

# Proposed Recommendations for Use of PPV23 among American Indians and Alaska Natives

Presented by  
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# Authors of proposed changes

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# Two Recommendations

1. PPV23 after PCV7 for 24 -59 month olds
2. PPV23 for adults

# Recommendation #1

PPV23 after PCV7 for 24 -59 month olds

# ACIP Recommendation for PPV23 in AI/AN Children\*

## *Administration of PCV7 Followed by PPV23 Among Children at High Risk for Pneumococcal Disease*

- Children who have completed the PCV7 vaccination series before age 2 years and who are among risk groups for which PPV23 is already recommended should receive one dose of PPV23 at age 2 years ( $\geq 2$  months after the last dose of PCV7).
- These groups at high risk include children with SCD, children with functional or anatomic asplenia, children who are HIV-infected, and children who have immunocompromising or chronic diseases. Although data regarding safety of PPV23 administered after PCV7 are limited, the opportunity to provide additional serotype coverage among these children at very high risk justifies use of the vaccines sequentially.
- **For children of Alaska Native or American Indian descent, addition of PPV23 after PCV7 can be considered.**

*\*From: "Preventing Pneumococcal Disease Among Infants and Young Children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR October 06, 2000 / 49(RR09);1-38*

**TABLE 12. Schedule for vaccination using 23-valent polysaccharide vaccine (PPV23) for children aged  $\geq 2$  years who have previously received the 7-valent conjugate vaccine (PCV7)**

Population	Schedule for PPV23	Revaccination with PPV23*
Healthy children	None <sup>†</sup>	No
Children with sickle cell disease or anatomic or functional asplenia; immunocompromised; <sup>§</sup> or who are infected with human immunodeficiency virus	1 dose of PPV23 administered at age $\geq 2$ yrs and $\geq 2$ mos after last dose of PCV7	Yes <sup>¶</sup>
Persons with chronic illness <sup>§</sup>	1 dose of PPV23 administered at age $\geq 2$ yrs and $\geq 2$ mos after last dose of PCV7	Not recommended

\* Recommendations for revaccination are adapted from CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 1997;46(No. RR-8):12.

<sup>†</sup> Health-care providers of Alaska Natives and American Indians should consider whether these children would benefit by the additional coverage provided by the expanded serotypes in PPV23 (see recommendations regarding Alaska Natives and American Indians).

<sup>§</sup> See Table 8.

<sup>¶</sup> Regardless of when administered, a second dose of PPV23 should not be administered  $< 3$  years after the previous PPV23 dose. If the patient is aged  $> 10$  years, one revaccination should be administered  $\geq 5$  years after the previous PPV23 dose. If the patient is aged  $\leq 10$  years, one revaccination 3–5 years after previous dose should be considered (Sources: CDC. Prevention of pneumococcal disease: recommendations of the Advisory Committee on Immunization Practices [ACIP]. MMWR 1997;46[No. RR-8]:1–24; and American Academy of Pediatrics.

# Current Recommendation

## Strengths

- Permissive language allows the option to use PPV23 in the AI/AN population which includes some groups at high risk.
- VFC will cover costs of vaccine

## Weaknesses

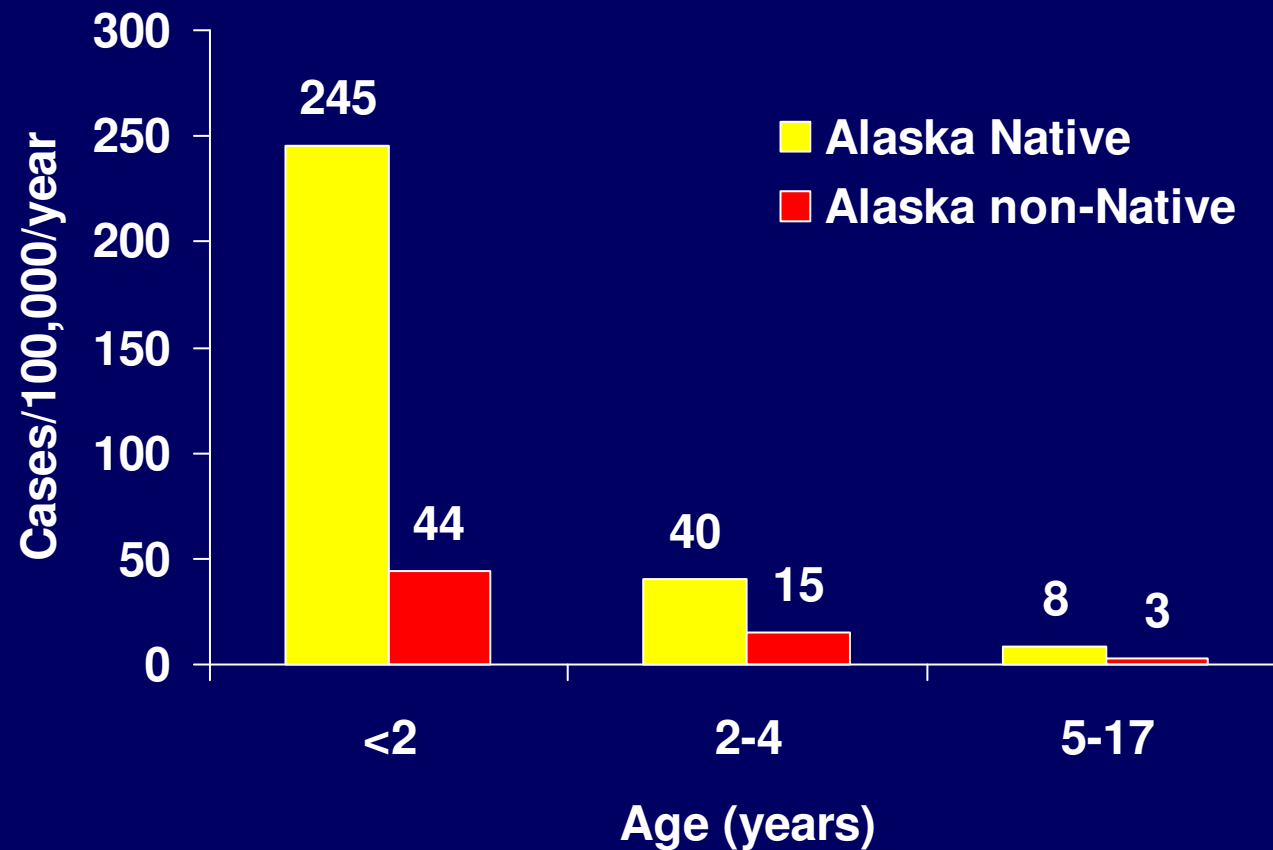
- Burden of decision on individual practitioner
  - ◆ Providers express that they don't have sufficient data on risk/benefits to make informed decisions.
- Language lacks specificity
  - ◆ All AI/AN groups are not at equal risk
    - Data on increased IPD risk limited to Alaska Native, White Mountain Apache and Navajo populations
  - ◆ “American Indian descent” is not defined

# Why include special recommendations for AI/AN children?

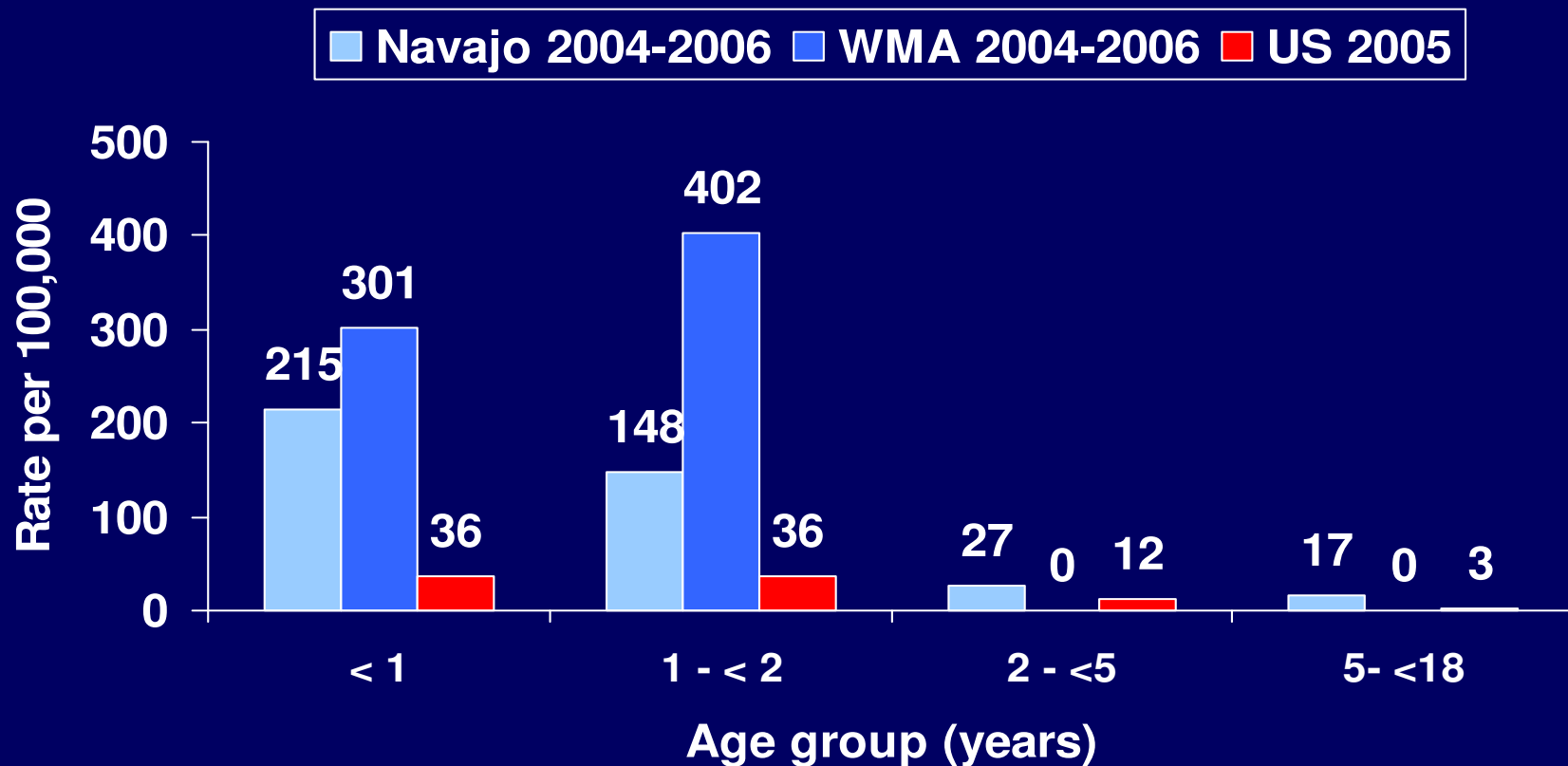
- High rates of invasive pneumococcal disease (IPD)
  - ◆ public health authorities and health care practitioners have considered use of PPV23.
- Considerations have included:
  - ◆ Age-specific IPD incidence
  - ◆ Serotype distribution of IPD
  - ◆ Limited data on effectiveness of PPV23 in this age group and population
  - ◆ Safety concerns related to immune tolerance / hyporesponsiveness
  - ◆ Potential for other intervention strategies, such as PCV13
  - ◆ Practical considerations such as cost, implementation into crowded vaccination schedule, multiple pneumococcal vaccine products



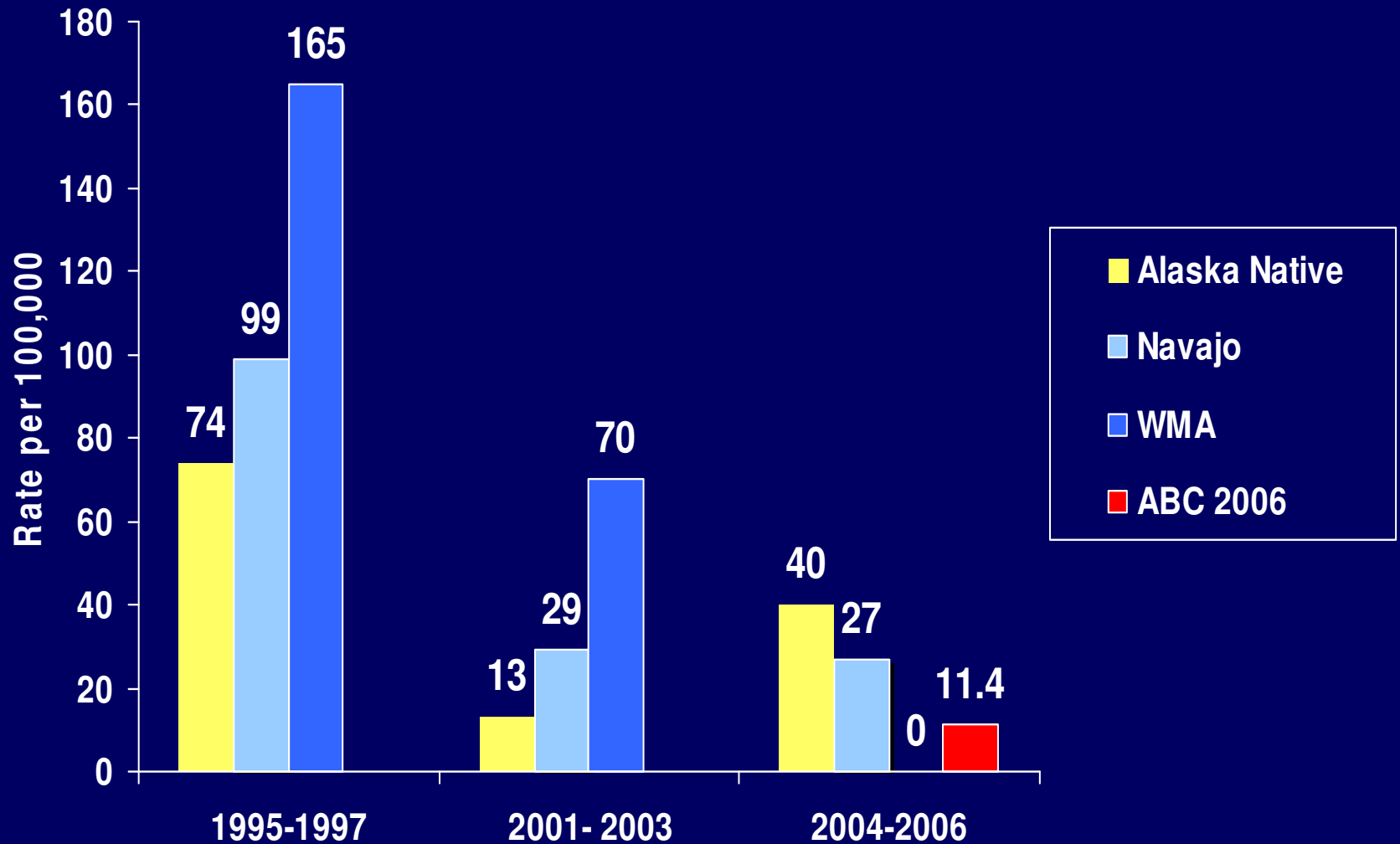
# Post-PCV7 IPD, Alaska Natives and non-Natives, 2004 -2006



# Post-PCV IPD rates among Navajo, WMA and general U.S.



# IPD Rates, 24-59 months, Alaska Natives, Navajo, WMA and general US population



# Post PCV7 Serotype Distribution, AI/AN 24-59 months of age

	Annual birth cohort	PCV7 Annual Cases	Non-PCV7 Annual Cases	% IPD caused by PPV23 types
WMA	300	None	0-1	>80%
Navajo	4,000	None	1-5	>80%
AN	2,600	None	3-9	90%

# Other Concerns

- ◆ Routine PPV23 has never been implemented in these populations, even when rates were higher
  - No local data on safety or reactogenicity
- ◆ Immune hyporesponsiveness has been demonstrated with PPV23 use
  - Clinical implications are not known
- ◆ Complexity of two-product vaccine strategy
- ◆ Little efficacy/effectiveness data on PS23 among children (e.g. Papua New Guinea)

# Current consensus

- Anticipated benefits of PPV23 use after PCV7 do not outweigh the potential risks and practical considerations

# Current Clinical Practice

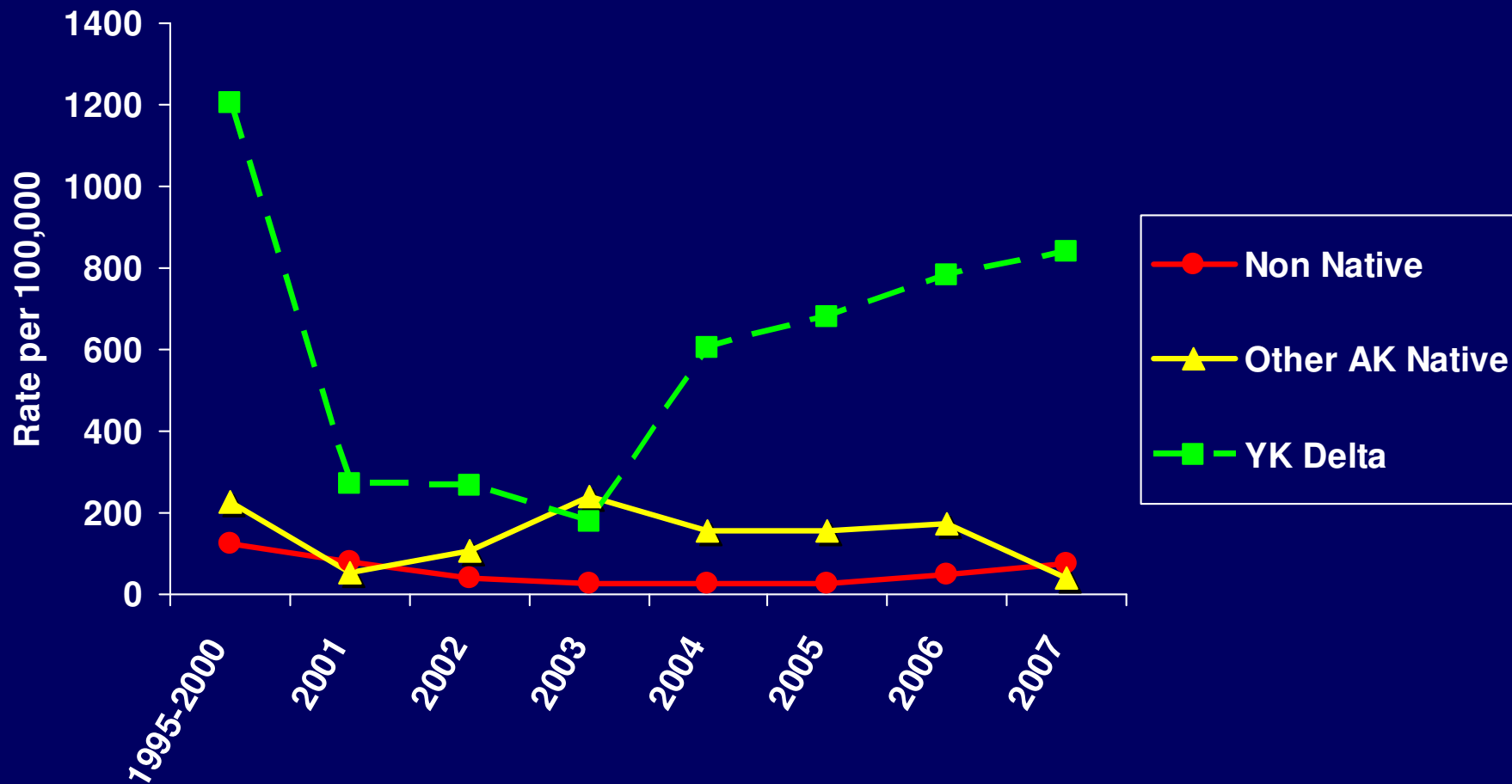
- PPV23 is not routinely used following PCV7 among AI/AN children  $\geq 2$  years
  - by any Indian Health Service or tribal health organization serving the populations with documented high rates of IPD
  - Some providers have used PPV23 for individual patients
- PPV23 is routinely given to those children with high risk medical conditions
  - ◆ Covered elsewhere in ACIP recommendations

# Why preserve a specific statement for AI/AN?

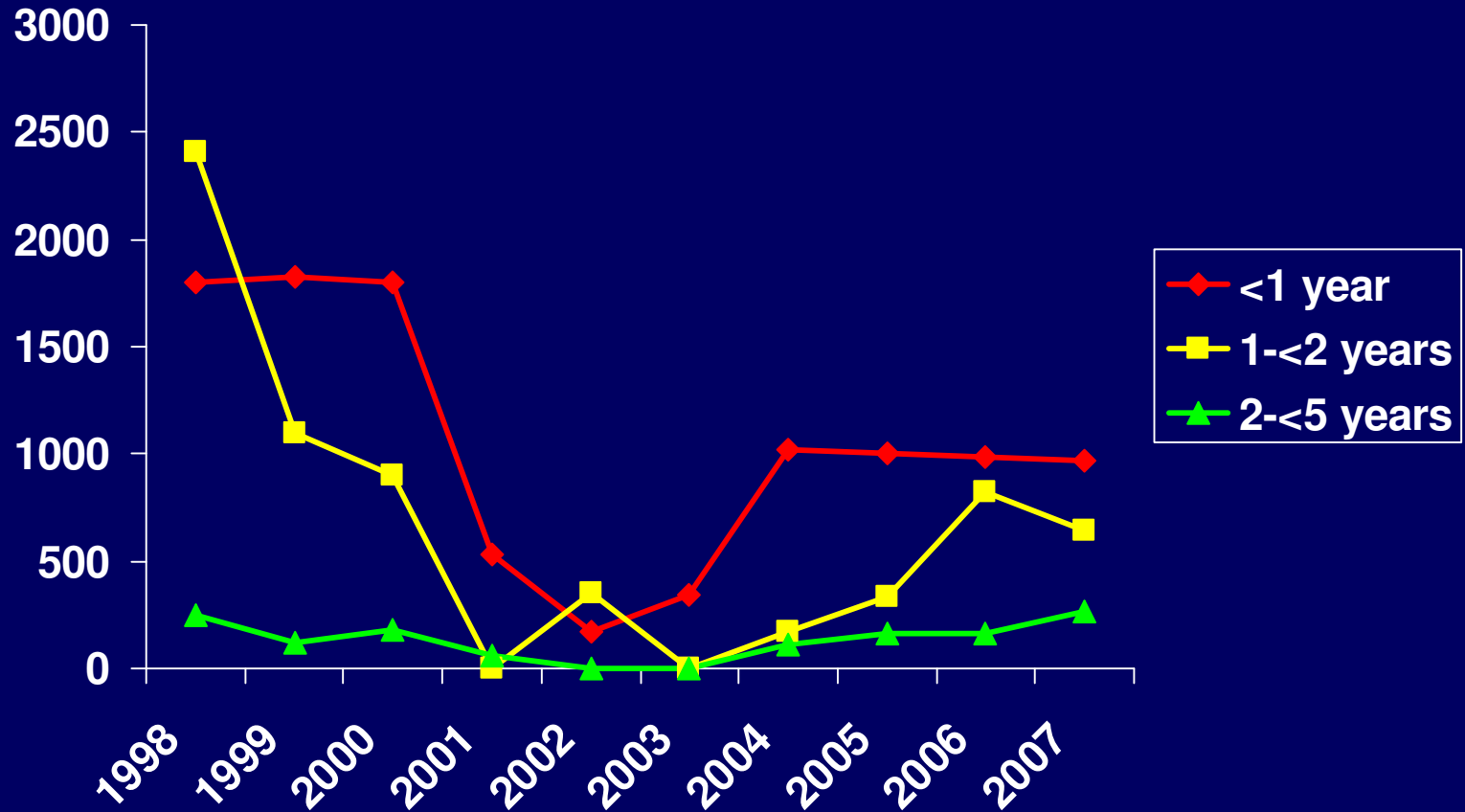
- We would like to preserve PPV23 as an option for the AI/AN population.
- The balance of risk/benefit could change in the future.
- Two examples:
  - ◆ Alaska Native children
    - Increased non-PCV7 type IPD rates since PCV7 intro
    - Plan to use PCV13 under compassionate-use IND, 2009
    - If PCV13 not successful, would reconsider PPV23 use
  - ◆ Indigenous Children, Northern Territories, Australia.
    - PPV23 used at 18 months following 3 dose PCV7 series
    - Safety and effectiveness data are anticipated



# IPD, Alaska, < 2 years old, 1995-2007

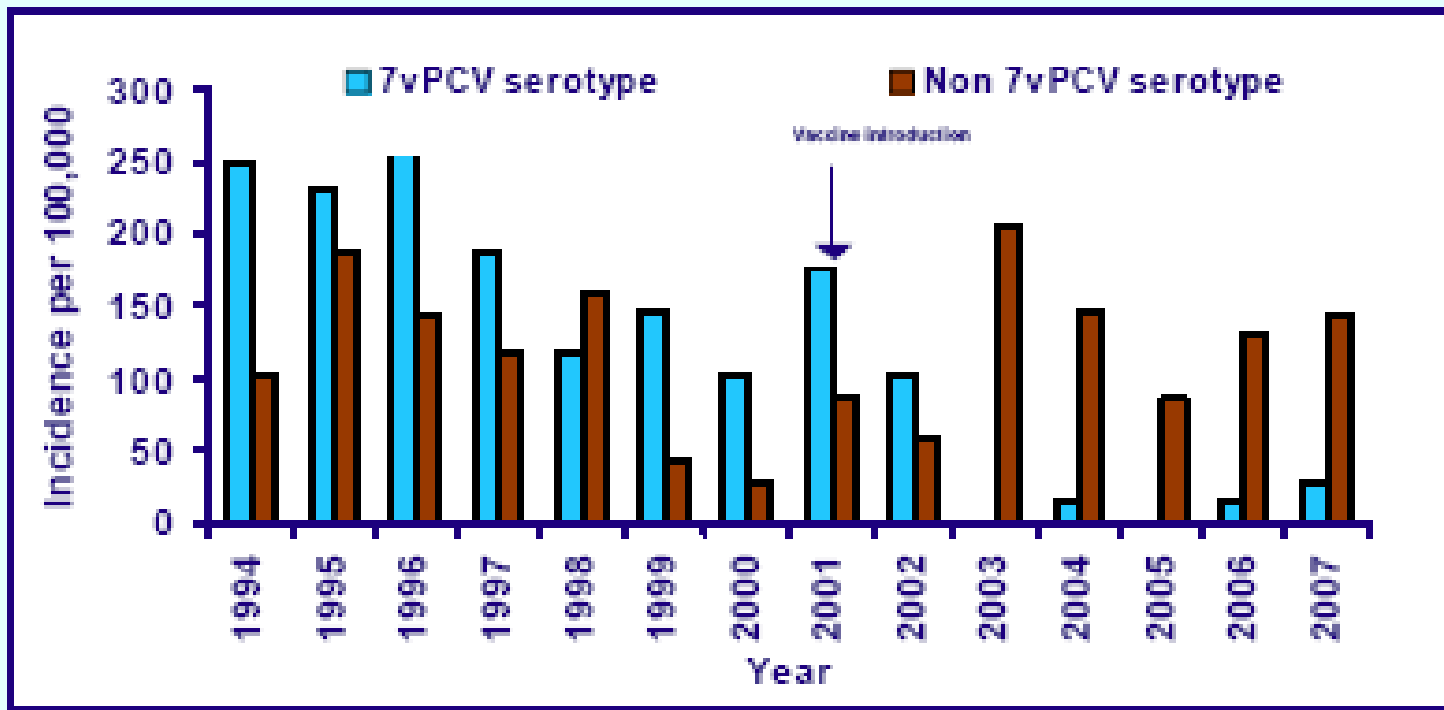


## IPD Rates in YK Region children, < 5 years of age, 1998-2007



# IPD Rates in Northern Territories, Australia, Indigenous Children <5 years

Figure 2. Rates of IPD in Indigenous children <5yrs of age, by serotype and year



Data courtesy of Heather Cook and Vicki Krause,  
Northern Territory CDC, Darwin, Australia

# What is needed in a recommendation for AI/AN?

- Indicate clearly to practitioners what the routine use of PPV23 should be
- Allow for future use if:
  - ◆ IPD epidemiology changes,
  - ◆ New data emerges on effectiveness or safety,
  - ◆ Effective higher valency conjugate vaccines do not become available
- Clarify that decisions for use should be based on increased risk of IPD rates
  - ◆ Background could include information on epidemiologic characteristics to consider (serotypes, absolute rates, age groups)
- Allow for VFC to purchase vaccine if use is indicated

# **Recommendation for Vote: Use of PPSV23 in AN/AI children**

**“Routine use of PPSV23 after PCV7 is not recommended for Alaska Native or American Indian children aged 24 through 59 months. However, in special situations, relevant public health authorities may consider addition of PPSV23 after PCV7 for Alaska Native or American Indian children aged 24 through 59 months who are living in areas in which risk of invasive pneumococcal disease is increased”**

# Current vs. Proposed

- **Routine Use.** *"For children of Alaska Native or American Indian descent, addition of PPV23 after PCV7 can be considered" (at age 2 years)*
- **Routine Use.** *"Routine use of PPSV23 after PCV7 is not recommended for Alaska Native or American Indian children aged 24-59 months."*

# Recommendation #2

PPV23 for adults

## ACIP recommendation for use of PPV23 in AI/AN populations (MMWR 1997)

*"Persons aged 2-64 years who are living in environments or social settings in which the risk for invasive pneumococcal disease or its complications is increased (e.g., Alaskan Natives and certain American Indian populations) should be vaccinated."*



# Current Recommendation

## Strengths

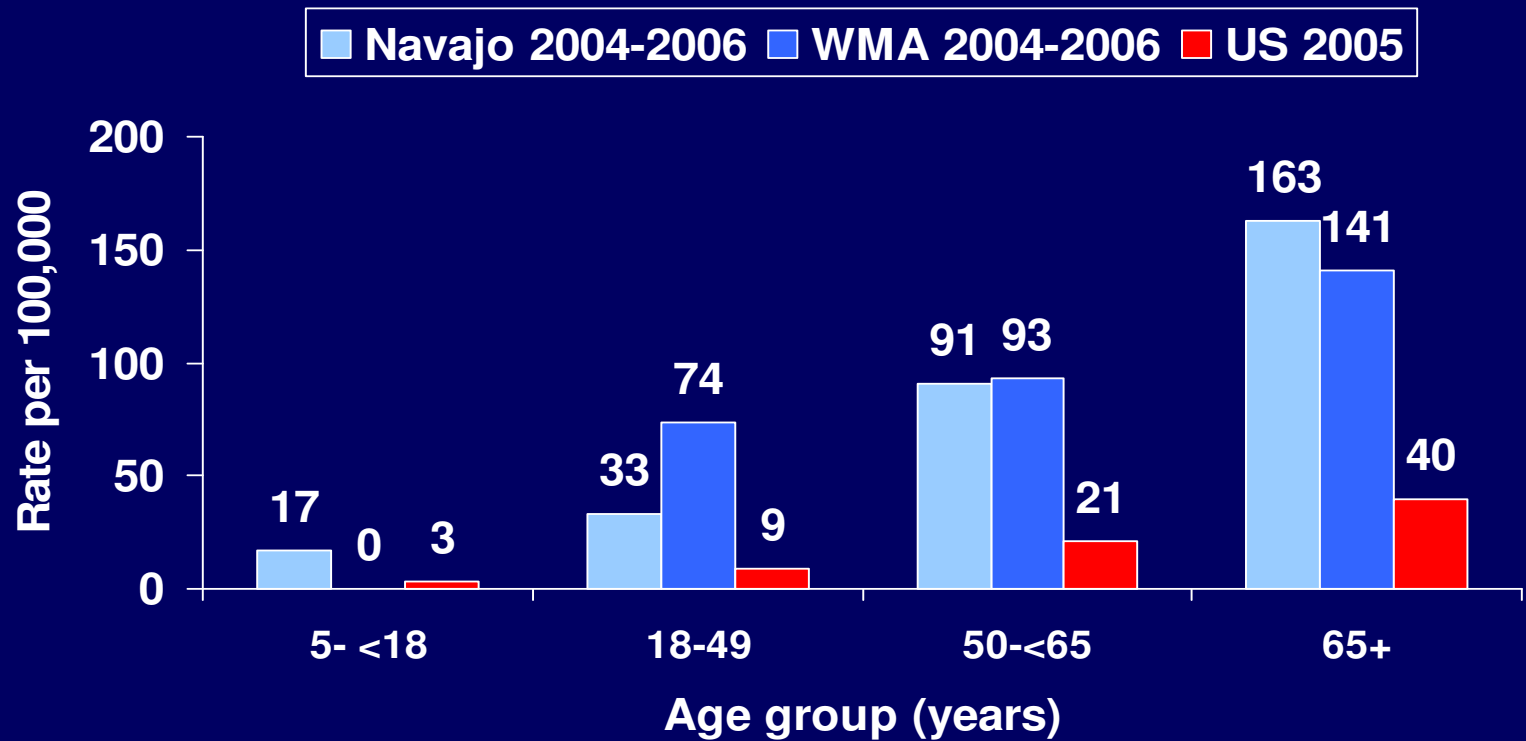
- Permissive language allows the option to use PPV23 in the AI/AN population
  - ◆ Some AI/AN groups are at high risk for IPD

# Current Recommendation

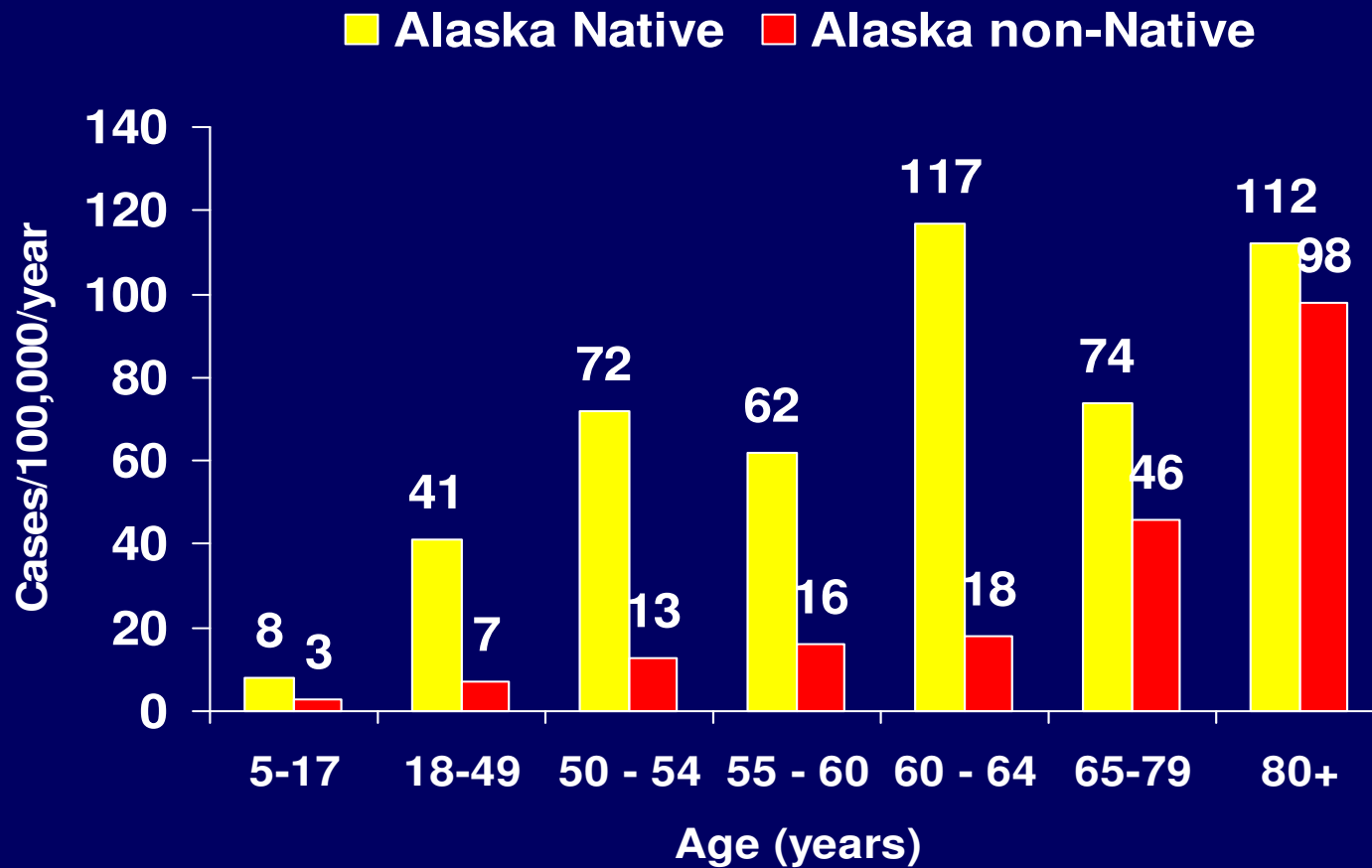
## Weaknesses

- All AI/AN are not at equal risk
  - Increased IPD risk data limited to Alaska Native, White Mountain Apache and Navajo populations
  - Risk and health disparity vary by age strata within 2-64 yo group
- Language lacks specificity
  - ◆ No definition of “environments and social settings” at high risk
    - Leads to confusion and variable interpretation
- Language is seen as offensive by some AI/AN
- The age group is over-inclusive.
  - ◆ The 2 - 5 year old group is already covered by another ACIP rec.
  - ◆ The absolute risk increases in the remaining age strata are of varying magnitude

# Post-PCV IPD rates among Navajo, WMA and general U.S.



# IPD rates, Alaska Natives and non-Natives, 2005-2007



# Current Practice

- This recommendation is not routinely followed among any of the I.H.S. or tribal health organizations who serve populations with high rates of IPD.
- A few groups do routinely use PPV23 among healthy adults younger than 65 years.
  - ◆ Alaska, PPV23 vaccine is recommended to begin at age 55 years.
  - ◆ White Mountain Apache reservation, routine vaccination begins at age 50 years.
- Other I.H.S. and tribal health groups follow the recommendation for first use of PPV23 at 65 years
- Medical Indications
  - ◆ 70 – 86% of AI/AN adults with IPD had underlying condition included in current ACIP recommendations for PPV23

# What is needed in a new ACIP recommendation?

- Remove wording regarding “environments and social settings” at high risk
- Focus on at-risk age group not already covered by an ACIP recommendation: > 50 year olds
- Allow current policies to continue
  - ◆ local decision-making has been evidence-based
  - ◆ no firm reason to force change in local policies
- Add permissive language to allow PPV23 use
  - ◆ Could be used if local IPD epidemiology changes or new data emerges on effectiveness or safety.

# Recommendation for Vote:

## Use of PPSV23 among AN/AI Adults

- *"Routine use of PPSV23 is not recommended for Alaska Native or American Indian persons younger than 65 years old unless they have underlying medical conditions that are PPSV23 indications. However, relevant public health authorities may consider PPSV23 for Alaska Natives and American Indians aged 50 through 64 years who are living in areas in which the risk of invasive pneumococcal disease is increased."*

# Current vs. Proposed

- *“Persons aged 2-64 years who are living in environments or social settings in which the risk for invasive pneumococcal disease or its complications is increased (e.g., Alaskan Natives and certain American Indian populations) should be vaccinated.”*
- *“Routine use of PPSV23 is not recommended for Alaska Native or American Indian persons younger than 65 years old unless they have underlying medical conditions that are PPSV23 indications.”*



# Recommendation for Vote: Use of PPSV23 in AN/AI children

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# Recommendation for Vote:

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