

# ***The Heart of the Matter*** **Case Studies in Vaccination Practice**

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**Shot Smarts Immunization Conferences**  
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# **Case Study: Caitlyn**

- **16 months old, new to your practice, recently moved from another state**
- **Healthy, no known medical problems**
- **Has a written record of previous vaccinations**
- **Routine well-child visit**
- **Your office stocks all routinely recommended childhood**

# Case Study: Caitlyn

- **Her written vaccination record indicates:**
  - **Birth dose of HepB**
  - **Up to date with Hib (4 doses) and PCV13 (4 doses)**
  - **Pediarix at 2 and 4 months**
  - **Kinrix and IPV at 6 and 12 months**
  - **1 dose of LAIV 3 weeks ago**

# Case Study: Caitlyn

- **Question 1: any issues with her vaccination history?**
  - **Birth dose of HepB**
  - **Up to date with Hib (4 doses) and PCV13 (4 doses)**
  - **Pediarix at 2 and 4 months**
  - **Kinrix and IPV at 6 and 12 months**
  - **1 dose of LAIV 3 weeks ago**

**Yes**



# KINRIX and Quadracel

- **Contain DTaP and IPV**
- **Approved by FDA only for the 5th dose of DTaP and 4th dose of IPV in children 4 through 6 years of age\***
- **Not approved or recommended for earlier doses in the DTaP or IPV series**

**\*Quadracel is approved by the FDA for either the 4<sup>th</sup> or 5<sup>th</sup> dose of IPV**



# **KINRIX Administration Error\***

- **KINRIX is frequently given inadvertently for doses other than DTaP5 and IPV4**
- **Use of KINRIX for any dose other than DTaP5 and IPV4 is off-label, and should be considered a medication error**
- **However, CDC does not advise repeating the DTaP or IPV dose if the appropriate ages and intervals have been used**

**\*Quadracel is relatively new so fewer administration errors have been reported; the same CDC recommendation applies**

# Case Study: Caitlyn

- **Question 2: is her hepatitis B series complete?**
  - **Birth dose of HepB**
  - **Up to date with Hib (4 doses) and PCV13 (4 doses)**
  - **Pediarix at 2 and 4 months**
  - **Kinrix and IPV 6 and 12 months**
  - **1 dose of LAIV 3 weeks ago**

**No**

# Third Dose of Hepatitis B Vaccine

- **Minimum of 8 weeks after second dose, *and***
- **At least 16 weeks after first dose, *and***
- **For infants, at least 24 weeks of age**

**Caitlyn's third dose was given at 4 months (16 weeks) of age so is not valid**

# Case Study: Caitlyn

- **Question 3: can you count the LAIV dose given 3 weeks ago?**
  - Birth dose of HepB
  - Up to date with Hib (4 doses) and PCV13 (4 doses)
  - Pediarix at 2 and 4 months
  - Kinrix and IPV at 6 and 12 months
  - 1 dose of LAIV 3 weeks ago

**Yes**

# **Live Attenuated Influenza Vaccine 2016-2017 Season**

- **FDA approved the 2016-2017 formulation of LAIV on July 1, 2016**
- **CDC recommendation is to count as valid doses of LAIV administered during the 2016-2017 season**

# Case Study: Caitlyn

- **Question 4: can you count the LAIV dose even though it was given at 15 months of age?**
  - Birth dose of HepB
  - Up to date with Hib (4 doses) and PCV13 (4 doses)
  - Pediarix at 2 and 4 months
  - Kinrix and IPV at 6 and 12 months
  - 1 dose of LAIV 3 weeks ago

**Yes**

# **Influenza Vaccine Age Violations**

- **Minimum approved age for LAIV is 2 years**
- **Minimum approved age for IIV products vary by product**
- **As long as the dosage is correct for age CDC does not recommend repeating a dose of vaccine given outside the approved age range except LAIV given to persons older than 49 years**

**CDC, personal communication, October 17, 2016**

# Case Study: Caitlyn

- **Question 54: she needs MMR and varicella vaccines. Can you give them today?**
  - Birth dose of HepB
  - Up to date with Hib (4 doses) and PCV13 (4 doses)
  - Pediarix at 2 and 4 months
  - Kinrix and IPV 6 and 12 months
  - 1 dose of LAIV 3 weeks ago

**No**

# **Nonsimultaneous Administration of Two Live Parenteral Vaccines**

- **Interference can occur between two live vaccines given less than 28 days apart**
- **If two live parenteral vaccines, or live intranasal influenza vaccine, are given less than 28 days apart the vaccine given second should be repeated**
- **Exception is yellow fever vaccine given less than 4 weeks after measles vaccine**

# **CDC Guidance on Influenza Vaccine Dosage Errors**

- **A person age 36 months or older is given a 0.25 mL dose of influenza vaccine**
  - **if the error is discovered on the same day the error occurred give the other “half” of the dose**
  - **if the error is discovered the next day or later give a full 0.5 mL repeat dose**
- **If a child younger than 36 months is given a 0.5 mL dose the dose can be counted as valid**

# Minimum Interval Violation

- **Vaccine doses should not be administered at intervals less than the minimum intervals or earlier than the minimum age\***
- **Doses of any vaccine administered 5 or more days earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age appropriate**
- **The repeat dose should be spaced after the invalid dose by the recommended minimum interval**

**\* A 4-day “grace period” may be subtracted from the minimum interval or age**

# **Case Study: Aimee History**

- **22 year old female entering a Physician Assistant (PA) training program**
- **No known medical conditions**
- **She has a written, dated vaccination record**
- **No vaccines since a dose of Tdap 8 years ago**
- **School requires serologic evidence of immunity to hepatitis B, measles and varicella**

# Case Study: Aimee History

- **Her vaccination record documents**
  - 5 doses of DTP
  - 1 dose of Tdap
  - 3 doses of hepatitis B vaccine
  - 3 doses of Hib (PRP-OMP)
  - 4 doses of oral polio vaccine
  - 2 doses of MMR vaccine
  - chickenpox as a child

# Case Study: Aimee

## Question 1

- **As a healthcare worker, what vaccine does Aimee NOT need?**



**A. Hepatitis A**

**B. MMR**

**C. Hepatitis B**

**D. Varicella**

**E. Aimee needs all these vaccines**

# Vaccines\* Recommended for Healthcare Personnel

- Hepatitis B
- Influenza
- Measles, mumps and rubella
- Varicella
- Pertussis
- Hepatitis A vaccine is NOT recommended because of healthcare occupation

\*or evidence of immunity in some cases.

*MMWR* 2011;60(RR-7):23.

# **Case Study: Aimee History**

- **Aimee comes to you for serologic testing for hepatitis B, measles and varicella as required by her training program**
- **Results of testing**
  - **hepatitis B surface antibody (anti-HBs) negative (less than 10 mIU/mL)**
  - **measles IgG negative**
  - **varicella IgG positive**

# Case Study: Aimee

## Question 2

- **Aimee's anti-HBs is negative. What should you do about it?**

**A. Do nothing. She has a documented vaccination series**

**B. Do nothing. She is a vaccine non-responder and more vaccine will not help her**

**C. Repeat the 3-dose series**

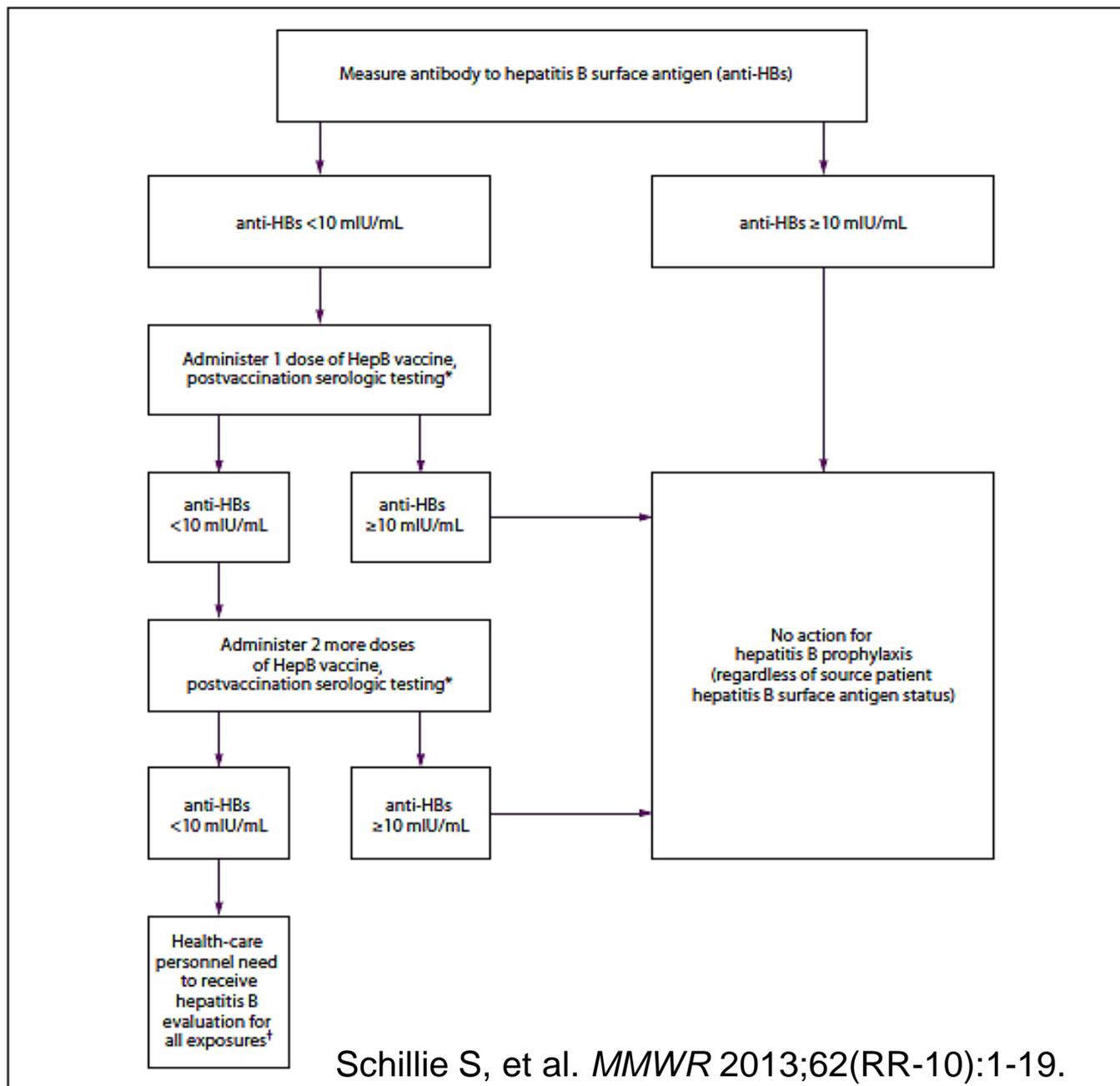


**D. Give 1 dose of hepatitis B vaccine now**

# Hepatitis B Vaccination

- **95% of healthy infants will achieve seroprotection against hepatitis B 1-2 months after a complete 3-dose series**
- **By 18 years after vaccination approximately 84% of persons vaccinated at younger than 1 year of age will not have detectable anti-HBs**

FIGURE 6. Pre-exposure evaluation for health-care personnel previously vaccinated with complete,  $\geq 3$ -dose HepB vaccine series who have not had postvaccination serologic testing\*



# Case Study: Aimee

## Question 3

- You give Aimee 1 dose of hepatitis B vaccine and retest for anti-HBs 6 weeks later
- Her repeat anti-HBs is 150 mIU/mL. What should you do now?

**A.** Do nothing. She is a vaccine non-responder and more vaccine will not help her.



**B.** Do nothing. She is immune.

**C.** Repeat the anti-HBs in 12 months to assure she is still immune.

# Hepatitis B Serologic Testing

- **HCP who have written documentation of a complete 3 (or more) hepatitis B vaccine series AND subsequent postvaccination anti-HBs 10 mIU/ml or higher are considered immune**
- **Immunocompetent persons have long-term protection against HBV infection and do not need further periodic testing to assess anti-HBs levels**

# Case Study: Aimee

## Question 4

- Aimee has written documentation of 2 age-appropriate doses of MMR vaccine but her measles IgG is negative. What should you do about this?



- A. Do nothing. She is immune to measles**
- B. Give 1 dose of MMR and do not retest**
- C. Give 1 dose of MMR and retest**
- D. Give 2 doses of MMR and retest**

# Measles Presumptive Immunity

- **Serologic testing for immunity is not recommended for HCP who have 2 documented doses of MMR vaccine or other acceptable evidence of immunity to measles**
- **In the event that a HCP who has 2 documented doses of MMR vaccine is tested serologically and determined to have negative or equivocal measles titer results, it is not recommended that the person receive an additional dose of MMR vaccine**
- **Such persons should be considered to have presumptive evidence of measles immunity**
- **Documented age-appropriate vaccination supersedes the results of subsequent serologic testing**

# Case Study: Aimee

## Question 4 – Reality Check

- Aimee has written documentation of 2 age-appropriate doses of MMR vaccine but her measles IgG is negative. What should you do about this?

**A. Do nothing. She is immune to measles**



**B. Give 1 dose of MMR and do not retest**

**C. Give 1 dose of MMR and retest**

**D. Give 2 doses of MMR and retest**

# Case Study: Aimee

## Question 5

- Aimee has no history chickenpox or varicella vaccination but her varicella IgG is positive. What should you do now?



- A. Do nothing. She is immune to varicella**
- B. Give 1 dose of varicella vaccine and do not retest**
- C. Give 1 dose of varicella vaccine and retest**
- D. Give 2 doses of varicella vaccine and retest**

**All healthcare providers  
should receive annual  
influenza vaccination**

**If pediatric DTaP is inadvertently administered to an adolescent aged 11–18 years, the dose should be counted as the adolescent Tdap booster.**

# Case Study: Henry History

- **65 year old retired aerospace engineer**
- **Lives with his wife and a 36 year old daughter who has a developmental disability**
- **History of psoriatic arthritis diagnosed 1 year ago**
- **Being treated with 50 mg of etanercept (Enbrel) once a week**
- **Takes daily medication to control his blood pressure and hyperlipidemia**
- **Henry has come to your practice seeking zoster vaccine**

# Case Study: Henry

## Question 1

- Can Henry receive zoster vaccine today?

- ★ A. Yes
- B. No
- C. Maybe

# **Zoster Vaccine**

## **Contraindications and Precautions**

- **Severe allergic reaction to a vaccine component or following a prior dose**
- **Immunosuppression from any cause**
- **Pregnancy or planned pregnancy within 4 weeks**
- **Moderate or severe acute illness**
- **Recent blood product is NOT a precaution**

# Zoster Vaccine and Immunosuppression

- **Contraindicated**
  - Leukemia, lymphoma, or other malignant neoplasms affecting the bone marrow or lymphatic system
  - Chemotherapy or radiation
  - HIV infection with CD4+ T-lymphocyte values  $\leq 200$  per mm<sup>3</sup> or  $\leq 15\%$  of total lymphocytes
  - High dose corticosteroids for  $\geq 2$  weeks ( $\geq 20$  mg prednisone)
  - clinical or laboratory evidence of other unspecified cellular immunodeficiency

# **Zoster Vaccine and Immunosuppression**

- **Evaluate on a case-by-case basis**
  - **Persons at least 24 weeks post-hematopoietic stem cell transplantation (HSCT)**
  - **Persons receiving recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor agents adalimumab, infliximab, and etanercept**

# Case Study: Henry

## Question 2

- If Henry cannot receive zoster vaccine today, when can he receive it?

**A. Never**

**B. 1 week after etanercept is discontinued**

**C. 1 month after etanercept is discontinued**

 **D. 3 months after etanercept is discontinued**

**E. 6 months after etanercept is discontinued**

# Immunosuppressive Agents

- **Live vaccines should be withheld 3 *months* following treatment with human immune mediators, immune modulators, and *tumor necrosis factor-alpha inhibitors***

# Case Study: Henry

## Question 2a

- You discontinue the etanercept for 4 weeks then give Henry zoster vaccine. When can you restart the etanercept?

**A. Same day as zoster vaccine is given**

**B. 1 week after zoster vaccine is given**



**C. 2 weeks after zoster vaccine is given**

**D. 1 month after zoster vaccine is given**

**E. 6 months after zoster vaccine is given**

# **Immunosuppressive Agents**

- **Inactivated and live vaccines should be administered at least 2 weeks before initiating immunosuppressive therapy**

**General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)  
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>  
Accessed on April 23, 2017**

# Case Study: Henry

## Question 4

- Henry has no recollection of ever having chickenpox. Should he be tested for varicella immunity prior to receiving zoster vaccine?

- ★ A. Yes
- B. No
- C. Maybe

# **Serologic Testing Before Zoster Vaccine**

- **It is not necessary or recommended to perform serologic testing to verify varicella immunity in a person who is otherwise eligible for vaccination**
- **If tested and seronegative the person should receive 2 doses of varicella vaccine (Varivax) separated by at least 4 weeks**
- **Zoster vaccine is not indicated for a person whose immunity is based on vaccination**

# **Transmission of Varicella Vaccine Virus**

- **Varicella vaccine virus is rarely, if ever, transmitted from the vaccinee to a contact**
  - **possible exception is if the vaccinee develops a post-vaccination rash**
- **Infants and young children should be immune from maternal antibody or varicella vaccination**
- **Persons who receive zoster vaccine can have contact with children, pregnant women and immunosuppressed persons**

***The more I know, the less I understand  
All the things I thought I'd figured out  
I have to learn again  
I've been trying to get down  
To the Heart of the Matter  
But everything changes  
and my friends seem to scatter...***

***The Heart of the Matter***

***From the album *The End of the Innocence****

***Performed by Don Henley***

***Written by Mike Campbell, Don Henley, and J. D. Souther***

***1989***

# Immunization Action Coalition Resources

- **Websites**

- [www.immunize.org](http://www.immunize.org) (for HCP)
- [www.vaccineinformation.org](http://www.vaccineinformation.org) (for the public)
- [www.izcoalitions.org](http://www.izcoalitions.org) (for coalitions)
- [www.izsummitpartners.org](http://www.izsummitpartners.org) (adult immunization)

- **Publications – Needle Tips, Vaccinate Adults, IAC Express**

- [www.immunize.org/publications/](http://www.immunize.org/publications/)

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