

# Vaccinology Overview

## **Complexity of the Vaccine Approval Process Including Lessons Learned**

**Larry K. Pickering, MD, FAAP, FIDSA, FPIDS**

**August 18, 2018**

## **Faculty Disclosure Information**

In the past 12 months, I have not had relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider(s) of commercial services discussed in this presentation.

# Topics to be discussed

- ❑ Clarify differences between FDA licensure of and ACIP recommendations for vaccines
- ❑ Discuss major components of and participant groups in the US vaccine system
- ❑ Highlight lessons learned from making vaccine recommendations
- ❑ Stress the importance of herd protection (community immunity)
- ❑ Review recent vaccine recommendations

# Recommended Childhood Immunization Schedule United States - January 1995

Vaccines are listed under the routinely recommended ages. Shaded bars indicate range of acceptable ages for vaccination.

Age ▶ Vaccine ▼	Birth	2 mos	4 mos	6 mos	12 <sup>1</sup> mos	15 mos	18 mos	4 - 6 yrs	11-12 yrs	14-16 yrs
Hepatitis B <sup>1</sup>	Hep B-1	Hep B-2		Hep B-3						
Diphtheria, Tetanus, Pertussis <sup>2</sup>		DTP	DTP	DTP	DTP or DTaP at 15+ m			DTP or DTaP	Td	
<i>H. influenzae</i> type b <sup>3</sup>		Hib	Hib	Hib	Hib					
Polio		OPV	OPV	OPV				OPV		
Measles, Mumps, Rubella <sup>4</sup>					MMR			MMR	or MMR	

<sup>1</sup> Infants born to HBsAg-negative mothers should receive the second dose of hepatitis B vaccine between 1 and 4 months of age, provided at least one month has elapsed since receipt of the first dose. The third dose is recommended between 18 and 24 months of age.

Infants born to HBsAg-positive mothers should receive immunoprophylaxis for hepatitis B with 0.5 ml Hepatitis B Immune Globulin (HBIG) within 12 hours of birth, and the appropriate dose of hepatitis B vaccine at a separate site (Hepatitis B vaccine doses vary according to manufacturer and mother's HBsAg status, and package insert should be consulted for information on doses). In these infants, the second dose of vaccine is recommended at 1 month of age and the third dose at 6 months of age. All pregnant women should be screened for HBsAg in an early prenatal visit.

<sup>2</sup> The fourth dose of DTP may be administered as early as 12 months of age, provided at least 6 months have elapsed since DTP3. Combined DTP-Hib products may be used when these two vaccines are to be administered simultaneously. DTaP (diphtheria and tetanus toxoids and acellular pertussis vaccine) is licensed for use for the 4th and/or 5th dose of DTP vaccine in children 15 months of age or older and may be preferred for these doses in children in this age group.

<sup>3</sup> Three *H. influenzae* type b conjugate vaccines are available for use in infants: HibCC (HibTITER) (Eli Lilly-Pfizer), PRP-T (ActHib, OverHib) (Pasteur Merieux), distributed by SmithKline Beecham, Coaxynight, and PRP-OMF (PedvaxHIB) (Merck Sharp & Dohme). Children who have received PRP-OMF at 2 and 4 months of age do not require a dose at 6 months of age. After the primary infant Hib conjugate vaccine series is completed, any licensed Hib conjugate vaccine may be used as a booster dose at age 12-15 months.

<sup>4</sup> The second dose of MMR vaccine should be administered EITHER at 4-6 years of age OR at 11-12 years of age.

<sup>5</sup> Vaccines recommended in the second year of life (12-15 months of age) may be given at either one or two visits.

Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP)

# Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2018

- Consult relevant ACIP statements for detailed recommendations ([www.cdc.gov/vaccines/hcp/acip-recs/index.html](http://www.cdc.gov/vaccines/hcp/acip-recs/index.html)).
- When a vaccine is not administered at the recommended age, administer at a subsequent visit.
- Use combination vaccines instead of separate injections when appropriate.
- Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) online ([www.vaers.hhs.gov](http://www.vaers.hhs.gov)) or by telephone (800-822-7967).
- Report suspected cases of reportable vaccine-preventable diseases to your state or local health department.
- For information about precautions and contraindications, see [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html).

Approved by the

**Advisory Committee on Immunization Practices**  
([www.cdc.gov/vaccines/acip](http://www.cdc.gov/vaccines/acip))

**American Academy of Pediatrics**  
([www.aap.org](http://www.aap.org))

**American Academy of Family Physicians**  
([www.aafp.org](http://www.aafp.org))

**American College of Obstetricians and Gynecologists**  
([www.acog.org](http://www.acog.org))

This schedule includes recommendations in effect as of January 1, 2018.

The table below shows vaccine acronyms, and brand names for vaccines routinely recommended for children and adolescents. The use of trade names in this immunization schedule is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Vaccine type	Abbreviation	Brand(s)
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Diphtheria, tetanus vaccine	DT	No Trade Name
<i>Haemophilus influenzae</i> type B vaccine	Hib (PRP-T) Hib (PRP-OMP)	ActHIB Hiberix PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated)	IIV	Multiple
Measles, mumps, and rubella vaccine	MMR	M-M-R II
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-D MenACWY-CRM	Menactra Menveo
Meningococcal serogroup B vaccine	MenB-4C MenB-FHbp	Bexsero Trumenba
Pneumococcal 13-valent conjugate vaccine	PCV13	Prennar 13
Pneumococcal 23-valent polysaccharide vaccine	PPSV23	Pneumovax
Poliovirus vaccine (inactivated)	IPV	IPOL
Rotavirus vaccines	RV1 RV5	Rotarix RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac No Trade Name
Varicella vaccine	VAR	Varivax
Combination Vaccines		
DTaP, hepatitis B and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus and <i>Haemophilus influenzae</i> type B vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
Measles, mumps, rubella, and varicella vaccines	MMRV	ProQuad

# Objective One

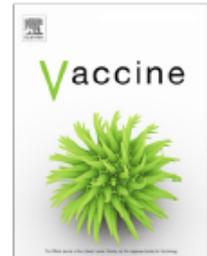
- Clarify differences between FDA licensure of and ACIP recommendations for vaccines



Contents lists available at [ScienceDirect](http://ScienceDirect)

# Vaccine

journal homepage: [www.elsevier.com/locate/vaccine](http://www.elsevier.com/locate/vaccine)



## FDA licensure of and ACIP recommendations for vaccines



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### ABSTRACT

Many healthcare providers are not familiar with the Food and Drug Administration (FDA) vaccine licensure process, the Advisory Committee on Immunization Practices (ACIP) vaccine recommendation process, and how FDA vaccine licensure and ACIP recommendations are related. Vaccines for use in the United States military and civilian populations are licensed by the FDA by several potential pathways but use of licensed vaccines in the civilian population should be based on recommendations made by the ACIP. In performing these distinct activities, FDA and ACIP function under different mandates. In this article, we discuss whether the FDA licensure pathways used to approve a vaccine impacts ACIP recommendation categories for vaccines licensed from 2006 to 2016.

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# FDA Licensure of Vaccines

- FDA is a regulatory agency, ACIP has no regulatory authority
- FDA licenses vaccines based only on results of clinical studies and other data submitted to FDA by vaccine manufacturers in a Biologic License Application (BLA)
- ACIP considers additional data and therefore recommendations may differ from FDA licensure.
- Manufacturers can only market vaccines based upon information in the package insert for that vaccine

## **Additional FDA Accelerated Approval Requirements**

- ❑ Sponsor must study the vaccine post licensure to verify and describe its clinical benefit**
- ❑ Post marketing studies must be adequate and well controlled and conducted with due diligence**
- ❑ Design and milestones of these studies are submitted to and reviewed by the FDA with the original BLA**
- ❑ Accelerated approval may be withdrawn if these studies do not verify clinical benefit or are not conducted with due diligence**

# Key Elements for Developing Evidence Based Recommendations by ACIP

- Vaccine safety
- Vaccine efficacy/effectiveness
- Burden of disease
- Implementation issues
- Economic analysis data are presented (evidence not graded, but these data are considered during policy development)
- Evidence tables are used to summarize benefits, harms, strengths, and limitations of studies

# Current ACIP Recommendation Categories

- ❑ **Category A** recommendations are made for all people in an age- or risk-factor-based group.
  - Most vaccines in the schedules are Category A
  - Ensures funding
- ❑ **Category B** recommendations are made for individual clinical decision making.
  - Ensures funding

**Note:** ACIP is moving toward an evidence to decision (recommendations) framework and will not use above categories in the future

# CDC Approval Process Following an ACIP Vaccine Recommendation

If approved by CDC Director, adopted by agency:

Published in *MMWR Weekly* as a Policy Note within 2 months of an ACIP vote

*Published in MMWR*  
*Recommendations & Reports* within 6-8 months of an ACIP

*Recommendation becomes official CDC/HHS policy upon publication in MMWR*

# Differences Between FDA and ACIP Vaccine Considerations

## Categories Differences

- |                            |    |
|----------------------------|----|
| • High risk groups*        | 12 |
| • Age                      | 06 |
| • Administration schedules | 04 |

\*Immunocompromised and pregnant women

# Examples of Differences Between FDA Licensure of and ACIP Recommendations for Vaccines

Vaccine	FDA	ACIP
Tdap during pregnancy	Not licensed	Recommended
Rabies post exposure prophylaxis	Five doses	Four doses
Flu Mist	Licensed 2 through 49 years of age	Not recommended for 2017-2018 season

# Examples of Differences Between FDA Licensure of and ACIP Recommendations for Vaccines

Vaccine	FDA	ACIP
Herpes zoster vaccine	Adults 50 years of age and older	Adults 60 years of age and older
Typhoid vaccine	Two years of age and older	Six months of age and older
Influenza vaccine during pregnancy	Not licensed	Recommended

# Objective Two

- Discuss major components of and participant groups in the US vaccine system

## Programs that Rely on ACIP Recommendations

- ❑ Vaccine Injury Compensation Program (VICP)
- ❑ Vaccines for Children (VFC )(public health insurance)
- ❑ Private health insurance
- ❑ Vaccine adverse event reporting system (VAERS)
- ❑ State health departments
- ❑ State school-entry immunization laws
- ❑ ACIP sets the standards for establishing state immunization mandates

# Vaccine Injury Compensation Program

- **The VICP is a no-fault alternative to the traditional legal system for resolving vaccine injury petitions.**
- The National Childhood Vaccine Injury Act of 1986 created the VICP, after a series of lawsuits threatened to cause vaccine shortages and reduce U.S. vaccination rates.
- The VICP covers both recipients and contacts.

# Vaccines for Children Program

- VFC helps provide vaccines to children whose parents or guardians may not be able to afford them. Vaccines available through VFC are those approved by ACIP
- CDC buys vaccines at a discount and distributes them to grantees—i.e., state health departments which in turn distribute them at no charge. A child is eligible for the VFC Program if he or she is <19 years of age and is:
  - Medicaid-eligible
  - Uninsured or underinsured
  - American Indian or Alaska Native

# Objective Three

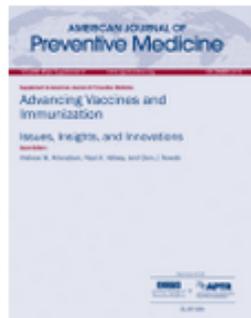
- ❑ **Lessons Learned  
Following Vaccine  
Recommendations**



ELSEVIER

# American Journal of Preventive Medicine

Volume 49, Issue 6, Supplement 4, December 2015, Pages  
S406-S411



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## Lessons Learned From Making and Implementing Vaccine Recommendations in the U.S.

After publication of certain vaccine recommendations made by the Advisory Committee on Immunization Practices, several unexpected events have occurred during implementation of these recommendations. These have included changes in recommendations following adverse events involved with a particular vaccine and the conferral of community protection as an offshoot of vaccination of a specific population. Vaccine shortages and hesitancy have also been proven impediments to full implementation, and vaccine recommendations have not gone unaffected by either public perception

## **Lessons Learned from Vaccine Recommendations**

- **Unanticipated positive effects (herd effect or community protection)**
- **Consequences of vaccine recommendations when they are changed to minimize adverse events**
- **Different vaccines to prevent infection from the same organism may cause confusion**
- **Public perception of a vaccine or the disease prevented can hinder vaccine uptake**

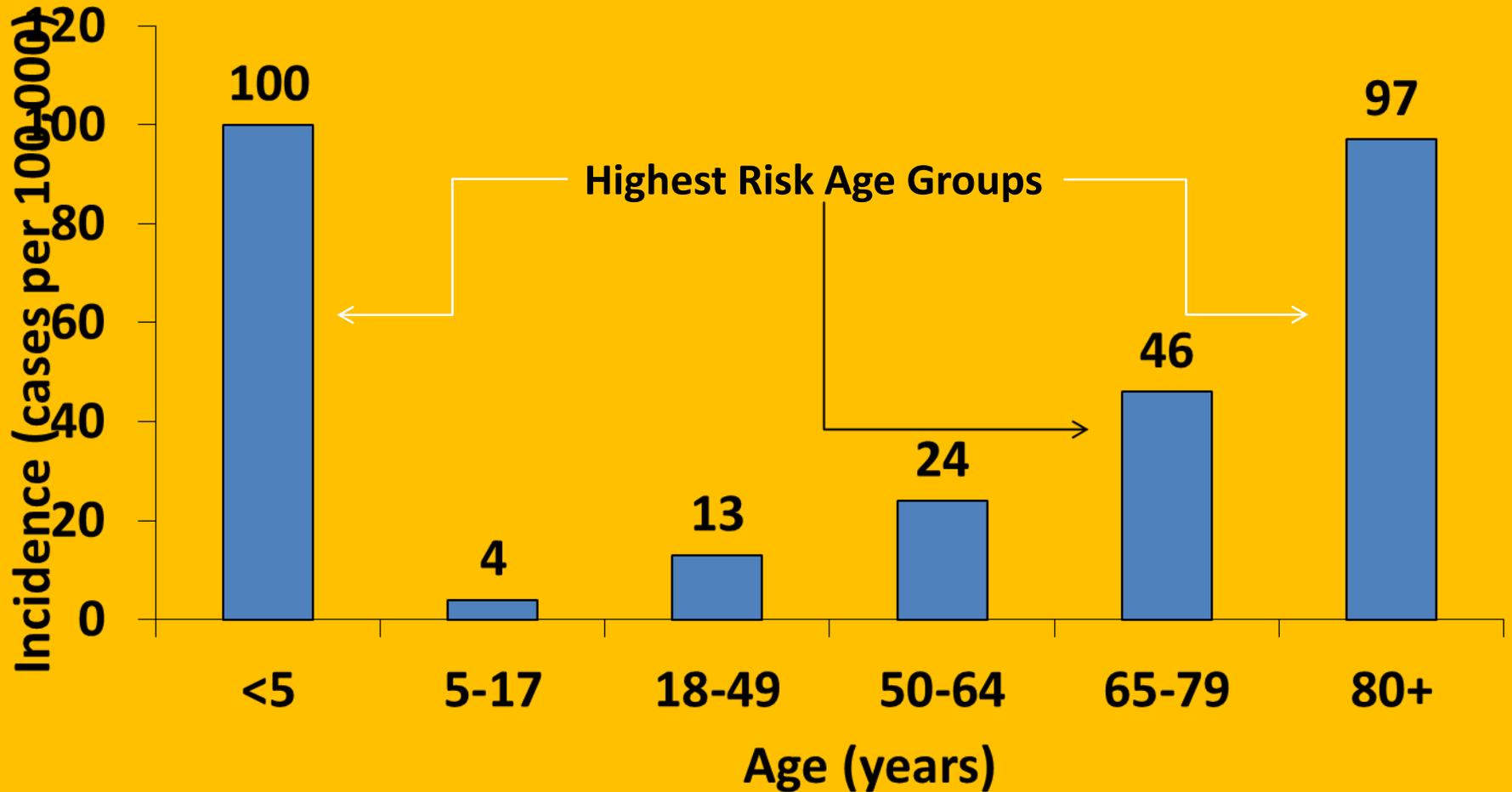
Lesson one: Unanticipated positive effects of a vaccine both in the population for which the vaccine was recommended and in the community

Pneumococcal Vaccine Use in Children

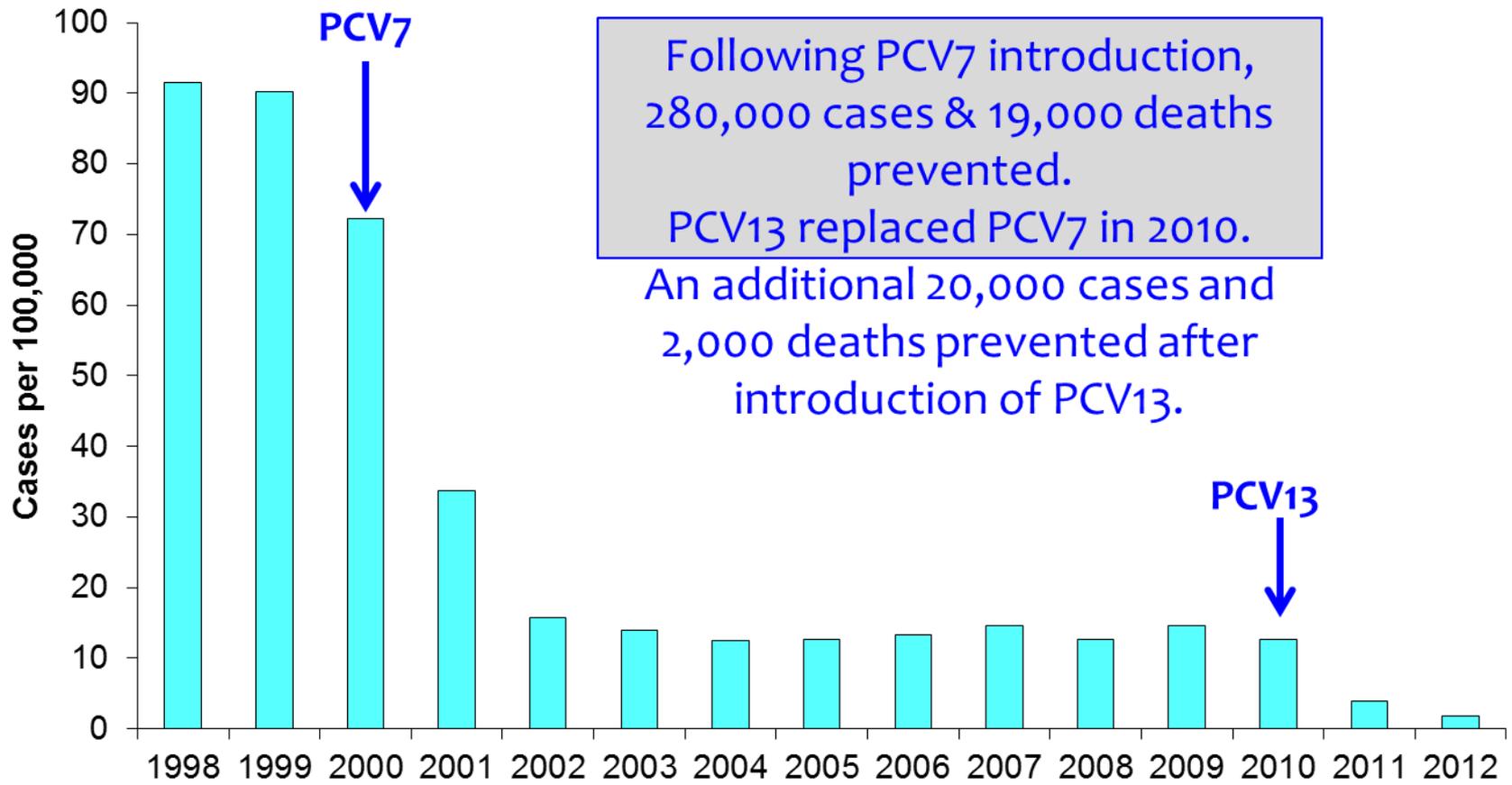
Rotavirus vaccine use in infants prevents seizures and hospitalizations

HPV vaccine in females protects

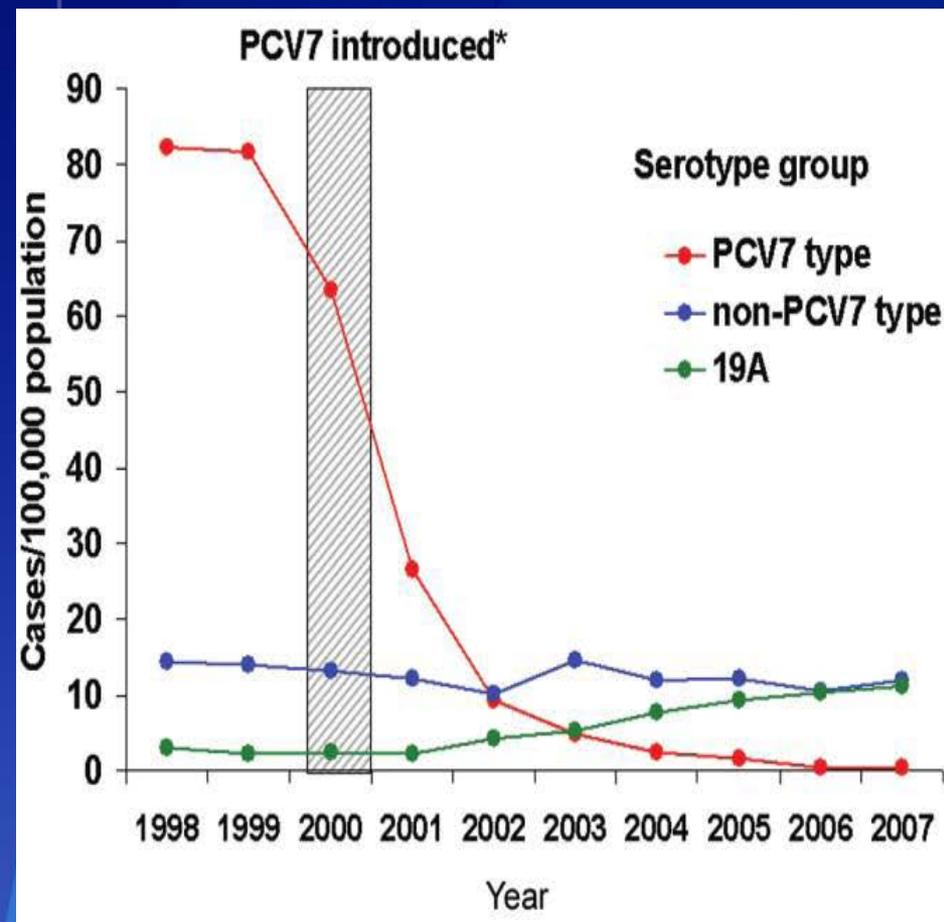
# Age-Specific Incidence of Invasive Pneumococcal Disease, US, 1998



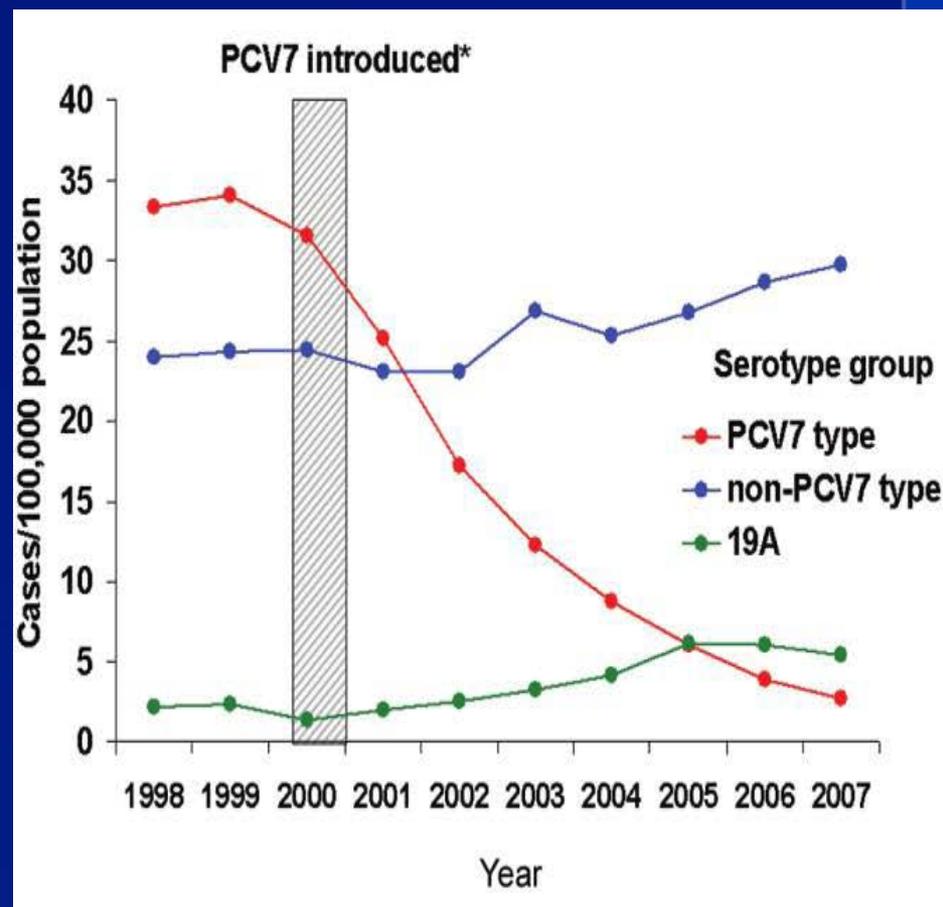
# Summary Impact of PCV7 and PCV13 Introduction, 1998-



# Impact of 7-valent Pneumococcal Conjugate Vaccine on Rate of Invasive Pneumococcal Disease, United States



**Less than 5 years**



**Over 65 years**

# Trends in Rate of Seizure-Associated Hospitalizations Among Children <5 Years Old Before and After Rotavirus Vaccine Introduction in the United States, 2000-2013.

Pringle KD<sup>1,2</sup>, Burke RM<sup>1,2</sup>, Steiner CA<sup>3</sup>, Parashar UD<sup>1</sup>, Tate JE<sup>1</sup>.

## Author information

### Abstract

**BACKGROUND:** Rotavirus is a common cause of acute gastroenteritis and has also been associated with generalized tonic-clonic afebrile seizures. Since rotavirus vaccine introduction, hospitalizations for treatment of acute gastroenteritis have decreased. We assess whether there has been an associated decrease in seizure-associated hospitalizations.

**METHODS:** We used discharge codes to abstract data on seizure hospitalizations among children <5 years old from the State Inpatient Databases of the Healthcare Cost and Utilization Project. We compared seizure hospitalization rates before and after vaccine introduction, using Poisson regression, stratifying by age and by month and year of admission. We performed a time-series analysis with negative binomial models, constructed using prevaccine data from 2000 to 2006 and controlling for admission month and year.

**RESULTS:** We examined 962899 seizure hospitalizations among children <5 years old during 2000-2013. Seizure rates after vaccine introduction were lower than those before vaccine introduction by 1%-8%, and rate ratios decreased over time. Time-series analyses demonstrated a decrease in the number of seizure-coded hospitalizations in 2012 and 2013, with notable decreases in children 12-17 months and 18-23 months.

# Three Rotavirus Outbreaks in the Postvaccine Era – California, 2017

*Weekly* / April 27, 2018 / 67(16);470-472

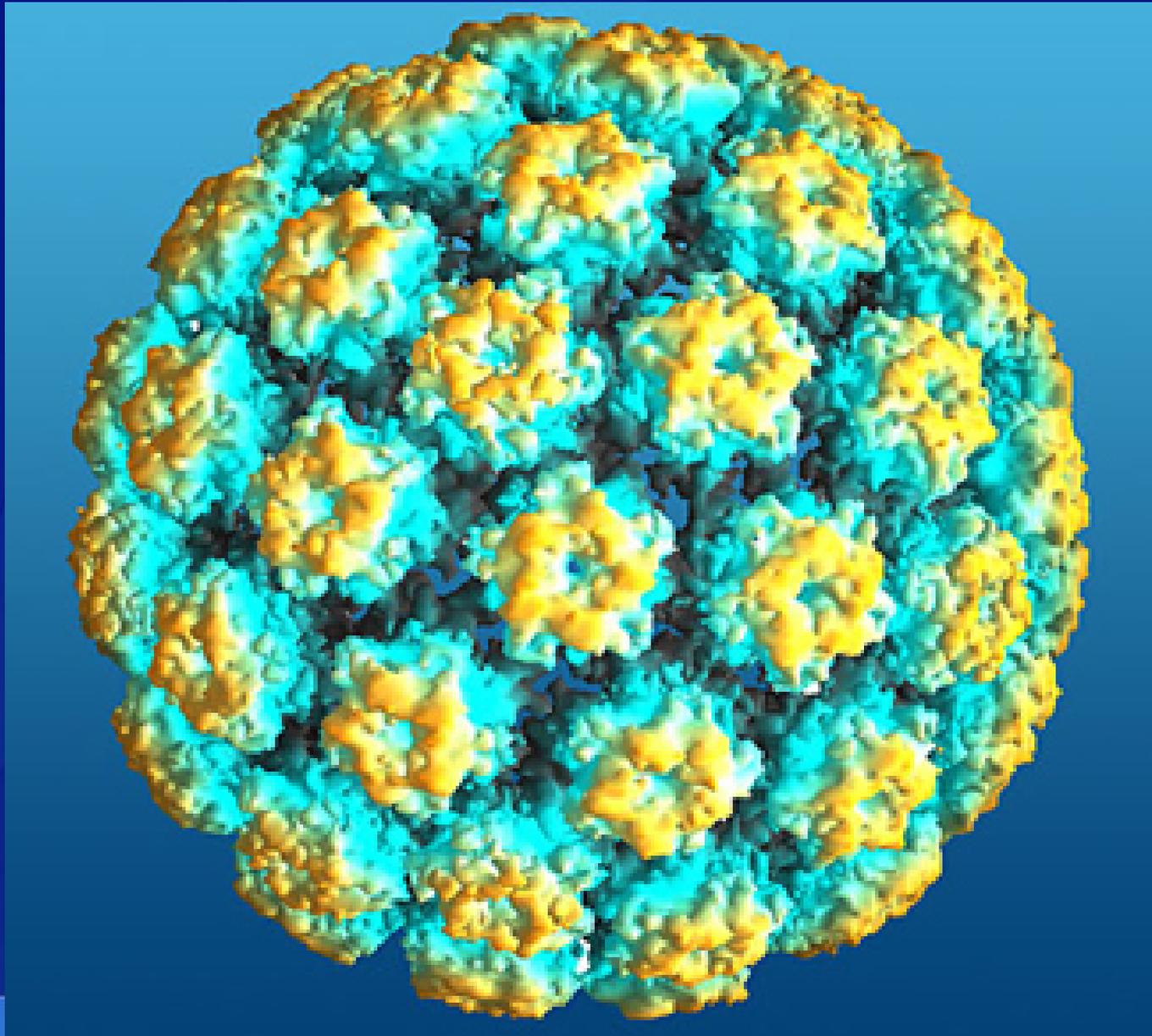


Rachel M. Burke, PhD<sup>1,2</sup>; Jacqueline E. Tate, PhD<sup>1</sup>; Nora Barin, MPH<sup>3</sup>; Carly Bock<sup>4</sup>; Michael D. Bowen, PhD<sup>1</sup>; David Chang, MD<sup>4</sup>; Rashi Gautam, PhD<sup>1</sup>; George Han, MD<sup>5</sup>; John Holguin, MPH<sup>3</sup>; Thalia Huynh<sup>6</sup>; Chao-Yang Pan, MPH<sup>6</sup>; Rebecca Quenelle, MPH<sup>5</sup>; Catherine Sallenave, MD<sup>4</sup>; Cindy Torres<sup>3</sup>; Debra Wadford, PhD<sup>6</sup>; Umesh Parashar, MBBS<sup>1</sup> ([View author affiliations](#))

[View suggested citation](#)

Before the introduction of rotavirus vaccine in 2006, rotavirus was the most common cause of severe diarrhea among U.S. children (1). Currently, two rotavirus vaccines are licensed for use in the United States, both of which have demonstrated good field effectiveness (78%–89%) against moderate to severe rotavirus illness (2), and the use of these vaccines has substantially reduced the prevalence of rotavirus in the United States (3). However, the most recent national vaccine coverage estimates indicate lower full rotavirus vaccine-series completion (73%) compared with

# Human Papillomavirus (HPV)



Lesson: Unanticipated positive effects of a vaccine both in the population for which the vaccine was recommended and in the community

HPV vaccine use in females protects males

## Population-Level Herd Protection of Males From a Female Human Papillomavirus Vaccination Program: Evidence from Australian Serosurveillance.

Pillsbury AJ<sup>1</sup>, Quinn HE<sup>1,2</sup>, Evans TD<sup>3</sup>, McIntyre PB<sup>1,2</sup>, Brotherton JML<sup>4,5</sup>.

### + Author information

#### Abstract

**BACKGROUND:** Australia instituted funded female human papillomavirus (HPV) immunization in 2007, followed by a targeted male vaccination program in 2013. To date, Australia is one of only several countries with a funded male HPV immunization program. In 2012-2013, we conducted a survey of HPV seroprevalence in males to assess whether or not a herd impact of female vaccination could be observed.

**METHODS:** We conducted a cross-sectional study of de-identified residual diagnostic test serum samples from males aged 15-39 years from laboratories in 3 Australian states and calculated the proportion seropositive to HPV types 6, 11, 16, and 18. We compared type-specific results by age group against those from a baseline 2005 Australian HPV serosurvey.

**RESULTS:** There were decreases in proportion seropositive for every HPV type across all age groups, many statistically significant. The largest decrease was observed for HPV-11, with decreases of 8- and 9-fold for ages 20-29 and 30-39 years, respectively. Despite substantial reductions in seroprevalence, at least 9% of males were seropositive for at least 1 of the 4 HPV types.

**CONCLUSIONS:** This is the first serosurvey confirming broad population-level impact in males from female HPV vaccination. Our research may assist policy makers considering implementing HPV vaccination programs.

# Objective Four

- ❑ **Stress the importance of herd protection (community immunity)**



# Herd Protection

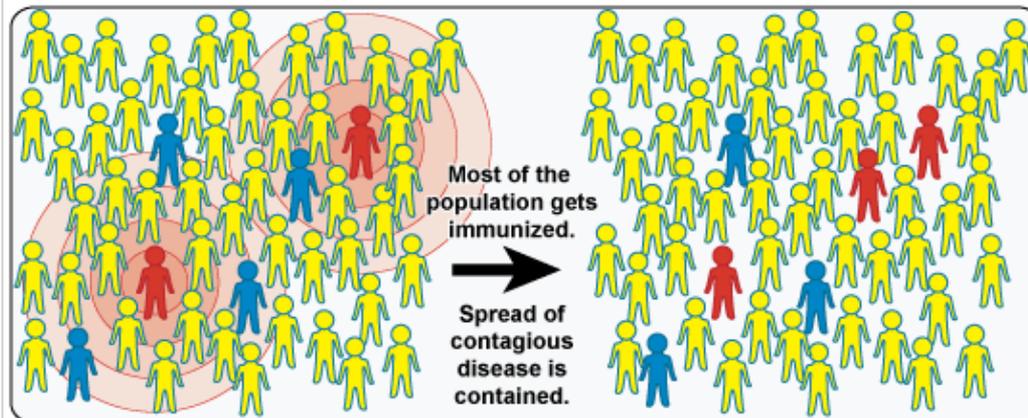
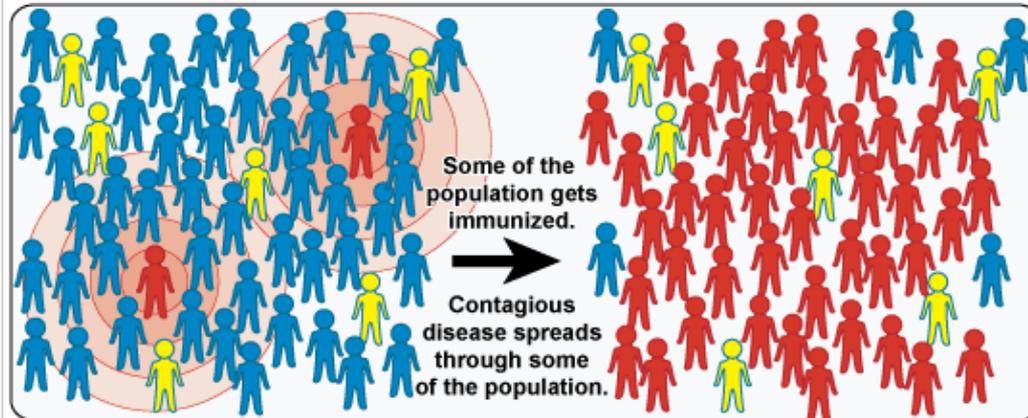
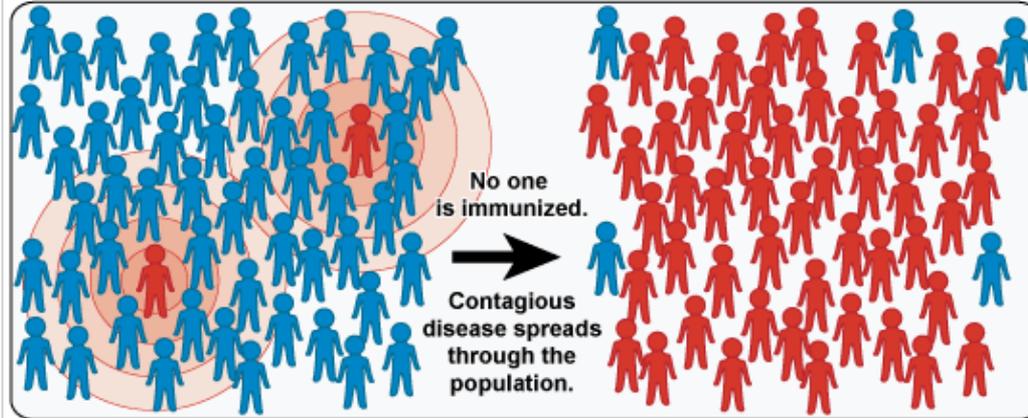
# History and Definition

- Herd “immunity” initially discussed around 1923
- Term not used widely until recent decades, stimulated by increasing use of vaccines, discussion of disease eradication and analyses of costs and benefits
- Herd immunity vs herd protection: herd immunity is not the same as biologic (immunologic) immunity
- Common theme of the term: Risk of infection among susceptible people in a population is reduced by the presence and proximity of immune people

 = not immunized but still healthy

 = immunized and healthy

 = not immunized, sick, and contagious



# Basic reproductive number

- The number of cases one case generates on average over the course of its infection period in an otherwise uninfected period.

Approximate Basic Reproduction Numbers (in Developed Countries) and implied crude herd immunity thresholds (H, Calculated as  $(1-1/R_0)$ ) for common vaccine-preventable diseases

Infection	Basic Reproduction Number ( $R_0$ )	Crude Herd Immunity Threshold, H (%)
Diphtheria	6-7	85
Influenza	1.4-4	30-75
Measles	12-18	92-94
Mumps	4-7	75-86
Pertussis	12-17	92-94
Polio	2-15	50-93
Rubella	6-7	83-85
Smallpox	5-7	80-85
Tetanus	Not applicable	Not applicable
Tuberculosis	?	?
Varicella	8-10	?

# Vaccine Preventable Diseases in the News

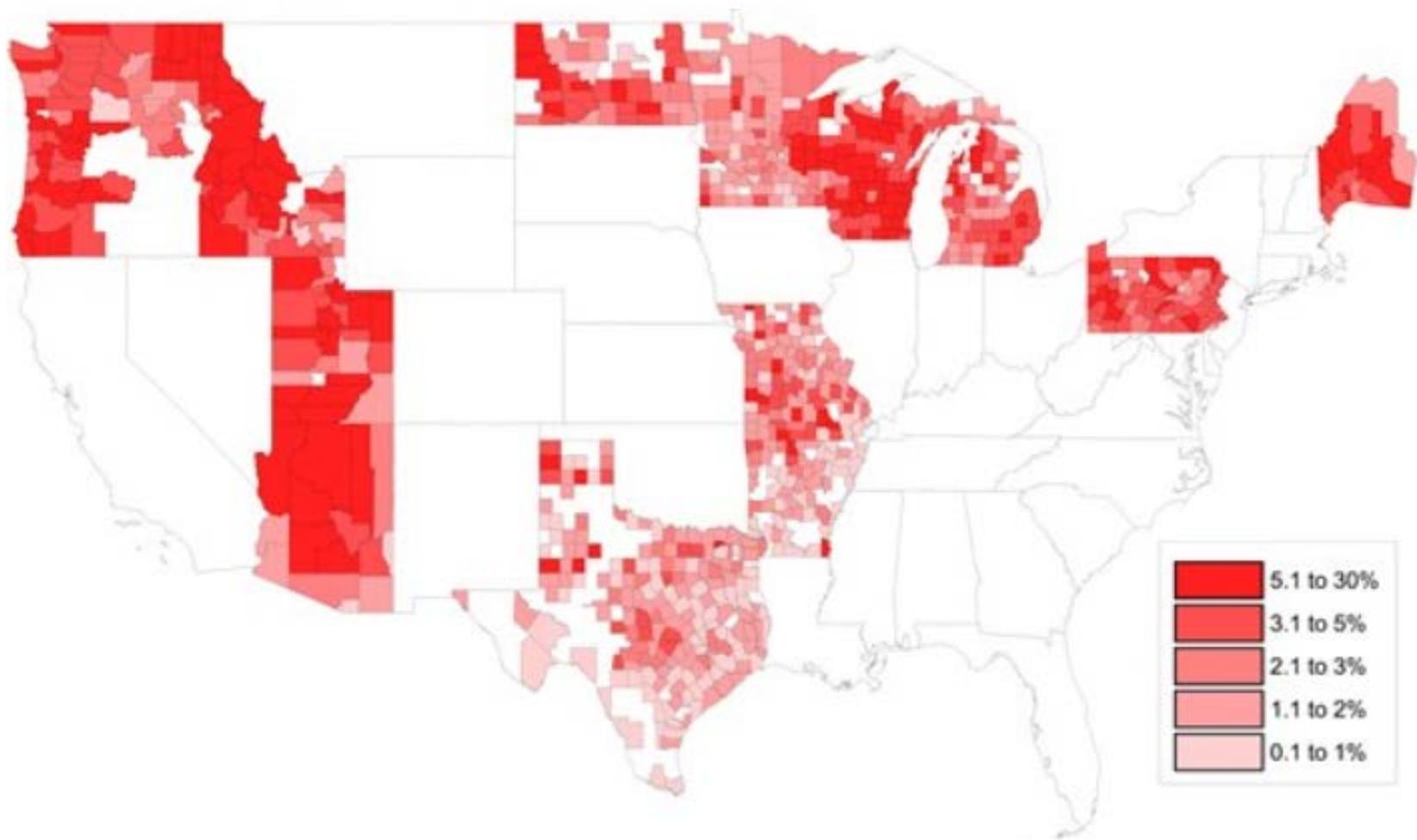
**2) "New Jersey alerts residents of suspected measles exposure" The Trentonian (NJ) (July 4, 2018) - "The New Jersey Department of Health is warning residents about an individual suspected of having measles who might have exposed others while in Burlington and Camden counties. This person developed symptoms after being exposed to another individual who acquired measles while traveling internationally... "It is critical that New Jersey residents and visitors are up to date on their vaccinations to avoid the possibility of becoming ill with measles," New Jersey Health Commissioner Dr. Shereef Elnahal said in a written statement."**

<http://www.trentonian.com/article/TT/20180704/NEWS/180709915>

**4) "Houston Has a Worryingly High Vaccination Opt-Out Rate" Houstonia Magazine (TX) (July 4, 2018) - "Today most children are still required to meet school immunization requirements by getting vaccinated for diseases such as tetanus, the measles, and the flu, a stipulation that has been found to help maintain the herd immunity in large populations. Ever since Texas became one of 18 states that allows parents to say "no thanks" to vaccination for either religious or philosophical reasons, the number of unvaccinated children in the schools-a prime location to pass around germs-has steadily grown, from around 2,000 in the state in 2003 to more than 44,000 in 2016, according to the Texas Department of State Health Services."**

# Infectious Diseases in the News

- ❑ Mumps continues to spread in Delaware
- ❑ Hepatitis A in AR, TN, KY
- ❑ New York's largest measles outbreak
- ❑ Pertussis outbreak in Alabama
- ❑ Hepatitis A in frozen strawberries
- ❑ Measles in a KC elementary school
- ❑ Mumps at Univ. Cincinnati
- ❑ Norovirus outbreak in NC



—— Heat map of county-level non medical exemption rates in 2016 to 2017.

Olive et al / Baylor College of Medicine

3) **"EDITORIAL: Lawmakers must close loophole on vaccination"** Longview News-Journal (TX) (June 17, 2018) - "Since 2003, Texas law has made it possible for parents to enroll unvaccinated children into school under a "conscientious exemption" for personal or religious reasons. And that, according to a new study by the Baylor College of Medicine in Houston, is making Texas a hot spot for possibility of outbreaks of disease."

[https://www.news-journal.com/opinion/editorial-lawmakers-must-close-loophole-on-vaccination/article\\_4e020966-7199-11e8-842f-a3bf70555388.html](https://www.news-journal.com/opinion/editorial-lawmakers-must-close-loophole-on-vaccination/article_4e020966-7199-11e8-842f-a3bf70555388.html)

# Objective Five

- Review recent vaccine recommendations made or to be considered by ACIP
-

**Final - June 13, 2018**

**MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)**

Centers for Disease Control and Prevention

1600 Clifton Road, NE, Tom Harkin Global Communications Center, Kent "Oz" Nelson Auditorium

Atlanta, Georgia 30329

June 20-21, 2018

<u>AGENDA ITEM</u>	<u>PURPOSE</u>	<u>PRESIDER/PRESENTER(s)</u>
<u>Wednesday, June 20</u>		
8:00 Welcome & Introductions		Dr. Nancy Bennett (ACIP Chair) Dr. Amanda Cohn (ACIP Executive Secretary; CDC)
8:30 Influenza Vaccines Introduction VE update		Dr. Chip Walter (ACIP, WG Chair) Dr. Brendan Flannery (CDC/NCIRD), Dr. Yun Lu (FDA)
2017-2018 influenza season vaccine safety update	Information	Dr. Tom Shimabukuro (CDC/NCEZID)
Narcolepsy following adjuvanted monovalent pandemic H1N1 influenza vaccines: Results of the SOMNIA study	&	Dr. Tom Shimabukuro (CDC/NCEZID)
Study results of an adjuvanted Quadrivalent Influenza vaccine in young children	Discussion	Dr. Gregg Sylvester (Seqirus)
2018-19 recommendations		Dr. Lisa Grohskopf (CDC/NCIRD)
Public Comment		
Vote	<u>Vote</u>	Dr. Lisa Grohskopf (CDC/NCIRD)
10:40 <i>Break</i>		
11:00 Anthrax Vaccines Introduction GRADE	Information	Dr. David Stephens (ACIP, WG Chair) Dr. William Bower (CDC/NCEZID)
Summary of Work Group considerations and proposed policy options	&	Dr. William Bower (CDC/NCEZID)
	Discussion	
Public comment		
Vote	<u>Vote</u>	Dr. William Bower (CDC/NCEZID)
12:15 <i>Lunch</i>		
1:30 HPV Vaccines Introduction Current issues and background HPV vaccine in mid-adults: results from clinical studies Considerations and Work Group plans	Information & Discussion	Dr. Peter Szilagyi (ACIP, WG Chair) Dr. Lauri Markowitz (CDC/NCIRD) Dr. Alain Luxembourg (Merck) ACIP HPV Vaccines Workgroup
2:40 Update on NITAGS Introduction Global NITAG activities and the GNN	Information	Dr. Abigail Shefer (CDC/GID) Dr. Joachim Hombach (Executive Secretary SAGE, WHO IVB)
3:10 <i>Break</i>		
3:40 Mumps Vaccine Introduction Current US mumps epidemiology and CDC guidance for implementation of the ACIP recommendation for a 3rd dose of MMR vaccine during outbreaks	Information & Discussion	Dr. Kelly Moore (ACIP, WG Chair) Dr. Mariel Marlow (CDC/NCIRD)
4:10 Zoster Vaccine Introduction Herpes Zoster vaccination: evaluation update	Information	Dr. Edward Belongia (ACIP, WG Chair) Dr. Kathleen Dooling (CDC/NCIRD)
4:35 Public Comment		
4:50 Adjourn		

# June 20-21, 2018 ACIP Meeting

- **Votes:** influenza and anthrax
- **Discussion:**
- HPV vaccine
- Mumps vaccine
- Zoster vaccine
- Japanese encephalitis vaccine
- Pneumococcal vaccines

# Objective

## Highlights of the ACIP Website

<https://www.cdc.gov/vaccines/acip/index.html>

# ACIP Vaccine Recommendations

- On the ACIP web site recommendations are provided by organism and by year published in MMWR
- [www.cdc.gov/vaccines/acip/index.html](http://www.cdc.gov/vaccines/acip/index.html) then go to vaccine recommendations

# ACIP Vaccine Recommendations and Guidelines

Advisory Committee on Immunization Practices (ACIP)



## Vaccine-Specific ACIP Recommendations

Anthrax

BCG

Cholera

DTaP

Hepatitis A

Hepatitis B **UPDATED**

Hib

HPV

Influenza

Japanese Encephalitis

Measles, Mumps and Rubella **UPDATED**

MMRV

Meningococcal

Pneumococcal

Polio

Rabies

Rotavirus

Smallpox (Vaccinia)

Tdap/Td

Typhoid

Varicella (Chickenpox)

Yellow Fever

Zoster (Shingles) **UPDATED**

# Vaccine Recommendations and Guidelines of the ACIP

ACIP Recs Home

Vaccine-Specific  
Recommendations



Recs Listed by Date

Comprehensive  
Recommendations and  
Guidelines



Archived ACIP Recs

Vaccine Recommendations  
for Emergency Situations

[CDC](#) > [ACIP Recs Home](#)

## Vaccine-Specific Recommendations (by Date Published)

Advisory Committee on Immunization Practices (ACIP)



Consult the [ACIP Recommendations](#) page for a complete list of Morbidity and Mortality Weekly Reports (MMWR) on Recommendations of the Advisory Committee on Immunization Practices (ACIP) related to vaccines and immunizations.

Links to final CDC vaccination recommendations (published in MMWR) from Advisory Committee on Immunization Practices (ACIP)

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# Register for a Meeting



## Registration for the ACIP meeting of October 24-25, 2018

In order to attend the ACIP meeting at CDC's Clifton Road campus, ACIP attendees (participants and visitors) must register online. The week prior to the meeting you will receive a placard for your vehicle (parking tag) and instructions for navigating the secure CDC environment to attend the ACIP meeting.

- **Meeting Location:**

Tom Harkin Global Communication Center

(Building 19), Room 232

Kent "Oz" Nelson Auditorium

Centers for Disease Control and Prevention

1600 Clifton Road, NE

Atlanta, Georgia 30329-4027

- [Meeting Registration](#) (U.S. citizens AND non-U.S. citizens)

**Deadline for meeting registration:**

**Non-US Citizens: September 26, 2018**



# Conclusions I

- ACIP is the center of vaccine policy in the U.S.
- Recommendations have the force of law, mandate that the vaccines are provided at no cost to any child, set the medical/clinical standard of care in the U.S., and fit into a larger governmental advisory committee structure
- FDA states what vaccines can be used, but the ACIP recommends how, when, and why to use them
- CDC scientists and ACIP work groups have critical roles in summarizing scientific evidence to help ACIP in its deliberations

# Conclusions II

- Routine immunizations provide a tremendous benefit to infants, children, adolescents, adults and society
- Immunization is a shared public / private responsibility
- During visits, vaccines and other evidence-based preventive services should be provided
- Continue monitoring adolescent vaccination coverage among different groups to assess coverage by race/ethnicity and other sociodemographic factors to identify barriers
- Every day, 11,000 births occur in the U.S.

A young girl with long brown hair, wearing a white dress with small yellow and red floral patterns, stands on a sandy beach. She is holding a long, white, sheer fabric aloft with both hands, and it is blowing in the wind. The background features a blue sky with scattered white clouds, a dark blue ocean with white-capped waves, and green beach grasses in the foreground. The overall scene is bright and sunny.

**The End**