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hosted by the Missouri Department of Health and Senior Services' Bureau of Immunization Assessment and Assurance
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webinar series

William Atkinson, MD, MPH
Pertussis: Importance of and
Scheduling the 4th Dose
March 19, 2015

Updates from the February 2015 ACIP meeting

- **Live Attenuated Influenza Vaccine (LAIV)
preference for 2 through 8 year-olds**
- **Meningococcal serogroup B vaccines**
- **9-valent HPV vaccine**
- **Yellow fever vaccine**
 - **“A single lifetime dose provides long-lasting
protection and is adequate for most travelers”**

LAIV Preference, 2014-2015

- **When immediately available, LAIV should be used for healthy children age 2 through 8 years who have no contraindications or precautions**
- **If LAIV is not immediately available, IIV should be used**
- **Vaccination should not be delayed to procure LAIV**

Influenza Vaccine Effectiveness

- **Studies conducted by CDC and MedImmune during the 2013-2014 influenza season found good efficacy against influenza B but little or no efficacy against influenza A H1N1**
- **MedImmune found efficacy lower for lots shipped in late summer – possible temperature effect on vaccine**
- **Interim VE estimates for 2014-2015 found no efficacy for LAIV or IIV**

LAIV – No Preference, 2015-2016

- **Recommendation approved at the February 2015 ACIP meeting:**
 - For healthy children aged 2 through 8 years who have no contraindications or precautions either LAIV or IIV is an appropriate option
 - No preference is expressed for LAIV or IIV for any person aged 2 through 49 years for whom either vaccine is appropriate

Meningococcal Serogroup B Vaccines

- **rLP2086 (Trumenba, Pfizer)**
 - Licensed by FDA on October 29, 2014
 - Approved for 10 through 25 years of age
 - 3 dose series (0, 2, 6 months)
- **4CMenB (Bexsero, Novartis)**
 - Licensed by FDA on January 23, 2015
 - Approved for 10 through 25 years of age
 - 2 dose series (0, 1 months)

ACIP Recommendations for Meningococcal B Vaccine

- Recommendation approved at the February 2015 ACIP meeting
- A serogroup B meningococcal vaccine [series] should be administered to persons aged 10 years and older at increased risk for meningococcal disease
 - persistent complement component deficiency
 - anatomic or functional asplenia
 - risk in a serogroup B meningococcal disease outbreak
 - certain microbiologists
- Will be included in VFC

ACIP Recommendations for Meningococcal B Vaccine

- **ACIP will consider a permissive (Category B) recommendation to vaccinate a larger population at their June 2015 meeting**
 - All adolescents (to align the MenB recommendations with those for MenACWY)?
 - College students?

9-Valent HPV Vaccine

- **9vHPV licensed by FDA on December 10, 2014**
- **Approved for females 9 through 26 years and males 9 through 15 years**
- **Same schedule as 4vHPV**
- **Both 4vHPV and 9vHPV will be available for up to 24 months after licensure**

9vHPV ACIP Recommendations

- **Recommendation approved at the February 2015 ACIP meeting**
- **Same as the current recommendations for 4vHPV**
 - routine vaccination at 11 or 12 years of age
 - female 9 through 26, male 9 through 21, permissive through 26 (off-label for males 16 years and older)
- **Any vaccine can be used to finish an incomplete series**

9vHPV ACIP Recommendations

- Same contraindication and precautions
- Revaccination with 9vHPV for persons who already completed a series of 2vHPV or 4vHPV was not discussed and is not included in the approved recommendation
- More discussion at June 2015 meeting

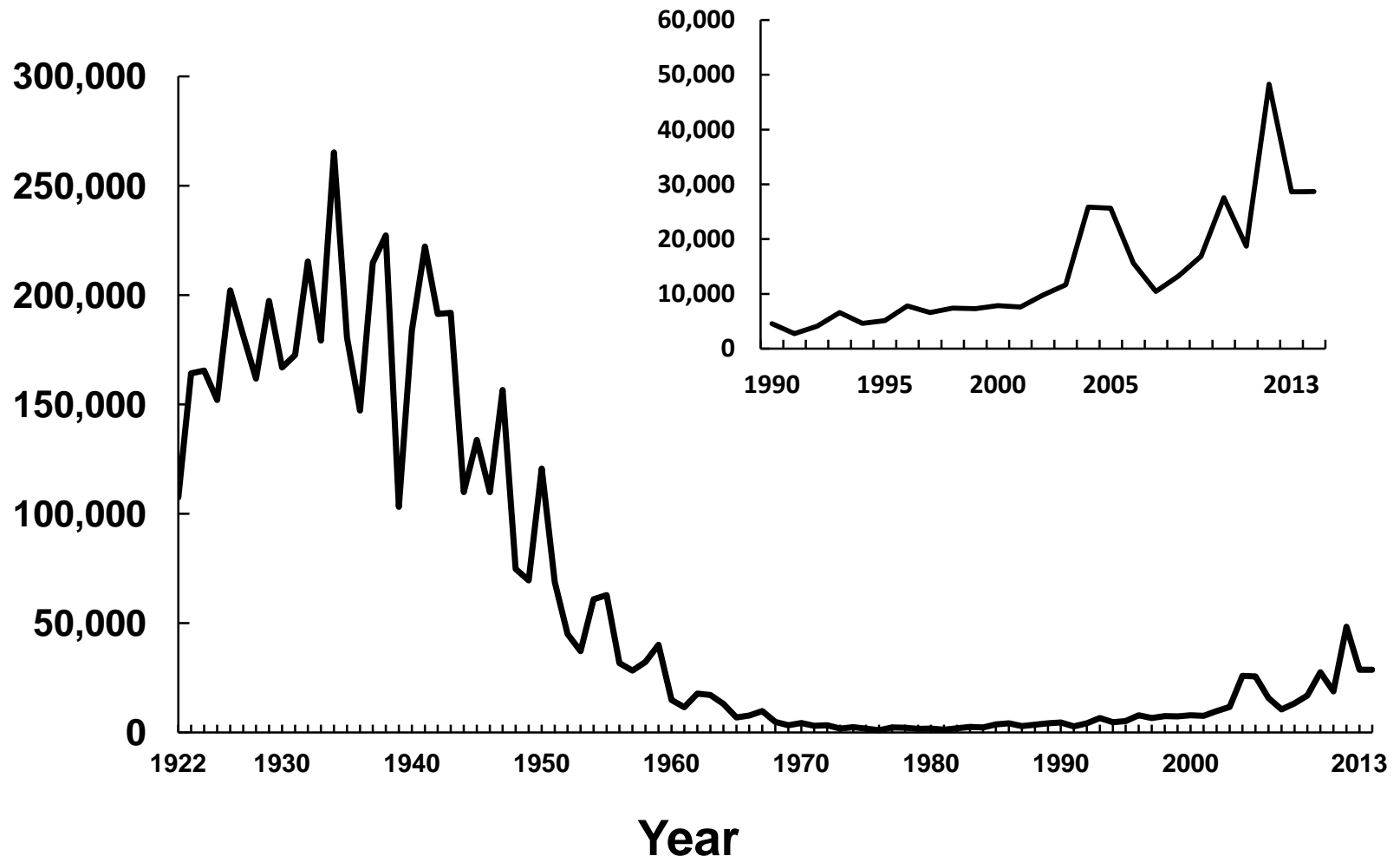
Recommendations of the Advisory Committee on Immunization Practices (ACIP)

- Recommendations approved by the Committee are just the first step
- Recommendations do not become official policy until
 - approved by the CDC Director
 - published in Morbidity and Mortality Weekly Report (MMWR)

Pertussis in the U.S. – 2013

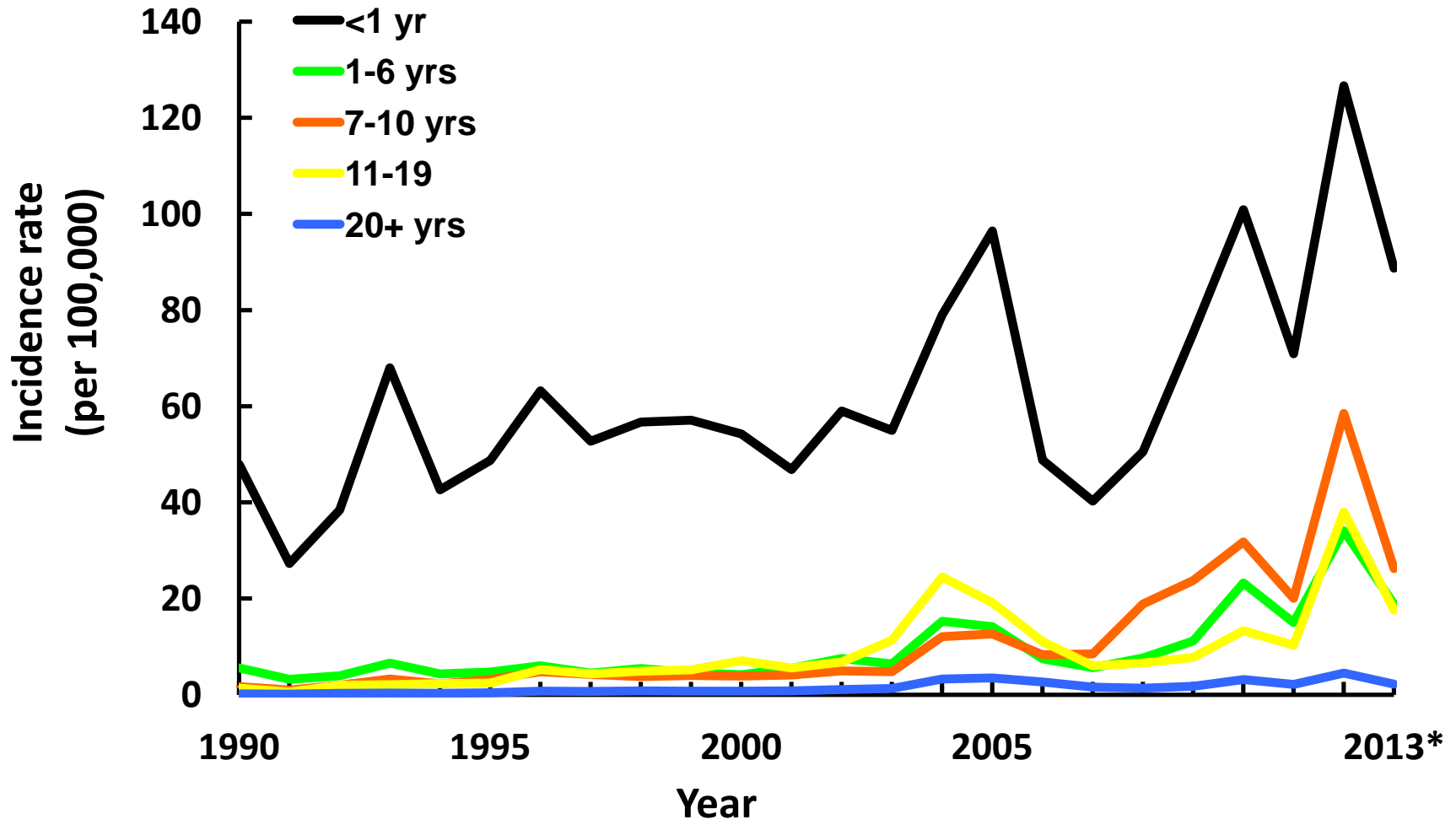
- **28,639 reported cases (559 in MO)**
- **28,660 provisional in 2014 (521 in MO)**
- **Highest incidence among infants (105/100,000), and adolescents age 7-10 years (30/100,000)**
- **9 deaths reported – all among infants less than 3 months of age)**

Reported Pertussis – United States, 1922-2014*



*2014 provisional data. SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System and 1922-1949, passive reports to the Public Health Service

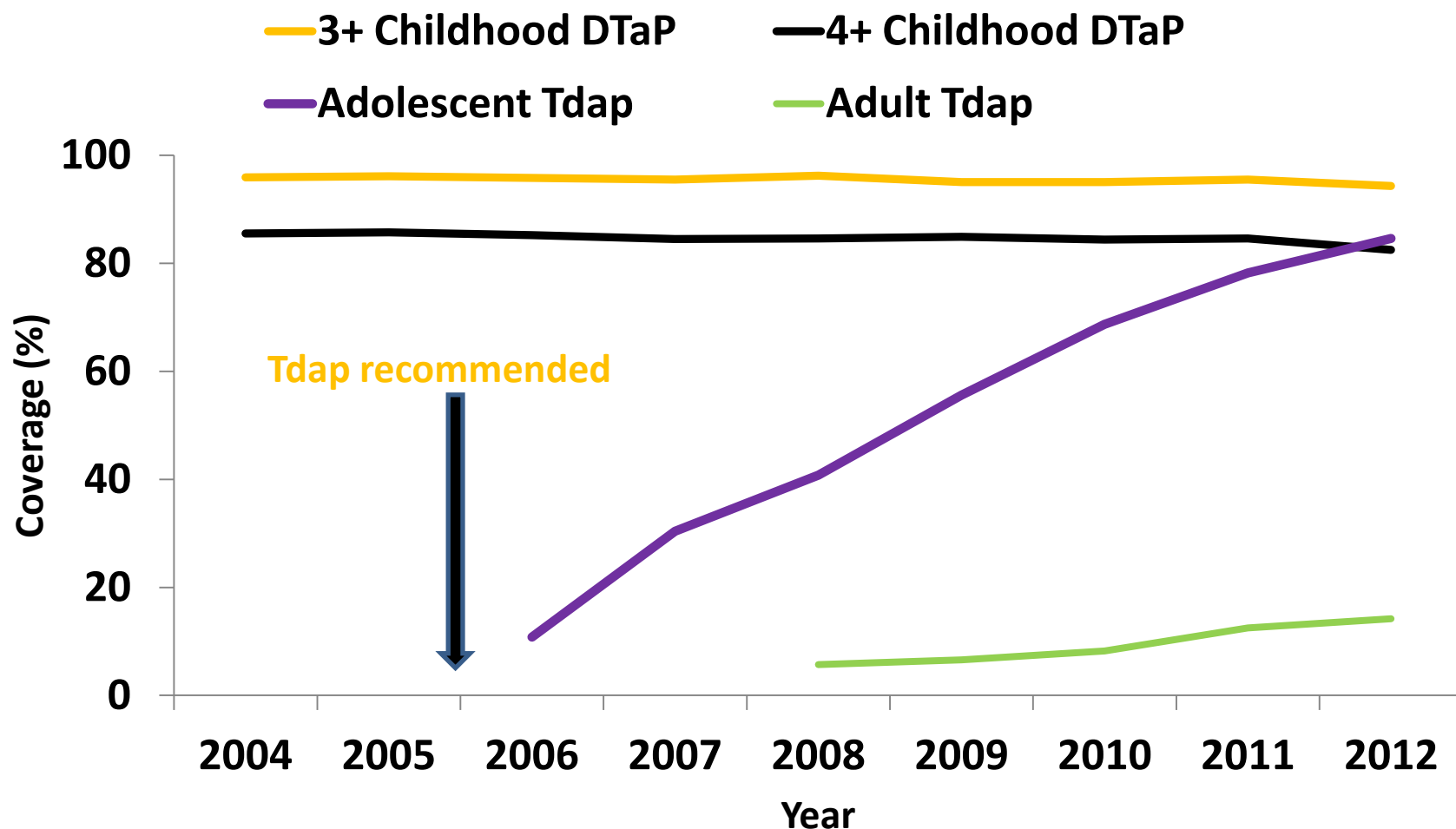
Reported Pertussis Incidence by Age Group, 1990-2013*



*2013 data are provisional.

SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System

DTaP Coverage Among Children and Tdap Coverage Among Adolescents and Adults



*CDC National Immunization Survey: DTaP among children aged 19 through 35 months , Tdap coverage among adolescents aged 13 through 17 years . Coverage among adults aged 19 through 64 years from National Health Information Survey .

DTaP Vaccine Coverage 2013*

MO

- **DTaP 3+ 92%**
- **DTaP 4+ 82%**

- **PCV13 3+ 90%**
- **PCV4+ 80%**
- **Hib FS 80%**

***among children 19-35 years of age**
National Immunization Survey
MMWR 2014;63(34):741-8

DTaP Vaccine Coverage 2013*

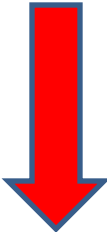
	MO	US
• DTaP 3+	92%	94%
• DTaP 4+	82%	83%
• PCV13 3+	90%	92%
• PCV4+	80%	82%
• Hib FS	80%	82%

*among children 19-35 years of age
National Immunization Survey
MMWR 2014;63(34):741-8

Routine DTaP Primary Vaccination Schedule

Dose	Age	Minimum Interval
Primary 1	2 months	---
Primary 2	4 months	4 wks
Primary 3	6 months	4 wks
Primary 4	15-18 months	6 mos
Boost	4-6 years	6 mos

Routine DTaP Primary Vaccination Schedule

Dose	Age	Minimum Interval
Primary 1	2 months	---
Primary 2	4 months	4 wks
Primary 3	6 months	4 wks
Primary 4		
Boost	4-6 years	6 mos

Fourth Dose of DTaP

- **NOT** an optional dose-integral to the primary series
- **Recommended at 15-18 months**
- **May be given at 12 months of age if:**
 - child is 12 months of age, and
 - 6 months since DTaP3, and
 - unlikely to return at 15-18 months
- **Incompletely vaccinated children may be more likely to become infected with *B. pertussis* and transmit to household contacts, including young infants**

DTaP Vaccine Efficacy

- **Trials conducted Europe in the early 1990s**
- **Used a variety of designs, case definitions and controls**
- **Generally measured VE after 3 or 4 doses**
 - Infanrix (3 doses) – 89% (77%-95%)
 - Tripedia (3 doses) – 93% (63%-99%)
- **Duration of follow-up usually less than 2 years**

Plotkin et al, Vaccines, 6th edition, 2013

TABLE 5. Distribution of 3 or 4 Valid DTP and DTaP Doses and VE, Compared With No Vaccination

	No. (%)		VE, %	95% CI
	Case Subjects	Control Subjects		
Only 3 valid doses	N = 47	N = 297		
All DTP	8 (17)	53 (18)	95.5	87.3–98.4
Mixture of DTP and DTaP	5 (11)	26 (9)	94.5	81.1–98.4
All DTaP	34 (72)	210 (71)	95.4	88.7–98.2
Unknown	0	8 (3)		
Only 4 valid doses	N = 63	N = 495		
All DTP	25 (40)	160 (32)	96.7	91.9–98.7
Mixture of DTP and DTaP*	17 (27)	190 (38)	98.0	95.0–99.2
All DTaP	20 (32)	126 (25)	96.7	90.8–98.8
Unknown	1 (1)	19† (4)		

* Of mixtures, 81% were 3 DTP doses (doses 1–3) and 1 DTaP dose (dose 4).

† Sixteen (84%) of 19 control children received 3 DTP doses (doses 1–3) and 1 unknown dose.

Bisgard et al, Pediatrics 2005;116:e285-e294

DTaP Vaccine Efficacy

- Observations in recent years indicates that the duration of immunity following pertussis vaccination is probably less than 10 years
- Duration of immunity is less durable for acellular vaccines than for whole cell vaccines
- Duration of immunity falls progressively after the last dose

Plotkin et al, Vaccines, 6th edition, 2013

DTaP VE and Duration of Protection Estimates— California, 2010

Model	Case (n)	Control (n)	VE, %	95% CI
Overall VE, All Ages				
0 dose	53	19	Ref	--
5 doses	629	1,997	88.7	79.4 – 93.8
Time since 5th dose				
0 doses	53	19	Ref	--
< 12 months	19	354	98.1	96.1 – 99.1
12 – 23 months	51	391	95.3	91.2 – 97.5
24 – 35 months	79	366	92.3	86.6 – 95.5
36 – 47 months	108	304	87.3	76.2 – 93.2
48 – 59 months	141	294	82.8	68.7 – 90.6
60+ months	231	288	71.2	45.8 – 84.8

DTaP4- The Australian Experience

- **Australia stopped recommending DTaP4 (at 18 months) in 2003**
- **During 2006-2012 the average annual notification rate for pertussis increased 280%**
- **Waning pertussis immunity may have contributed to this increase**
- **Australia is now reinstating the 18 month dose of DTaP**

Pertussis Vaccination – Bottom Line

- **DTaP provides good protection at least in the months following vaccination**
- **Immunity wanes following the last dose**
- **The 4th dose is important to bridge the 3 year gap between the third and fifth dose**
- **Pertussis risk increases if the 4th dose is missed**

Why Does Coverage Fall For The Full Series?

- In 2012 and 2013, coverage for DTaP4+, PCV4+, and the full series of Hib remained at similar levels (81%–83%)
- These vaccines require a booster dose during the second year of life, when the opportunities for catch-up doses with these vaccines are fewer because of declining frequency of well-child visits.

MMWR 2014;63(34):741-8

Why Does Coverage Fall For The Full Series?

- **Patients do not return**
 - don't know they were supposed to come back
 - knew but forgot, too busy, no appointment, other reasons
- **Patients return but**
 - insufficient interval since prior dose (not eligible for the dose)
 - vaccines not offered
 - vaccines offered but refused

Recommendations and Reinforcement

- **For all: reinforce the need to return**
 - verbal
 - written reminder
 - link to calendar event
- **For those who return: recommend the vaccine**
 - clinician recommendation is a powerful motivator
 - likely to follow recommendation of the provider

Missed Opportunity

A health care encounter in which a person is eligible to receive vaccination but is not vaccinated completely

Causes of Missed Opportunities

- Lack of simultaneous administration
- Unaware child needs additional vaccines
- Invalid contraindications
- Avoidance of accelerated schedule
- Inappropriate clinic policies

How To Improve Full Series Coverage

- **CDC recommends the use of clinician and system-based interventions to increase opportunities for vaccination, including**
 - use of immunization information systems (IIS)
 - clinician assessment and feedback
 - clinician reminders
 - standing orders

MMWR 2014;63(34):741-8

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This section contains information on the Missouri immunization registry. Missouri's immunization registry, ShowMeVax, offers health care professionals, schools and child care organizations a one-stop shop for tracking an individual's immunization history and status and allows providers to monitor vaccine inventory. To learn how to gain access to ShowMeVax, contact the help desk at 877.813.0933 or showmevaxsupport@health.mo.gov.

Release Notes 

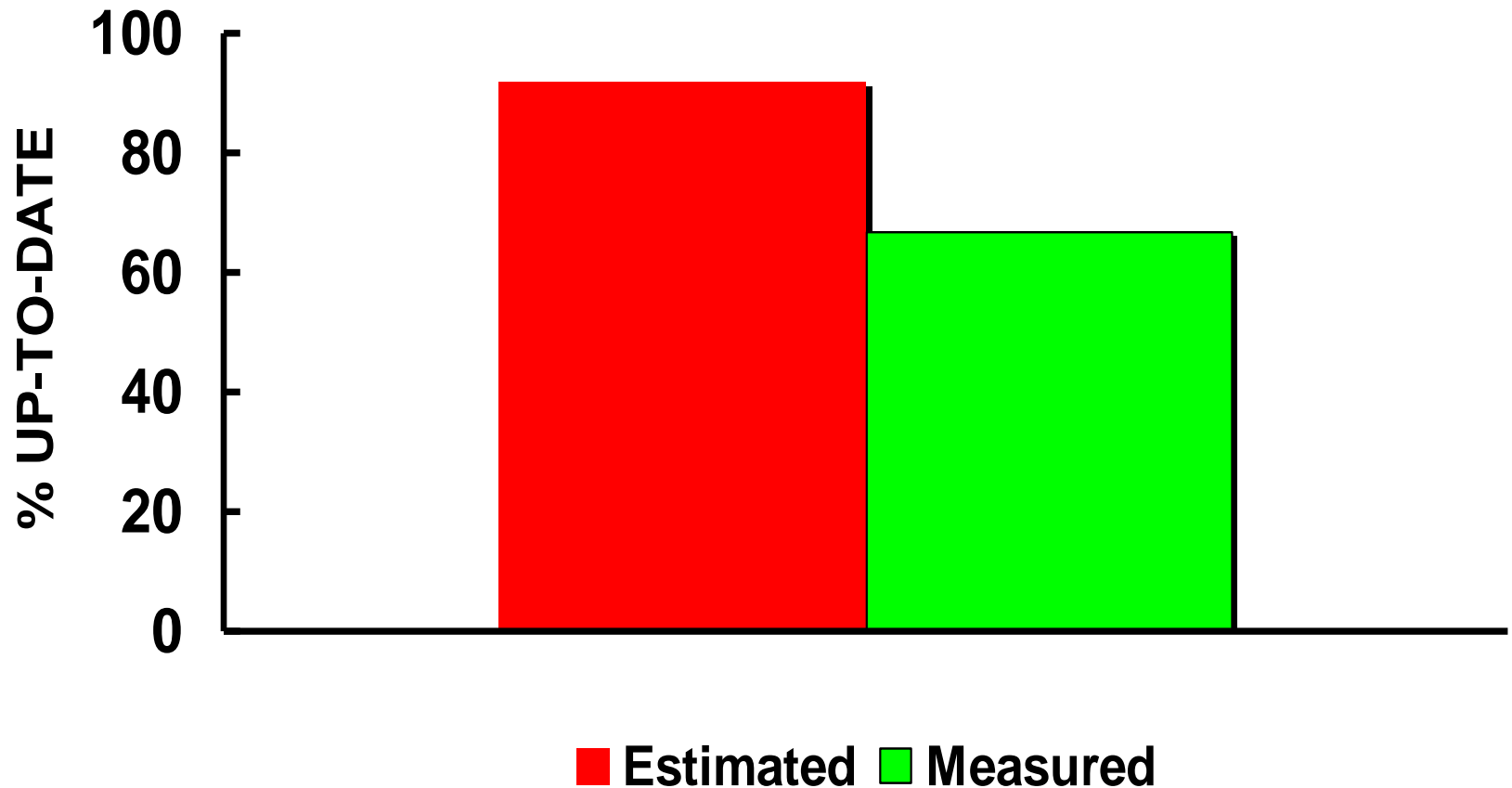
<http://health.mo.gov/living/wellness/immunizations/>

You Cannot Fix What You Do Not Recognize as a Problem

- **Immunization providers often do not know the vaccination levels in their practices**
- **Providers overestimate coverage in their office by 10% or more**
- **Knowledge of actual vaccination coverage level leads to positive interventions**

Bordeley et al. Pediatrics 1996;97:467-73

Physician-Estimated vs Measured Performance of 45 Practices



Smith N, Watt J, et al. Presented before Pediatric Academic Societies Meeting, 1999

Office Coverage Assessment and Feedback

- Immunization level in your practice is determined by reviewing a sample of charts
- Provides helpful diagnostic information
 - is your coverage as high as you think it is?
 - what can you do to improve your practice?

Reminder and Recall Systems

- Reminders inform that vaccines are due
- Recalls inform that vaccines are overdue
- Do not need to be computerized or complicated
 - post card, telephone, autodialer
 - centralized registry
- Reminder/recall conducted in practice settings shown to increase rates by 5%-20%

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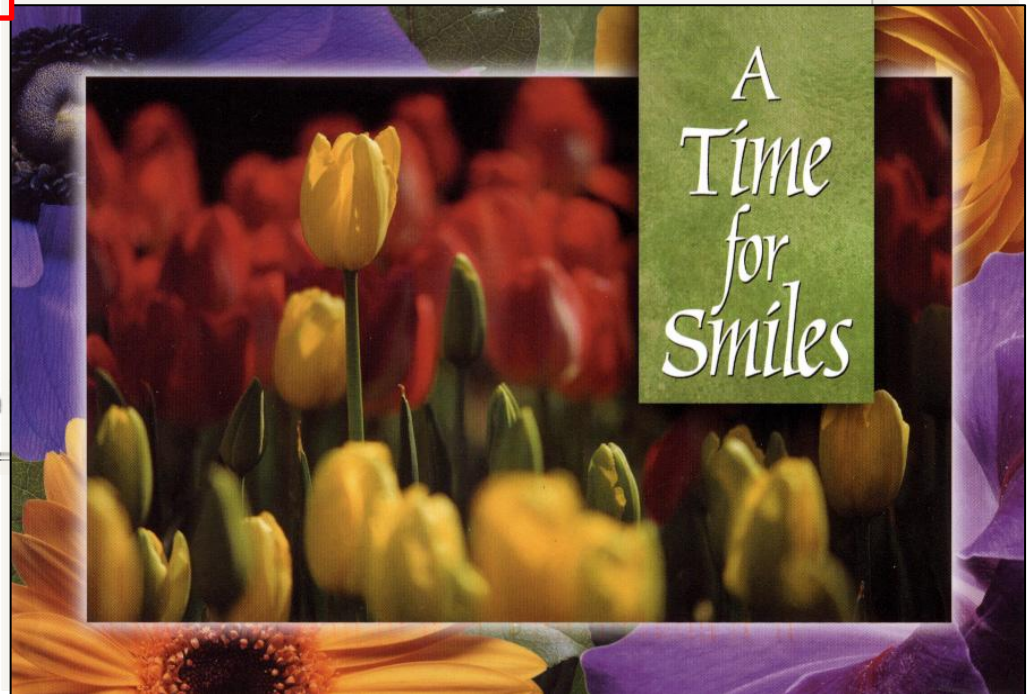


Dear Valerie,

Because your dental health is important to us, we'd like to remind you that it is past time for your examination. Your last visit was 08/11/2003. Please call at your earliest convenience to make an appointment. We look forward to seeing you.

**Valerie Walters
1112 Houston Mill Rd NE
Atlanta, GA 30329**

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Recall card

For Pet's Sake

3761 N. Druid Hills Road
Decatur, GA 30033
(404)248-8977

Dear Ms. Briggs,

Our records show that Pete is due
to come in for her annual examination
and the procedures listed below:

Annual Exam & Fecal Check

Please call us to schedule and appointment.
Remember that Pete's health depends on you



Ms. Barbara Briggs

1112 Peachtree Street
Atlanta, GA 30309

Reminder card





Reminders and Recall to Providers

- **Communication to health care providers that an individual client's immunizations are due soon or past due**
- **Examples**
 - computer-generated list
 - stamped note in the chart
 - “Immunization Due” clip on chart

Standing Orders

- **Definition**

- a written order stipulating that all persons meeting certain criteria (such as age or underlying medical condition) should be vaccinated
- eliminates the need for individual physician's orders for each patient

- **Advantage**

- consistently effective method for increasing vaccination rates and the easiest to implement

- **Disadvantage**

- only reach people already contacting the health care system

Standing Orders

- **Implementation Steps**

The clinician:

- decides on the criteria that will be used to indicate patient eligibility for vaccination and for specific vaccines
- writes (or signs) the standing order
- meets with staff to discuss implementation of the standing order strategy

Impact of Standing Orders on Adolescent Immunization Rates, Denver Health, 2013

Vaccine	National (2013)	Colorado (2013)	Denver Health (2013)
Tdap	86.0	87.1	95.9
MCV4	77.8	73.6	93.5
HPV – Females ≥ 1	57.3	58.2	89.8
HPV – Females ≥ 3	37.6	39.1	66.0
HPV – Males ≥ 1	34.6	33.5	89.3
HPV – Males ≥ 3	13.9	9.9	52.5

Kempe A, unpublished data, 2014

Standing Orders for Administering DTaP to Children Younger than Age 7 Years

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and pertussis by vaccinating all infants and children who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate infants and children who meet the criteria below.

Procedure

1. Identify infants and children ages 2 months through 6 years who have not completed a diphtheria, tetanus, and acellular pertussis (DTaP) vaccination series.
2. Screen all patients for contraindications and precautions to DTaP:
 - a. **Contraindications:**
 - a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of DTaP or to a DTaP component. For a list of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
 - a history of encephalopathy (e.g., coma, decreased level of consciousness; prolonged seizures) not attributable to another identifiable cause within 7 days of a previous dose of pertussis-containing vaccine.
 - b. **Precautions:**
 - moderate or severe acute illness with or without fever
 - history of arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid containing vaccine
 - progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures, or progressive

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Patient name: _____

Date of birth: ____/____/____
(mo.) (day) (yr.)

Screening Checklist for Contraindications to Vaccines for Children and Teens

For parents/guardians: The following questions will help us determine which vaccines your child may be given today. If you answer "yes" to any question, it does not necessarily mean your child should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	Yes	No	Don't Know
1. Is the child sick today?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the child have allergies to medications, food, a vaccine component, or latex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has the child had a serious reaction to a vaccine in the past?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Has the child had a health problem with lung, heart, kidney or metabolic disease (e.g., diabetes), asthma, or a blood disorder? Is he/she on long-term aspirin therapy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. If the child to be vaccinated is 2 through 4 years of age, has a healthcare provider told you that the child had wheezing or asthma in the past 12 months?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Has the child had intussusception?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Summary

- **Pertussis is still a threat**
- **Inadequate full series coverage puts children at risk**
- **Immunity from DTaP wanes in the months following the last dose**
- **The 4th dose of DTaP is critical to protect children until the last dose at 4-6 years of age**
- **Many strategies can improve vaccination levels especially reminder/recall and standing orders**

Thank you

Questions?

