Q4 2021 approval anticipated if granted priority review by the FDA.

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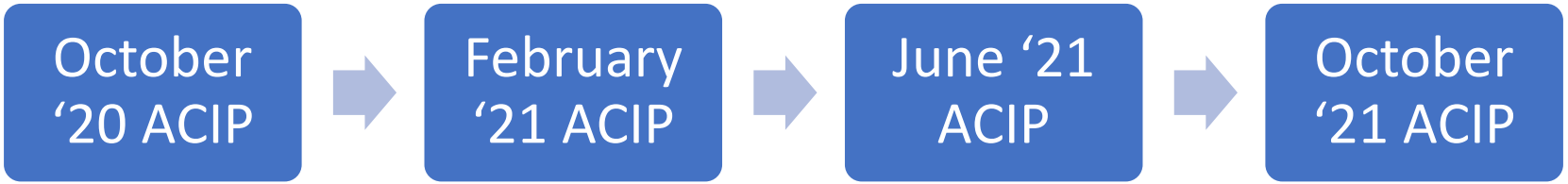

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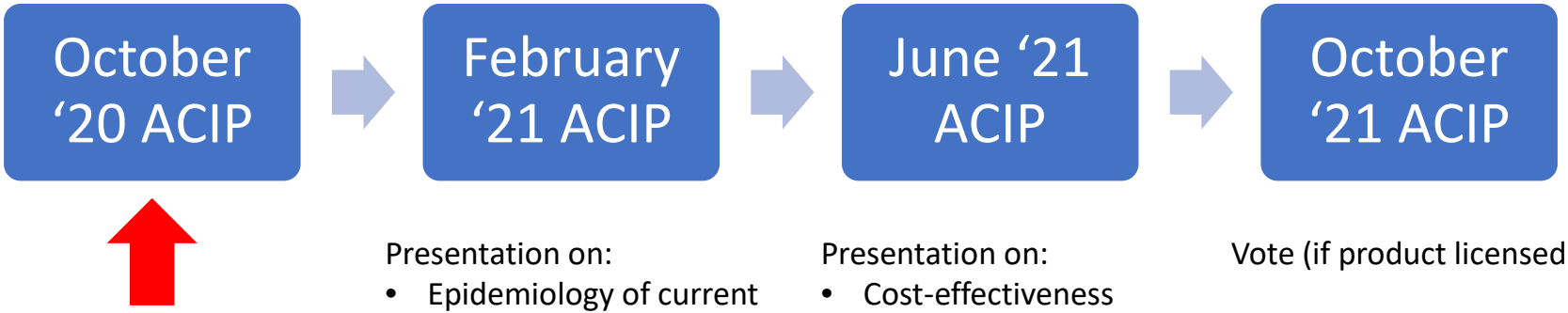
Licensure for children anticipated in Q2-Q3 2022 (PCV15) or mid-2023 (PCV20)

*Q3 2021 approval is assuming US standard review. Q4 2021 approval anticipated if granted priority review by the FDA.

Evidence to be Reviewed by the Work Group

- Immunogenicity and safety for new PCVs (Phase 3 studies)
- Epidemiology of pneumococcal disease and vaccine-preventable disease burden for
  - Invasive pneumococcal disease
  - Non-invasive pneumococcal pneumonia
  - Mortality
- Expected public health impact and cost-effectiveness of PCV15/PCV20
  - Estimated direct effects in adults
  - Estimated indirect effects from vaccine use in children
  - Impact on health equity
- Review new evidence on the effectiveness of PPSV23
- GRADE and EtR

Proposed Timeline of ACIP Presentations



Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov