Adult Immunization: Tdap, HPV, Meningococcal, Pneumococcal, and *Haemophilus influenzae* type b Vaccines

Raymond A. Strikas, MD, MPH
Immunization Services Division
National Center for Immunization and Respiratory Diseases

Presentation Outline

- Adult Immunization Schedule review
- Specific vaccines: limited disease epidemiology in adults, and vaccine recommendations
  - Tdap vaccines
  - HPV vaccines
  - Meningococcal vaccines
  - Pneumococcal vaccines
  - *Haemophilus infuenzae* type b (Hib) vaccines

Recommended Adult Immunization Schedule

United States - 2014

The 2014 ACIP Adult Immunization Schedule was approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Nurse-Midwives (ACNM). On February 3, 2014, the adult immunization schedule and a summary of changes from 2013 were published in Annals of Internal Medicine, and a summary of changes was published in the MMWR on February 7, 2014.

All clinically significant postvaccination reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Additional details regarding ACIP recommendations for each of the vaccines listed in the schedule can be found at: http://www.cdc.gov/vaccines/hcp/acip-recs/index.html

American Academy of Family Physicians (AAFP)

http://www.aafp.org/home.html

American College of Physicians (ACP)

http://www.acponline.org/

American College of Obstetricians and Gynecologists (ACOG)

http://www.acog.org/

American College of Nurse-Midwives (ACNM)

http://www.midwife.org/

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Recommended Adult Immunization Schedule—United States - 2014

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group[1]

VACCINE ▼ / AGE GROUP ▶	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza[2,*]	1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap)[3,*]	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Varicella[4,*]	2 doses					
Human papillomavirus (HPV) Female[5,*]	3 doses					
Human papillomavirus (HPV) Male[5,*]	3 doses					
Zoster[6]					1 dose	
Measles, mumps, rubella (MMR)[7,*]	1 or 2 doses					
Pneumococcal 13-valent conjugate (PCV13)[8,*]	1 dose					
Pneumococcal polysaccharide (PPSV23)[9,10]	1 or 2 doses					1 dose
Meningococcal[11,*]	1 or more doses					
Hepatitis A[12,*]	2 doses					
Hepatitis B[13,*]	3 doses					
Haemophilus influenzae type b (Hib)[14,*]	1 or 3 doses					

*Covered by the Vaccine Injury Compensation Program

- For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster
- Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)
- No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

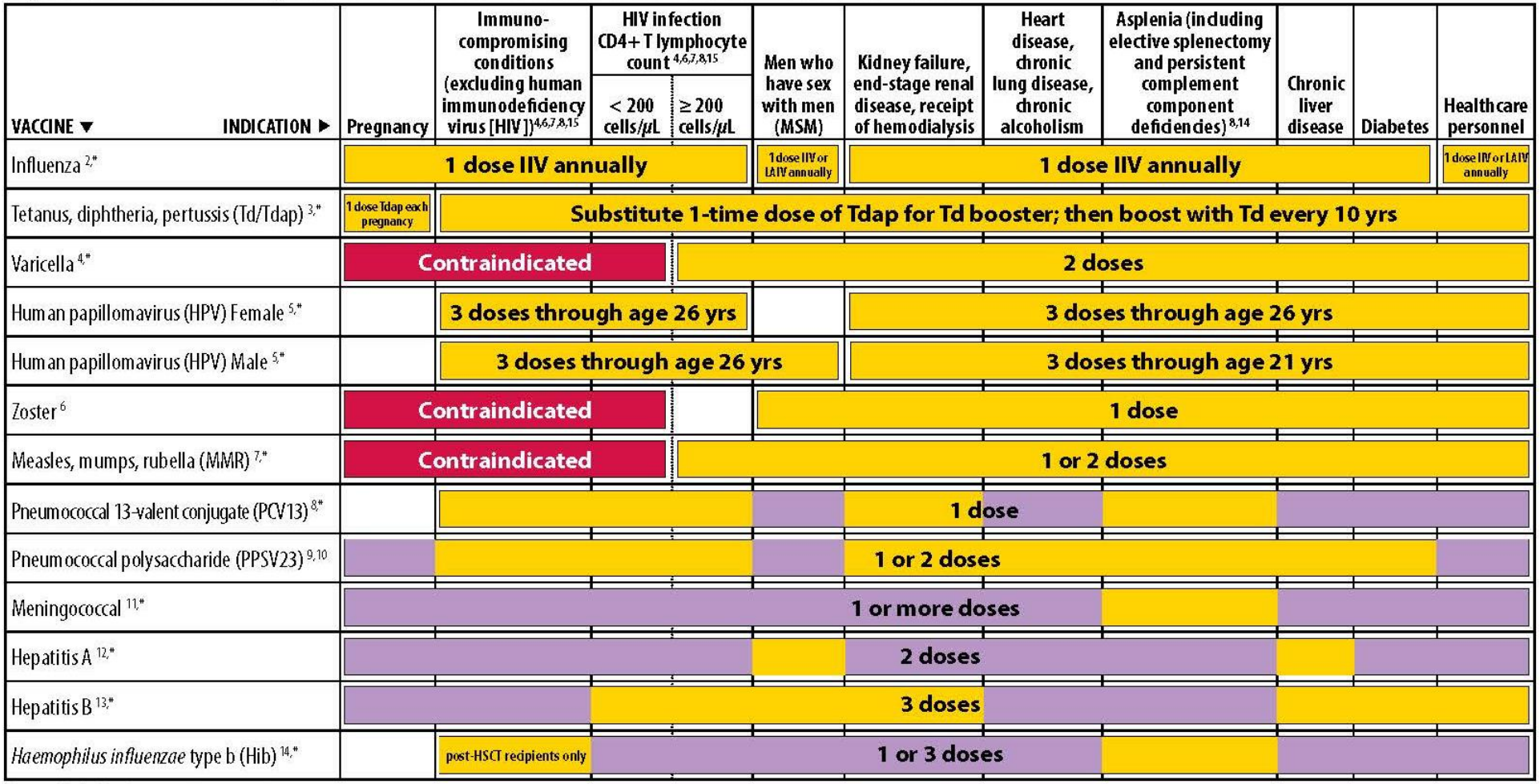
Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

Figure 2. Vaccines that might be indicated for adults based on medical and other indications[1]



*Covered by the Vaccine Injury Compensation Program

For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

No recommendation

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of February 1, 2014. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/hcp/acip-recs/index.html). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

Why Adolescents and Adults Need Pertussis Vaccine

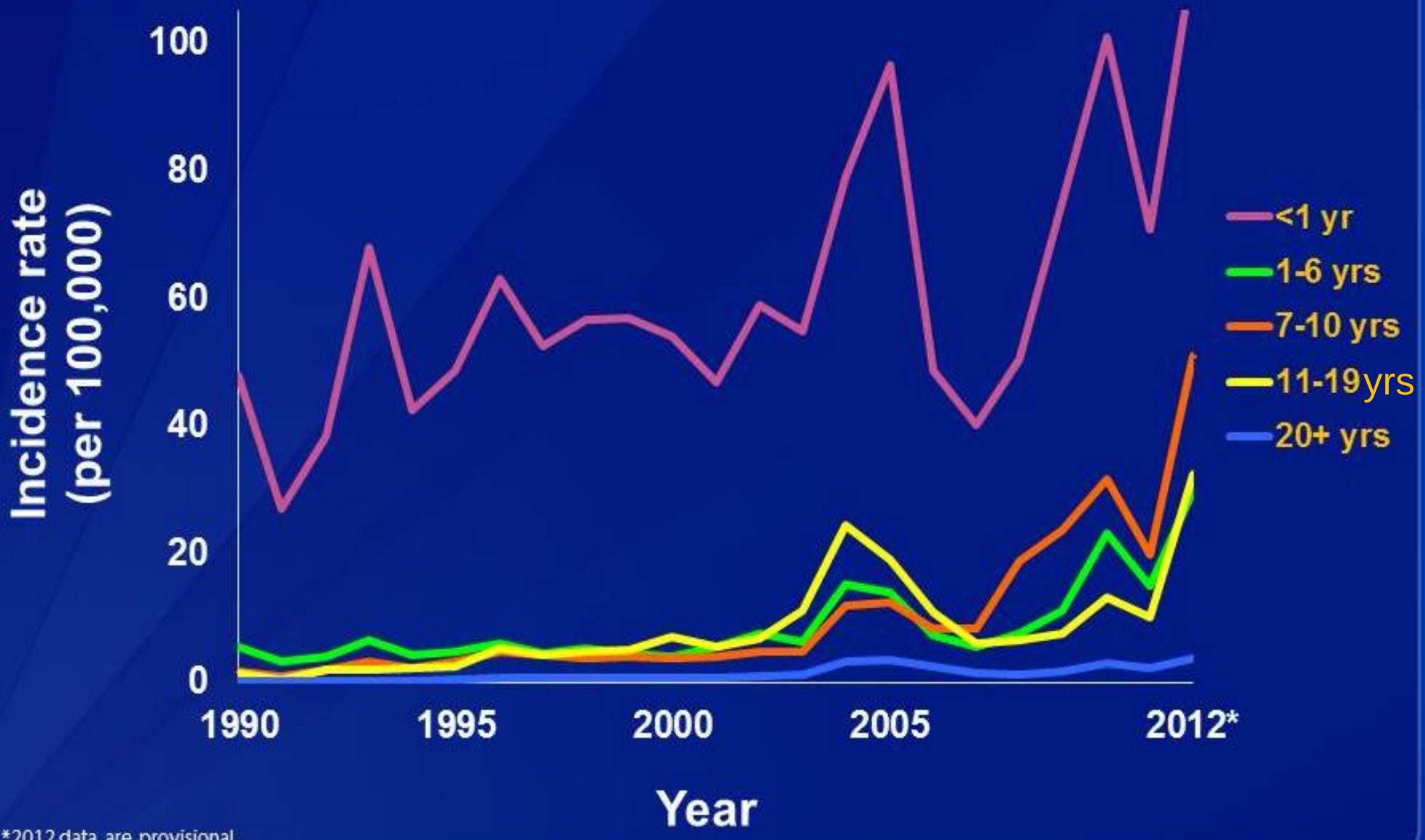
- **Pertussis cases increased in the late 1990s and early 2000s**
- **2004 – 25,827 pertussis cases, highest recorded since 1959**
  - 67% of cases among adolescents or adults
- **Severe illness among young infants with pertussis**
- **Pertussis immunity wanes in 5-10 years**

Reported NNDSS Pertussis Cases

*2013 data are provisional.

SOURCE: CDC National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System and 1922-1949 passive reports to the Public Health Service

Reported Pertussis Incidence by Age Group, 1990-2012*



*2012 data are provisional.

SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System

Adolescent and Adult Pertussis Vaccination

- **Primary objective**
  - Protect the adolescent or adult
- **Secondary objective**
  - Reduce reservoir of *B. pertussis*
  - Potentially reduce incidence of pertussis in other age groups and settings

Tdap Vaccines

- **2 products available licensed with different age indications**

- **Boostrix (GlaxoSmithKline)**
  - FDA approved for persons 10 years of age and older
  - Single dose

- **Adacel (sanofi pasteur)**
  - FDA approved for persons 11-64 years of age
  - Single dose

General Principles for Use of Tdap

- Tdap preferred to Td to provide protection against pertussis
- Both Tdap products approved as a single dose
- Tdap vaccine may be administered regardless of the interval since the last tetanus- or diphtheria toxoid-containing vaccine

Tdap Vaccines

- **Schedule: 1 dose in a lifetime for most persons**
  - Tdap not approved for multiple doses
  - Revaccination issue still being evaluated

- **Formulation:**
  - Tetanus: Same amount of antigen as DTaP and Td
  - Diphtheria: ~ 1/3 less diphtheria antigen than DTaP; same amount of antigen as Td
  - Pertussis: ~ 1/3 less diphtheria antigen than DTaP

Lowercase letters = less antigen!

Persons Without Documentation of Pertussis Vaccination

- **All adolescents and adults should have documentation of having received a series of DTaP, DTP, DT, or Td**

- **Persons without documentation or with an incomplete series should receive or complete a series of 3 doses**
  - Preferred schedule:
    - Single dose of Tdap*
    - Td at least 4 weeks after the Tdap dose
    - Second dose of Td at least 6 months after the prior Td dose

ACIP Conclusions
Tdap Protection for Subsequent Pregnancies

- A single dose of Tdap at one pregnancy is insufficient to provide protection for subsequent pregnancies

Tdap for Every Pregnancy Rationale

- **Continue efforts to remove barriers to improve Tdap uptake**
  - 78% - Adolescents (2011)
  - 12.2% - Adults (2011)
  - 2.6% - Women vaccinated during pregnancy (April 2012)

- **Maternal antibodies from women immunized before pregnancy waned quickly (Healy 2012)**
  - Concentration of maternal antibodies unlikely high enough to provide passive protection to infants

- **Optimize strategies to prevent infant pertussis morbidity and mortality in light of record-setting increase in cases**

Healy CM, Rench MA, Baker CJ. Importance of timing of maternal Tdap immunization and protection of young infants. *Clin Infect Dis* 2013;56:539–44.

CDC. National and State Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2011. *MMWR*. 61(34);671-677

CDC. Noninfluenza Vaccination Coverage Among Adults — United States, 2011. *MMWR* 62(04);66-72

CDC. Tdap vaccination coverage among U.S. women who were pregnant any time during August 2011-April 2012, Internet Panel Survey, April 2012. Unpublished.

Tdap and Pregnancy

- Administer Tdap to pregnant women during each pregnancy, regardless of previous Tdap vaccination history

- Vaccine should ideally be administered between 27 and 37 weeks gestation, although Tdap may be given at any time during pregnancy

*Off-label recommendation; MMWR. Vol. 62 No. 7; February 22, 2013.

ACIP Conclusions
Safety of Tdap for Every Pregnancy

- Data reassuring on 2 doses of Tdap
- Data and experience with tetanus toxoid vaccine suggest no excess risk of adverse events
  - ~5% of women would receive 4 or more doses
- Supported ongoing safety monitoring and requested that CDC commit to safety studies to address concerns about the potential increase in severe adverse events after Tdap is given during subsequent pregnancies

Tdap and Postpartum Women

- **Unvaccinated postpartum women (never received a dose of Tdap) should be given Tdap immediately**
  - Including women who are breast feeding
- **Do not administer Tdap to postpartum women who have already been vaccinated with Tdap**
  - Regardless of the length of time since Tdap vaccination

Tdap AND HEALTHCARE PERSONNEL

Tdap and Healthcare Personnel (HCP)

- **Previously unvaccinated HCP who have direct patient contact should receive a single dose of Tdap as soon as feasible, regardless of age* and time since last Td dose**

*Off-label recommendation.

ACIP Provisional Recommendations for Healthcare Personnel on Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine (Tdap) and use of Post-exposure Antimicrobial Prophylaxis.

Preventing Pertussis Infection of Infants

- **Assure that you and other staff in your office or facility have received Tdap**

- **Partner with clinicians who have access to parents and siblings of infants (e.g., OB-GYN providers, prenatal/new parent educators) to provide Tdap to families of infants**

MMWR 2006; 55(RR-3):1-43. *MMWR* 2006;55(RR-17):1-36. *MMWR* 2011; Vol. 60 (RR-7):19-21.

References

- Preventing Tetanus, Diphtheria, and Pertussis Among Adolescents: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccines) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5503a1.htm

- Preventing Tetanus, Diphtheria, and Pertussis Among Adults: Use of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm

- Immunization of Health-Care Personnel http://www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

- Updated Recommendations for Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis (Tdap) Vaccine in Adults Aged 65 Years and Older — Advisory Committee on Immunization Practices (ACIP), 2012 http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6125a4.htm

HUMAN PAPILLOMAVIRUS DISEASE AND VACCINES

HPV Clinical Features

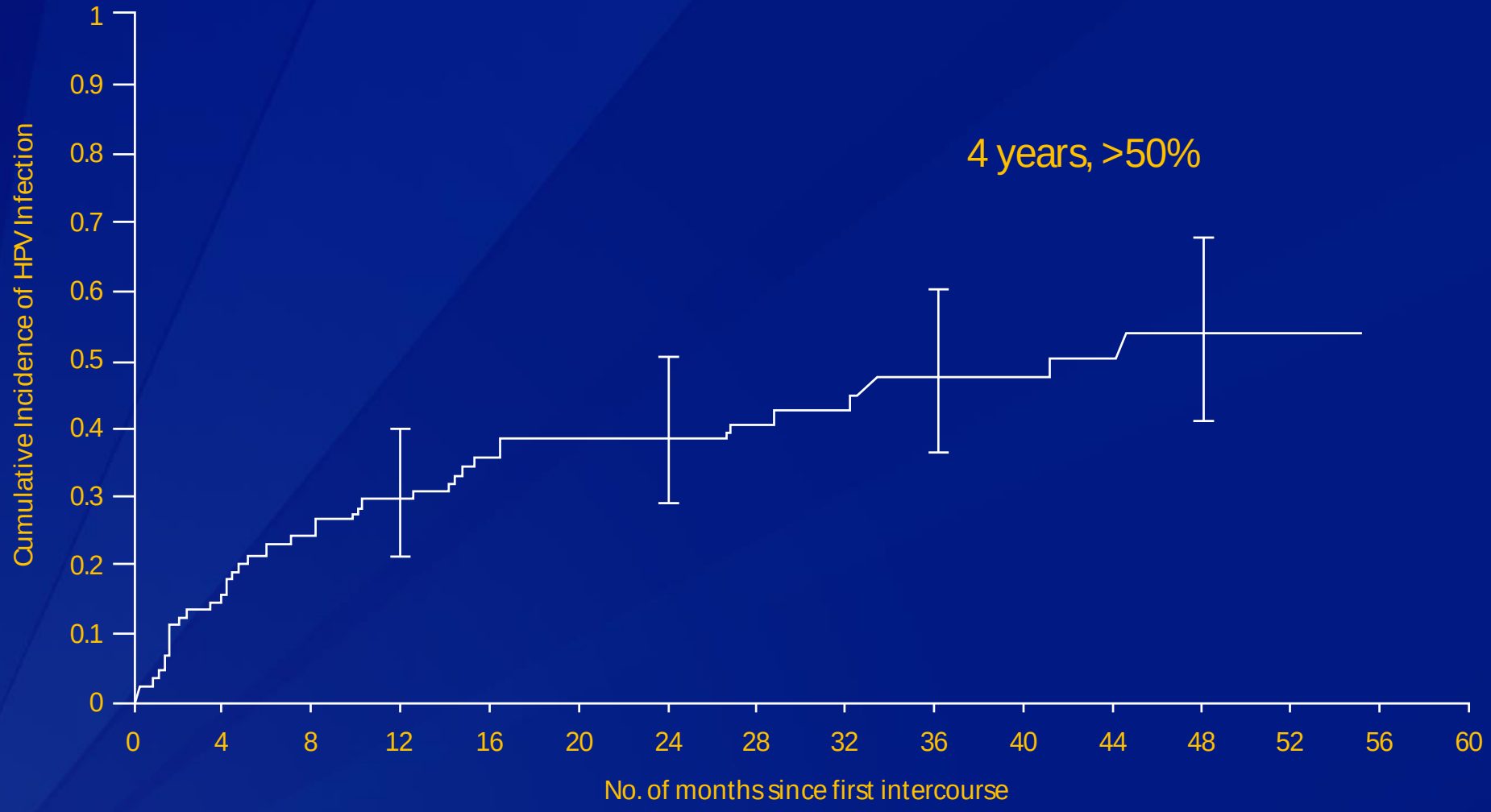
- **Most HPV infections are asymptomatic and result in no clinical disease**

- **Clinical manifestations of HPV infection include:**
  - Anogenital warts
  - Recurrent respiratory papillomatosis
  - Cervical cancer precursors (cervical intraepithelial neoplasia)
  - Cancer (cervical, anal, vaginal, vulvar, penile, and some head and neck cancer)

Human Papillomavirus (HPV) Disease

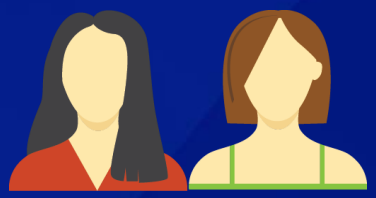
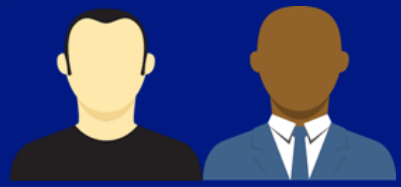
- **Common sexually transmitted infection**
  - Estimated 20 million persons are currently infected
  - 6.2 million new infections annually
- **More than 100 types**
- **Established cause of cervical and other anogenital cancers**

Cumulative Incidence of Any HPV Infection Months after Sexual Initiation



Am J Epidemiol, 2003;157(3):218-26

HPV Associated Disease

TYPE	WOMEN	MEN
		
16/18	70% of cervical cancers 70% of anal/genital cancers	70% of anal cancers
6/11	90% of genital warts 90% of RRP* lesions	90% if genital warts 90% of RRP lesions Transmission to women

* RRP = recurrent respiratory papillomatosis

Cervical Cancer Disease Burden in the United States

- **American Cancer Society's estimates for cervical cancer in the U.S. for 2013 are:**
  - About 12,340 new cases of invasive cervical cancer will be diagnosed
  - About 4,030 women will die from cervical cancer
- **Hispanic women are most likely to get cervical cancer, followed by African-Americans, Asians and Pacific Islanders, and whites**
- **Almost 100% of these cervical cancer cases were caused by one of the 40 HPV types that infect the mucosa**

Source: American Cancer Society
www.cancer.org/cancer/cervicalcancer

HPV Vaccines

Vaccine	HPV types	Gender	FDA Approved Ages
HPV4 (Gardasil, Merck)	16 and 18 (high risk) 6 and 11 (low risk)	females AND males	9 through 26 years
HPV2 (Cervarix, GSK)	16 and 18 (high risk)	females	10 through 25 years

HPV Vaccine Efficacy

- High efficacy among females without evidence of infection with vaccine HPV types
- No evidence of efficacy against disease caused by vaccine types or which participants were infected at the time of vaccination
- Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types

ACIP HPV Recommendations

Types	**HPV 4 (Gardasil)** Types 6, 11, 16, 18	**HPV2 (Cervarix)** Types 16, 18
Recommendations for Females	Routine: 11-12 yrs Catch-up: 13-26 yrs	Routine: 11-12 yrs Catch-up: 13-26* yrs
Recommendations for Males	Routine: 11-12 yrs Catch-up: 13-21 yrs Immunocompromised: 11-26 yrs MSM: 11-26 yrs	Do NOT administer to males
Schedule	0, 1-2*, 6 months	
Route	Intramuscular (IM)	

*Off-label ACIP recommendation HPV4 only. *MMWR* 2007;56(RR-2):1-24 *MMWR* 2011;60(No. 50):1705-8

HPV Vaccination Schedule

- **Recommended schedule is 0, 1-2, 6 months**
  - Following the recommended schedule is preferred
- **Minimum intervals**
  - 4 weeks between doses 1 and 2*
  - 12 weeks between doses 2 and 3
  - 24 weeks between doses 1 and 3
- **The vaccination series can be started as young as 9 years of age at the clinician's discretion**

* Off-label ACIP recommendation- HPV4 only

HPV Vaccine Intervals

- **There is no MAXIMUM interval between HPV vaccine doses**

- **If the interval between doses is longer than recommended the series should be continued where it was interrupted**
  - Do not re-start a valid, documented series

HPV Vaccine
Duration of Immunity

- **The duration of immunity after a complete 3-dose schedule is not known**
  - Available evidence indicates protection for at least 5 years
  - Multiple cohort studies are in progress to monitor the duration of immunity

*booster dose should follow prior dose by >2 months

HPV Vaccination During Pregnancy

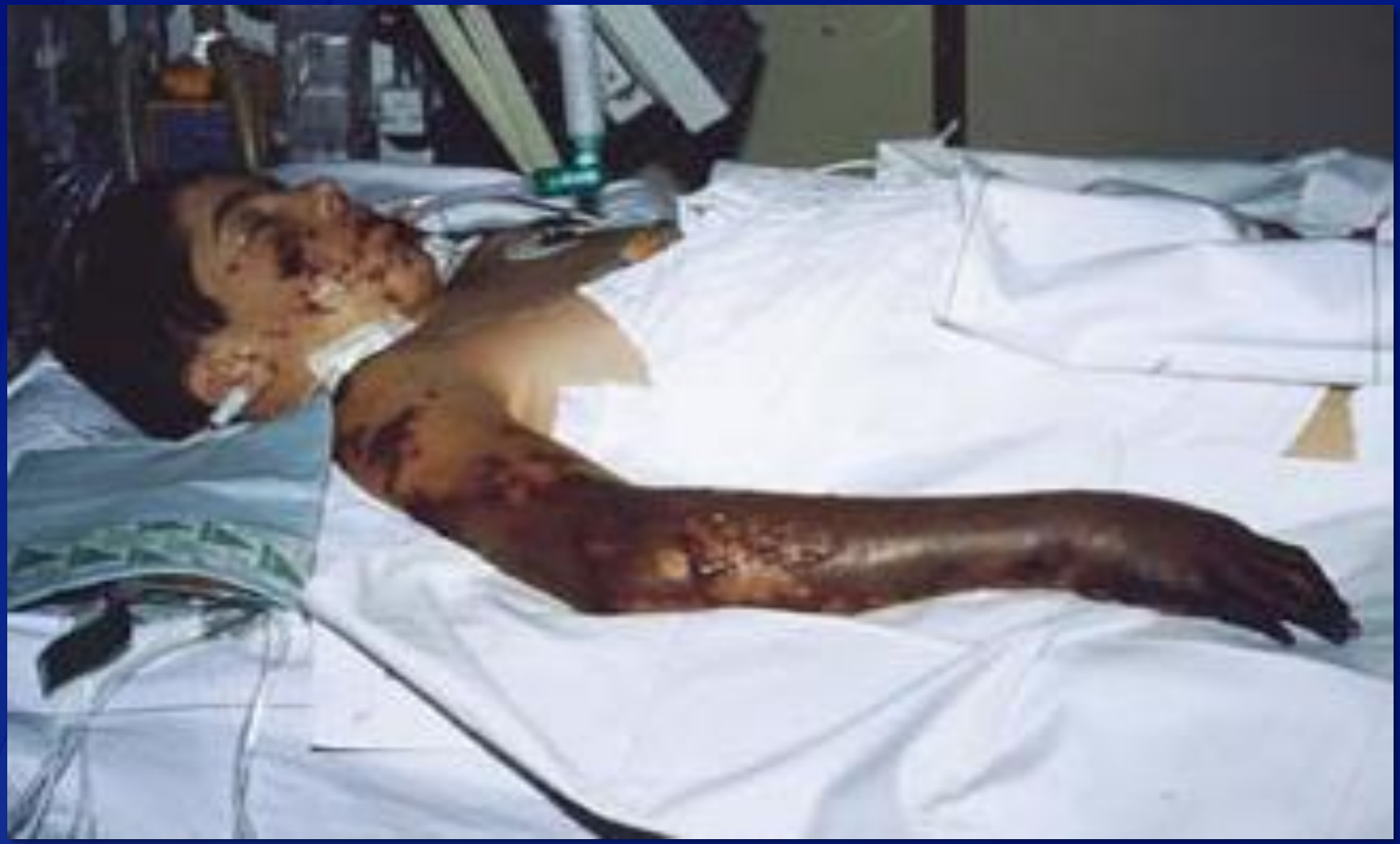
- **Initiation of the vaccine series should be delayed until after completion of pregnancy**
- **If a woman is found to be pregnant after initiating the vaccination series, remaining doses should be delayed until after the pregnancy**
- **If a vaccine dose has been administered during pregnancy, there is no indication for intervention**
- **Women vaccinated during pregnancy should be reported to the respective manufacturer**
  - Telephone numbers are in the package insert

MMWR 2010;59(No. 20):626-9

References

- **Slide content was obtained from:**
  - Quadrivalent Human Papillomavirus Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm
  - FDA Licensure of Bivalent Human Papillomavirus Vaccine (HPV2, Cervarix) for Use in Females and Updated HPV Vaccination Recommendations from the Advisory Committee on Immunization Practices (ACIP) http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a4.htm
  - FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP) http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5920a5.htm

Meningococcal Disease



N Engl J Med. 2001;344:1372

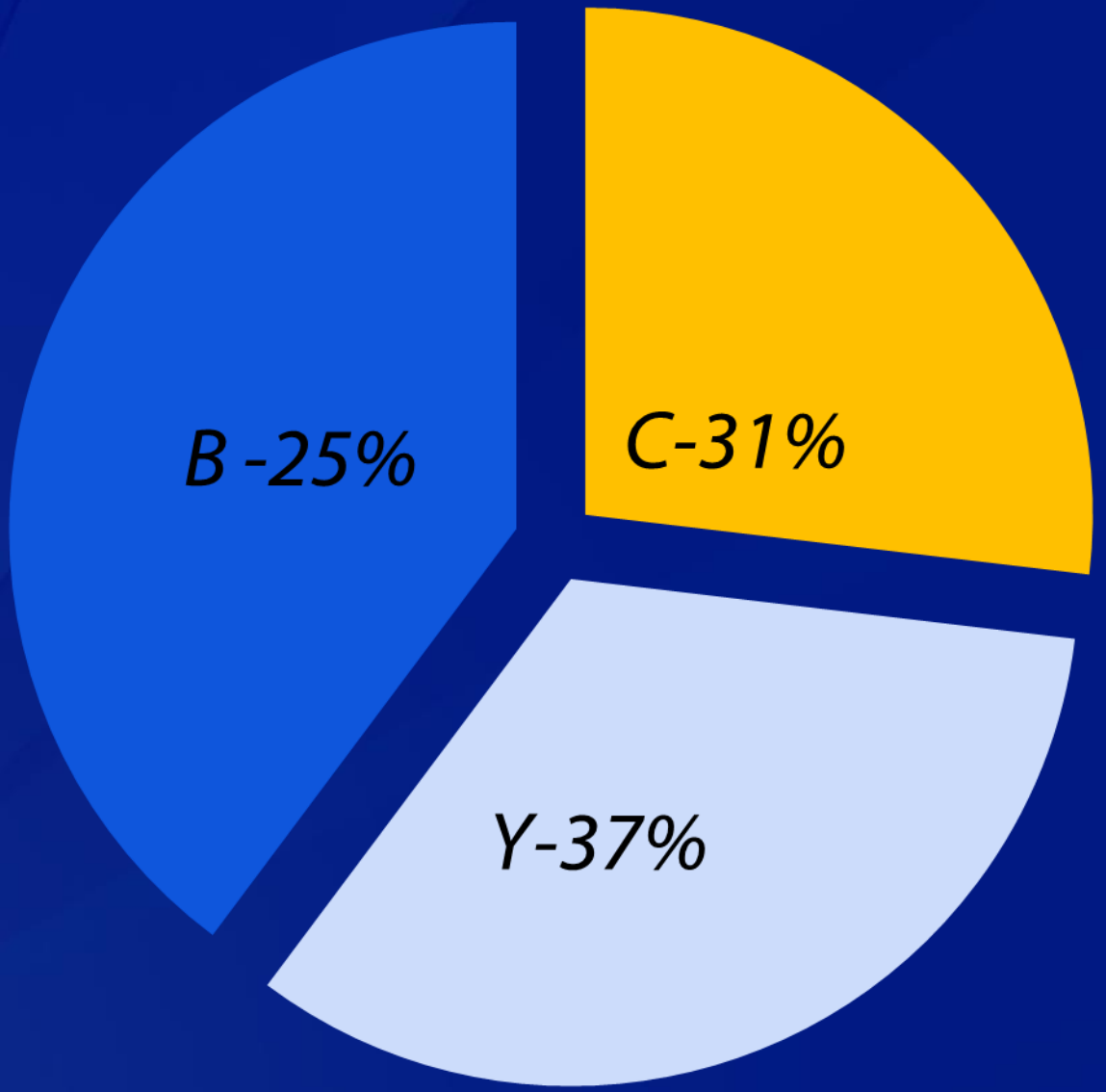
Neisseria meningitidis

- Aerobic gram-negative bacteria
- At least 13 serogroups based polysaccharide capsule
- Most invasive disease caused by serogroups A, B, C, Y, and W
- Relative importance of serogroups depends on geographic location and other factors (e.g., age)

Meningococcal Disease in the United States

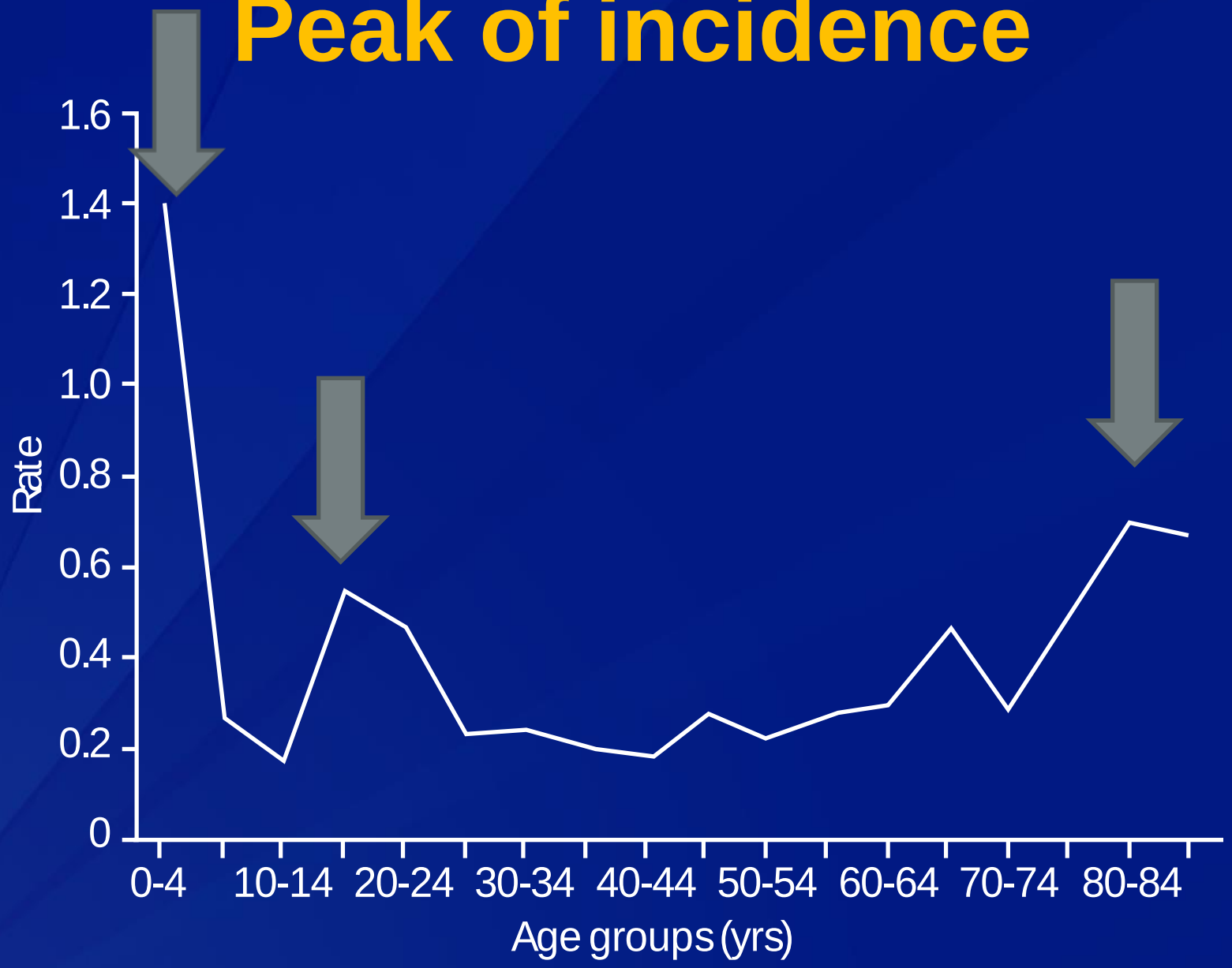
- B, C, Y are the major causes in the US – each accounting for approximately a third of cases

Meningococcal Disease Serotypes in the US 1997-2002

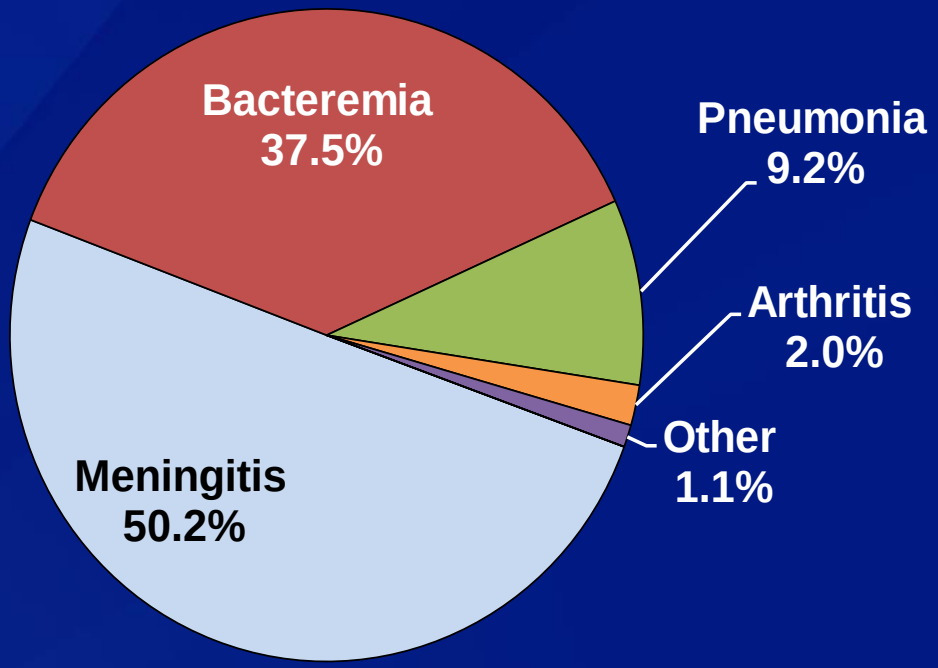


Meningococcal Disease – United States, 1972-2010

Peak of incidence



Neisseria meningitidis Clinical Manifestations*



*1998-2007 data; *Clin Inf Dis* 2010;50(2):184

Neisseria meningitidis
Risk Factors for Invasive Disease

- Persistent complement component deficiency
  - 10,000 fold increased risk, can experience recurrent disease
- Functional or anatomic asplenia
- Genetic risk factors
- Chronic underlying illness
- Active and passive smoking
- Concurrent viral infection
- Household Crowding

Neisseria meningitidis Risk Factors for Invasive Disease (2)

- HIV infection (not independent risk factor) however, incidence higher in persons with AIDS
- Microbiologists working with *N. meningitidis* isolates

Neisseria meningitidis Risk Factors for Invasive Disease (3)

- **College Students:**
  - Studies in 1990's – overall incidence similar to or lower than their counterparts in general population
  - Case control study of 50 cases and other studies in the 1990's
    - First year college students living in residence halls at higher risk

Meningococcal Polysaccharide Vaccine (MPSV4)

- Menomune (sanofi pasteur)
- Quadrivalent polysaccharide vaccine (A, C, Y, W-135)
- Administered by subcutaneous injection
- 10-dose vial contains thimerosal as a preservative
- Single dose vial available

Meningococcal Conjugate Vaccines

- Meningococcal polysaccharide conjugated to protein carrier
- Elicit both T- and B-cell immunity (T-cell dependent immunity)
- 3 brands currently licensed in the United States (will not discuss MenHibRix for infants)

Menactra MCV4 Vaccine

- Quadrivalent polysaccharide vaccine (A, C, Y, W-135) conjugated to diphtheria toxoid
- Licensed by FDA in January 2005
- Approved for persons 9 months* through 55 years of age
  - 2 – dose series in 9 through 23 month olds
  - Single dose for persons 2 through 55 years (except HIV patients)
- FDA approval based on serologic non-inferiority compared to meningococcal polysaccharide vaccine

*as of April 22, 2011

Menveo MCV4 Vaccine

- Licensed by FDA in February 2010
- Approved for persons 2 mos. through 55 years of age (as of 8/1/2013)
- Lyophilized serogroup A vaccine reconstituted with liquid containing serogroups C, Y, and W135
- May be used for any person 2 mos. through 55 years of age for whom MCV4 is indicated including revaccination
- Single dose (except HIV patients, and high risk infants 2-23 mos)

MMWR 2013: Vol 62(2); *MMWR* 2014: Vol 63(24)

Persons at Highest Risk of Meningococcal Disease or Suboptimal Vaccine Response

- Complement deficiency
  - very high antibody titer required to compensate for complement deficiency
- Asplenia
  - evidence of suboptimal response
- Administer 2 doses* of MCV4 at least 8 weeks apart to persons with persistent complement component deficiency and anatomic or functional asplenia, and 1 dose every 5 years* thereafter OR administer MenHIbRix on a 4-dose schedule at 2,4,6, 12-15 months

* off-label recommendations. *MMWR* 2011;60(No. 3):72-6.

MCV4 Recommendations and HIV

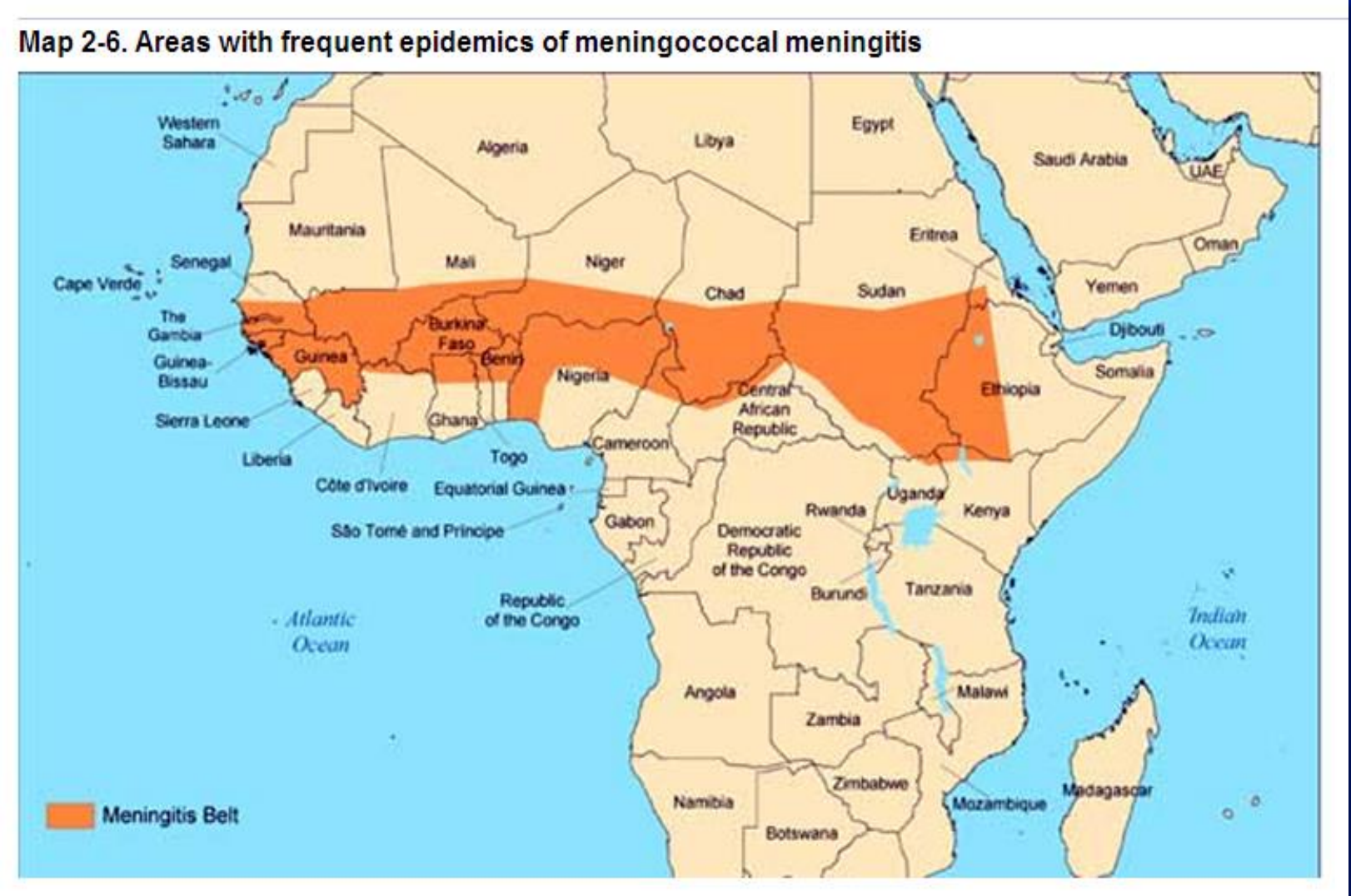
- HIV infection alone is not an indication for MCV4 vaccination
- Persons with HIV infection show evidence of suboptimal response to vaccination
- Some persons with HIV infection should receive MCV4 (adolescents, some international travelers, microbiologists, etc)
- Persons with HIV infection who are vaccinated with MCV4 should receive 2 doses at least 8 weeks apart

MMWR 2011;60(No. 3):72-6.

Meningococcal Vaccine Recommendations for Persons 2 through 55 years at High Risk (2)

- Persons who:
  - are first-year college students aged ≤21 years living in residential housing
  - travel to or are residents of countries where meningococcal disease is hyperendemic or epidemic (i.e., the “Meningitis belt”)
  - are at risk during a community outbreak attributable to a vaccine serogroup
  - are microbiologists routinely exposed to isolates of *Neisseria meningitidis*
- Administer: 1 dose of MenACWY

The “Meningitis Belt”



wwwnc.cdc.gov/travel/yellowbook/

Meningococcal Vaccine Booster doses for

- Person remains at increased risk* and completed the primary dose or series at age:
- 2 mos–6 yrs: Should receive additional dose of MenACWY 3 yrs after primary immunization; boosters should be repeated every 5 yrs thereafter
- ≥7 yrs: Should receive additional dose of MenACWY 5 yrs after primary immunization; boosters should be repeated every 5 yrs thereafter

Meningococcal Vaccine Booster doses for

- Persons with
  - Complement component deficiency
  - Anatomic/functional asplenia

MCV4 Revaccination Recommendations

- Other high-risk persons recommended for boosters
  - microbiologists with prolonged exposure to *Neisseria meningitidis*
  - frequent travelers to or persons living in areas with high rates of meningococcal disease (see next slide)

- Revaccinate every 5 years as long as the person remains at increased risk
  - MCV for persons 2 through 55 years of age, and
    - For persons 56 years and older who previously received MCV, and are at continued risk
  - MPSV for persons 56 years and older who need only one dose of meningococcal vaccine

*off-label recommendation. *MMWR* 2013;62(No. 02):15-16

International Travelers and Revaccination

- International travelers should receive a booster dose of MenACWY if the last dose was administered 5 or more years previously.
  - Vaccination in the 3 years before the date of travel is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

Resources

- **Information for these slides obtained from:**
  - http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf
  - Prevention and Control of Meningococcal Disease, Recommendations of the ACIP. MMWR / March 22, 2013 / Vol. 62 / No. 2, and
  - MMWR/June 20, 2014/Vol. 63/ No. 24.

Pneumococcal Disease and Pneumococcal Vaccines

National Center for Immunization & Respiratory Diseases
Immunization Services Division

Pneumococcal Disease

- Second most common cause of vaccine-preventable death in the U.S.

- Major clinical syndromes
  - Pneumonia
  - Bacteremia
  - Meningitis

Pneumococcal Disease

- Pneumonia
  - Estimated 400,000 hospitalizations/year in the United States
  - Case-fatality rate (CFR) higher in the elderly
- Bacteremia
  - About 12,000 cases per year in the United States
  - CFR: 15%, can be much higher in the elderly
- Meningitis
  - About 3,000 cases per year in the United States
  - CFR ~10%, up to 80% in the elderly

CDC data at http://www.cdc.gov/pneumococcal/clinicians/clinical-features.html

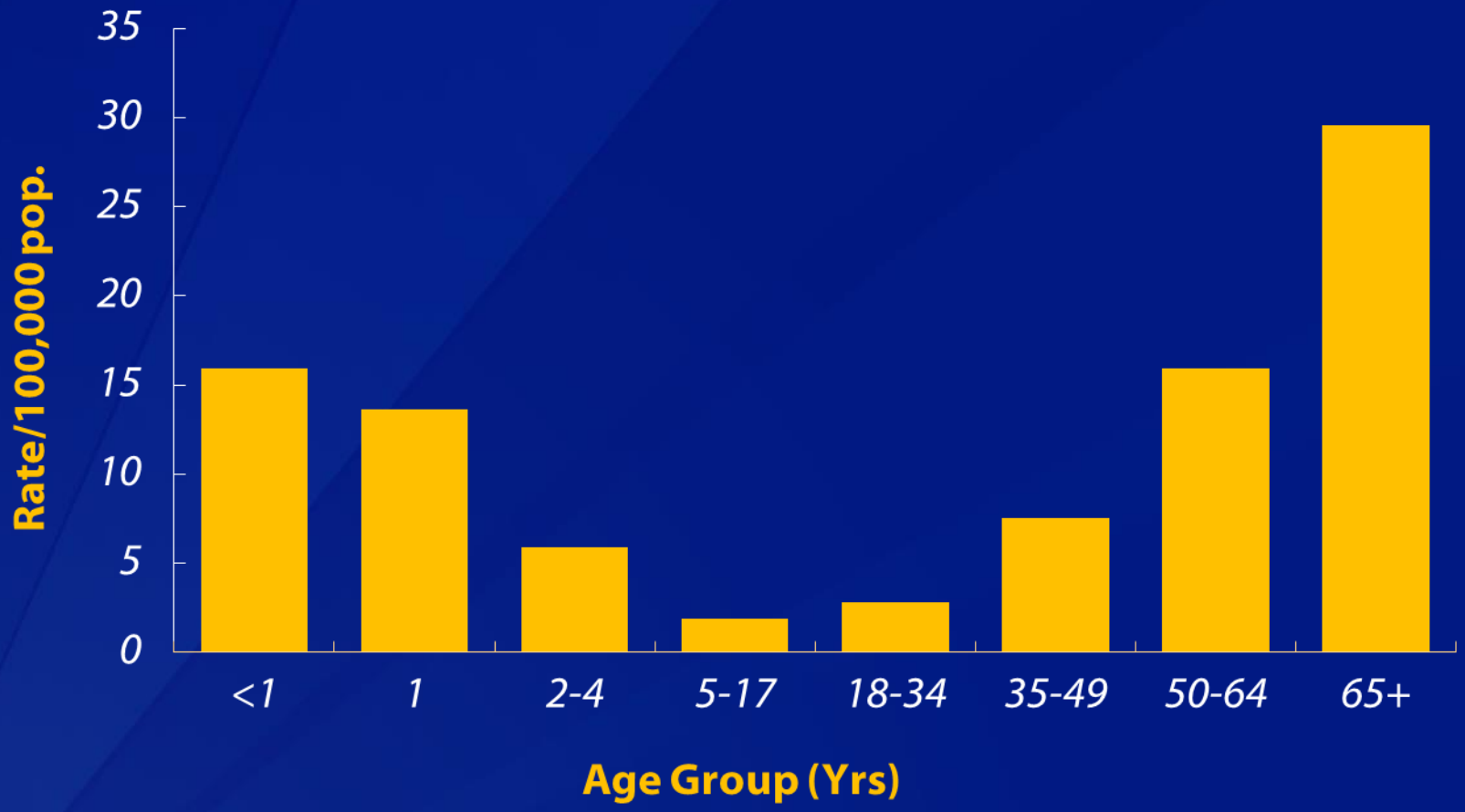
Risk Factors for Invasive Pneumococcal Disease

- Children 2 years of age and younger
- Persons 65 years of age and older
- Underlying medical conditions
- Cigarette smoking (adults 19 years and older)
- Cochlear implant

Other Conditions that Increase Risk for Invasive Pneumococcal Disease

- Decreased immune function
- Asplenia (functional or anatomic)
- Cerebrospinal fluid (CSF) leak

Invasive Pneumococcal Disease Incidence by Age Group – 2012*



CDC ABC's report: http://www.cdc.gov/abcs/reports-findings/survreports/spneu12.html

Pneumococcal Polysaccharide Vaccine

- Purified capsular polysaccharide antigen from 23 types of pneumococcus
- Account for 88% of bacteremic pneumococcal disease in adults*

*Muhammad RH, et al. *Clin Inf Dis* 2012;56(5)e59-67

Pneumococcal Polysaccharide Vaccine

- Not effective in children younger than 2 years
- Most estimates range between 60%-70% effective against invasive disease among immunocompetent older persons and adults with underlying illnesses; some as low as 10%
- Effectiveness among immunocompromised or very old persons not demonstrated
- Less effective (if at all) in preventing pneumococcal pneumonia

Pneumococcal Polysaccharide Vaccine (PPSV23) Recommendations (1)

- Previously unvaccinated adults 65 years and older
- Persons 65 years or older who received PPSV23 for any reason prior to age 65 years*
- Persons 19 years and older with:
  - Cigarette smoking
  - Asthma

*At least 5 years after previous dose

Pneumococcal Polysaccharide Vaccine (PPSV23) Recommendations (2)

- Persons in environments or settings with increased risk

- Persons 2 years and older with normal immune systems who have chronic illness
  - Cardiovascular or pulmonary disease
  - Diabetes
  - Alcoholism
  - CSF leak
  - Cochlear implant

Pneumococcal Polysaccharide Vaccine (PPSV23) Recommendations (3)

- Persons 2 years and older who are immunocompromised (due to disease or Rx)
  - Asplenia (functional or anatomic)
  - Chronic renal failure
  - Nephrotic syndrome
  - Hodgkin disease
  - Lymphoma
  - Multiple myeloma
  - Organ transplant
  - HIV infection

Pneumococcal Polysaccharide Vaccine Revaccination

- Routine revaccination of immunocompetent persons is not recommended
- Revaccination recommended for persons 2 through 64 years of age who are at highest risk of serious pneumococcal infection
- Single revaccination dose at least 5 years after the first dose, before age 65

MMWR 2010;59(No.34):1102-5

Pneumococcal Polysaccharide Vaccine Revaccination

- If vaccinated when younger than 65 years old and it's been at least 5 years, give a dose at age 65 or older (this may be a 3rd dose)
- If vaccinated twice at younger than 65 years old, vaccinate once after turning 65 (and 5 years after last dose)
- If vaccinated at 65 years or older, no revaccination recommended

MMWR 2010;59(No.34):1102-5

Pneumococcal Polysaccharide Vaccine Candidates for Revaccination

- Persons 2 years or older with:
  - Functional or anatomic asplenia (including sickle cell disease)
  - Immunosuppression (including HIV infection)
  - Transplant
  - Chronic renal failure
  - Nephrotic syndrome

MMWR 2010;59(No.34):1102-5 and 2010;59(RR-11)

Pneumococcal Conjugate Vaccine 13-Valent

- Contains the same serotypes of *S. pneumoniae* as PCV7 plus serotypes 1, 3, 5, 6A, 7F, and 19A conjugated to nontoxic diphtheria CRM_{197} carrier protein

- FDA approval for adults based on demonstration of immunologic non-inferiority to PCV7 rather than clinical efficacy

MMWR 2010;59(No. 9):258-61

PCV13 Licensure

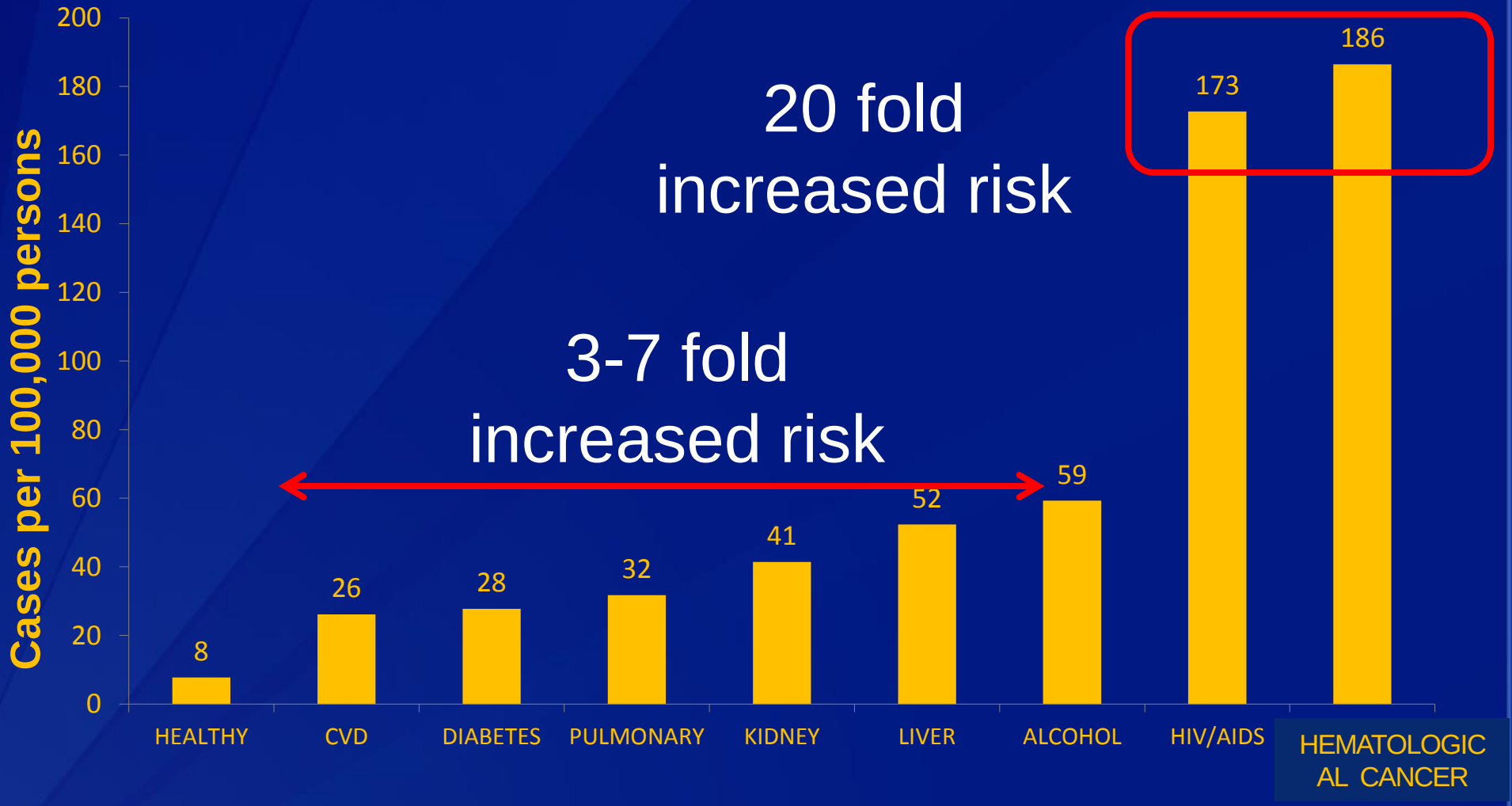
- PCV13 is approved by the Food and Drug Administration for:
  - Children 6 weeks through 71 months of age
  - Adults 50 years of age and older

- ACIP recommended use of PCV13 for immunocompromised persons 6 years and older (June 20, 2012, and February 20, 2013)

Summary of February 2012 ACIP Deliberations: PCV13 for Adults

- ACIP deferred universal recommendation for all adults pending the further collection of data
  - Efficacy of PCV13 against pneumonia (CAPITA trial, results in 2014)
  - Indirect (herd) effects of PCV13 use in children

Incidence of IPD in Adults Aged 18-64 Years with Selected Underlying Conditions, United States, 2009



Active Bacterial Core Surveillance, 2009. Unpublished data

ACIP Recommendations June 2012 PCV13 for Immunocompromised Adults - Rationale

- Extremely high burden of disease among immunocompromised adults
- Benefits outweigh any risks for use of PCV13 in some adults
- Indirect effects of PCV13 use in children not likely to eliminate IPD due to PCV13 serotypes in adults
- PCV13 use alone may not provide adequate coverage of serotypes causing disease in adults
- Combined use of PCV13 and PPSV23 more effective than either vaccine alone

ACIP Pneumococcal Recommendations

- ACIP voted to recommend PCV13 vaccine in addition to PPSV23 to certain high-risk adults 19 years of age and older with:
  - Immunocompromising conditions
  - Functional or anatomic asplenia
  - Cochlear implants
  - CSF leak

ACIP Recommendations for PCV13 for Immunocompromised Adults*

- Adults 19 years of age or older with:
  - Immunocompromising conditions
  - Functional or anatomic asplenia
  - CSF leaks
  - Cochlear implants

- Have not previously received PCV13 or PPSV23
  - Should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later, with a booster dose or PPSV23 5 or more years later

**MMWR*. October 12, 2012 / 61(40);816-819

Administering PCV13 and PPSV23 Vaccines

- PCV13 and PPSV23 should not be administered simultaneously
- Administer PCV13 before PPSV23 whenever possible
- PPSV23 recommendations and indications for those at highest risk for invasive pneumococcal disease remain unchanged from earlier recommendations

Recommendations for Use of PCV13 and PPSV23 in Pneumococcal Vaccine-naïve Adults

- Adults 19 years and older with:
  - Functional or anatomic asplenia
  - Immunocompromising conditions
  - CSF leak
  - A cochlear implant

  who are vaccine-naïve should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later

- For those that require additional doses of PPSV23, (functional/anatomic asplenia, immunocompromising conditions) a second dose of PPSV23 is recommended 5 years after the first dose of PPSV23

Recommendations for Use of PCV13 in Adults Previously Vaccinated with PPSV23

- Adults with,
  - Immunocompromising conditions
  - Functional or anatomic asplenia,
  - CSF leak
  - A cochlear implant

  Who were previously vaccinated with PPSV23 should receive PCV13 1 or more years after the last PPSV23 dose

- For those that require additional doses of PPSV23 (immunocompromising conditions, functional/anatomic asplenia), the first dose should be administered no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23

- Revaccination with PPSV23 after 5 years does NOT apply to those with CSF leaks or cochlear implants

http://www.cdc.gov/vaccines/recs/provisional/downloads/pcv13-adults-

Haemophilus influenzae type b and Hib Vaccine

National Center for Immunization & Respiratory Diseases
Immunization Services Division

Haemophilus influenzae type b United States, 2002 – 2008

- Incidence has fallen 99% since prevaccine era
- 175 confirmed Hib cases reported (average of 25 cases per year)
- Most recent cases in unvaccinated or incompletely vaccinated children

Haemophilus influenzae type b Vaccine Use in Older Children and Adults

- Generally not recommended for persons older than 59 months of age
- Consider for high risk persons: asplenia, immunodeficiency, HIV infection (not for HIV-infected adults)
- One pediatric dose of any conjugate vaccine
- Three doses if post-hematopoietic cell transplant (HCT)

Surgically-induced Asplenia

- Vaccinate before surgery if possible
- If not possible, vaccinate as soon as medical condition stabilizes after surgery

QUESTIONS?