

Immunization Update Across the Lifespan

**William L. Atkinson, MD, MPH
National Center for Immunization and
Respiratory Diseases**



**Iowa Immunization Conference
Des Moines, Iowa
June 11, 2009**

Disclosures

- **The speaker is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation**
- **The speaker will discuss the off-label use of rotavirus, Pentacel and Kinrix vaccines**
- **The speaker will not discuss products not currently licensed by the Food and Drug Administration**

Critical Virologic Events Leading to a Pandemic

- **Emergence of a novel influenza virus subtype through reassortment or adaptive mutation**
 - **Little or no existing immunity in the population**
- **Capable of sustained person-to-person transmission**
- **The novel H1N1 (swine) influenza virus identified in early 2009 meets both these criteria**

H1N1 “Swine” Influenza Virus

- **Type A influenza virus first isolated from a pig in 1930**
- **Causes respiratory disease in pigs**
- **1-2 human infections reported per year since 2005**
- **Until 2009 all infected persons had direct contact with pigs or people who had contact with pigs**
- **Not transmitted by eating pork**

H1N1 Swine-origin Influenza Virus 2009*

- **An update of the current status of H1N1 swine-origin influenza virus will be given**

***See www.cdc.gov/h1n1flu/ for updates**

2009 Immunization Schedules for Persons 0 Through 18 Years

- **Published in MMWR on January 2, 2009**
- **Same basic format as 2008**
- **Revisions**
 - **new age recommendations for rotavirus vaccines**
 - **revised influenza vaccine recommendations (6 months through 18 years)**
 - **Hib vaccine for persons 5 years and older**
 - **revised minimum intervals for HPV vaccine**

Available at www.cdc.gov/vaccines/recs/schedules/

2009 Schedule New Hib Footnote

- Hib vaccine is not generally recommended for persons aged 5 years or older. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults. However, studies suggest good immunogenicity in persons who have sickle cell disease, leukemia, or HIV infection, or who have had a splenectomy; administering 1 dose of Hib vaccine to these persons is not contraindicated.**

The Sears “Alternative” Immunization Schedule*

- No more than 2 vaccines per visit
- Requires 15 visits over 42 months to complete the series for all recommended childhood vaccines
- Uses single antigen measles, mumps and rubella vaccines
- Completes most vaccine series within age range recommended by ACIP except:
 - HepB vaccine delayed until 30-42 months
 - Measles vaccine delayed until 3 years of age

*Sears R. *The Vaccine Book*. New York: Little Brown and Co, 2007:234-42

See commentary by Offit: *Pediatrics* 2009;123:e164-9

Available on Pediatrics website at <http://pediatrics.aappublications.org/>

Single Antigen MMR

- **As of 2009 Merck no longer produces single antigen measles, mumps or rubella vaccine for distribution**
- **Only MMR is available**
- **Unknown if single antigen products will be available in the future**
- **MMRV expected to be available later in 2009**

Post hoc ergo propter hoc

“After this therefore because of this”

**Temporal association does not prove
causation**

**Just because one event follows
another does not mean that the first
caused the second**

Elements Needed To Assess Causation of Vaccine Adverse Events

	<u>Disease</u>	<u>No disease</u>
<u>Vaccine</u>	a	b
<u>No vaccine</u>	c	d

$$\begin{aligned} \text{Risk in "vaccine" group} &= \frac{a}{a + b} \\ \text{Risk in "no vaccine" group} &= \frac{c}{c + d} \end{aligned}$$

If the rate in "vaccine" group is higher than the rate in the "no vaccine" group then vaccines may be the cause

Autism and Vaccines

- **Multiple studies have examined the rate of autism among vaccinated and unvaccinated children**
- **Available evidence does not indicate that autism is more common among children who receive MMR or thimerosal-containing vaccines than among children who do not receive vaccines**
- **On February 12, 2009 U.S. Court of Federal Claims ruled that the measles-mumps-rubella vaccine, whether administered alone or in conjunction with thimerosal-containing vaccines, were not causal factors in the development of autism or autism spectrum disorders. See www.uscfc.uscourts.gov/node/5026**

Sources of Information about Autism

- **Centers for Disease Control and Prevention
Autism Information Center**
 - www.cdc.gov/ncbddd/autism/index.htm
- **American Academy of Pediatrics**
 - www.aap.org/healthtopics/autism.cfm
- **Vaccine Education Center at the Children's
Hospital of Philadelphia**
 - www.chop.edu/consumer/your_child/index.jsp
- ***Autism's False Prophets*, by Dr. Paul Offit
(Columbia University Press, 2008)**

Rotarix[®] Rotavirus Vaccine

- **Approved by FDA in April 2008**
- **Contains one strain of live attenuated human rotavirus (G1P[8])**
- **Two oral doses at 2 and 4 months of age (minimum interval 4 weeks)**
- **Minimum age 6 weeks**
- **Maximum (labeled) age 24 weeks**

Rotavirus Vaccine Recommendations

	Rotarix (RV1)	RotaTeq (RV5)	ACIP Recs
Doses	2	3	--
Min age	6 wks	6 wks	6 wks
Max age- 1st dose	20 wks	12 wks	15 wks 0 days*
Max age- any dose	24 wks	32 wks	8 mos 0 days*

*off-label. See *MMWR* 2009;58(RR-2)

Rotavirus Vaccine Recommendations

- **Provider may not stock or may not know the brand of rotavirus vaccine received for previous dose or doses**
- **If any dose in the series was RV5 (RotaTeq) or the product is unknown for any dose in the series, a total of three doses of rotavirus vaccine should be given**

KINRIX™ Vaccine

- **Contains DTaP (Infanrix) and IPV**
- **Approved ONLY for the 5th dose of DTaP and 4th dose of IPV in children 4 through 6 years of age***
- **Do NOT use for earlier doses in the DTaP or IPV series**
- **Use of KINRIX for any dose other than DTaP5 and IPV4 is off-label, and should be considered a medication error (but dose does not need to be repeated)**

***whose previous doses have been with Infanrix and/or Pediarix for the first 3 doses and Infanrix for the 4th dose**

Pentacel[®] Vaccine

- **Contains DTaP, Hib, and IPV**
- **Approved for doses 1 through 4 among children 6 weeks through 4 years of age**
- **Do NOT use for in children 5 years or older**
- **Package contains lyophilized Hib (ActHib) that is reconstituted with a liquid DTaP (Daptacel)/IPV solution**

Pentacel[®] Vaccine

- **If the DTaP-IPV solution is administered separately there will be no diluent for the Hib component!**
- **You will be unable to use the Hib dose because**
 - **Hib must only be reconstituted with DTaP-IPV or specific ActHib diluent (NOT with MMR/varicella diluent, normal saline or any other vaccine)**

Pentacel[®] Vaccine

- **Do NOT use the Hib (ActHib) and liquid DTaP/IPV solution separately**
- **If Hib reconstituted with an inappropriate diluent* is administered it should NOT be counted as a valid dose and should be repeated as soon as possible**
- **Keep components together in the box to avoid administration errors**
- **Guidance for clinicians for the use of Pentacel**
 - www.cdc.gov/vaccines/pubs/pentacel-guidance.htm

PedvaxHib[®] Shortage

- **PedvaxHib is currently not available**
- **Improvement in the supply is expected during mid- to late-2009**
- **During the shortage the booster dose of Hib vaccine (including Pentacel) for healthy children 12 months of age and older should be deferred**
- **If you only have Pentacel in stock, and a child needs Hib vaccine you should administer Pentacel even though the child will receive an extra dose of DTaP and IPV**

Human Papillomavirus Vaccine Recommendations

- **ACIP recommends routine vaccination of females 11 or 12 years of age with three doses of quadrivalent HPV vaccine**
- **The vaccination series can be started as young as 9 years of age at the clinician's discretion**
- **Maximum age 26 years (i.e. until the 27th birthday)**

HPV Vaccination Schedule

- **Routine schedule is 0, 2, 6 months**
- **Third dose should be at least 24 weeks after the first dose**
- **An accelerated schedule using minimum intervals is NOT recommended**
- **If the 3 dose series was administered over at least 16 weeks then no doses need to be repeated**

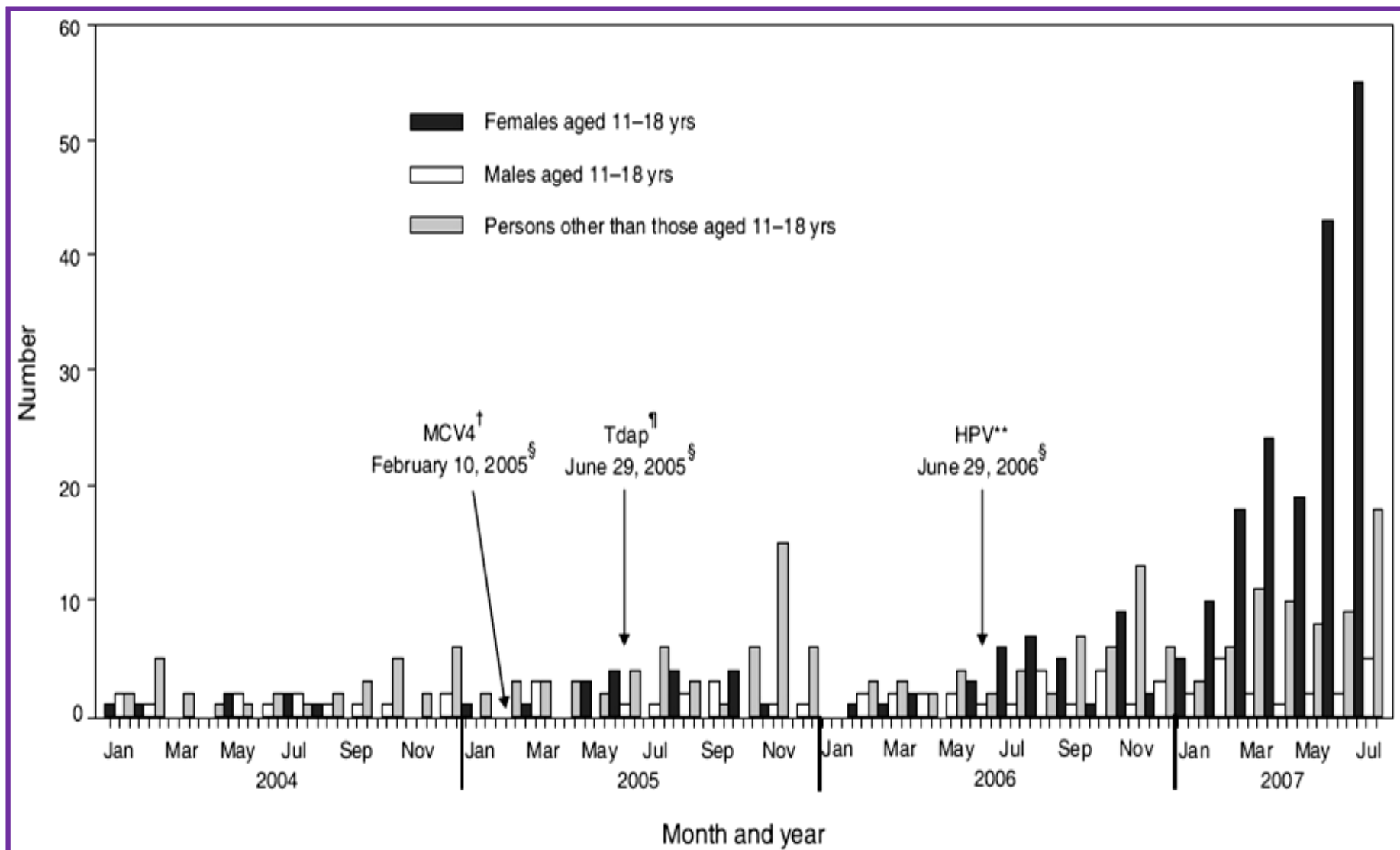
HPV Vaccine Interval Violations

- **There is no MAXIMUM interval between HPV vaccine doses**
- **If the interval between doses is longer than recommended you should just continue the series where it was interrupted**

Syncope Following Vaccination

- **An increase in the number of reports of syncope has been detected by the Vaccine Adverse Event Reporting System (VAERS)**
- **11-18 year old females have contributed most of the increase, many of whom received HPV vaccine**
- **Serious injuries have resulted, including 1 death due to intracranial hemorrhage**
- **70% of syncopal episodes occurred within 15 minutes of vaccination**

Number of Postvaccination Syncope* Episodes Reported to the Vaccine Adverse Event Reporting System



Prevention of Syncope After Vaccination

- Vaccine providers should strongly consider observing patients for 15 minutes after they are vaccinated**
- If syncope develops, patients should be observed until symptoms resolve**
- Clinicians should be aware of presyncopal manifestations (weakness, dizziness, pallor, etc) and take appropriate measures to prevent injuries if they occur**

HPV Vaccine VAERS Reports*

- **More than 23 million doses distributed**
- **11,916 VAERS reports**
 - **94% classified as non-serious (local reactions, syncope, fatigue, etc)**
 - **6% classified as serious (involves hospitalization, death, permanent disability or life-threatening illness)**

*As of December 31, 2008

www.cdc.gov/vaccinesafety/vaers/gardasil.htm

HPV Vaccine VAERS Reports*

- **32 deaths reported**
 - no common pattern to the deaths
 - the cause of death was explained by factors other than the vaccine
- **Guillain-Barré Syndrome (GBS)**
 - no evidence that HPV vaccine has increased the rate above that expected in the population
- **Thromboembolic disorders (blood clots)**
 - Most had known risk factors (e.g., oral contraceptive use)
 - Additional studies are being conducted

*As of December 31, 2008

www.cdc.gov/vaccinesafety/vaers/gardasil.htm

Herpes Zoster Vaccine (Zostavax[®])

- Administered to persons who had chickenpox to reduce the risk of subsequent development of zoster and postherpetic neuralgia**
- Contains live varicella vaccine virus in much larger amount (14x) than standard varicella vaccine (Varivax[®])**
- Requires freezer storage AT ALL TIMES**

Herpes Zoster Vaccine Trial

- **36,716 persons 60-80+ years of age followed for average of 3.12 years after vaccination**
- **Compared to the placebo group the vaccinated group had**
 - **51.3% fewer episodes of HZ**
 - **Less severe illnesses**
 - **66.5% less postherpetic neuralgia**

ACIP Recommendations for Zoster Vaccine

- **Adults 60 years and older should receive a single dose of zoster vaccine**
- **Routine vaccination of persons younger than 60 years is NOT recommended**
- **Need for booster dose or doses not known at this time**
- **A history of herpes zoster should not influence the decision to vaccinate**

MMWR 2008;57(RR-5)

Zoster Vaccine

- **It is not necessary to inquire about chickenpox or test for varicella immunity before administering zoster vaccine**
- **Persons 60 years of age and older can be assumed to be immune* regardless of their recollection of chickenpox**

MMWR 2008;57(RR-5)

*for the purpose of establishing eligibility for zoster vaccine

Serologic Testing for Varicella Immunity

- **If a person 60 years or older is tested for varicella antibody and found to be negative**
 - **Administer 2 doses of regular varicella vaccine (not zoster vaccine)**
 - **Zoster vaccine is not indicated for persons whose immunity is based upon varicella vaccination**

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**

CDC Vaccines and Immunization Contact Information

- **Telephone** **800.CDC.INFO**
(for patients and parents)
- **Email** **nipinfo@cdc.gov**
(for providers)
- **Website** **www.cdc.gov/vaccines/**
- **Vaccine Safety**
www.cdc.gov/od/science/iso/