NEW MEXICO PHARMACIST'S PRESCRIPTIVE AUTHORITY

IMMUNIZATION CERTIFICATION

2017

PRESCRIPTIVE AUTHORITY

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DISCLOSURE

The presenter of this program has no financial conflict or interest with the manufacturer of any product named during this presentation.

CLASS

Vaccination Principles Vaccines and diseases – "Pink Book" Storage and handling - safety Childhood Schedule - cases "Nuts and Bolts" of Practice – Your Tool Kit - Protocol/Regulations – the law Injection techniques and practice

ROLE OF THE PHARMACIST

ADVOCATE -

Immunization educate and advocate

FACILITATOR -

Host immunization clinics

IMMUNIZER -

DO IT/ENJOY IT!!

VACCINES ARE DRUGS

Pharmacists are responsible for drugs

Pharmaceutical care – responsible for patients' health and outcomes.

- Cure of disease
- Elimination/reduction of symptoms
- Arresting or slowing disease process
- Preventing disease or symptoms

VACCINE-PREVENTABLE INFECTIOUS DISEASES



OBJECTIVES

- 1. Describe the principles of active and passive immunity.
- Identify the differences in immunologic response and contraindications between live attenuated and inactivated vaccines.
- 3. Identify the recommended vaccines for vaccine-preventable diseases for both children and adults.
- 4. Develop a vaccination plan, given a patient's age, immunization history, and medical history.
- 5. Educate a patient or caretaker on the benefits and risks associated with vaccines.
- 6. Distinguish between appropriate and inappropriate reasons for deferring vaccination.
- 7. Recognize possible adverse reactions.

VACCINES THAT WILL BE COVERED

- Influenza
- Measles, Mumps, and Rubella
- Varicella
- Zoster
- Diptheria, Tetanus, and Pertussis
- Pneumococcal
- Meningococcal
- Rotavirus
- Inactivated poliovirus
- Human Papillomavirus
- Hepatitis A and B
- Haemophilus influenzae type b
- Rabies

PREVENTING DISEASE

- Sanitation
- Immunization

MORBIDITY <u>COMPARISON IN U.S.</u>

DISEASE	PRE-VACCINE ERA (Cases/Year)	Cases in 2006
Diptheria	175,885	0
Measles	503,282	55
Mumps	152,209	6,534
Pertussis	147,271	15,632
Paralytic Polio	16,316	0
Rubella	47,745	11
Tetanus	1,314	41

Smallpox

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SMALLPOX

- Global Eradication Program in 1966
 - Last case reported in U.S. was in 1949
 - Routine vaccination discontinued 1972
 - Last indigenous case reported on earth was in 1977



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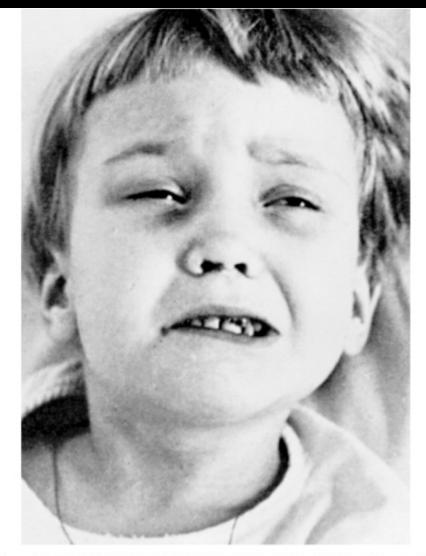
MUMPS





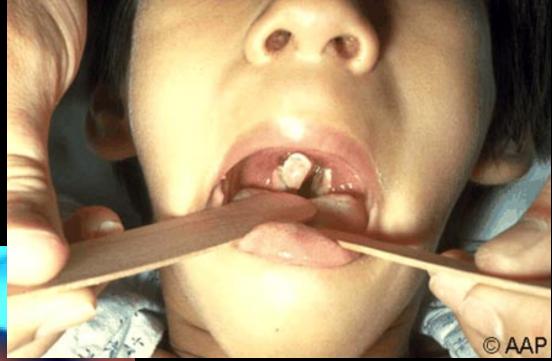
TETANUS





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DIPTHERIA





HERPES ZOSTER







The Truth About Vaccines

Will Michelle Obama Hurt Barack In November?

UNE 2. 2008

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The Last Hurrah: Indiana Jones Shows His Age

Worried about autism, many parents are opting out of immunizations. How they're putting the rest of us at risk BY ALICE PARK

Formaldehude, Aluminum Phosphate, Appartame, Human Fetal Tissue, Moniev Kidnev & Lung Cells, MSG, Boulve Fetal Serum

MYTH OR REALITY

"Vaccine-preventable diseases have been virtually eliminated from the U.S., so my child does not need to be vaccinated."

- Some vaccine preventable diseases are no longer endemic in the U.S.
- These diseases may still be prevalent or even epidemic in other parts of the world.
- Outbreaks in the U.S. are often associated with foreign travel.
- Without vaccination, few cases could quickly become tens or hundreds of thousands.

MYTH OR REALITY

"Aborted fetuses are used to make vaccines."

- Varicella, rubella, hepatitis A, and one rabies vaccine are made in fetal embryo fibroblast cells.
- Obtained from therapeutic termination of two pregnancies in 1960s.
- These same embryonic cells are used today.
- Rubella vaccine prevents congenital abnormalities and miscarriages.

TRUE OR FALSE

The amount of aluminum found in vaccines is similar to the amount found in 1 liter of infant formula?

- A. True
- B. False

True. Aluminum is used as an adjuvant in some vaccines and is closely monitored by the FDA.

ADDRESSING PARENTS CONCERNS

- Establish rapport
- Be open and honest
- Identify concerns
- Identify their sources of information
- Be prepared to respond with evidence-based information
- Appeal to civic duty and risk

COMMUNITY BENEFIT

- Untreated children become threat to others
- Some individuals cannot be vaccinated and rely on 'herd immunity'
- Even with a fully immunized population, infection is still possible
- Costs on community

PHARMACISTS' RESPONSIBILITY

- Promote vaccination Public Health issue
- Ensure proper storage and administration
- Observe correct timing and appropriate intervals of vaccinations
- Follow contraindications and precautions

RESOURCES

- CDC vaccine safety <u>www.cdc.gov/vaccines</u>
- Flu info <u>http://www.flu.gov/</u>
- Local flu info <u>www.tricore.org</u>
- Immunization Action Coalition www.immunize.org
- American Academy of Pediatrics -<u>www.cispimmunize.org</u>
- Children's Hospital of Philidelphia <u>www.chop.edu</u>
- Vaccine Adverse Event Reporting System (VAERS) -<u>http://vaers.hhs.gov/</u>

ADVERSE EVENT REPORTING

- Vaccine Adverse Event Reporting System (VAERS)
 - FDA and CDC
 - Voluntary reporting (by anyone)
- Adverse reaction
 - Side effect caused by vaccine
- Adverse event
 - Temporal event following vaccination
 - An adverse event can be an adverse reaction
- Vaccine Injury Compensation Program (1986)
 - Routinely recommended childhood vaccines

Immune System

- Distinguishes self from non-self
- Ability to recognize and eliminate infectious agents

Antigen

• A live or inactivated substance that is capable of inducing immune response

Antibody

 Protein molecules produced by the B lymphocytes that assist in the elimination of antigens

Passive Immunity

- Transferred protection from exogenous source
 - Maternal/transplacental
 - Blood products
- Temporary (wanes with time)

Active Immunity

- Produced protection by person's own immune system
 - Exposure to infectious disease
 - Vaccination
 - Live attenuated vaccine
 - Inactivated vaccine
- Usually permanent

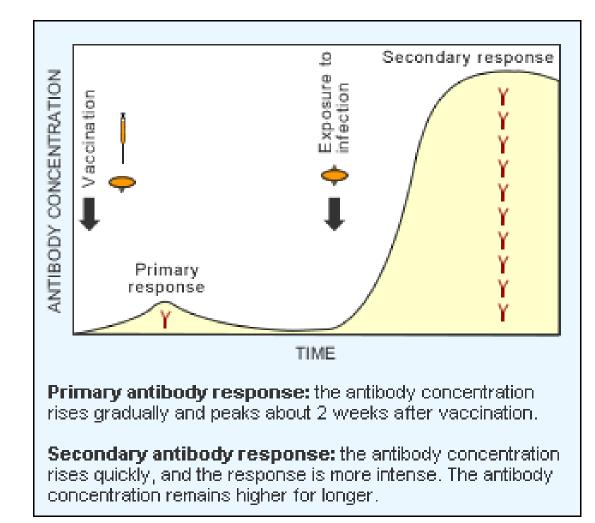
ACTIVE IMMUNE RESPONSE TO PRIMARY EXPOSURE

- Primary Response
 - Innate immune response (rapid)
 - Adaptive response (delayed)
 - Antibody titers peak around 2-6 weeks postexposure
 - Titers fall gradually with memory B-cells being produced

ACTIVE IMMUNE RESPONSE TO SECONDARY EXPOSURE

- Secondary Response
 - Delayed response
 - Memory cells rapidly make antibodies
 - Host often unaware that exposure ever occurred

ANTIBODY PRODUCTION FOLLOWING VACCINATION



VACCINATION PRINCIPLES

- Successful vaccination relies on active immunity of individual
- Immunologic response is similar to natural infection (without risk of disease)
- Response and persistence of protection is determined by several factors:
 - Live attenuated vs inactivated
 - Host characteristics and immune status
 - Administration

IMMUNIZING AGENTS

- Immunoglobulins (acute protection)
- Vaccines (viral or bacterial)
 - Live attenuated vaccine
 - Inactivated vaccine
 - Whole
 - Fractional
 - Protein (toxoid or subunit)
 - Polysaccharide-based (pure or conjugate)

IMMUNIZING AGENTS -COMPONENTS

- Suspending fluid
 - Typically sterile water or saline
- Preservatives, stabilizers, and antibiotics
 - Used to prevent contamination or to stabilize the antigen
 - Includes such materials as:
 - Mercurials (thimerosal)
 - Gelatin
 - Specific antibiotics (neomycin)
- Adjuvants
 - Typically aluminum salts
 - Added to inactive vaccines to enhance immune response

LIVE ATTENUATED VACCINES

- Weakened form of infectious agent
- Does not cause disease
- Requires replication to produce a sufficient response
- Most resembles the immune response produced by
- Usually effective with one dose (unless oral)
- May be contraindicated in:
 Immunosuppressed patients
 Pregnant women

AVAILABLE LIVE VIRUS VACCINES

- Viral
 - Measles/Mumps/Rubella
 - Varicella/Zoster
 - Rotavirus
 - Influenza (Intranasal LAIV)
 - Yellow Fever
 - Vaccinia (smallpox)
 - Oral polio (OPV)*

- Bacterial
 - BCG
 - Typhoid (oral)
 - Plague*

*Not available in US

THE VARICELLA VACCINE AND THE ZOSTER VACCINE ARE COMPOSED OF THE SAME LIVE VACCINE VIRUS

Which vaccine is used in adults and at what age is the vaccine administered?

Zoster vaccine is used in adults 60 years or older.

New approval – 50 and older – NOT ACIP recommended YET

INACTIVATED VACCINES

- Contains fractional antigen or whole dead infectious agent
- Does not cause disease
- Generally not as effective as live vaccines
 - Larger doses
 - Multiple doses (3-5)
 - Boosters may be necessary
- May administer to immunosuppressed patients and pregnant women
- Circulating maternal antibody does not interfere with vaccine

AVAILABLE INACTIVATED VACCINES

- <u>Viral</u>
 - Whole
 - Polio
 - Rabies
 - Hepatitis A
 - Japanese encephalitis
 - Fractional
 - Hepatitis B
 - Influenza
 - Human papillomavirus
 - Anthrax

- <u>Bacterial</u>
 - Whole
 - Cholera*
 - Plague*
 - Pertussis*
 - Fractional
 - Acellular pertussis
 - Pneumococcal (PPV, PCV)
 - Meningococcal (MPSV, MCV)
 - Typhoid Vi
 - Haemophilus influenzae type B
 - Diptheria toxoid
 - Tetanus toxoid

*Not available in US

PURE POLYSACCHARIDE VACCINES

- Not consistently immunogenic in children
 <2 years of age
 - Induce T-cell-independent immune response
 - Antibody with less functional activity
 - No booster response
 - Immunogenicity improved by conjugation

POLYSACCHARIDE CONJUGATE VACCINES

- Stimulates T-cell-dependent immunity
- Enhanced antibody production, especially in young children
- Repeat doses elicit booster response

IMMUNIZATION SCHEDULES

- Children and Adolescent Schedule
 - Revised and Available January 2017
 - Collaborative effort of:
 - Advisory Committee on Immunization Practices (ACIP)
 - American Academy of Pediatrics
 - American Academy of Family Physicians
- Adult Schedule
 - Revised and available January 2017
 - Collaborative effort of:
 - Advisory Committee on Immunization Practices (ACIP)
 - American Academy of Family Physicians
 - American College of Physicians
 - American College of Obstetricians and Gynecologists

IMMUNIZATION SCHEDULE FOR AGES 0-18 YEARS

• See schedule online

IMMUNIZATION SCHEDULE FOR AGES 0-18 YEARS - COMBINED

- What vaccinations should be given within the first year of life? Are these live attenuated or inactivated vaccines?
 - Hep B, RV, DTaP, Hib, PCV, IPV, influenza (All inactivated)
- The 4th dose of DTaP may be administered as early as age 12 months, provided what (stated in footnote)?
 - 6 months have elapsed since the third dose
- How many doses are in the MMR series? Is this a live attenuated or inactivated vaccine?
 - 2 doses (Live vaccine administered after 1 year old)

IMMUNIZATION SCHEDULE FOR AGES 0-18 YEARS

- What is the pediatric version of Tdap?
 - DTaP

- What is the minimum age for administration of HPV vaccination?
 - 9 years old

IMMUNIZATION SCHEDULE FOR ADULTS BY AGE

ACCINE 🚽 AGE GROUP 🕨	19-26 years	27–49 years	50–59 years	60–64 years	≥65 years				
Tetanus, diphtheria, pertussis (Td/Tdap):-	Substitute 1-time do	se of Tdap for Td I	pooster; then boost w	Td booster every 10 yrs					
Human papillomavirus (HPV):	3 doses (females)								
Varicella ^{3,*}	2 doses								
Zoster		Se							
Measles, mumps, rubella (MMR)»."	1 or 2 doses 1 dose								
Influenza ^{s.•}	1 dose annually								
Pneumococcal (polysaccharide) ^{7,8}			1 dose						
Hepatitis As:	2 doses								
Hepatitis B ^{18,*}			3 doses						
Meningococcal ^{a.}	1 or more doses								

INDICATION SCHEDULE FOR ADULTS BY

INDICATION >	Pregnancy	Immuno- compromising conditions (excluding human immunodeficiency virus (HIV))»	CD4+ T cyte <200	lympho- count >200 cells/µL	Diabetes, heart disease, chronic lung disease, chronic alcoholism	Asplenia (including elective splenectomy and terminal complement component deficiencies)	Chronic liver disease	Kidney failure, end-stage renal disease, receipt of hemodialysis	Health-care personnel
Tetanus, diphtheria, pertussis (Td/Tdap):-	Td	Substit	ute 1-1	time do	se of Tdap fo	or Td booster	; then boost	with Td every	/ 10 yrs
Human papillomavirus (HPV) ^{z.•}		3 doses for females through age 26 yrs							
Varicella**	Cont	raindicated 2 doses							
Zoster	Cont	traindicated					1 dose		
Measles, mumps, rubella (MMR)».	Cont	traindicated 1 or 2 doses							
Influenza ^{e,•}		1 dose TIV annually						1 dose TI or LAIV annually	
Pneumococcal (polysaccharide) ^{7,8}		1 or 2 doses							uniuni
Hepatitis A ^s		2 doses							
····		3 doses							
Hepatitis B ^{10.1}		1 or more doses							

IMMUNIZATION SCHEDULE FOR ADULTS

- How often should the Td booster be given?
 - Every 10 years, first booster should be Tdap
- What is the maximum age of administration for HPV vaccination?
 - 26 years old
- Which vaccinations are contraindicated in pregnant women and immunocompromised patients?
 - Live vaccines
 - For example,
 - MMR (or MMRV), Varicella, Zoster

ADMINISTRATION

Simultaneous administration is recommended

- No contraindications for any vaccines
- Increases likelihood of receiving all vaccines
- We are NOT 'overloading' the immune system
- If two LIVE vaccines are not administered simultaneously, they should be given at least 4 weeks apart (does not apply to inactivated)

ADMINISTRATION

Dosing intervals

- Do not administer before the minimum recommended AGE
- Do not administer before the minimum recommended INTERVAL
- Minimum interval is determined by the component with the longest required interval
- Increasing the interval between doses in a series does not diminish response – DO NOT RESTART SERIES

SOME VACCINES CANNOT BE ADMINISTERED DURING THE FIRST YEAR OF LIFE BECAUSE:

- a) the infant's immune system will be overwhelmed if he/she receives too many vaccinations.
- b) circulating maternal antibodies inactivate the vaccine antigen.
- c) administration increases the infant's risk for autism.
- d) the infant may develop the disease from the vaccine.

CONTRAINDICATIONS OR PRECAUTIONS

- Severe allergic reaction to vaccine or component
- Encephalopathy occurring within 7 days of pertussiscontaining vaccine
- Conditions that increase chance of serious reaction or may compromise ability to produce immune response
 - Immunosuppression
 - Pregnancy
- Severe illness (Delay)
- Recent administration of blood product (Delay live vaccines)

INVALID CONTRAINDICATIONS

- Antibiotic therapy
- Breastfeeding
- Premature birth
- Mild disease low-grade fever, URI, otitis media, mild diarrhea
- Pregnancy or immunosuppression in household
- Warfarin

ADVERSE REACTIONS

- Local pain, swelling, redness (common with inactivated)
- Systemic fever, malaise, headache
- Allergic reaction
- Syncope most common in adolescents have them wait 20 min

A 4-YEAR OLD GIRL PRESENTS AT YOUR PHARMACY INFLUENZA CLINIC WITH A NON-PRODUCTIVE COUGH. SHE HAS NO OTHER SYMPTOMS AND HAS NEVER RECEIVED AN INFLUENZA VACCINE IN THE PAST. SHE RECENTLY RECEIVED HER 5TH DTAP VACCINATION 3 WEEKS AGO AND HAS NO OTHER CONTRAINDICATIONS TO VACCINATION. YOU:

a. Delay the vaccination until the patient is feeling better.

b. Delay the vaccination for one week, because patient received her DTaP shot three weeks ago.

c. Give her an influenza vaccination and tell her to return in 4 weeks for a second.

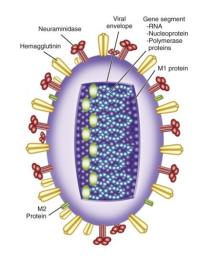
d. I have no idea what you are talking about Dean Disco because I've been on Facebook.

DISEASES AND VACCINES





- Single-stranded RNA genome
- Classified into three distinct types on the basis of antigenic differences:
 - Influenza A responsible for pandemics
 - Hemagglutinin
 - Neuraminidase
 - Influenza B
 - Influenza C



- <u>Epidemic</u>: Outbreak confined to one location (e.g., city, town, country)
- <u>Pandemic</u>: Severe outbreaks that rapidly progress to involve all parts of the world

- Antigenic variation occurs frequently
 - <u>Drift (epidemics)</u> minor changes like point mutations
 - <u>Shift (pandemics)</u> major genetic changes resulting in alterations of antigen structure usually caused by reassortment
- Explains why influenza continues to be a major epidemic disease of humans
- Severity is dependent upon:
 - Antigenic variation
 - Transmission capability

2016-2017 INFLUENZA

- All 2015-2016 influenza vaccine is made to protect against the following three viruses:
 - an A/California/7/2009 (H1N1)pdm09-like virus
 - an A/Switzerland/9715293/2013 (H3N2)-like virus
 - a B/Phuket/3073/2013-like virus. (This is a B/Yamagata lineage virus
- Some of the 2015-2016 flu vaccine also protects against an additional <u>B virus</u>

INFLUENZA VACCINES

- Inactivated (IIV)
 - intramuscular
 - trivalent (A/H3N2, A/H1N1, B (Massachusetts)
 - quadrivalent (A/H3N2, A/H1N1, B(Massachusetts), B(Brisbane)
 - duration of immunity 1 year or less
- Live attenuated vaccine (LAIV)
 - intranasal
 - quadrivalent (A/H3N2, A/H1N1, B(Yamagata), B(Victoria)
 - duration of immunity at least 1 year



- Recombinant Influenza Vaccine (RIV3)
- Trivalent
- Uses a baculovirus vector (virus which infects insects)
- Approved for persons 18 through 49 years of age
- No egg protein

FLUCELVAX

- Inactivated Influenza Vaccine manufactured by Novartis IIV3
- Initial reference strains from WHO have been passaged in eggs, therefore can not be considered to be completely egg-free
- Trivalent
- Grown in Madin-Darby Canine Kidney Cells
- Approved for persons ≥ 18 years old

FLUZONE INTRADERMAL

- Licensed by FDA in May 2011
- Approved only for persons 18 through 64 years of age
- Dose is 0.1 mL administered in the deltoid area by a specially designed micro-needle and injector system
- Formulated to contain more HA (27 mcg) than a 0.1 mL dose of regular Fluzone formulation (9 mcg)

CHOICE OF INFLUENZA VACCINE

- The choice should primarily be driven by the ageindication and contraindications and precautions
- No current preference for quadrivalent vs trivalent
- No current preference for high-dose vs standard dose
- No current preference for IIV vs LAIV in any age group for whom either is indicated

INACTIVATED INFLUENZA VACCINE CONTRAINDICATIONS AND PRECAUTIONS

- Contraindication:
 - severe allergic reaction to a vaccine component (e.g., latex) or following a prior dose of vaccine
- Precautions:
 - moderate or severe acute illness
 - history of Guillian-Barré syndrome within 6 weeks following a previous dose of IIV

SEVERE ALLERGY TO EGG

- Most influenza vaccine available for the 2015-2016 season will be produced in hen's eggs
 - ovalbumin concentrations up to 1.4 mcg per mL
- In clinical studies of egg-allergic persons IIV was tolerated without serious reactions
- Flucelvax not manufactured in egg (MDCK cells) but consists of strains isolated in eggs (amount of ovalbumin 50 femtograms)
- FluBlok not manufactured in eggs (baculovirus vector)

INFLUENZA VACCINATION – EGG ALLERGY

Addition of the following:

- For individuals with no known history of exposure to egg, but who are suspected of being egg-allergic on the basis of previously performed allergy testing:
 - Consultation with a physician with expertise in the management of allergic conditions should be obtained prior to vaccination
 - Alternatively, RIV3 may be administered if the recipient is 18 through 49 years of age

SEASONAL VACCINE

- Side effects:
 - Injection site reactions
 - Muscle aches and fatigue
 - Fever
 - Nausea
 - Headache
- Contains egg components, trace amounts of neomycin, gelatin, and arginine

SEASONAL FLU TARGET GROUPS

No target groups this year – everyone over the age of 6 months

INFLUENZA TREATMENT

- Relenza® (zanamavir)
 - 5mg/inhalation
- Tamiflu® (oseltamivir)
 - 75mg capsules
- Both are antiretrovirals
- May be used in the treatment or prophylaxis of:
 - Seasonal influenza
 - H1N1 influenza
- Do not induce immune response

MMR-MMRV

Measles Mumps Rubella (German Measles) Varicella



MEASLES

- Rubeolla virus (not to be confused with rubella)
- Respiratory transmission
- Presentation:
 - Cough, coryza (runny nose), conjunctivitis
 - Stepwise increase in temperature to 103° F or higher
 - Koplik spots
 - Maculopapular rash
- 1,000,000 children still die worldwide
- Measles may be more severe in adults





- Paramyxovirus
- Respiratory transmission
- Presentation:
 - Lower respiratory infection



- Swelling and tenderness of salivary glands (parotitis in 30-40%)
- Occurs primarily in school-aged children and adolescents
- Course of infection rarely exceeds two weeks
- Complications: arthralgias, orchitis, death (usually from encephalitis)

MUMPS RESURGENCE

- Previous outbreaks in 1987 and 1988
- 2006 was the largest mumps epidemic in past 20 years
- 5783 cases in 45 states and the District of Columbia
- Majority reported in 7 midwest states
- Majority were college students who had received at least 1 dose of vaccination
- Attributed to waning immunity group and crowding

- Togavirus
- Humans are only reservoir
- Respiratory transmission
- Presentation:
 - Mild illness
 - Rash that is more pronounced on face, but doesn't coalesce like measles
- No longer endemic in US
- Biggest concern is in regards to Congenital Rubella Syndrome (CRS)





CONGENITAL RUBELLA SYNDROME

- Mother may be asymptomatic
- Infection during first trimester is most severe
- Permanent complications of CRS
 - Deafness, cataracts, heart defects (triad)
 - Bone alterations
 - Mental retardation
 - Liver and spleen damage
 - Premature delivery
 - Miscarriage

VARICELLA/ZOSTER

- Herpesvirus
- Humans are only reservoir
- Highly contagious
- Transmitted by direct contact with lesions

VARICELLA (CHICKENPOX)

Primary infection results in varicella

- Pruritic vesicles concentrated on trunk
- 13% of individuals have more than one primary infection
- Asymptomatic primary infections unusual
- Complications:
 - Lesion infections
 - Encephalitis
 - Pneumonia
 - Congenital Varicella Syndrome (CVS)
 - Death Adults are 25% more likely to die from varicella





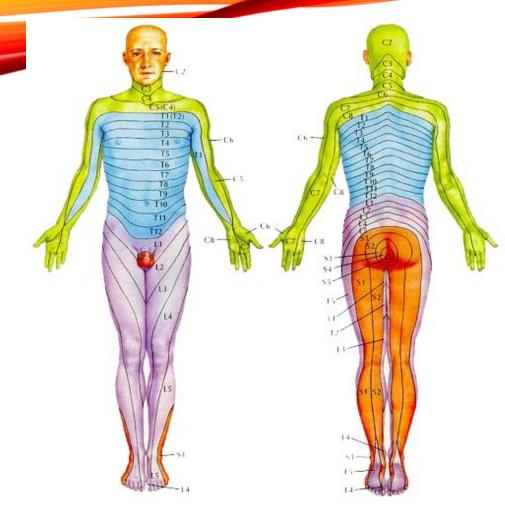
HERPES ZOSTER (SHINGLES)

- Recurrent infection results in herpes zoster
- Reactivation of latent varicella
- Unilateral vesicular rash and pain on singular dermatome
- Can occur decades after initial infection
- Generally associated with aging or immunosuppression
 - Lifetime risk of 20 %
 - 50% of Individuals <u>></u> 80 years will develop zoster





HERPES ZOSTER



ZOSTER COMPLICATIONS

• Post-herpetic neuralgia (PHN)

- No effective treatment for pain
- Depression
- Sleep disturbances
- Opthalmic zoster (blindness)
- Dissemination into CNS, lungs, liver, and pancreas

MMR-MMRV VACCINE

- Live virus components
- Single primary dose
- Second dose is given to ensure close to 100% immunity
 - Damaged vaccine
 - Present maternal antibody
- No more than 2 doses/lifetime
- Single antigens are available through Merck

VARICELLA AND ZOSTER VACCINES

All vaccines contain Oka-Merck vaccine strain

Varicella

- Varivax® (1400 pfu)
- MMRV or Pro-quad® (9,800 pfu)
- 2 doses given 12-15 months and 4-6 years
- Zoster
 - Zostavax[®] approved 2006 (19,000 pfu)

EVIDENCE OF IMMUNITY

- Born before 1966
- Vaccination documentation
- History documented by healthcare provider
- Laboratory evidence
- Current: 2 doses or titer (UNMH)

HERPES ZOSTER VACCINE

- Single dose for \geq 60 years (50 years approved FDA)
- Unknown if additional doses will be needed
- Should be given whether or not individual reports prior episode of shingles
- Do not need to screen for varicella disease or vaccine
- Contraindicated in immunocompromised or pregnant patients

WHAT ARE THE CONTRAINDICATIONS FOR THE MMR-MMRV VACCINE?

I. Contraindicated in pregnant women

II. Contraindicated in patients with allergy to vaccine components (egg allergy, neomycin, gelatin)
 III. Contraindicated in severely immunocompromised patients

- a. I only
- b. III only
- c. I and II
- d. II and III
- e. I, II, and III

CONTRAINDICATIONS

- Allergy
- Pregnancy
- Immunosuppression
 - Administer to HIV-infected children with CD4 counts >15%
 - Administer to HIV-infected adults with CD4 counts >200cells/mm3
- Coadministration of recent blood products

MMR-MMRV VACCINE IN PREGNANCY

- 321 women vaccinated
- 324 live births
- No observed CRS
- 95% confidence limits 0%-1.2%

MMR-MMRV VACCINE ADVERSE REACTIONS

• Live – attenuated vaccines mimic s/s of infection

Common:

- Rash or zoster (measles, rubella, varicella)
- Joint symptoms (mumps, rubella)

Rare:

- Thrombocytopenia (rubella)
- Parotitis (mumps)
- Deafness (mumps)
- Encephalopathy (measles, mumps, rubella)

MMR VACCINE AND AUTISM

- Flawed Wakefield studies suggested that MMR caused intestinal inflammation that allowed absorption of proteins that are harmful to the brain
- Numerous studies that reject causal role
- Signs and symptoms may be temporal (diagnosis of autism often made in second year of life)
- CDC, Vaccine Injury Compensation Program, and Institute of Medicine do not support the association
- Autism has both genetic and environmental component

MMR VACCINE AND AUTISM

- 1. Madsen KM, Hviid A, Vestergaard M, et al. A population-based study of measles, mumps, rubella vaccination in autism. N Engl J Med 2002;347:1477-1482.
- 2. Kaye JA, Melero-Montes M, Jick H, et al. Mumps, measles, rubella vaccine and the incidence of autism recorded by general practitioners: A time trend analysis. BMJ 2001;322:460-463.
- 3. Farrington CP, Miller E, Taylor B, et al. MMR and autism: Further evidence against a causal association. Vaccine 2001;19:3632-3635.
- 4. Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet 1998;351:637-641.

WHICH OF THE FOLLOWING ARE FALSE?

- A. The MMRV vaccine contains live attenuated virus components of measles, mumps, rubella, and varicella.
- B. The MMRV vaccine may prevent CRS.
- C. The second dose of MMRV ensures nearly 100% immunity.
- D. The first dose of MMRV vaccine should be given at 6 months of age.

• Live vaccines

- Please list the live vaccines that are recommended in both the childhood and adult schedules. When should patients receive these vaccines?
 - Influenza yearly (age 2-49)
 - Measles, Mumps, Rubella, and Varicella at age 1 and before entering school between the ages of 4-6
 - Zoster ages <u>>60</u>

A PARENT REFUSES THE MMR VACCINE BECAUSE THE PARENT DOES NOT WANT THEIR CHILD EXPOSED TO MERCURY (THIMEROSAL) FOR FEAR THAT IT WILL CAUSE AUTISM IS THERE CHILD. WHAT CAN YOU TELL THIS PARENT TO ENCOURAGE THEM TO HAVE THEIR CHILD VACCINATED?

- 1. Ask them where they obtained their information.
- 2. Let them know that MMR does not contain thimerosal.
- 3. The Institute of Medicine conducted several studies and found no correlation between the MMR vaccine and autism.
- 4. CDC and Vaccine Injury Compensation Program also do not support the association.
- Appeal to their civic duty to the community.
- 6. Remind them that their child will be at risk for these diseases

- Name three things that can affect vaccine response and persistence of protection.
 - Type of vaccine (live or inactivated)
 - Host characteristics and immune status
 - Administration and storage

- Which type of vaccine is not consistently immunogenic in children <2 years of age?
 - Pure polysaccharide vaccines

- Why are aluminum salts added to inactivated vaccines?
 - They are adjuvants that increase the rate of response and the duration of immunity

- If two LIVE vaccines are not administered simultaneously, how long should you delay vaccination with the 2nd LIVE vaccine? And why?
- 4 weeks because the second vaccine will not induce an effective response

- Which of the following is a TRUE contraindication to vaccination?
 - a. Severe illness
 - b. Premature birth
 - c. Breastfeeding
 - d. Warfarin therapy

DTAP – DT – TD – TDAP

Diphtheria
Tetanus
Pertussis

DTAP-DT-TD-TDAP

- Diphtheria and Tetanus Toxoids
 - DT = pediatric
 - Follows DTaP schedule
 - For individuals that have contraindication to pertussis
 - Td = adult (every 10 years after Tdap)
- Diphtheria, Tetanus, and Acellular Pertussis
 - DTaP = pediatric
 - Tdap = adult (1st booster)

DIPHTHERIA

- Corynebacterium diptheriae
- Transmitted by droplet spread or direct contact with cutaneous infection
- Some strains are able to produce diptheria toxin
- Infects mucous membranes
- Presents as pharyngitis (membraneous) or tonsillitis
- Fever not high but patient appears toxic





DIPTHERIA COMPLICATIONS

- Respiratory obstruction
- Myocarditis and heart failure
- CNS complications including neuritis and paralysis

TETANUS

- Clostridium tetani
- Found in soil and animal feces
- Acquired through surgery, puncture, laceration, wound, IVDU, tattoo, diabetesrelated infections (rusty nail)
- Incubation period of 4 days-several weeks
- Minimal or no inflammation at primary site of infection
- Neurotoxin results in unopposed firing of motor neurons



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TETANUS COMPLICATIONS

- Pulmonary embolism
- Aspiration pneumonia
- Fractures
- Death (25% mortality) respiratory failure

DIPTHERIA AND TETANUS TOXOIDS

- Inactivated toxins
- Aluminum-precipitated (or adsorbed) preparation is more immunogenic
- Prevents disease, not acquisition or carriage

DIPTHERIA AND TETANUS TOXOIDS

- Available in combination, not as single antigen:
 - Diptheria, tetanus, and acellular pertussis
 - Diptheria and tetanus
- Adult formulations contain lower concentrations of diptheria toxoid (to prevent local reactions)
- Reported local site reactions higher with each additional dose

PERTUSSIS

- Bordetella pertussis
- Humans are only reservoir for disease
- Spread by airborne droplets
- Highly contagious with no strong seasonal pattern
- Presents as URI
- Milder in adolescents/adults

PERTUSSIS – '100 DAY COUGH'

- Catarrhal stage
 - 1-2 weeks cough gradually worsens
 - Maximum communicability

Paroxysmal cough

- 1-6 weeks
- Local tissue damage with thick mucous production
- '<u>Whooping' cough</u>
- Cyanosis, vomiting
- Antibiotics have little effect on course of disease by this stage

Convalescence

- Gradually improves over weeks to months
- Complications: seizures, cerebral bleeding, encephalopathy, death

PERTUSSIS VACCINE

- 1930s available as whole cell vaccine
 - Associated with greater side effects and seizures
 - No longer distributed in U.S.
- Acellular vaccine
 - Purified components of Bordetella pertussis and detoxified pertussis toxin
 - Efficacy is comparable to whole cell vaccine but with decreased side effects

PERTUSSIS VACCINE

Precautions

- Temperature greater than 40.5° C within 48 hours of prior dose without identifiable cause
- Convulsions occurring within 3 days
- May use acetaminophen 15mg/kg at time of vaccination, then Q4h for 24h
- Contraindications
 - Encephalopathy within the 7 days following previous administration

DTAP-DT-TD-TDAP

- Childrens formulations: DTaP and DT
- Boosters: Tdap, Td
- Adult formulations contain lower concentrations of diptheria toxoid and acellular pertussis vaccine

 Reported local site reactions higher with age and each additional dose

DTAP

- Approved for children 6 weeks through 6 years
- Number of doses depends on child's age at the first dose
 - If <12 months, 4 doses are recommended
 - If >12 months, 3 doses are recommended
- 1st booster at 4-6 years: DTaP
- 2nd booster at ages 11-12 years: Tdap
- Following boosters: Tdap once for adolescent, then once as adult, then Td every 10 years

AN 11-YEAR OLD PATIENT IS IN YOUR CLINIC TO RECEIVE HIS TETANUS/DIPTHERIA BOOSTER. HE RECEIVED HIS DTAP SERIES AT 13 MONTHS, 14 MONTHS, 15 MONTHS, AND A DTAP BOOSTER AT 4 YEARS OLD. HE HAD NO REACTION TO HIS PREVIOUS VACCINATION. WHAT DO YOU WANT TO GIVE HIM TODAY?

Tdap

WHEN SHOULD HE COME BACK FOR HIS BOOSTER AND WHICH FORMULATION SHOULD HE RECEIVE?

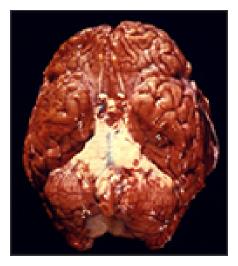
Tdap in 10 years, then Td every 10 years thereafter

PNEUMOCOCCAL DISEASE

- Streptococcus pneumoniae
- 90 serotypes
- Type-specific antibody protection

PNEUMOCOCCAL MENINGITIS

- Most common cause of bacterial meningitis
- High fatality rates (80%) in children <2 years old and adults >65 years old



PNEUMOCOCCAL PNEUMONIA

- Most common complication
- 100,000-135,000 cases requiring hospitalization per year
- Responsible for up to 30% of CAP and 50% of HAP

PNEUMOCOCCAL VACCINE

- 23-valent polysaccharide vaccine (PPSV)
- 13-valent polysaccharide conjugate vaccine (PCV) – the former vaccine was 7-valent

Prevnar-13

PNEUMOCOCCAL POLYSACCHARIDE VACCINE (PPSV)

- 23 serotypes account for 88% of pneumococcal disease
- Schedule is one dose for ages > 65
 - High risk patients may receive 1 dose with selective revaccination (>5 years)
- Duration of immunity is at least 6 years
- NOT EFFECTIVE IN CHILDREN <2 YEARS

PNEUMOCOCCAL CONJUGATED VACCINE (PCV)

- Covers 13 serotypes of S. pneumoniae
- Conjugated to nontoxic diptheria toxin
- Conjugation improves immunologic response in children <2 years old
- New dosing with PCV13
- No special contraindications or adverse reactions

PNEUMOCOCCAL CONJUGATE VACCINE (PCV)

- Approved in children 6 weeks-9 years old
 - Risk is greatest <24 months
 - ACIP recommends ages 6 weeks 59 months
- 3-dose series recommended at 2, 4, 6 months
- First dose may be given as early as 6 weeks
- Booster given at 12-15 months
- Unvaccinated children >7 months of age require less doses
- Everyone age 65 and older once
- Available resources per CDC and MMWR

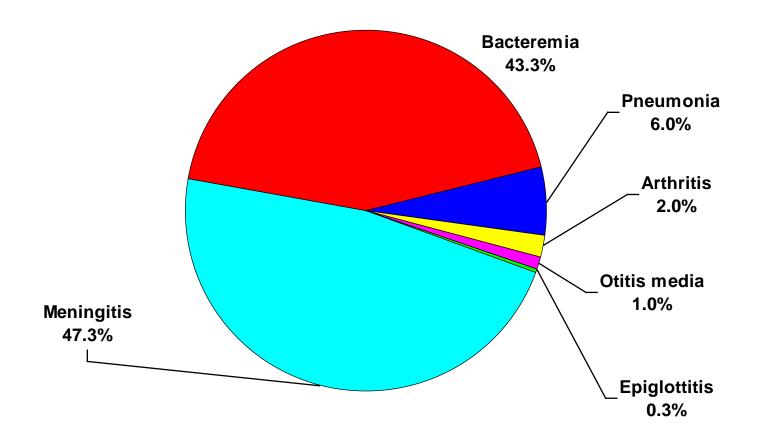
YOU ARE ADMINISTERING THE 4TH PNEUMOCOCCAL VACCINE TO A 12-MONTH OLD LITTLE GIRL AND YOU REALIZE THAT YOU GAVE HER THE PURE POLYSACCHARIDE PNEUMOCOCCAL VACCINE INSTEAD OF THE CONJUGATED VACCINE. YOU:

- a. You record this PPSV dose as her 4th dose to complete her pneumococcal series.
- b. You tell her to come back for her PCV, but she must wait 4 weeks.
- c. You administer the PCV today.
- d. You administer an additional PPSV at age 2.

MENINGOCOCCAL DISEASE

- Neisseria meningitidis
- 13 serotypes
- 5 serotypes cause 90% of cases (A, B, C, Y, and W-135)
- Respiratory transmission
- Less common in U.S. but associated with high mortality (9-12%)
- Symptoms progress rapidly and can lead to death within 24-48 hours

CLINICAL MANIFESTATIONS OF NEISSERIA MENINGITIDIS



INDIVIDUALS AT RISK FOR NEISSERIA MENINGITIDIS INFECTION

- Persons with anatomic or functional asplenia
- Persons with terminal complement deficiency
- Laboratory personnel exposed to N. meningitidis
- College freshmen
- Military recruits
- Foreign travelers

MENINGOCOCCAL VACCINES

- Quadrivalent polysaccharide vaccine
- Quadrivalent conjugated-polysaccharide vaccine

MENINGOCOCCAL POLYSACCHARIDE VACCINE (MPSV)

- Quadrivalent polysaccharide vaccine (A, C, Y, W-135)
- MPSV contains thimerosal
- Approved for individuals \geq 2 years of age
- 80-90% effective
- No longer routinely used
- Duration of immunity is short (<5 years)

MENINGOCOCCAL CONJUGATE VACCINE (MCV)

- Quadrivalent polysaccharide vaccine (A, C, Y, W-135) conjugated to inactivated diptheria toxin (2005)
- >90% effective with single dose
- Routinely recommended for 11-18 year olds
- Revaccination not currently recommended unless in high-risk group

ROTAVIRUS GASTROENTERITIS

- Most common cause of severe dehydrating gastroenteritis in children
- Almost all children have been infected by 5 years of age
- Five strains account for 90% of isolates (G1-4, G9)
- 1st infection after 3 months of age is the most severe with temperatures >102F
- GI symptoms generally resolve in 3-7 days
- Low mortality but high healthcare burden

ROTAVIRUS VACCINE-ROTATEQ®

- Live, oral vaccine
- Contains five reassortment rotaviruses
 - Nonhuman rotaviruses used
 - Manipulated to express human rotavirus antigens on surface
 - Have low pathogenicity for humans
 - Replicate, but do not cause disease

ROTAVIRUS VACCINE-ROTATEQ®

- 3-dose series beginning at about 2 months of age
- Vaccination should not be initiated for infants older than 15 weeks
- ACIP recommends immunization of all infants without a contraindication
- No special contraindications or adverse reactions

WHICH VACCINE IS INEFFECTIVE IN CHILDREN UNDER 2 YEARS OF AGE?

A. PPV (Pneumococcal polysaccharide vaccine)

B. PCV (Pneumococcal conjugate vaccine)

C. Rotavirus vaccine

POLIOMYELITIS

- Enterovirus with three distinct serotypes (1,2,3)
- Oral-fecal transmission
- Immunity to one does not protect against the others
- Most infections are asymptomatic
- Infection spreads to CNS causing destruction of motor neurons



PARALYTIC POLIO

- Some or all motor function may be recovered
- 1:200 develop permanent paralysis (usually asymmetric)
- Sensory function remains intact
- Severity increases with age
- Fatal in 2-5% of cases

POLIO EPIDEMIC IN U.S.

- 1920s outbreaks crippled and killed thousands, with the epidemic peaking in 1952 (57,628 cases)
- 1955 vaccine was developed and reduced incidence by 90% within 2 years
- Eradicated in the U.S.
- Hundreds of new cases are still reported each year worldwide
- Will be the 2nd virus eradicated from the planet by vaccine



THE 'IRON LUNG'



POLIO VACCINE

1955 Inactivated vaccine (IPV)

1963 Oral Polio Vaccine (OPV)

1979 Last case of 'wild virus' reported

1987 Enhanced IPV (Original IPV taken off the market)

2000 OPV use discontinued in U.S.

2004 Last imported case

INACTIVATED POLIO VACCINE

- IPV contains 3 viruses
- No special contraindications
- IPV is safe (if not the safest vaccine)
- OPV still widely used outside of U.S.

INACTIVATED POLIO VACCINE

- Children
 - 99% effective after 3 doses
 - 4th dose given as booster given before school entry
- Adults who are not vaccinated
 - Not recommended unless traveling to polioendemic areas
 - Only require 3 dose series of same dose
- Any 4 dose combination of IPV and OPV may be used

HUMAN PAPILLOMAVIRUS (HPV)

- More than 100 types of HPV
- Transmitted through direct skin-to-skin contact
- Over 40 types infect mucosal surfaces, including anogenital epithelium
- Most common sexually transmitted infection
 - 20,000,000 Americans currently infected with HPV
 - Up to 30% are infected with multiple strains

HUMAN PAPILLOMAVIRUS (HPV)

- Certain strains increase risk for cancer
 - "High-risk" oncogenic strains (16,18)
 - "Low-risk" oncogenic strains (6, 11)
- Approximately 11,000 women diagnosed with cancer in 2007 (3500 deaths)
- Most individuals are able to clear infection
 - 70% become HPV DNA negative within one year
 - 90% become HPV DNA negative within two years

OUADRIVALENT HPV VACCINE • Inactivated vaccine

- Protects against four HPV types (6,11,16,18)
- 3-dose series ideally received before sexually active (0,2, 6 months)
- Cover strains that are responsible for 70% of cervical cancers (types 16, 18) and 90% of genital warts (types 6, 11)

QUADRIVALENT HPV VACCINE

- FDA Approval
 - 2006 for women 9-26 years old for genital warts and cervical cancer
 - October 2009 for men 9-26 years old for genital warts and anal cancers
- ACIP recommends use of vaccine in girls ages 11-12
- Cervical cancer screen recommendations have not changed

QUADRIVALENT HPV VACCINE

- Studied in 11,000 females (ages 9-26)
 - 100% effective in preventing cervical precancers
 - >95% effective in preventing vulvar and vaginal precancers and genital warts
 - Duration of protection unknown
 - No serious side effects
 - Efficacy studies in males is ongoing

VAERS REPORTING

- 26,000,000 doses have been dispensed
- 15,037 VAERS reports
 - Non-serious (93%)
 - Syncope requiring patients to wait 15 minutes
 - Serious (7%)
 - **Blood clots** Majority had risk factors (e.g. oral contraceptives
 - **Deaths** 44 reports with no pattern that would suggest they were caused by the vaccine

HPV VACCINE CONTRAINDICATIONS

- Severe allergic reaction to a vaccine component or following a prior dose
- Defer in pregnancy even if series was already initiated

HEPATITIS A VACCINE

- 2-dose series
 - Pediatric dose for 0-18 years of age
 - Adult dose for \geq 19 years of age
- Recommended for children, and also adults that are high-risk:
 - International travelers
 - MSM
 - IVDU
 - Occupational risk
 - Chronic liver disease
- Available in single or combo formulations

HEPATITIS B VACCINE

- 3-dose series
 - Pediatric dose for 0-19 years of age
 - Adult dose for <u>></u> 20 years of age
- Recommended for children, and also adults that are high-risk:
 - MSM
 - Heterosexuals with multiple partners
 - Persons diagnosed with STD
 - Prostitutes
 - IVDU
 - Inmates of long-term correctional facilities
 - Healthcare workers
- Available in single or combo formulations that are interchangeable
- No need for booster

HEPATITIS A/B COFORMULATION - TWINRIX®

- 3-dose series approved for \geq 18 years
- Each contains pediatric dose of hepatitis A
- Twinrix[®] in combination with hepatitis A vaccine
 - 2 Twinrix[®] + 1 hepatitis A
 - 1 Twinrix + 2 hepatitis A

HAEMOPHILUS INFLUENZAE TYPE B VACCINE

- Available in single or combo formulations (DTaP-Hib or Hepatitis B-Hib)
- All vaccines are interchangeable for primary series and booster dose
- 3-dose series with one booster
- Children who fall behind may not need all of the remaining doses
- Not recommended in children >59 months unless high risk:
 - Asplenic
 - Immunosuppressed
 - HSCT



- Post-Exposure
- Pre-Exposure now recommended
 - Veterinarians
 - Forest workers
 - Zoo workers





- RS is a 3-year-old male adopted from Russia.
- He is seeing you in clinic for the first time in November. He appears healthy today.
- PMH: HIV+ with CD4 of 13%. He has no history of chickenpox.

- Vaccination history:
 - BCG at birth
 - OPV at birth, 1, 3, 4 months
 - DPT at birth, 1month, and 3 months
 - Measles vaccine at 10
 months
 - 1st dose of seasonal influenza vaccine 5 weeks ago, 1st time patient has ever received influenza
 - Completed Hib and PCV vaccine at 2, 4, 6, and 12 months

• What vaccinations does RS need today?

- Hepatitis B #1 (#2 in 4 weeks)
- DTaP #2 (#3 in 4 weeks)
- IPV #3 (# 4 at 4-6 years of age)
- Influenza #2 (will need 1 annually there after)
- MMR #1 (#2 at 4-6 years of age)
- Varicella #1 (#2 next at 4-6 years of age)
- Hepatitis A #1 (#2 in 6 months)

- Does he have any contraindications to the vaccinations that he will need today?
 - MMR, Varicella, and live seasonal flu
 - May administer when CD4 >15%
- When should RS return to clinic and what vaccinations will he need at her next visit?
 - 4 weeks to receive hepatitis B #2, DTaP #3

- MR is a 25-year-old female nurse that was just hired to work in the UNMH emergency department this October. There has been a recent reported pertussis outbreak in community served by hospital since her hire and several cases have been seen in ED. Two hospital staff have been diagnosed with pertussis in the last month.
- She is seeing you at the employee health clinic for the first time. She appears healthy today.
- PHM: No significant PMH. Chickenpox at age 5, with no documentation.

- Vaccination history:
 - IPV completed at age 4
 - MMR completed at age 4
 - Diptheria, tetanus, and pertusis
 - Temp of 105° F following 1st dose of DTP at 2 months of age.
 - Completed series with pediatric DT at age 4
 - Adult Td booster 16 months ago
 - Hepatitis A and B
 completed September 2007
 - Influenza in 2007

- What vaccinations does MR need today?
 - HPV #1 (#2 in 2 months)
 - Tdap booster with tylenol (booster in 10 years)
 - Influenza (should receive annually)
 - Varicella??
- Does she have any contraindications to the vaccinations that she will need today?
 - No, prior history is considered a precaution.
 - Risk as provider during outbreak outweighs risk of side effect.
 - 10 years is recommended interval to decrease the local reactions.

- When should MR return to clinic and what vaccinations will she need at her next visit?
 - 2 Months for HPV #2
 - Varicella potentially serotesting needs to be completed for confirmation of varicella protection

- Your 16-year old patient returns home from summer camp, where a bunkmate was sent to the hospital for invasive meningococcal disease. You proceed to: (select all that apply)
- A. Monitor the patient for illness. Advise the family to watch patient closely for symptoms such as fever, aches, chills and rash for at least 10 days since last exposure to the ill bunkmate.
- B. Review the patient's immunization status, and, if not yet received, immunize the patient with quadrivalent meningococcal conjugate vaccine; two doses are recommended, the first at 11 or 12 years of age, with a booster dose at age 16.
- C. Offer the patient a brief course of an appropriate antibiotic to further reduce the risk of contracting meningococcal disease.
- D. If the patient was previously immunized, reassure the patient and family that antibiotic prophylaxis is not needed.

CASE #3 ANSWERS:

• A, B, and C are correct.

 <u>D is incorrect</u>. Close contacts of people with invasive meningococcal disease are at risk of becoming ill and should receive appropriate antibiotic prophylaxis regardless of prior immunization. Current meningococcal conjugate vaccines are not designed to protect against serogroup B meningococcus, associated with 30% of cases in California.