Active Bacterial Surveillance

March 2022 Newsletter

JOHNS HOPKINS CENTER FOR AMERICAN INDIAN HEALTH

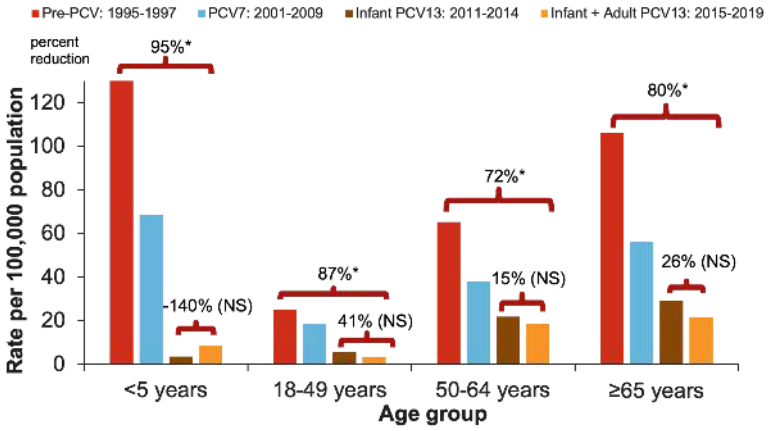
JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

What we do

In partnership with tribal communities and healthcare facilities, the Center for American Indian Health (CAIH) actively monitors serious diseases caused by the bacteria *Streptococcus pneumoniae* (pneumococcus), *Haemophilus influenzae, Neisseria meningitidis*, and *Staphylococcus aureus* in people living on and around the Navajo and White Mountain Apache (WMA) tribal lands. Native American people have higher rates of disease caused by these bacteria compared to the general US population. In this issue of the newsletter, we provide an update on vaccination for invasive disease caused by *S. pneumoniae.*

Vaccine impact

For over 20 years, the CAIH has conducted surveillance for *S. pneumoniae*, a cause of serious invasive diseases including pneumonia, meningitis, and blood stream infections. Routine use of pneumococcal conjugate vaccines (PCV7 and PCV13) as part of the routine infant immunization schedule has led to a dramatic reduction in invasive disease caused by the serotypes contained in these vaccines (Figure 1). However, continued disease caused by serotypes not covered by existing vaccines highlights the need for vaccines with expanded serotype protection. To address the continued burden of disease among adults, PCV13 (Prevnar 13), which replaced PCV7 for use in children in 2010, was recommended for adults 65 years and older in late 2014. The recommendation changed in 2019, with PCV13 no longer recommended for routine administration among adults 65 years and older. Instead, shared clinical decision making was recommended – the decision to administer PCV13 should be made jointly by patients and their providers.



PNEU-DAY trial

From 2018 to 2020, in collaboration with tribal communities and funded by Merck & Co., Inc, CAIH participated in a global, multi-site randomized, double-blind, active comparator-controlled study to evaluate the safety, tolerability, and immunogenicity of a 15-valent investigational pneumococcal conjugate vaccine (V114, now approved as Vaxneuvance™, also known as PCV15) (Navajo Nation Human Research Review Board Study #NNR-18.307 and IHS Phoenix Area Institutional Review Board PXR 18.08). This vaccine includes all serotypes included in PCV13 and two additional serotypes (22F and 33F). These two additional serotypes caused 6% of invasive pneumococcal disease detected by our active bacterial surveillance system from 2015-2020. Following informed consent, Native American adults aged 18-49 year with or without risk factors for pneumococcal disease were randomized to receive either PCV15 or PCV13.

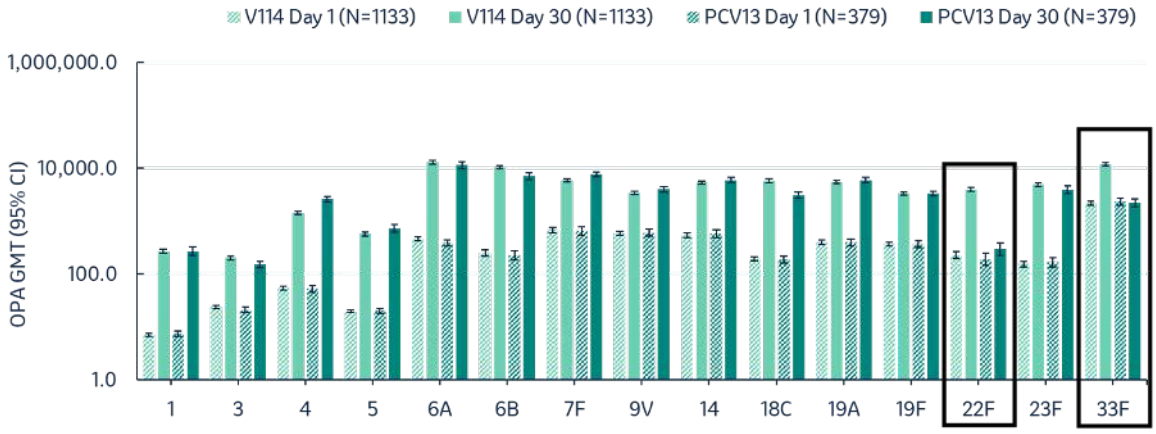
Safety and tolerability

PCV15 was well-tolerated on its own and with sequential administration of the polysaccharide vaccine PPSV23 six months later. Rates of injection-site and systemic reactions were similar for participants receiving PCV15 and PCV13. The most common reactions to PCV15 were injection-site pain, fatigue, and muscle pain. There were no vaccine-related serious adverse events detected during the study.

Immunogenicity

Thirty days after vaccination, PCV15 (light green bars) stimulated a strong immune response for all 15 serotypes contained in the vaccine, including the 13 contained in PCV13 (dark green bars) and the additional 2 serotypes (boxed) (Figure 2). Sequential administration of PPSV23 6 months after PCV15 maintained immune responses for shared serotypes.

Figure 2: Serotype-specific antibody titers 30 days after vaccination with PCV15 or PCV13. PCV15-specific serotypes are boxed.



Update to vaccination recommendations:

In July 2021, the FDA authorized PCV15 for the prevention of invasive disease caused by *S. pneumoniae*. The Advisory Committee on Immunization Practices (ACIP) develops recommendations on the use of vaccines in the United States. During the October 2021 meeting, the ACIP revised the recommendation for routine use of pneumococcal conjugate vaccines among adults.

The ACIP now recommends that adults 65 years and older as well as adults 19-64 years with certain underlying medical conditions (such as diabetes and chronic heart disease) or other risk factors (including alcoholism and smoking) who have not previously received a pneumococcal conjugate vaccine or do not know their vaccination status should receive either PCV20 (Prevnar 20™) or PCV15 (Vaxneuvance™). If PCV15 is used, it should be followed by a dose of PPSV23 (Pneumovax™).

Updated recommendations for PCV-use in adults: Kobayashi M, Farrar J, Gierke R, et al. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:109-117.

How can you protect yourself and your family from community-acquired pneumonia?

- Know the signs of pneumonia and contact your healthcare provider if you think you have an infection
- Get vaccinated: Talk to a doctor or nurse to see if you are eligible to receive vaccination to protect against pneumonia
- Encourage good hygiene such as cleaning hands regularly

Upcoming activities

Given the historically high burden of *H. influenzae* type b (Hib) disease among young Native American infants, the PedvaxHIB™ vaccine, which can provide good protection after the first dose, has been given a preferential recommendation for Native American infants. Vaxelis™ is a combination vaccine that protects against Hib, hepatitis B virus, polio virus, diphtheria, pertussis, and tetanus, that was recently licensed and recommended for use in the infant immunization schedule. The CDC Advisory Committee on Immunization Practices deferred giving a preferential recommendation for Vaxelis™ for Native American infants until data were available on the immune response following the first dose.

In collaboration with the IHS, Tribal Health Organizations, and the CDC Arctic Investigations Program, CAIH is offering participation in an open-label randomized trial to evaluate the antibody response to two licensed Hib-containing vaccines. Enrollment in the study will begin in early 2022 in Anchorage AK, Chinle, AZ, Fort Defiance, AZ, Gallup, NM, Shiprock, NM, and Whiteriver, AZ. Following informed consent from the parents, enrolled children will be assigned to receive either of two licensed Hib vaccines (Vaxelis™ or PedvaxHIB™) at their well-child check and will have their antibody levels checked after vaccination. If antibody responses are comparable, Vaxelis™ would decrease the number of shots an infant would need at their well-child visits.

Thanks to our many community partners!

Navajo Nation
- Represented by 20+ laboratories
- Navajo Epidemiology Center
- Navajo Area Indian Health Service
- Tribal Health Facilities
- Navajo Nation Human Research Review Board

White Mountain Apache
- Represented by 3 laboratories
- White Mountain Apache Tribal Council
- Phoenix Area Indian Health Service

What bacterial isolates do we look for?

- *Streptococcus pneumoniae*
- *Haemophilus influenzae*
- *Neisseria meningitidis*
- *Staphylococcus aureus*
- Group A *Streptococcus* (WMA only)

Isolate from sterile body sites:

- Blood
- Bone
- Cerebrospinal fluid
- Pericardial fluid
- Peritoneal fluid
- Pleural fluid
- Synovial fluid (joint fluid)
- Middle ear (*S. pneumo* only)

We request ONE slant of the *S. pneumoniae, H. influenzae, N. meningitidis, S. aureus*, or Group A *Streptococcus* isolate. CAIH will provide the chocolate agar slants upon request. Isolates are sent to our reference labs for additional testing. Please maintain the isolate in your lab until you receive confirmation from us that the isolate was viable.

If you have any questions about Active Bacterial Surveillance, please contact us:

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The mission of the Johns Hopkins Center for American Indian Health:

We work in partnership with American Indian and Alaska Native communities to improve the health status, self-sufficiency, and health leadership of Native people. *This mission is accomplished through three core activities:*

Research **Training/Education** **Service**