Prenatal Tdap Workgroup
July 25, 2018

Immunization Branch
California Department of Public Health

Agenda

I. Special Presentation (30 min + 10 min Q&A)

- LA County Efforts in Recruiting Providers for State Tdap Program: Arnold Hartoonian & Kevin Burdett

II. Announcements (10 min)

- Pertussis Quicksheet: Kathleen Winter
- New MIHA Report: Kathleen Winter
- First confirmed Whooping Death in CA Infant Since 2016: Kathleen Winter
- Study: Safety & Immunogenicity of Tdap during Pregnancy and Subsequent Infant Immune Response : Kathleen Winter
- Additions to the Prenatal Tdap Toolkit: Rebeca Boyte

III. Feedback from the workgroup: (10 min): ALL

- What other information would be helpful as part of these group meetings?

SGF Prenatal Tdap Program

- **~ 23,000 doses of Tdap** (Adacel®, single dose vials) to jumpstart prenatal care provider offices not offering Tdap
  - Can providers who already stock Tdap onsite sign up?
    - No. This This program is only for providers who do NOT stock Tdap. Providers with Tdap in stock should be immunizing ALL pregnant women with private or public insurance. If you hear otherwise, please email amberchristiansen@cdph.ca.gov.
  - Can doses be shipped directly to providers?
    - We can ship to non-profit providers only. For-profit providers must get their Tdap from the local health department.
  - Can local health departments order Tdap for their own clinics?
    - Yes! BUT LHDs must agree to send a letter to referring prenatal care providers

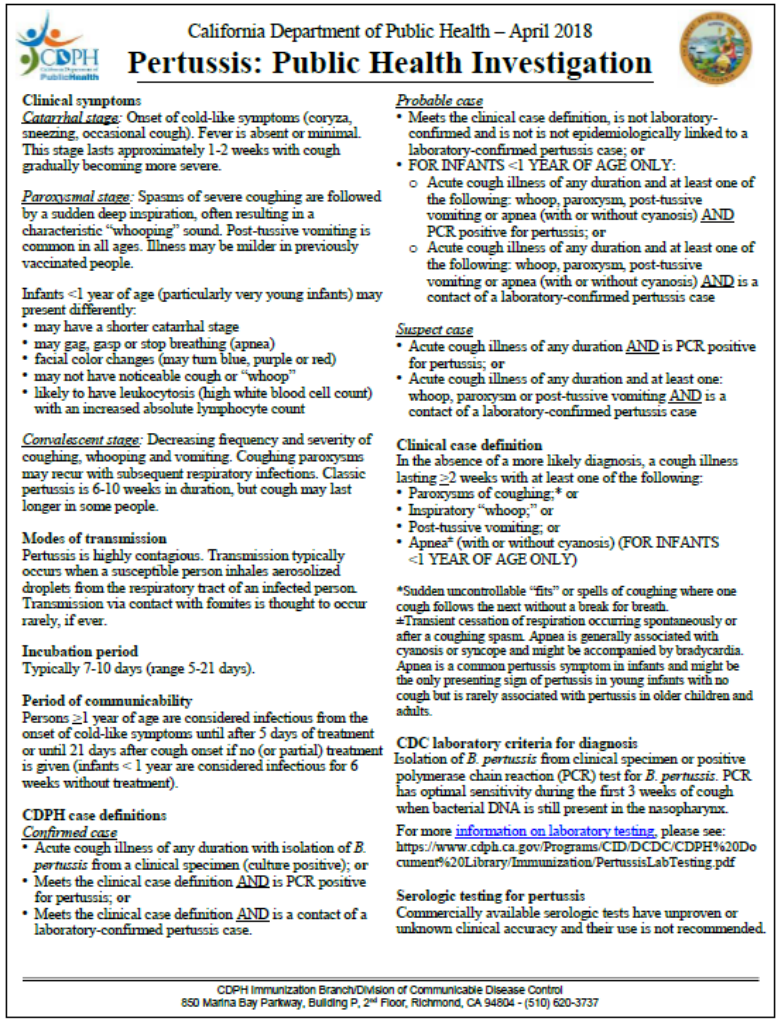
For more info: http://izcoordinators.org/flu/pagesflustate-purchase-tdap/

Special Presentation from LA County

Maternal, Child, & Adolescent Health

Immunization Branch Announcements

Pertussis Quicksheet



California Department of Public Health – April 2018

Pertussis: Public Health Investigation

Clinical symptoms

Catarrhal stage: Onset of cold-like symptoms (coryza, sneezing, occasional cough). Fever is absent or minimal. This stage lasts approximately 1-2 weeks with cough gradually becoming more severe.

Paroxysmal stage: Spasms of severe coughing are followed by a sudden deep inspiration, often resulting in a characteristic "whooping" sound. Post-tussive vomiting is common in all ages. Illness may be milder in previously vaccinated people.

Infants <1 year of age (particularly very young infants) may present differently:
- may have a shorter catarrhal stage
- may gag, gasp or stop breathing (apnea)
- facial color changes (may turn blue, purple or red)
- may not have noticeable cough or "whoop"
- likely to have leukocytosis (high white blood cell count) with an increased absolute lymphocyte count

Convalescent stage: Decreasing frequency and severity of coughing, whooping and vomiting. Coughing paroxysms may recur with subsequent respiratory infections. Classic pertussis is 6-10 weeks in duration, but cough may last longer in some people.

Modes of transmission

Pertussis is highly contagious. Transmission typically occurs when a susceptible person inhales aerosolized droplets from the respiratory tract of an infected person. Transmission via contact with fomites is thought to occur rarely, if ever.

Incubation period

Typically 7-10 days (range 5-21 days).

Period of communicability

Persons ≥1 year of age are considered infectious from the onset of cold-like symptoms until after 5 days of treatment or until 21 days after cough onset if no (or partial) treatment is given (infants < 1 year are considered infectious for 6 weeks without treatment).

CDPH case definitions

Confirmed case
- Acute cough illness of any duration with isolation of *B. pertussis* from a clinical specimen (culture positive); **or**
- Meets the clinical case definition AND is PCR positive for pertussis; **or**
- Meets the clinical case definition AND is a contact of a laboratory-confirmed pertussis case.

Probable case
- Meets the clinical case definition, is not laboratory-confirmed and is not is not epidemiologically linked to a laboratory-confirmed pertussis case; **or**
- FOR INFANTS <1 YEAR OF AGE ONLY:
  - Acute cough illness of any duration and at least one of the following: whoop, paroxysm, post-tussive vomiting or apnea (with or without cyanosis) AND PCR positive for pertussis; **or**
  - Acute cough illness of any duration and at least one of the following: whoop, paroxysm, post-tussive vomiting or apnea (with or without cyanosis) AND is a contact of a laboratory-confirmed pertussis case

Suspect case
- Acute cough illness of any duration AND is PCR positive for pertussis; **or**
- Acute cough illness of any duration and at least one: whoop, paroxysm or post-tussive vomiting AND is a contact of a laboratory-confirmed pertussis case

Clinical case definition

In the absence of a more likely diagnosis, a cough illness lasting ≥2 weeks with at least one of the following:
- Paroxysms of coughing;* or
- Inspiratory "whoop;" or
- Post-tussive vomiting; or
- Apnea≠ (with or without cyanosis) (FOR INFANTS <1 YEAR OF AGE ONLY)

*Sudden uncontrollable "fits" or spells of coughing where one cough follows the next without a break for breath.
≠Transient cessation of respiration occurring spontaneously or after a coughing spasm. Apnea is generally associated with cyanosis or syncope and might be accompanied by bradycardia. Apnea is a common pertussis symptom in infants and might be the only presenting sign of pertussis in young infants with no cough but is rarely associated with pertussis in older children and adults.

CDC laboratory criteria for diagnosis

Isolation of *B. pertussis* from clinical specimen or positive polymerase chain reaction (PCR) test for *B. pertussis*. PCR has optimal sensitivity during the first 3 weeks of cough when bacterial DNA is still present in the nasopharynx.

For more information on laboratory testing, please see: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/PertussisLabTesting.pdf

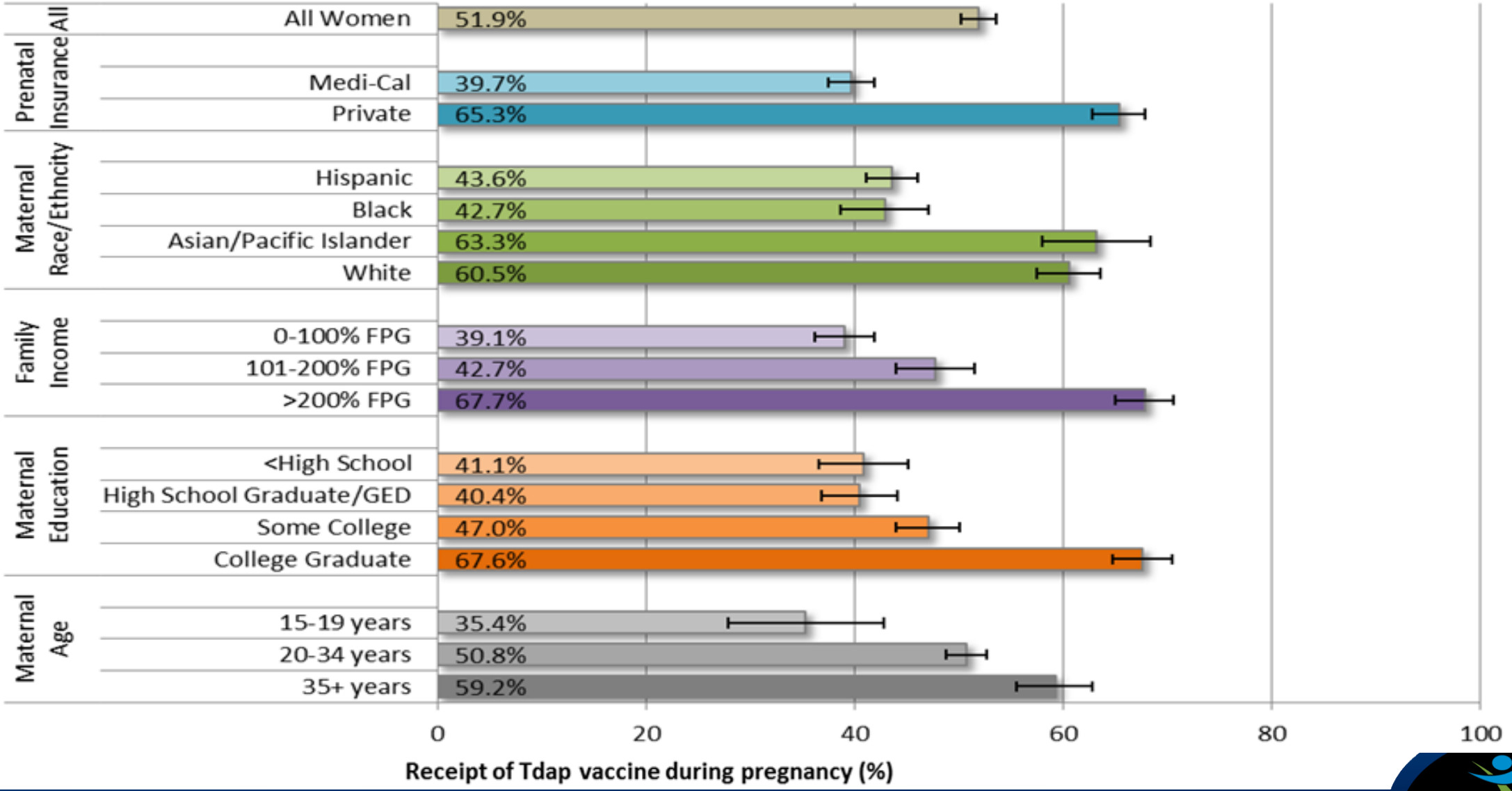
Serologic testing for pertussis

Commercially available serologic tests have unproven or unknown clinical accuracy and their use is not recommended.

CDPH Immunization Branch/Division of Communicable Disease Control
850 Marina Bay Parkway, Building P, 2nd Floor, Richmond, CA 94804 - (510) 620-3737

Available at:
https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/PertussisQuicksheet.pdf

Receipt of Prenatal Tdap by maternal characteristics – MIHA, 2016*

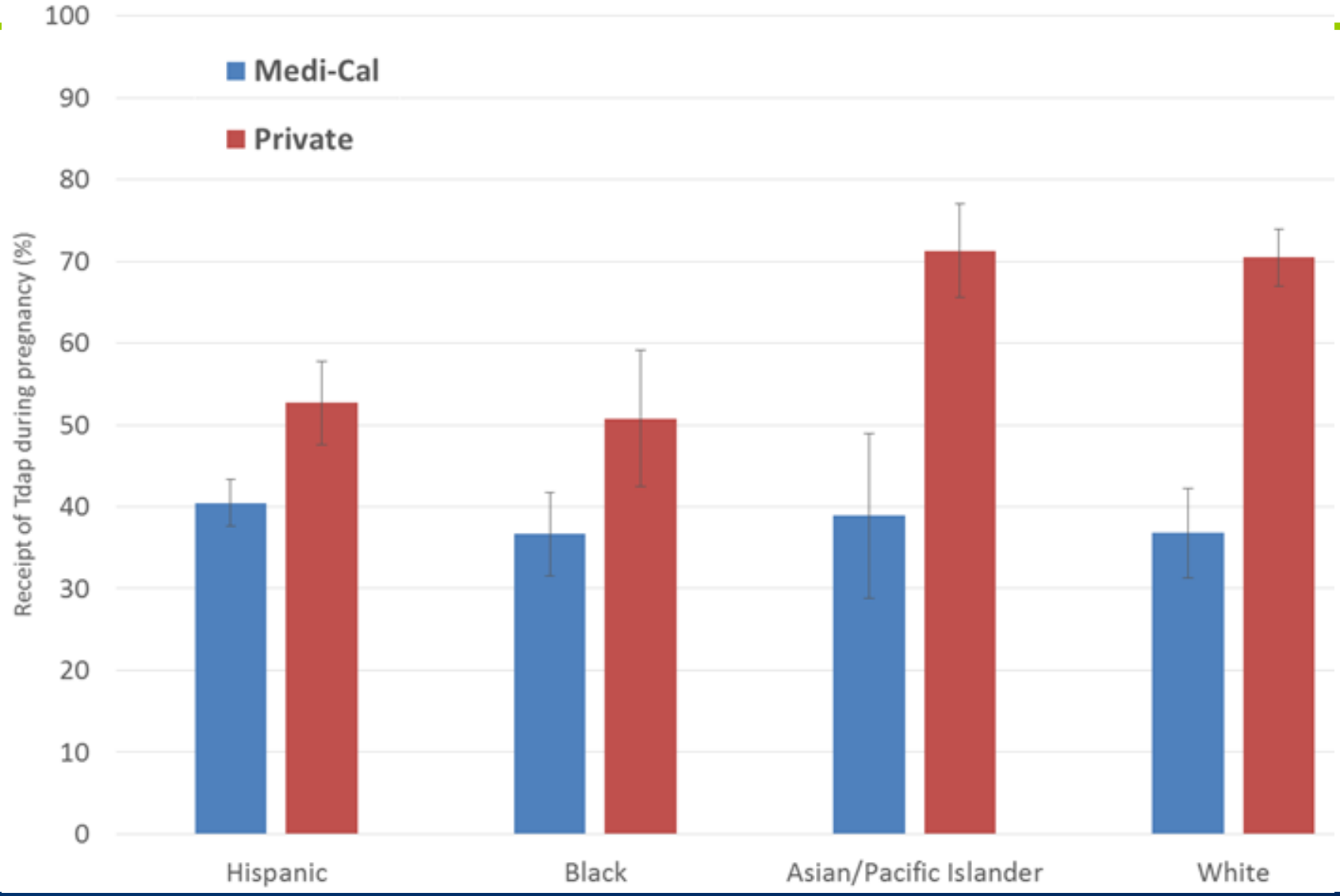


Available at:

https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/MIHA-FactSheet2016.pdf

*Maternal and Infant Health Assessment

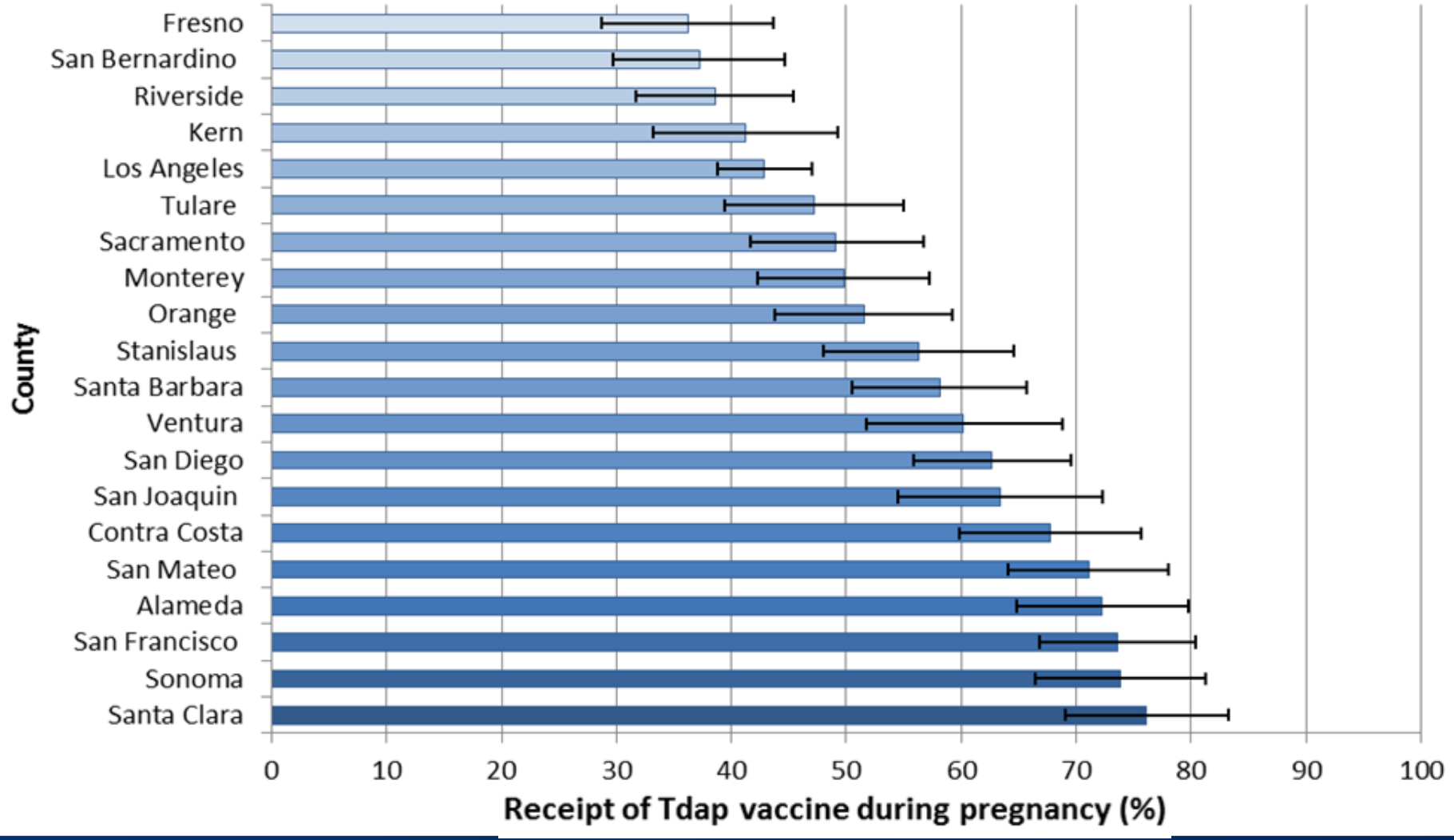
Receipt of Prenatal Tdap, by insurance - MIHA, 2016



Location of Prenatal Tdap - MIHA, 2016

- Among women who received prenatal Tdap:
  - 85% were vaccinated at the same clinic where they received their prenatal care
  - 7% were vaccinated at a pharmacy/supermarket
  - 5% were vaccinated at a different doctor's office
  - 3% unknown location

Receipt of prenatal Tdap by county – MIHA, 2016

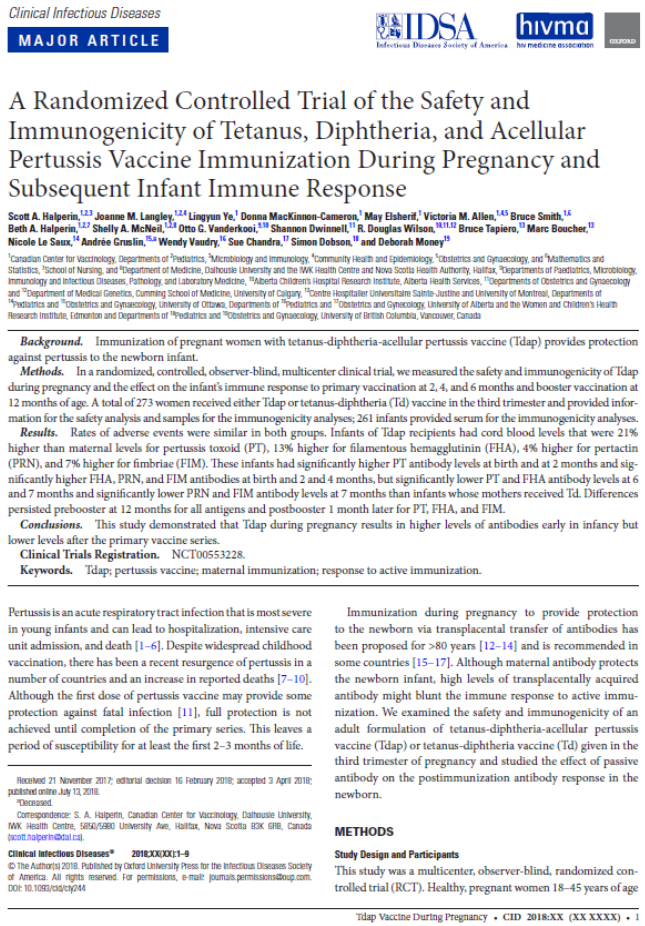


First Pertussis Infant Death in 2018

First Confirmed Whooping Cough Death in a California Infant Since 2016

https://www.cdph.ca.gov/Programs/OPA/Pages/NR18-038.aspx

Safety & Immunogenicity of Tdap during Pregnancy and Subsequent Infant Immune Response



Clinical Infectious Diseases

MAJOR ARTICLE

A Randomized Controlled Trial of the Safety and Immunogenicity of Tetanus, Diphtheria, and Acellular Pertussis Vaccine Immunization During Pregnancy and Subsequent Infant Immune Response

Scott A. Halperin,[1,2,3] Joanne M. Langley,[1,2,4] Lingyun Ye,[1] Donna MacKinnon-Cameron,[1] May Elsherif,[1] Victoria M. Allen,[1,4,5] Bruce Smith,[1,6] Beth A. Halperin,[1,2,7] Shelly A. McNeil,[1,2,8] Otto G. Vanderkooi,[9,10] Shannon Dwinnell,[11] R. Douglas Wilson,[10,11,12] Bruce Tapiero,[13] Marc Boucher,[13] Nicole Le Saux,[14] Andrée Gruslin,[15,a] Wendy Vaudry,[16] Sue Chandra,[17] Simon Dobson,[18] and Deborah Money[19]

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Background. Immunization of pregnant women with tetanus-diphtheria-acellular pertussis vaccine (Tdap) provides protection against pertussis to the newborn infant.

Methods. In a randomized, controlled, observer-blind, multicenter clinical trial, we measured the safety and immunogenicity of Tdap during pregnancy and the effect on the infant's immune response to primary vaccination at 2, 4, and 6 months and booster vaccination at 12 months of age. A total of 273 women received either Tdap or tetanus-diphtheria (Td) vaccine in the third trimester and provided information for the safety analysis and samples for the immunogenicity analyses; 261 infants provided serum for the immunogenicity analyses.

Results. Rates of adverse events were similar in both groups. Infants of Tdap recipients had cord blood levels that were 21% higher than maternal levels for pertussis toxoid (PT), 13% higher for filamentous hemagglutinin (FHA), 4% higher for pertactin (PRN), and 7% higher for fimbriae (FIM). These infants had significantly higher PT antibody levels at birth and at 2 months and significantly higher FHA, PRN, and FIM antibodies at birth and 2 and 4 months, but significantly lower PT and FHA antibody levels at 6 and 7 months and significantly lower PRN and FIM antibody levels at 7 months than infants whose mothers received Td. Differences persisted preboooster at 12 months for all antigens and postbooster 1 month later for PT, FHA, and FIM.

Conclusions. This study demonstrated that Tdap during pregnancy results in higher levels of antibodies early in infancy but lower levels after the primary vaccine series.

Clinical Trials Registration. NCT00553228.

Keywords. Tdap; pertussis vaccine; maternal immunization; response to active immunization.

Pertussis is an acute respiratory tract infection that is most severe in young infants and can lead to hospitalization, intensive care unit admission, and death [1–6]. Despite widespread childhood vaccination, there has been a recent resurgence of pertussis in a number of countries and an increase in reported deaths [7–10]. Although the first dose of pertussis vaccine may provide some protection against fatal infection [11], full protection is not achieved until completion of the primary series. This leaves a period of susceptibility for at least the first 2–3 months of life.

Immunization during pregnancy to provide protection to the newborn via transplacental transfer of antibodies has been proposed for >80 years [12–14] and is recommended in some countries [15–17]. Although maternal antibody protects the newborn infant, high levels of transplacentally acquired antibody might blunt the immune response to active immunization. We examined the safety and immunogenicity of an adult formulation of tetanus-diphtheria-acellular pertussis vaccine (Tdap) or tetanus-diphtheria vaccine (Td) given in the third trimester of pregnancy and studied the effect of passive antibody on the postimmunization antibody response in the newborn.

METHODS

Study Design and Participants

This study was a multicenter, observer-blind, randomized controlled trial (RCT). Healthy, pregnant women 18–45 years of age

Received 21 November 2017; editorial decision 16 February 2018; accepted 3 April 2018; published online July 13, 2018.

[a]Deceased.

Correspondence: S. A. Halperin, Canadian Center for Vaccinology, Dalhousie University, IWK Health Centre, 5850/5980 University Ave, Halifax, Nova Scotia B3K 6R8, Canada (scott.halperin@dal.ca).

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DOI: 10.1093/cid/ciy244

- Large RCT provides strong evidence of effectiveness of maternal immunization in providing high levels of transplacental antibodies against pertussis to newborn infants and the persistence of those high levels to 2–4 months of age
- Demonstrated high levels of antibodies led to a blunting of the immune response to the primary pertussis vaccine series
- Ongoing surveillance of pertussis in early childhood is needed when maternal immunization programs are implemented

Available at: https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciy244/5053576

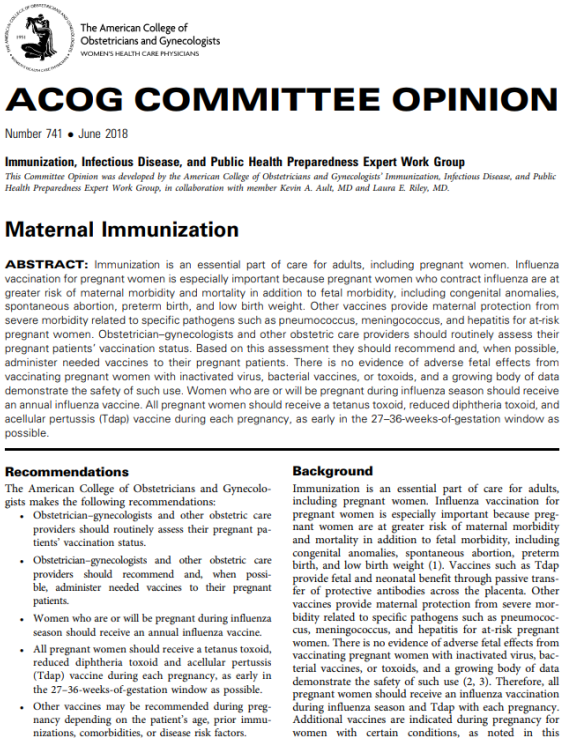
Prenatal Toolkit: What's New

Toolkit: http://eziz.org/resources/pertussis-promo-materials/prenatal-tdap/

- Included:
  - Stanislaus's Pertussis Toolkit for Schools and Child Care Centers
  - Orange's prenatal care provider pre-and post-conference survey
  - ACOG Committee Opinion Maternal Immunization—June 2018

ACOG Committee Opinion—June 2018

- " Studies consistently demonstrate that when the recommendation and availability of vaccination during pregnancy comes directly from a woman's obstetrician or other obstetric provider, the odds of **vaccine acceptance and receipt are 5-fold to 50-fold higher**. As such, obstetricians-gynecologists and other obstetric care providers **should routinely assess** their pregnant patients' vaccination status. Based on this assessment, they should **recommend and, when possible, administer** needed vaccines to their pregnant patients."



The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

ACOG COMMITTEE OPINION

Number 741 • June 2018

Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Immunization, Infectious Disease, and Public Health Preparedness Expert Work Group, in collaboration with member Kevin A. Ault, MD and Laura E. Riley, MD.

Maternal Immunization

ABSTRACT: Immunization is an essential part of care for adults, including pregnant women. Influenza vaccination for pregnant women is especially important because pregnant women who contract influenza are at greater risk of maternal morbidity and mortality in addition to fetal morbidity, including congenital anomalies, spontaneous abortion, preterm birth, and low birth weight. Other vaccines provide maternal protection from severe morbidity related to specific pathogens such as pneumococcus, meningococcus, and hepatitis for at-risk pregnant women. Obstetrician–gynecologists and other obstetric care providers should routinely assess their pregnant patients' vaccination status. Based on this assessment they should recommend and, when possible, administer needed vaccines to their pregnant patients. There is no evidence of adverse fetal effects from vaccinating pregnant women with inactivated virus, bacterial vaccines, or toxoids, and a growing body of data demonstrate the safety of such use. Women who are or will be pregnant during influenza season should receive an annual influenza vaccine. All pregnant women should receive a tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine during each pregnancy, as early in the 27–36-weeks-of-gestation window as possible.

Recommendations

The American College of Obstetricians and Gynecologists makes the following recommendations:

- Obstetrician–gynecologists and other obstetric care providers should routinely assess their pregnant patients' vaccination status.
- Obstetrician–gynecologists and other obstetric care providers should recommend and, when possible, administer needed vaccines to their pregnant patients.
- Women who are or will be pregnant during influenza season should receive an annual influenza vaccine.
- All pregnant women should receive a tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) vaccine during each pregnancy, as early in the 27–36-weeks-of-gestation window as possible.
- Other vaccines may be recommended during pregnancy depending on the patient's age, prior immunizations, comorbidities, or disease risk factors.

Background

Immunization is an essential part of care for adults, including pregnant women. Influenza vaccination for pregnant women is especially important because pregnant women are at greater risk of maternal morbidity and mortality in addition to fetal morbidity, including congenital anomalies, spontaneous abortion, preterm birth, and low birth weight (1). Vaccines such as Tdap provide fetal and neonatal benefit through passive transfer of protective antibodies across the placenta. Other vaccines provide maternal protection from severe morbidity related to specific pathogens such as pneumococcus, meningococcus, and hepatitis for at-risk pregnant women. There is no evidence of adverse fetal effects from vaccinating pregnant women with inactivated virus, bacterial vaccines, or toxoids, and a growing body of data demonstrate the safety of such use (2, 3). Therefore, all pregnant women should receive an influenza vaccination during influenza season and Tdap with each pregnancy. Additional vaccines are indicated during pregnancy for women with certain conditions, as noted in this

Updated Brochure IMM-887

Where can I get immunized... if?

I have a doctor

Call your doctor and ask:

- Do you offer flu and Tdap shots?
- How soon can you see me?

My doctor does NOT have the shots I need or can't see me soon enough

Call the pharmacy where you usually pick up your prescriptions. Ask:

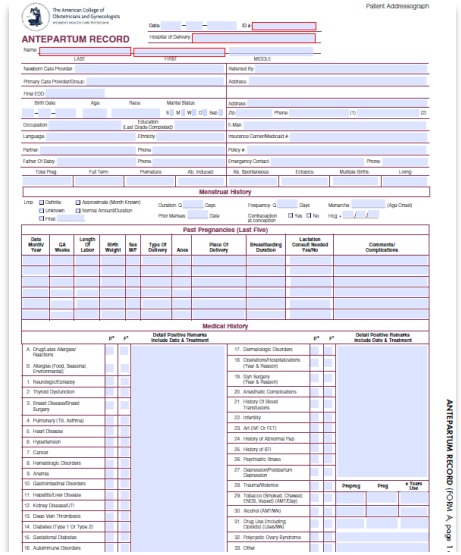
- Do you offer flu and Tdap shots?
- Does my insurance cover these shots at your pharmacy? *(Note: If you have Medi-Cal, shots should be covered at this pharmacy.)*
- What are your immunization clinic hours?

The pharmacy I usually go to for prescriptions does not offer the shots I need or my insurance does not cover them there

Call your health plan's member services. (This number is usually on the back of your insurance card.) Ask:

- What nearby pharmacies do you cover? Call the nearby pharmacies and ask:
  - Do you offer flu and Tdap shots?
  - What are your immunization clinic hours?

Reminder: ACOG Antepartum Records



ANTEPARTUM RECORD

Patient Addressograph

Date: – – ID #

Hospital of Delivery

Name: LAST FIRST MI/OLD

Newborn Care Provider | Referred By

Primary Care Provider/Group | Address

Final EDD

Birth Date | Age | Race | Marital Status | Address

Education (Last Grade Completed) | Zip | Phone | H | O

Occupation | E-Mail

Language | Ethnicity | Insurance Carrier/Medicaid #

Partner | Phone | Policy #

Father Of Baby | Phone | Emergency Contact | Phone

Total Preg. | Full Term | Premature | Ab. Induced | Ab. Spontaneous | Ectopics | Multiple Births | Living

Menstrual History

LMP: Definite, Approximate (Month Known), Unknown, Normal Amount/Duration, Irreg. | Duration | Days | Frequency | Days | Menarche (Age Onset) | Prior Menses | Date | Contraception at conception: Yes, No | Hrtg + / /

Past Pregnancies (Last Five)

Date Month/ Year	GA Weeks	Length Of Labor	Birth Weight	Sex M/F	Type Of Delivery	Anes	Place Of Delivery	Breastfeeding Duration	Lactation Consult Needed Yes/No	Comments/ Complications

Medical History

	P*	F*	Detail Positive Remarks Include Date & Treatment
A. Drug/Latex Allergies/ Reactions			
B. Allergies (Food, Seasonal, Environmental)			
1. Neurologic/Epilepsy			
2. Thyroid Dysfunction			
3. Breast Disease/Breast Surgery			
4. Pulmonary (TB, Asthma)			
5. Heart Disease			
6. Hypertension			
7. Cancer			
8. Hematologic Disorders			
9. Anemia			
10. Gastrointestinal Disorders			
11. Hepatitis/Liver Disease			
12. Kidney Disease/UTI			
13. Deep Vein Thrombosis			
14. Diabetes (Type I Or Type II)			
15. Gestational Diabetes			
16. Autoimmune Disorders			

	P*	F*	Detail Positive Remarks Include Date & Treatment
17. Dermatologic Disorders			
18. Cholecystitis/Hospitalizations (Year & Reason)			
19. Gyn Surgery (Year & Reason)			
20. Anesthetic Complications			
21. History Of Blood Transfusions			
22. Infertility			
23. Art (IVF Or FET)			
24. History of Abnormal Pap			
25. History of STI			
26. Psychiatric Illness			
27. Depression/Postpartum Depression			
28. Trauma/Violence			
29. Tobacco (Smoked, Chewed, ENDS, Vaped) (#PD/Day)			Pregnancy / Prep / # Years Use
30. Alcohol (#/PD/Wk)			
31. Drug Use (Including Opioids) (Use/Wk)			
32. Polycystic Ovary Syndrome			
33. Other			

ANTEPARTUM RECORD (FORM) A, page 1

Immunizations	Yes (Month/Year) ____ / ____	No	If No, Vaccine Indicated?*	Immunizations	Yes (Month/Year) ____ / ____	No	If No, Vaccine Indicated?*
TDAP (Each pregnancy, between 27-36 weeks)				Hepatitis A (When Indicated)			
Influenza† (Each pregnancy as soon as vaccine is available)				Hepatitis B (When Indicated)			
Varicella†				Meningococcal (When Indicated)			
MMR (Rubella-containing vaccine)†				Pneumococcal (When Indicated)			
HPV							

*Yes/No & date to be administered

- We still have copies in stock!
- Please send email: Rebeca.Boyte@cdph.ca.gov indicating desired quantity.

Feedback from the group

- What other information would be helpful as part of these group meetings?

Questions?

As always, these slides are posted on Prenatal Tdap Toolkit page: http://eziz.org/resources/pertussis-promo-materials/prenatal-tdap/.

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