

## 2009 Immunization Update: New vaccines, Epidemiology and Questions Parents Ask

February 3, 2009

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## Disclosure

- I have no financial associations with any product discussed.
- If products are named by trade name, this naming is solely for educational purposes and does not constitute endorsement of the product.
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## Objectives

- Discuss new vaccines that have been approved in the U.S.
- Answer the questions:
  - Do vaccine-preventable diseases still occur in Colorado? in the United States?
- Review common questions parents might ask about vaccination

## DTaP-IPV-Hib

- Pentacel (DTaP-IPV-Hib)
- Combination of:
  - Diphtheria toxoid
  - Tetanus toxoid
  - Acellular pertussis antigens
  - Inactivated poliovirus
  - Haemophilus influenzae, type b capsular polysaccharide – conjugate

## DTaP-IPV-Hib

- Intramuscular administration
- 0.5 mL per dose
- Approved for 4 doses from 6 weeks through 4 years of age (prior to the 5<sup>th</sup> birthday)
- VIS forms – combination form
- Schedule: 2, 4, 6, 15 – 18 months

## DTaP-IPV-Hib

- Other ingredients
  - Aluminum phosphate (330 mcg Al)
  - Polysorbate 80 (emulsifier)
  - Residual formaldehyde, glutaraldehyde, bovine serum albumin,
  - 2-phenoxyethanol
  - Neomycin, Polymyxin B both < 4 trillionths of a gram ( $10^{-12}$ )

## DTaP-IPV-Hib Efficacy

- Is this vaccine as effective as the individual components?
- Efficacy compared to individual vaccines
  - Serological protection correlates exist for D, T, polio 1,2, 3 and Hib
  - For pertussis, no serological correlates of protection defined. Compared to DTaP of same co., DTaP-IPV-Hib has:
    - 2X detoxified PT
    - 4X FHA

## DTaP-IPV-Hib Studies

- Diphtheria, tetanus non-inferior to DTaP responses
- Pertussis
  - In two studies, DTaP-IPV-Hib met non-inferiority criteria for anti-FHA and anti-FIM, did not meet non-inferiority criteria for anti-pertactin after 4<sup>th</sup> doses
  - In one study DTaP-IPV-Hib met non-inferiority criteria for anti-pertussis toxin

## DTaP-IPV-Hib Studies

- In one of three studies of Hib responses, DTaP-IPV-Hib did not meet non-inferiority criteria compared to separately administered ActHIB

## DTaP-IPV-Hib

- Concomitantly administered vaccines:
  - No evidence of interference with:
    - PCV7
    - Hepatitis B
    - MMR
    - Varicella

## DTaP-IPV-Hib

- Bottom-line:
  - Evidence suggests an effective vaccine
  - 10 years of experience in Canada
  - FDA approved after review of complex data

## DTaP-IPV-Hep B (Pediatrix)

- 3 dose schedule
- For 4<sup>th</sup> dose of DTaP, routine DTaP vaccine.

### DTaP-IPV (Kinrix)

- Licensed for 4 – 6 year olds
- Fifth dose of DTaP, 4<sup>th</sup> of IPV
- Intended to follow those having gotten DTaP-IPV-hepatitis B (and now finished with hepatitis B series)

### Hib Vaccine Supply

- In December 2007, Merck ceased manufacture of Hib vaccines
- Two other Hib vaccine manufacturers
- During shortage, withhold the booster (final) dose of Hib vaccine, be it the third or the fourth dose
- Shortage forecast to end in mid-2009
- H. flu disease is being monitored

### DTaP-IPV-Hib vs. DTaP-IPV-Hep B

- DTaP-IPV-Hib - withhold final dose just as with other Hib-containing vaccines
- DTaP-IPV-Hib requires reconstitution
  - DTaP-IPV-Hep B does not
- If switching to DTaP-IPV-Hib – will need to increase Hep B vaccine orders

### Examples of Schedules

- 1. Using DTaP-IPV-Hib:

Birth	2 mos	4 mos	6 mos	15-18 mos	4-6 years
Hep B	Hep B		Hep B		
				DTaP	DTaP
					IPV
	DTaP/IPV /Hib	DTaP/IPV /Hib	DTaP/IPV /Hib	Defer dose* due to Hib	

### Examples of Schedules

- 2. DTaP-IPV-Hib for First Dose Only & DTaP-IPV-Hep B for Remainder of Doses

Birth	2 mos	4 mos	6 mos	15-18 mos	4-6 years
Hep B	Hep B				
		Hib	Hib	Defer Hib	
				DTaP	DTaP
					IPV
		DTaP/IPV / HepB	DTaP/IPV/ Hep B		
	DTaP/IPV /Hib				

### Examples of Schedules

- 3. Without DTaP-IPV+ combinations

Birth	2 mos	4 mos	6 mos	15-18 mos	4-6 years
Hep B	Hep B		Hep B		
	Hib	Hib	Hib	Defer Hib	
	DTaP	DTaP	DTaP	DTaP	DTaP
	IPV	IPV	IPV		IPV

## Examples of Schedules

### ■ 4. Using DTaP-IPV-Hep B Only

Birth	2 mos	4 mos	6 mos	15-18 mos	4-6 years
Hep B					
	Hib	Hib	Hib	Defer Hib	
				DTaP	
					DTaP/IPV
	DTaP/IPV /HepB	DTaP/IPV/ Hep B	DTaP/IPV/ HepB		

## DTaP-IPV-Hib

- Contraindications
  - Severe allergy to previous dose or any vaccine constituent
  - Encephalopathy within 7 days of a previous pertussis dose
  - Progressive neurologic disorder

## DTaP-IPV-Hib

- Warnings: If prior dose caused:
  - Febrile response to > 40.5°C
  - Collapse or shock-like state
  - Persistent, inconsolable crying lasting > 3 hrs
  - Seizure, with or without fever, within 3 days
  - Guillain-Barre syndrome within 6 weeks of a prior vaccine

## DTaP-IPV-Hib

- Precautions
  - For those at increased risk of seizure
    - Anti-pyretic administered at time of DTaP-IPV-Hib and appropriate doses for 24 hours
  - Immunocompromised
    - Response not studied, may be sub-optimal (as with all vaccines)

## DTaP-IPV-Hib

- Adverse Events
  - No difference in
    - Redness
    - Swelling
    - Tenderness
    - Increase in arm circumference
 vs individual antigen-containing vaccines

## DTaP-IPV-Hib

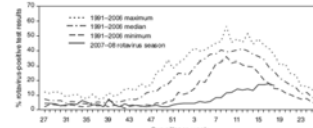
- If previous individual antigens received, may use DTaP-IPV-Hib to complete recommended vaccine series
- A fifth dose of DTaP is recommended to be from the same company.
- A 4<sup>th</sup> dose of polio at 4 years of age is NOT indicated

## DTaP-IPV-Hib

- Refrigerate
  - Discard
    - If frozen
    - After expiration date
- Requires re-constitution (DTaP-IPV) with ActHIB
- (All Hib vaccines require reconstitution)
- Give immediately after reconstitution

## Rotavirus epidemiology

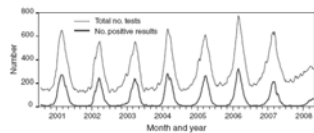
FIGURE 1. Percentage of rotavirus tests with positive results from participating laboratories, by week of year — National Respiratory and Enteric Virus Surveillance System, United States, 1991–2006 rotavirus seasons and 2007–08 rotavirus season\*



\*2008 data current through week ending 3 May 2008. Data from July 2006–June 2007 were excluded from the (1991–2006) prevaccine baseline data because some persons tested likely received vaccine during that period.

## Rotavirus epidemiology

FIGURE 2. Total number of rotavirus tests and number of positive test results\* from 32 continuously reporting laboratories† — National Respiratory and Enteric Virus Surveillance System, United States, July 2, 2000–May 3, 2008‡



\*3-week moving averages.  
 †Laboratories that reported for at least 30 weeks during July 2000–June 2007 and reported for at least 2 months during the 2007–08 rotavirus season.  
 ‡2007–08 rotavirus season data through week ending May 3, 2008.

## Rotavirus disease

- By age 5 years
  - 80% will have had symptomatic episodes
    - 2.7 million cases annually
  - 10% will visit a clinician
  - 6% will visit an emergency department
  - 1.4% will be hospitalized
  - Estimated 20 to 60 deaths in US annually

## New rotavirus vaccine

- Trade name: Rotarix
- Abbreviation: RV1
- 2 dose, oral series to start between 6 and weeks
- Minimum interval: 4 weeks
- Maximum age: 24 weeks

## RV1

- ½ or more by volume spit out – repeat dose
- 2 dose series
- Maximum age for first dose is 14 weeks, 6 days – should not be initiated for infants aged 15 weeks and older.
- Minimum interval: 4 weeks
- All doses administered by 8 months.

## RV5

- 5-valent rotavirus vaccine
- Trade name: RotaTeg
- Abbreviation: RV5
- 3 dose, oral series
- Given at ages 2, 4 and 6 months
- Maximum age for first dose is 14 weeks, 6 days
- Minimum interval: 4 weeks
- All doses administered by 8 months.

## RV1 vs. RV5

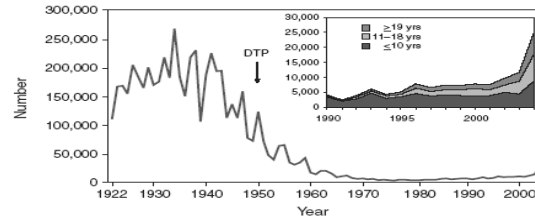
- RV1 is a 2 dose series
- RV5 is 3 dose series
- RV1 requires re-constitution; RV5 does not

## Candidate vaccines

- LAIV approved to 2 years, no wheezing
- Tdap (Trade name: Boostrix) approved 10 – 64 years
- 2<sup>nd</sup> HPV – FDA application reviewed
- Hopes for the future
  - HIV, Malaria, RSV-Para-influenza type 3

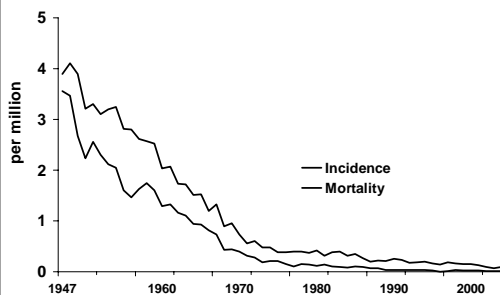
## Pertussis

FIGURE 1. Number of reported pertussis cases, by year — United States, 1922–2004

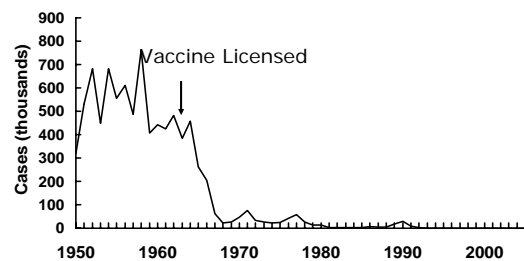


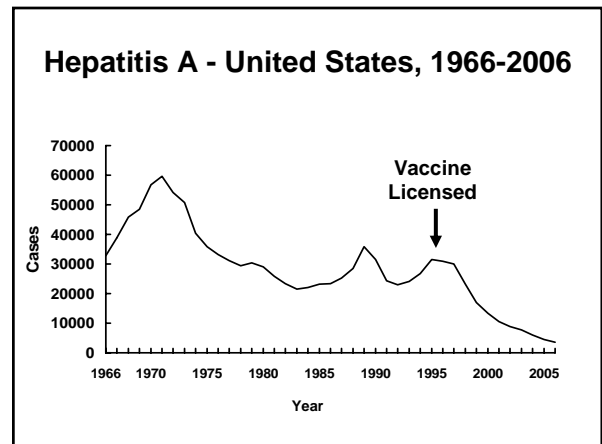
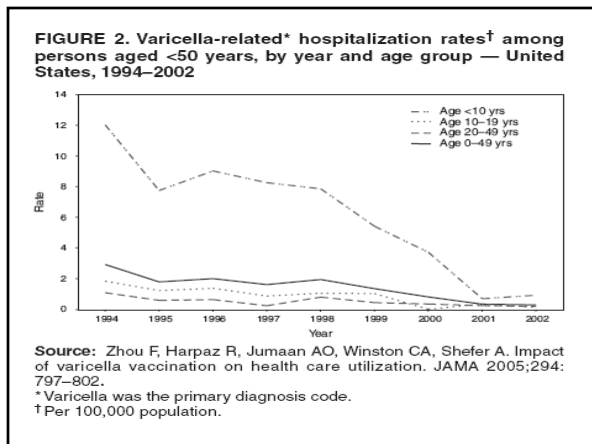
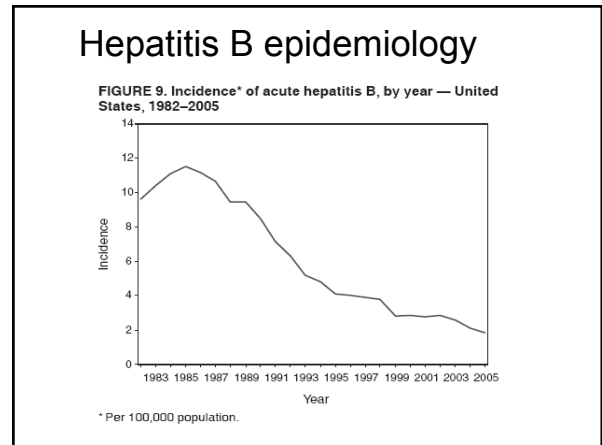
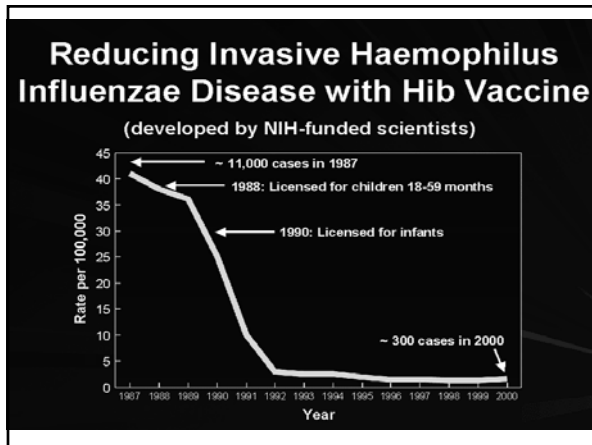
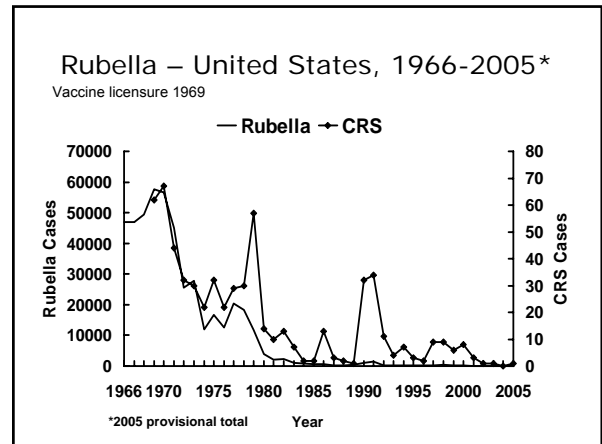
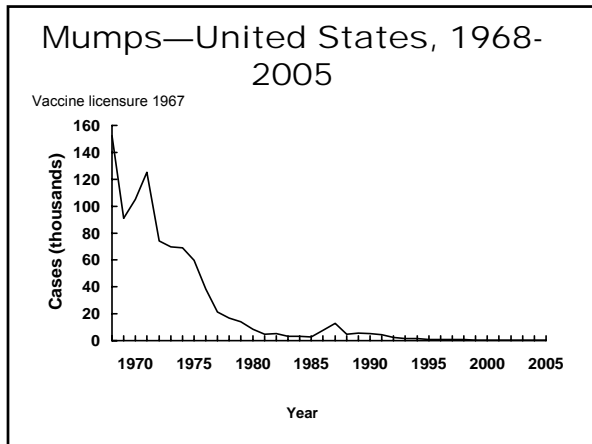
SOURCE: 1950–2004, National Notifiable Diseases Surveillance System and 1922–1949, passive reports to the Public Health Service.

## Tetanus incidence, US 1947 - 2003



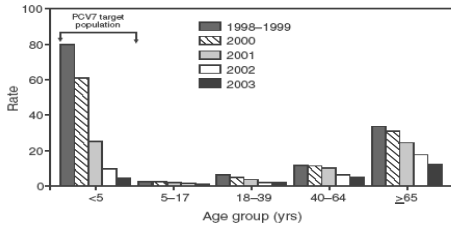
## Measles epidemiology, United States, 1950-2005





## Pneumococcal conjugate vaccine

FIGURE 1. Rate\* of vaccine-type (VT) invasive pneumococcal disease (IPD) before and after introduction of pneumococcal conjugate vaccine (PCV7), by age group and year — Active Bacterial Core surveillance, United States, 1998–2003



\* Per 100,000 population.

† For each age group, the decrease in VT IPD rate for 2003 compared with the 1998–1999 baseline is statistically significant ( $p < 0.05$ ).

## Do cases of VPD still occur in Colorado?

- Yes
- 2007 data
  - No cases of diphtheria, measles, polio, rubella, tetanus
- Haemophilus influenzae 58
- Hepatitis A 27
- Acute hepatitis B 41
- Hospitalized influenza 443

## Colorado cases 2007

- Meningococcal disease 22
- Mumps 17
- Pertussis 306
- Strep pneumoniae, invasive 459
- Varicella 1089
- Rotavirus, HPV are not reported

## Questions parents might ask

- Do vaccines cause autism?
- No
- As well as a negative can be “proven”, vaccines do not cause autism.
- “The weight of the evidence is so great that I don’t think there is any room for debate” Nancy Minshew, Director, University of Pittsburgh Center for Excellence in Autism.

## If the diseases are gone, is it still important to get vaccines?

- Yes. The diseases are nearly gone, but they would come back if people were not protected.



## How do we know that multiple vaccines can be given safely?

- The body has billions of infection-fighting cells that protect people every day.
- The FDA requires studies to demonstrate the effect, if any, of new vaccines on vaccines that are routinely given.
- Theoretically, people could make immunity to thousands of vaccines at a single time



### I thought chickenpox was a mild disease?!

- When everyone got chickenpox, it was mild for most, but not all
- Vaccination against chickenpox prevents all types of chickenpox, including the severe cases
- Pre-vaccine era:
  - 11,000 hospitalizations/year
  - 103 deaths/yr (1990 – 1996)

### Regarding vaccines, how can I discern good information from bad?

- Talk to a medical professional that you trust
- [http://www.immunizationinfo.org/immunization\\_issues\\_detail.cfv?id=52](http://www.immunizationinfo.org/immunization_issues_detail.cfv?id=52)
- <http://www.cdc.gov/vaccines/>

### Reputable videos

- Video information made by The Children's Hospital of Philadelphia about vaccines can be found at:  
<http://www.chop.edu/consumer/jsp/division/generic.jsp?id=77288>

### Thank You for Attending!

- Please fill out the evaluation questionnaire and email or fax it back to us.
- Please fill out the CME Questions too if you are requesting CME credit.

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