How Vaccine Recommendations and Policy are Developed in the United States

Examples of Missed Opportunities for Vaccination
Objectives

• Discuss responsibilities, structure, and function of the Advisory Committee on Immunization Practices (ACIP)
• Review the process of immunization policy development in the U.S.
• Summarize the interaction of ACIP with professional organizations and societies in the public and private sectors
• Highlight key issues facing ACIP
• Describe missed opportunities for vaccination
Example: Biologics License Application Approval Letter from FDA (PCV13)

February 24, 2010 Approval Letter - Prevnar 13

Our STN: BL 125324/0
Wyeth Pharmaceuticals, Incorporated
Attention: Jack Love, Ph.D.
Assistant Vice President, Global Regulatory Affairs
401 Middleton Road
Pearl River, NY 10965

Dear Dr. Love:

We have approved your biologics license application for Pneumococcal 13-Valent Conjugate Vaccine [Diphtheria CRM197 Protein] effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce Pneumococcal 13-Valent Conjugate Vaccine [Diphtheria CRM197 Protein] under your existing Department of Health and Human Services U.S. License Number 0003. Pneumococcal 13-Valent Conjugate Vaccine [Diphtheria CRM197 Protein] is indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F, and for the prevention of otitis media caused by serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F when administered to children 6 weeks through 5 years of age.

Under this license, you are approved to manufacture Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]. Commercial manufacturing will be distributed among the following - (b)(4) - facilities: Wyeth Pharmaceuticals, Inc., located in (b)(4)
Key Dates in U.S. Immunization Policy

- 1955: Poliomyelitis Vaccination Assistance Act (Eisenhower) – start of Federal funding for vaccine purchase
- 1962: Vaccination Assistance Act (Kennedy) – Federal funds for purchase of polio, diphtheria, pertussis, tetanus vaccines (measles added in 1965)
- 1963: Creation of National Immunization Program at CDC
- **1964: Establishment of ACIP**
- 1972: Federal Advisory Committee Act (Nixon) – ACIP designated as a Federal Advisory Committee
- 1993: Childhood Immunization Initiative (Clinton) – Vaccines for Children (VFC) Program adopted
Origins of the ACIP

• ACIP was established in 1964 by the Surgeon General of U.S. Public Health Service

• Role: to provide advice and guidance to Director, CDC and Office of the Secretary of the Department of Health and Human Services on the most effective means to prevent vaccine-preventable diseases in the civilian population
  ▪ Vaccines and related agents (e.g., antisera, immune globulins, antivirals)
  ▪ FDA-licensed vaccines (and unlicensed vaccines if warranted)

• ACIP votes on recommendations for vaccines covered by all 3 Office of Infectious Diseases Centers (NCIRD, NCHHSTP, NCEZID*) and reports directly to the Director of CDC

*NCIRD: National Center for Immunization and Respiratory Diseases
NCHHSTP: National Center for HIV/AIDS, Hepatitis, STD, and TB Prevention
NCEZID: National Center for Emerging and Zoonotic Infectious Diseases
First Meeting of the ACIP
Communicable Disease Center, Atlanta, GA
May 25-26, 1964

Agenda
Surgeon General's Advisory Committee on Immunization Practice
Room 207
Communicable Disease Center
May 25-26, 1964

Monday, May 25 - 9:30

1. Introduction - Committee purpose and function
   Dr. Goddard

2. Previous Immunization Advisory Committees
   Dr. Langmuir

3. Definition of committee responsibility
   a. Relationship to "Red Book" Committee
   Dr. Goddard
   b. Relationship to other committees on immunization,
   e.g., APHA, AFEO, etc.

4. Simplification of Immunization Schedules
   Dr. Bell

5. Influenza
   a. Influenza; 1963-1964, national and international
      Dr. Silverman
   b. Influenza strains
      Dr. Robinson
   c. Vaccine use - 1963
      Dr. Henderson
   d. Field studies of vaccine efficacy - 1963-64
      Dr. Henderson
   e. Vaccine composition
      Dr. Murray
   f. Blood group antibodies induced by vaccine
      Dr. Henderson
   g. Recommendations - 1964-65
      (1) Probability of outbreaks
      (2) Recommendations for vaccine use
      (3) Recommendations regarding field studies

Tuesday, May 26 - 9:00

6. Rubella
   a. Status report - probability of vaccines
      Dr. Murray
   b. Immune globulin in prophylaxis
      Drs. Murray & Henderson
   c. Recommendation regarding immune globulin
      in prophylaxis

7. Rubeola
   a. Status report - vaccine use
      Dr. Henderson
   b. Combination schedules employing killed and
      live vaccines
      Dr. Guineas
   c. Recommendations regarding use of combined
      killed and live vaccines

8. Smallpox
   a. Status report - vaccine use
      Dr. Henderson
   b. Complications of vaccination
      Dr. Millar
   c. Smallpox Control in the U.S.
      Dr. Langmuir
   d. Changes proposed by the World Health
      Organization in the international
      vaccination requirements

9. Simultaneous administration of live vaccines
   Drs. Henderson & Murray

10. Concluding discussion
Federal Advisory Committee Act (FACA)

• FACA was enacted by Public Law 92-463 on October 6, 1972

• Provides a mechanism for the Federal Government to obtain advice and recommendations from U.S. citizens who are not employed by the Federal Government
  ▪ Committees provide relevant, objective advice
  ▪ FACA committee meetings are open to the public; all committee documents are available for public inspection

• ACIP was designated as a FACA committee in 1972
Vaccines for Children (VFC) Program

• The VFC Program was established in August 1993 and has been operational since October 1994
  ▪ Unique statutory authority established by Omnibus Budget Reconciliation Act of 1993 (42 U.S.C. §1396a) gives ACIP the authority to determine vaccines provided in the VFC Program

• VFC is a federal entitlement program - current U.S. cost is ~$4 billion annually; current cost in CA is ~$500 million
  ▪ http://www.cdc.gov/vaccines/programs/vfc/default.htm
  ▪ http://www.cdc.gov/vaccines/programs/vfc/providers/acip-whatis.htm
VFC Program, continued

• Who is eligible?
  ▪ Children 0 through 18 years of age who are:
    ✔ Medicaid (or Child Health and Disability Program) eligible; or
    ✔ Uninsured or underinsured; or
    ✔ American Indian/Alaska native

• Currently, approximately 48% of young children in the U.S. are entitled to VFC

• During ACIP meetings the first vote is on the vaccine recommendation for children 0-18 years; then there is a separate vote on whether to include the vaccine in VFC
Number of Diseases Prevented by Vaccines Included in the Routine Pediatric Immunization Schedule

1964 (6)
- Smallpox
- Polio
- Diphtheria
- Pertussis
- Tetanus
- Measles
- Rubella
- Mumps

1985 (7)
- Polio
- Diphtheria
- Pertussis
- Tetanus
- Measles
- Rubella
- Mumps

1995 (10)
- Polio
- Diphtheria
- Pertussis
- Tetanus
- Measles
- Rubella
- Mumps
- Hib
- Hepatitis B
- Varicella

2016 (16)
- Polio
- Diphtheria
- Pertussis
- Tetanus
- Measles
- Rubella
- Mumps
- Hib
- Hepatitis B
- Varicella
- Pneumococcal
- Influenza
- Meningococcal
- Hepatitis A
- Rotavirus
- HPV
ACIP Structure

• 15 voting members including chairperson (non-government)
  ▪ 4 year terms – at least 2 new members each year
  ▪ ACIP steering committee nominates, HHS selects
  ▪ One consumer representative
  ▪ Members screened for conflicts of interest

• 8 *ex officio members* – represent other government agencies involved in immunization (non-voting)

• 31 liaison organizations – representatives of professional societies and organizations responsible for vaccine development and immunization programs (non-voting)

• Behind the scenes: ACIP Work Groups
Expertise and Perspective of ACIP Members

- Pediatrics
- Internal medicine
- Family medicine
- Infectious diseases
- State/local health department
- Public health, preventive medicine
- Nursing
- Immunology
- Vaccine research and policy
- Economics, cost-effectiveness
- Consumer concerns
Ex Officio Members (8)

• Centers for Medicaid & Medicare Services (CMS)
• Department of Defense (DOD)
• Department of Veterans Affairs (DVA)
• Food and Drug Administration (FDA)
• Health Resources and Services Administration (HRSA)
• Indian Health Service (IHS)
• National Institute of Health (NIH)
• National Vaccine Program Office (NVPO)
Liaison Organizations*

- Members serve on work groups
- Members attend and participate in every ACIP meeting
- Four organizations assist with development and publication of immunization schedules “harmonized” with ACIP (AAP, AAFP, ACOG, ACP)
- Organizations support ACIP recommendations

*Non-voting
<table>
<thead>
<tr>
<th></th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>American Academy of Family Physicians</td>
</tr>
<tr>
<td>2</td>
<td>American Academy of Pediatrics</td>
</tr>
<tr>
<td>3</td>
<td>American Academy of Physician Assistants</td>
</tr>
<tr>
<td>4</td>
<td>American Geriatric Society</td>
</tr>
<tr>
<td>5</td>
<td>America's Health Insurance Plans</td>
</tr>
<tr>
<td>6</td>
<td>American College Health Association</td>
</tr>
<tr>
<td>7</td>
<td>American College of Obstetricians and Gynecologists</td>
</tr>
<tr>
<td>8</td>
<td>American College of Physicians</td>
</tr>
<tr>
<td>9</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>10</td>
<td>American Nurses Association</td>
</tr>
<tr>
<td>11</td>
<td>American Osteopathic Association</td>
</tr>
<tr>
<td>12</td>
<td>American Pharmacists Association</td>
</tr>
<tr>
<td>13</td>
<td>Association of Immunization Managers</td>
</tr>
<tr>
<td>14</td>
<td>Association of State and Territorial Health Officials</td>
</tr>
<tr>
<td>15</td>
<td>Association of Teachers of Preventive Medicine</td>
</tr>
<tr>
<td>16</td>
<td>Biotechnology Industry Organization</td>
</tr>
<tr>
<td>17</td>
<td>Canadian National Advisory Committee on Immunization</td>
</tr>
<tr>
<td>18</td>
<td>Council of State and Territorial Epidemiologists</td>
</tr>
<tr>
<td>19</td>
<td>Department of Health, United Kingdom</td>
</tr>
<tr>
<td>20</td>
<td>Healthcare Infection Control Practices Advisory Committee</td>
</tr>
<tr>
<td>21</td>
<td>Infectious Diseases Society of America</td>
</tr>
<tr>
<td>22</td>
<td>National Association of County and City Health Official</td>
</tr>
<tr>
<td>23</td>
<td>National Association of Pediatric Nurse Practitioners</td>
</tr>
<tr>
<td>24</td>
<td>National Foundation for Infectious Diseases</td>
</tr>
<tr>
<td>25</td>
<td>National Immunization Council &amp; Child Health Program (Mexico)</td>
</tr>
<tr>
<td>26</td>
<td>National Medical Association</td>
</tr>
<tr>
<td>27</td>
<td>National Vaccine Advisory Committee</td>
</tr>
<tr>
<td>28</td>
<td>Pediatric Infectious Diseases Society</td>
</tr>
<tr>
<td>29</td>
<td>Pharmaceutical Research &amp; Manufacturers of America</td>
</tr>
<tr>
<td>30</td>
<td>Society for Adolescent Medicine</td>
</tr>
<tr>
<td>31</td>
<td>Society for Healthcare Epidemiology of America</td>
</tr>
</tbody>
</table>
ACIP Process

- Three 2-day meetings annually – February, June, and October; held in CDC Global Communications Center
- Meetings follow FACA* rules and procedures and must be open to the public with time for public comment
- Meeting slides, live webcast archive, minutes posted on ACIP website within 90 days of meeting
- Recommendations become final once adopted by CDC Director and published in MMWR
- Vaccine recommendations are recommendations only – not mandates; however, states and professional organizations usually endorse or follow ACIP recommendations

*Federal Advisory Committee Act
ACIP Work Groups

- Gather, analyze and prepare information for presentation to ACIP
- Develop draft policies/options for review/vote by full ACIP
- Work by teleconference/webinar throughout the year
- WG is chaired by an ACIP member and must include at least 1 other ACIP member
  - Other members: lead CDC staff, other CDC staff including Immunization Safety Office, *ex officio* members (e.g., FDA), liaison representatives, invited consultants
- Task oriented WGs are disbanded when their work is complete and new WGs formed as required
Current ACIP Work Groups

1. Adult immunization
2. Child/adolescent immunization
3. General recommendations
4. Influenza
5. Human papillomavirus vaccines
6. Meningococcal vaccines
7. Meningococcal outbreaks
8. Pneumococcal vaccines
9. Herpes zoster vaccine
10. Japanese encephalitis/Yellow fever vaccines
11. Hexavalent vaccine
12. Cholera vaccine
13. Evidence-based recommendations
14. Hepatitis vaccines
15. RSV vaccine

The first 4 Work Groups are permanent
Evidence-Based Recommendations (EBRs)

• EBR approach approved by ACIP in October 2010
• GRADE system to be used: Grading of Recommendations, Assessment, Development and Evaluation (GRADE)
• Key elements for developing EBRs
  ▪ Vaccine safety
  ▪ Vaccine efficacy/effectiveness
  ▪ Burden of disease
  ▪ Economic analysis and implementation issues (evidence for these is not graded, but is considered during policy development)
• Evidence tables are used to summarize the benefits and harms and strengths and limitations of studies
Types of Evidence

1. Randomized controlled trials (RCTs) – typically considered the “gold standard”, or overwhelming evidence from observational studies

2. RCTs with important limitations, or exceptionally strong evidence from observational studies

3. RCTs or observational studies with notable limitations

4. Clinical experience and observations, observational studies with important limitations, or RCTs with several major limitations

Vaccine 2011; 29:9171-76
ACIP Recommendation Categories

• **Category A** recommendations are made for all persons in an age- or risk-factor-based group
  - Hib vaccine for infants
    [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6301a1.htm)

• **Category B** recommendations are made for individual clinical decision making (“permissive recommendation”)
  - Hepatitis B vaccine in adults aged ≥60 years with diabetes mellitus
    [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm)
  - Meningococcal B vaccine for healthy adolescents
    [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm)

• Under the Affordable Care Act, both category A and category vaccines must be covered by insurance
Immunization Policy Product: Two Immunization Schedules

- ACIP, AAP, and AAFP produce a “harmonized” child/adolescent immunization schedule
  - First harmonized in 1994
  - Before 1994, differing schedules existed

- ACIP, AAFP, ACOG and ACP produce a harmonized adult immunization schedule

- Both schedules are updated annually and are published in February in *MMWR*

- Display the complete schedule, with each vaccine in the context of the other vaccines; currently trying to make schedules more user-friendly
CDC Approval Process Following an ACIP Vaccine Recommendation

If adopted by CDC Director:

Brief Recommendation
Published in *MMWR Weekly* as a Policy Note within 2 months of an ACIP vote

Full Recommendation ("ACIP Statement")
Published in *MMWR Recommendations & Reports* within 6-8 months of an ACIP vote
General Recommendations on Immunization
Recommendations of the Advisory Committee on Immunization Practices (ACIP)
Challenging Issues - General

• Role of cost-effectiveness (economic) analyses
  ▪ ACIP is required to consider cost-effectiveness, which is usually evaluated by assessing the cost of a Quality Adjusted Life Year (QALY); 1 QALY = 1 year in perfect health
  ▪ Should cost matter? If so, who should decide?

• ACIP recommendations may differ from FDA licensing
  ▪ Examples: Tdap not licensed for persons >64 years and no safety and effectiveness data in pregnant women

• Increasing number of vaccines in the routine child/adolescent immunization schedule (30 doses targeting 16 diseases)

• Vaccine hesitancy among some members of the public
Challenging Issues – Specific

- Tdap vaccine limited duration of protection
- HPV vaccine transition from HPV4 to HPV9, and possible transition from 4- to 3-dose series
- Consideration of a possible PCV13 dose reduction in children (from 4 doses to 3 doses)
- Use of PCV13 in adults and integration with PPSV23
- Meningococcal B vaccines for adolescents/young adults
- Quadrivalent (ACWY) and MenB vaccines for infants
- Many influenza vaccine preparations
- Use of herpes zoster vaccine in adults beginning at 50 years of age (licensed age) and duration of protection, and new herpes zoster vaccine on the horizon
Advisory Committee on Immunization Practices (ACIP)

The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develop recommendations on how to use vaccines to control diseases in the United States...more

August ACIP Webinar: Use of Pneumococcal Vaccines in Adults
August 13, 2014 (2:00-4:00 pm)
Draft Meeting Agenda and Web/Telephone Access Instructions (no registration needed)

Register for the upcoming October ACIP meeting
October 29-30, 2014
(Wednesday - Thursday)
Deadline for registration: Non-US Citizens: October 6, 2014
US Citizens: October 13, 2014

ACIP Recommendations

More information and resources can be found at the ACIP website at www.cdc.gov/vaccines/acip
Okay – we have the recommendations, now what?

It doesn’t matter if there’s a recommendation if people aren’t vaccinated.
Missed Opportunities for Influenza Vaccination of Pregnant Women and High-Risk Children
People at Higher Risk for Influenza-Related Complications*

- Children younger than 5, but especially children younger than 2 years old
- Adults 65 years of age and older
- Pregnant women (and women up to two weeks post partum)
- Residents of nursing homes and other long-term care facilities
- Also, American Indians and Alaskan Natives seem to be at higher risk of flu complications

*http://www.cdc.gov/flu/about/disease/high_risk.htm
People Who Have Certain Medical Conditions Are Also At Higher Risk

- People with:
  - Asthma
  - Neurological and neurodevelopmental conditions
  - Chronic lung disease
  - Heart disease
  - Blood disorders (such as sickle cell disease)
  - Endocrine disorders (such as diabetes mellitus)
  - Kidney disorders
  - Liver disorders
  - Metabolic disorders
  - Weakened immune system due to disease or medication (such as people with HIV or AIDS, or cancer, or those on chronic steroids)

- People <19 years of age who are receiving long-term aspirin therapy

People who are morbidly obese (BMI >40)
Case 1

- 41 year old pregnant woman who received prenatal care, but did not receive influenza vaccine
- Illness onset 1/11/14
  - Fever 100.7F, cough, rhinorrhea/congestion, nausea/vomiting, shortness of breath, headache, malaise, dizziness, pleuritic chest pain
- Underlying medical conditions
  - 26 weeks pregnant, gestational diabetes
- Presented to ED on 1/14/14, admitted to ICU
- Complications
  - Intubated (1/14/14), pneumonia, acute respiratory distress syndrome, sepsis/multi-organ failure, acute renal failure, multiple arrests
- PCR positive for influenza 2009 A (H1N1)
- Fetal demise in utero
- Died 1/25/14
Case 2

- 4 year old girl who did not receive influenza vaccine
- Illness onset 2/26/15
  - Fever 100.7F, cough, muscle aches, headache, anorexia, fatigue
- Underlying medical conditions
  - Asthma
- Found unresponsive after going down for nap
- Taken to ED and intubated 2/26/15
- Died 2/26/15
  - Cause of death influenza viral pneumonia
- Autopsy tissue specimens PCR positive for influenza A (H3N2)
Case 3

- 16 year old girl who did not receive influenza vaccine
- Illness onset 3/2/16
  - Fever (101°F), cough, vomiting
- Underlying medical conditions
  - Quadriplegia, cerebral palsy, epilepsy, developmental delay, diabetes mellitus, idiopathic pancreatitis, chronic lung disease, G-tube dependent
- Presented to ED and admitted to PICU on 3/9/16
- Intubated
- Complications
  - Pneumonia
- Rapid test positive for influenza B
- Died 3/16/16
Take Home Message

- Influenza vaccine is recommended for all persons 6 months of age and older
- Certain groups of people are at higher risk of severe influenza than the general population
- Special efforts should be made to ensure that people at increased risk of severe influenza are vaccinated every year
Missed Opportunities for Pneumococcal Vaccination in Adults
Invasive Pneumococcal Disease (IPD)

- Second most common cause of vaccine-preventable death in the U.S. (after influenza)
- Major clinical syndromes include pneumonia, bacteremia, and meningitis
- Conditions that increase risk for IPD
  - Decreased immune function
  - Asplenia (functional or anatomic)
  - Chronic heart, pulmonary (including asthma in adults), liver or renal disease
  - Cigarette smoking
  - Cerebrospinal fluid (CSF) leak
  - Cochlear implant
History of Pneumococcal Vaccines

- 1977: 14-valent polysaccharide vaccine licensed
- 1983: 23-valent polysaccharide vaccine licensed (PPSV23/Pneumovax)
- 2000: 7-valent polysaccharide conjugate vaccine (PCV7/Prevnar7)
- 2010: 13-valent polysaccharide conjugate vaccine licensed (PCV13/Prevnar13)
Pneumovax (PPV23) Recommendations for Adults, Aged ≥19 Years

- All adults ≥65 years
- Immunocompromised persons 19—64 years
  - Congenital or acquired immunodeficiency
  - HIV infection
  - Chronic renal failure
  - Nephrotic syndrome
  - Leukemia
  - Hodgkin disease
  - Generalized malignancy
  - Iatrogenic immunosuppression
  - Solid organ transplant
  - Multiple myeloma
Pneumovax (PPV23) Recommendations for Adults, Aged ≥19 Years

- Persons with functional or anatomic asplenia
  - Sickle cell or other hemoglobinopathy
  - Congenital or acquired asplenia
- Immunocompetent 19—64 years who are at high risk of serious pneumococcal infection
  - Chronic heart disease
  - Chronic lung disease (including asthma)
  - Diabetes mellitus
  - CSF leak
  - Cochlear implant
  - Alcoholism
  - Chronic liver disease, cirrhosis
  - Cigarette smokers
Prevnar (PCV13) Recommendations for Adults, Aged ≥19 Years

• All adults ≥65 years
• Immunocompromised persons 19—64 years
  - Congenital or acquired immunodeficiency
  - HIV infection
  - Chronic renal failure
  - Nephrotic syndrome
  - Leukemia
  - Hodgkin disease
  - Generalized malignancy
  - Iatrogenic immunosuppression
  - Solid organ transplant
  - Multiple myeloma
Prevnar (PCV13) Recommendations for Adults, Aged ≥19 Years

- Persons with functional or anatomic asplenia
  - Sickle cell or other hemaglobulinopathy
  - Congenital or acquired asplenia
- Immunocompetent 19-64 years who are at high risk of serious pneumococcal infection
  - CSF leak
  - Cochlear implant
Case 1

- November 25, 2013: CDPH notified by San Diego County of a 54 year-old female found dead at home by her boyfriend
- She had reported vomiting, diarrhea and flu-like symptoms
- Autopsy performed; brain abscess found
Pneumococcal Brain Abscess
Pneumococcal Brain Abscesses

- Account for <1% of all brain abscesses
- Most commonly described in immunocompromised patients
- *S. pneumoniae* may cause meningitis and brain abscesses via:
  - Bacteremia
  - Otitis media and sinusitis
  - Direct spread from nasopharynx (in patients with traumatic injuries)
Medical History

- Alpha-1 trypsin deficiency
  - Causes respiratory symptoms
  - May develop emphysema, impaired liver function, cirrhosis and liver failure
  - Not known to be immunocompromising
- Smoker for 37 years
- Pneumococcal vaccination history unknown, but not thought to be vaccinated
Smoking and IPD

- Approximately half of IPD patients aged 18–64 years are current cigarette smokers.
- In one study, risk for IPD among immunocompetent cigarette smokers aged 18–64 years was 4x the risk for controls who had never smoked.
- Dose-response relationships with risk for IPD were also observed for number of cigarettes smoked and pack-years of smoking.
Serotype Results

- Serotype 3 included in PPV23 (Pneumovax) and PCV13 (Prevnar)
Take Home Message

• Adults aged ≥19 years who smoke cigarettes should receive a single dose of Pneumovax
• Pneumovax covered by all insurance plans (including MediCal) for smokers <65 years of age
• Pneumovax recommended for all persons ≥65 years and is covered by Medicare Part B
Case 2

- July 9, 2015: CDPH notified by Ventura County of a 50 year-old male with meningitis who was hospitalized in the intensive care unit
- CSF culture positive for *S. pneumoniae*
Medical History

- Prior episodes of bacterial meningitis
- Prior head trauma
- Splenectomy in 2003
- No record of pneumococcal vaccination
- Received antibiotics 2 hours prior to lumbar puncture to obtain CSF
Serotype Results

- Blood culture isolate sent to CDPH and CDC
- Serotype 23B identified – not included in vaccine serotypes
Take Home Message

• Adults aged ≥19 years with functional or anatomic asplenia should receive 1 dose of Prevnar13 followed by 1 dose of Pneumovax
• In this case, there were >10 years of missed opportunities to vaccinate (splenectomy in 2003)
• Although this infection was not vaccine-preventable, pneumococcal vaccination might have prevented earlier episodes of bacterial meningitis in this patient
Case 3

- December 1, 2015: CDPH notified by San Diego County of a 25 year-old female with severe sepsis, shock, respiratory failure, diffuse cerebral edema, and a brain flow study indicating brain death
- *S. pneumoniae* isolated from CSF and blood
Medical History

- Hypotension
- Anemia
- Chronic kidney disease
- Lupus
- On immunosuppressive medications - prednisone and CellCept
- No record of pneumococcal vaccination
Serotype Results

- Identified as serotype 20
- Serotype 20 included in Pneumovax 23
Take Home Message

- Adults with immunocompromising conditions (including those on immunosuppressive drugs) aged ≥19 years should receive 1 dose of Prevnar13 followed by 1 dose of Pneumovax
- Pneumococcal vaccination might have saved this patient’s life
Summary

- Adults aged 19-64 years with certain underlying medical conditions or behaviors such as smoking should receive pneumococcal vaccination per ACIP recommendations*
- These tragic cases reveal missed opportunities for vaccination

*http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/pneumo.html
You Can Help Ensure That These Patients are Vaccinated

What do they all have in common?

Bill, Age 28
Smoker

Diane, Age 50
Heart Disease

David, Age 30
Asthma

Lily, Age 65

Carl, Age 37
HIV

Patricia, Age 41
Lymphoma

Miguel, Age 55
Diabetes

They are all at increased risk for an infection called pneumococcal disease