

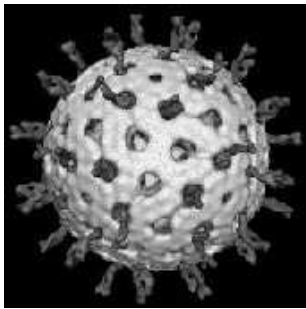
New Vaccines and New Guidelines

Special Considerations for
American Indian/Alaska
Native Children

Objectives

- Review new vaccinations that have become available in the past 5 years
- Review new guidelines for existing vaccines
- Describe unique conditions for AI/AN populations that will influence vaccine selection and schedules

Rotavirus



Rotavirus Disease Burden in the United States

- Accounts for about 40% of all infant diarrhea episodes and 70% of severe cases
- Annually responsible in children for:
 - More than 600,000 physician visits
 - 55,000 hospitalizations
 - 20-60 deaths
- Diarrheal hospitalization rate in AI/AN infants <1 year of age (262/10,000) remains significantly higher than the US infant rate (154/10,000).

Rotavirus Vaccines

RotaTeq® (RV5, Rota-Pent)

- Merck vaccine approved by FDA in 2006
- Contains five reassortant rotaviruses developed from human and bovine parent rotavirus strains
- Three oral doses administered at 2, 4, and 6 months of age

Rotarix® (RV1, Rota-Mono)

- GSK vaccine approved by FDA in April 2008
- Contains one strain of live attenuated human rotavirus (G1P[8])
- Two oral doses at 2 and 4 months of age

- Both vaccines are covered by the VFC program for all AI/AN children

Efficacy Data

MMWR August 11, 2006

- After 3 doses
 - 86% effective against any rotavirus diarrhea
 - 95% effective against severe rotavirus diarrhea

TABLE 3. Efficacy of RotaTeq® in reducing the rate of health-care use for rotavirus gastroenteritis

Type of contact	No. of cases	Vaccine	Placebo	% Rate reduction	% Rate reduction (95% CI) ¹
Hospitalizations ²	6	144	144	85.8	(60.5-98.2)
Emergency department visits ³	14	225	225	93.7	(88.8-98.5)
Office visits ⁴	19	69	69	88.0	(79.9-92.5)

² Per protocol population (includes only cases that occurred at least 14 days after dose 3).

³ Confidence interval.

⁴ N = 34,035 vaccine and 34,033 placebo recipients.

⁵ N = 2,834 vaccine and 2,832 placebo recipients.

Rotavirus ACIP Recommendations

Routine Administration

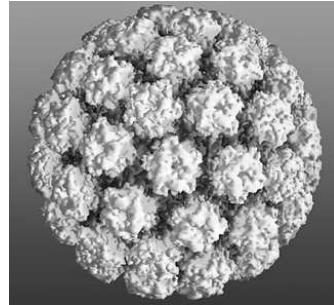
- Routine immunization of all infants
- Minimum age first dose – 6 weeks
- Vaccination should not be initiated for infants of age 15 weeks 0 days or older.
- All doses should be completed by age 8 months 0 days.

Interchangeability of Rotavirus Vaccines

- No data on mixing
- If any dose in the series was RV5 or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given.

Source: <http://www.cdc.gov/vaccines/recs/provisional/downloads/roto-7-1-08-508.pdf>

Human Papilloma Virus



Human Papillomavirus (HPV) Disease Burden in the United States

- HPV is the most common sexually transmitted infection in the US with 6,200,000 new infections/year
- There are 40 serotypes but...
- 2 serotypes (6 & 11) are responsible for 90% of genital warts
- 2 serotypes (16 & 18) are responsible for 70% of cervical dysplasia/cancer-
- Prevalence of HPV is 2X higher in some tribes than overall US
- Incidence of cervical cancer is up to 2X higher in some tribes compared to US average

Gynecol Oncol. 2007 November; 107(2): 236-241

HPV Vaccine

Gardasil®

- Merck product approved by FDA June 2006
- Quadrivalent vaccine containing HPV strains 16, 18, 6 and 11
- 3 dose series with the second and third doses administered 2 and 6 months after the first dose

ACIP Recommendation*

- Routine vaccination of females 11--12 years of age.
- Vaccine can be administered as young as age 9 years.
- Catch-up vaccination is recommended for females aged 13--26 years who have not been previously vaccinated.

VFC

- HPV vaccine is covered through the VFC program for AI/AN females 9 – 18 years of age

Source: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm>

Efficacy Data

- 70% of cervical cancer caused by serotypes 16/18
- 90% of genital warts caused by serotypes 9/11
- Gardasil® appears to be 100% effective in preventing infection from vaccine serotypes
- Can be used in women who have evidence of current or past infection

Pertussis



Pertussis

- Highly contagious respiratory infection caused by *Bordetella pertussis*
- Severe or fatal infection in infants < 6 months
- Disease in adults/adolescents often milder than in infants and children
- Older persons with mild disease are often source of infection for infants
- 2000-2004 pertussis hospitalization rate for AI/AN infants in Alaska and the Southwest was double the rate for U.S. infants

J Pediatr. 2008;152:839-43

Tetanus, diphtheria and pertussis (Tdap) vaccines

Adacel®

- Sanofi Pasteur vaccine
- Approved by FDA May 2005
- Licensed for use in 10 – 64 year olds

Boostrix®

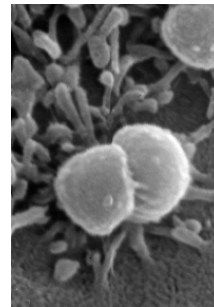
- GSK vaccine
- Approved by FDA June 2005
- Licensed for use in 11 – 64 year olds

ACIP Tdap Recommendations

Single dose of Tdap recommended for:

- Adolescents aged 11--18 years
 - Usual age is 11-12 years old
 - Adults with close contact with infants < 12 months
 - post partum women, caregivers, siblings
 - Health care personnel who care for children
- Minimum intervals
- A minimum interval of 5 years from the last Td is suggested; however, interval as short as 2 years can be used if pertussis protection is needed

Neisseria meningitidis



Neisseria meningitidis

- Most common cause of bacterial meningitis in adolescents and young adults
- Only 1,400 - 2,800 cases/year but extremely contagious
- Rate of infection is 4X higher in college freshman who live in dorms
- No increased rate noted in AI/AN

Meningococcal Conjugate Vaccine (MCV4)

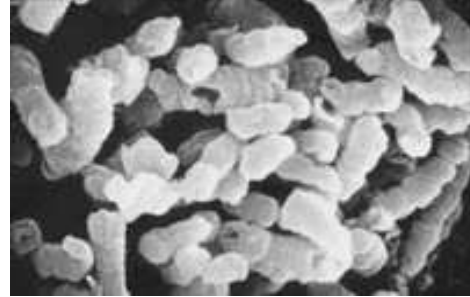
Menactra®

- Sanofi Pasteur
- Quadrivalent polysaccharide vaccine (A, C, Y, W-135) conjugated to diphtheria toxoid
- Approved by FDA 2005
- Licensed for use in 2 – 55 year olds

ACIP MCV4 Recommendations

- Routinely recommended for:
 - All children 11-18 years of age
 - Preferred age: 11-12 year olds
 - All college freshmen living in a dormitory
 - Other persons 2 through 55 years of age at increased risk of invasive meningococcal disease
 - Microbiologists, military recruits, travelers, and certain immunodeficient persons
- I would add all AI/AN children ages 11- 18 years who live in residential settings (treatment centers, dorms, work camps)

Hemophilus influenzae type b (Hib)



Hib Disease in AI/AN Children

- AI/AN annual case rates were at least 10 - 20X greater than U.S. rate prior to the development of an effective vaccine
- Incidence of up to 2% of AI/AN infants
- Also occurred at younger age, particularly in Alaska Natives, but also in Navajo and Apache – most cases under 6 months of age

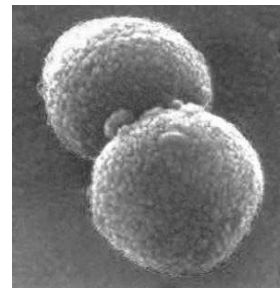
Hib vaccine for AI/AN children

- There are 2 Hib vaccines
 - PRP-OMP (PedvaxHib® by Merck)
 - PRP-T (ActHib® by Sanofi)
- PedvaxHib® provides immunity after 1 dose vs. 3 doses in ActHib®
- Because of the earlier onset of Hib disease in some AI/AN communities, the IHS and the AAP recommend that providers serving AI/AN communities use Pedvax Hib® vaccine
- Pentacel® has PRP-T – not the ideal choice

Hib Vaccine Shortage

- November, 2007 – Suspension of PedvaxHib® production
- December 2007 – CDC releases Hib guidelines for shortage
 - AI/AN children prioritized to continue to receive all doses of Hib vaccine
 - CDC stockpile of PedvaxHib® to supply IHS and tribal sites
- Current Status
 - AI/AN children should continue to receive all doses of Hib vaccine

Pneumococcus



Pneumococcal Disease in AI/AN Children

- Incidence 5 to 24 times higher in Alaska Natives and in Southwest tribes
- Highest rates under age 2
- The adult 23 valent polysaccharide vaccine was not effective under 2 years of age

Pneumococcal Conjugate Vaccine Pevnar® (PCV7) licensed in 2000

- Overall decrease in invasive pneumococcal disease of 66%
- Decrease in PCN resistance
- An increase in non-vaccine serotype disease has been noted recently

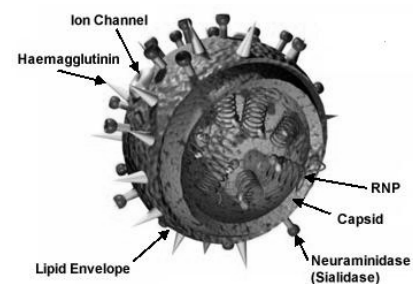
New Pneumococcal Vaccine Guidelines

Specific AI/AN recommendations:

- *Routine use of PPV23 after PCV7 is NOT recommended for Alaska Native or American Indian children aged 24-59 months. However, in special situations, public health authorities may consider recommending the use of PPV23 after PCV7 for Alaska Native or American Indian children aged 24-59 months who are living in areas where the risk of invasive pneumococcal disease is increased.*

Source: <http://www.cdc.gov/vaccines/recs/provisional/downloads/pneumo-Oct-2008-508.pdf>

Influenza Virus



- Risk of influenza hospitalization is equivalent for children < 2 years old and adults > 65 years
- Less than 25% of high risk children are vaccinated against influenza
- Preschool children ages 2 – 5 years are identified as vectors of flu to adults

- Flu epidemics often first begin and spread in preschool group
- Greatest benefit for herd immunity may be to immunize all children
- Vaccinate all children ages 6 months to 18 years
- Flu vaccine is covered under VFC for all children ages 6 months - 18 years



Slowly he would cruise the neighborhood, waiting
for that occasional careless child who confused
him with another vendor.