

# Prenatal Tdap Workgroup

## January 17, 2018



Immunization Branch  
California Department of Public Health

# Agenda

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- i. Welcome
- ii. Post-licensure Tdap Safety Data and Tdap formulations:  
Dr. Robert Schechter
- iii. Kern County's Efforts: Kimberly Hernandez
- iv. SGF Tdap doses Guidelines: Nisha Gandhi
- v. Announcements

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# Prenatal immunization with Tdap is Safe

# Summary

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- Multiple studies in women and infants indicate that prenatal immunization with Tdap is safe and effective
- Tdap product labels reflect limited animal studies conducted prior to licensure a decade ago and do not reflect many subsequent studies in humans
- Tdap product labels will be revised under the 2014 FDA rule change - multiyear transition in progress
- Prenatal Tdap immunization continues to be recommended by ACIP, ACOG and other national authorities

# Multiple recent safety studies...

## Safety

- DeSilva M, Vazquez-Benitez G, Nordin JD, et al. [Maternal Tdap vaccination and risk of infant morbidity](#) *et al. Vaccine*. 2017;35(29):3655–60.
- McMillan M, Clarke M, Parrella A, Fell DB, Amirthalingam G, Marshall HS. [Safety of tetanus, diphtheria, and pertussis vaccination during pregnancy: A systematic review](#) *et al. Obstet Gynecol*. 2017;129(3):560–73.
- DeSilva M, Vazquez-Benitez G, Nordin JD, et al. [Tdap vaccination during pregnancy and microcephaly and other structural birth defects in offspring](#). *JAMA*. 2016;316(17):1823–5.
- Sukumaran L, McCarthy NL, Kharbanda EO, et al. [Safety of tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis and influenza vaccinations in pregnancy](#) *et al. Obstet Gynecol*. 2015;126(5):1069–74.
- Sukumaran L, McCarthy NL, Kharbanda EO, et al. [Association of Tdap vaccination with acute events and adverse birth outcomes among pregnant women with prior tetanus-containing immunizations](#) *et al. JAMA*. 2015;314(15):1581–7.
- Morgan JL, Baggari SR, McIntire DD, Sheffield JS. [Pregnancy outcomes after antepartum tetanus, diphtheria, and acellular pertussis vaccination](#) *et al. Obstet Gynecol*. 2015;125(6):1433–8.
- Czeizel AE, Rockenbauer M. [Tetanus toxoid and congenital abnormalities](#) *et al. Int J Gynecol Obstet*. 1999;64:253–8.
- Donegan K, King B, Bryan P. [Safety of pertussis vaccination in pregnant women in UK: Observational study](#) *et al. BMJ*. 2014;349:g4219.
- Hardy-Fairbanks AJ, Pan SJ, Decker MD, et al. [Immune responses in infants whose mothers received Tdap vaccine during pregnancy](#) *et al. Pediatr Infect Dis J*. 2013;32:1257–60.
- Kharbanda EO, Vazquez-Benitez G, Lipkind HS, et al. [Evaluation of the Association of Maternal Pertussis Vaccination With Obstetric Events and Birth Outcomes](#) *et al. JAMA*. 2014;312(18):1897–1904.
- Kharbanda EO, Vazquez-Benitez G, Lipkind H, et al. [Receipt of pertussis vaccine during pregnancy across 7 Vaccine Safety Datalink Sites](#) *et al. Prev Med*. 2014;67:316–9.
- Liang J. Overview of Tdap use during pregnancy: unpublished and recent data. Advisory Committee on Immunization Practices (ACIP), Atlanta, GA; February 23, 2011.
- Moro P. Safety of Tdap vaccine during pregnancy: enhanced surveillance in VAERS presented to the Advisory Committee on Immunization Practices (ACIP), Atlanta, GA; February 26, 2014.
- Munoz FM, Bond NH, Maccato M, et al. [Safety and immunogenicity of tetanus diphtheria and acellular pertussis \(Tdap\) immunization during pregnancy in mothers and infants: A randomized clinical trial](#) *et al. JAMA*. 2014;311(17):1760–9.
- Rasmussen S. Safety of maternal Tdap vaccination for mother and fetus presented to the Advisory Committee on Immunization Practices (ACIP), Atlanta, GA; June 22, 2011.
- Schofield FD, Tucker VM, Westbrook GR. [Neonatal tetanus in New Guinea. Effect of active immunization in pregnancy](#) *et al. Br Med J*. 1961;2:785–9.
- Silveria CM, Caceres VM, Dutra MG, Lopes-Camelo J, Castilla EE. [Safety of tetanus toxoid in pregnant women: a hospital-based case-control study of congenital anomalies](#) *et al. Bull World Health Organ*. 1995;73:605–8.
- Shakib JH, Korgenski K, Sheng X, Varner MW, Pavia AT, Byington CL. Tetanus, diphtheria, acellular pertussis vaccine during pregnancy: pregnancy and infant health outcomes. *J Pediatr*. 2013; 163(5):1422–26.
- Zheteyeva YA, Moro PL, Tepper NK, et al. [Adverse event reports after tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis vaccines in pregnant women](#) *et al. Am J Obstet Gynecol*. 2012;207(1):59e1–7.

<https://www.cdc.gov/pertussis/pregnant/research.html>

# Multiple human studies consistent with the safety of prenatal Tdap immunization

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- 21 safety studies reviewed. Estimates of risk in immunized mothers and their infants (<1 consistent with reduced risk)
  - Pre-term birth: 0.5–1.5
  - Small for Gestational Age: 0.7–1.0
  - Stillbirth 0.4–0.9
  - Neonatal death 0.2–1.0
  - Low birth weight 0.8–1.2
  - Congenital anomalies 0.2–0.9
  - All lower 95% confidence intervals (CIs) were less than 1.0.

# Multiple human studies consistent with the safety of prenatal Tdap immunization

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- Review: 3 retrospective studies assessing chorioamnionitis after vaccination,
  - One showed a small but statistically significant increase
- Additional recent study of the Vaccine Safety Datalink: risk of chorioamnionitis modestly increased in mothers receiving prenatal Tdap , but no increase in adverse outcomes for infants
  - Chorioamnionitis 1.23 [1.17, 1.28]
  - TTN 1.04 [0.98, 1.11]
  - Neonatal sepsis 1.06 [0.91, 1.23]
  - Neonatal pneumonia 0.94 [0.72, 1.22]
  - RDS 0.91 [0.66, 1.26]
  - Newborn convulsions 1.16 [0.87, 1.53]

McMillan M, et al. *Obstet Gynecol.* 2017;129:560-573

DeSilva M, et al. *Vaccine* 2017; 35: 3655-3660.

# Prior FDA Label framework - basis for 2005 Tdap labels

## “Only if clearly needed”

| Pregnancy Category         | Description   |
|----------------------------|---|
| A                          | <b>No risk in controlled human studies:</b> Adequate and well-controlled human studies have failed to demonstrate a risk to the fetus   |
| B<br><u>Boostrix, 2005</u> | <b>No risk in other studies:</b> Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus |
| C<br><u>Adacel, 2005</u>   | <b>Risk not ruled out:</b> Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.   |
| D                          | <b>Positive evidence of risk:</b> There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.  |
| X                          | <b>Contraindicated in pregnancy:</b> Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.   |



# Transition in FDA Labeling for Use in Pregnancy 2014 - present

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## Labeling Background

Until now, FDA categorized the risks of taking a drug or biological product during pregnancy under a five-letter system (A, B, C, D and X) based on what was known about that product. But comments received by FDA showed that the letter system was often confusing because it was overly simplistic, and did not reflect the available information. This system could lead to false assumptions about medications based on their category.

“The revised labeling will change that,” Kweder says. “Now doctors will have up-to-date and well-organized information on pregnancy and lactation. They will be in a better position to help their patients make critical decisions.”

- [www.fda.gov/ForConsumers/ConsumerUpdates/ucm423773.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm423773.htm)

# Transition in FDA Labeling for Use in Pregnancy 2014 - present

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## Look of the Revised Labeling

The revised labeling will replace the old five-letter system with more helpful information about a medication's risks to the expectant mother, the developing fetus and the breastfed infant.

Companies will have to remove the pregnancy letter categories from the labeling for all prescription drugs and biological products and, for many of them, revise the labeling with updated information. This is a large undertaking that will take several years.

- [www.fda.gov/ForConsumers/ConsumerUpdates/ucm423773.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm423773.htm)

# Summary

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# Vaccine Injury Compensation Program

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- Federal program that compensates people found to have been injured by routine vaccines.
- No-fault alternative to the traditional legal system for resolving vaccine injury petitions.
- Prenatal immunizations (e.g., Tdap, Influenza) included under VICP since December 2016
- Liability coverage through VICP might reassure prenatal providers hesitant to immunize

# Prenatal Tdap Survey of Kern County Providers

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Kimberly Hernandez, MPH

Kern County Public Health Services Department

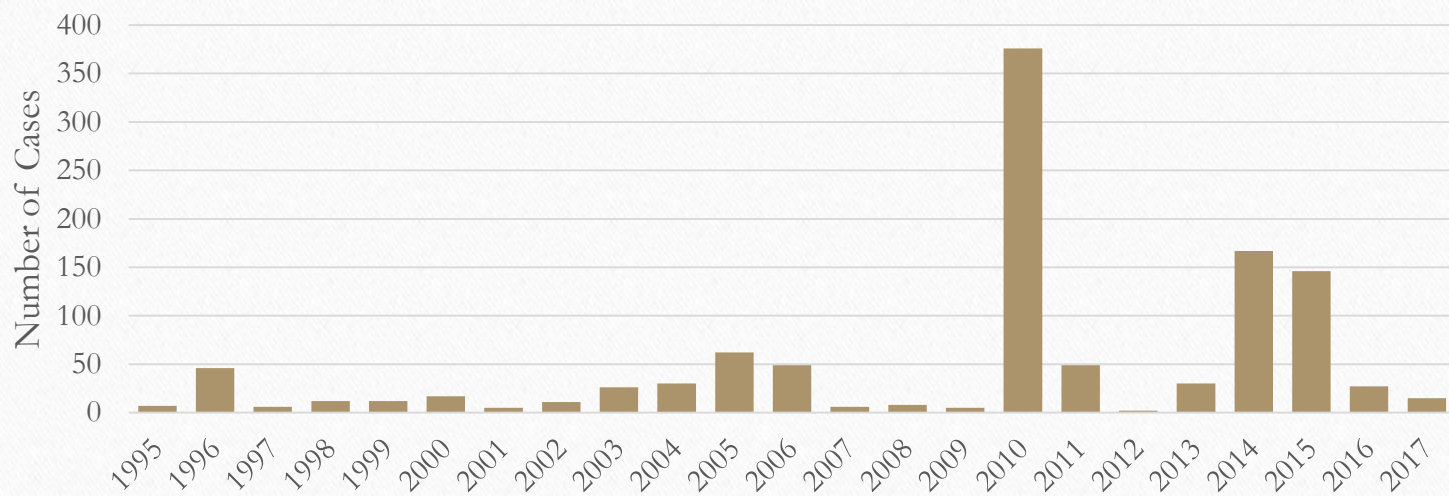
Prenatal Tdap Working Group Meeting

January 17, 2018

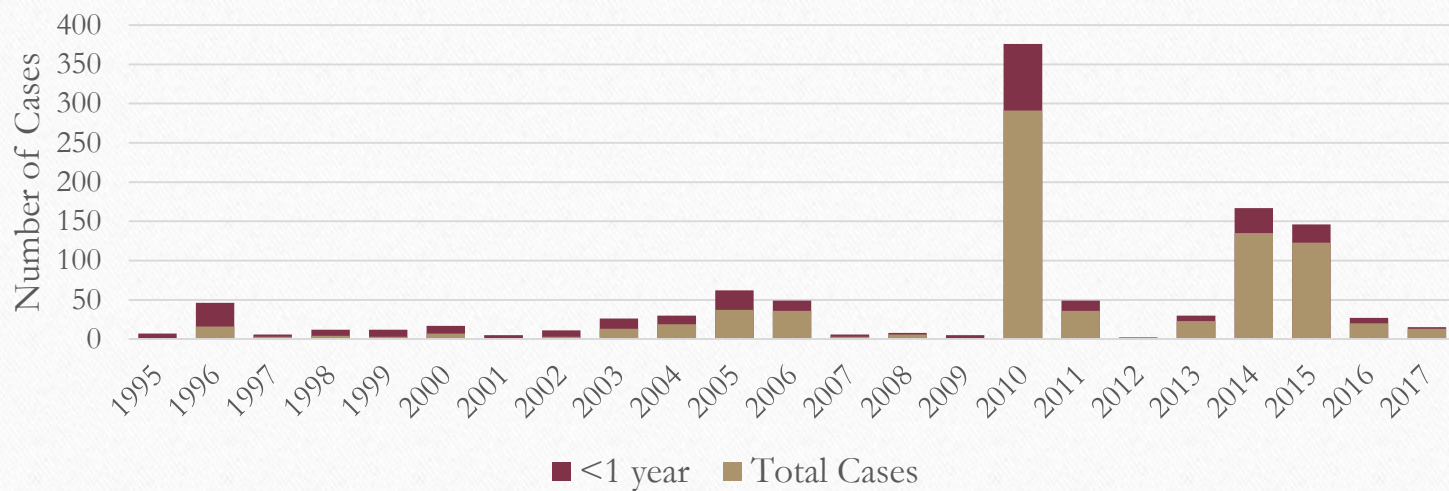


KERN COUNTY  
Public Health Services  
DEPARTMENT

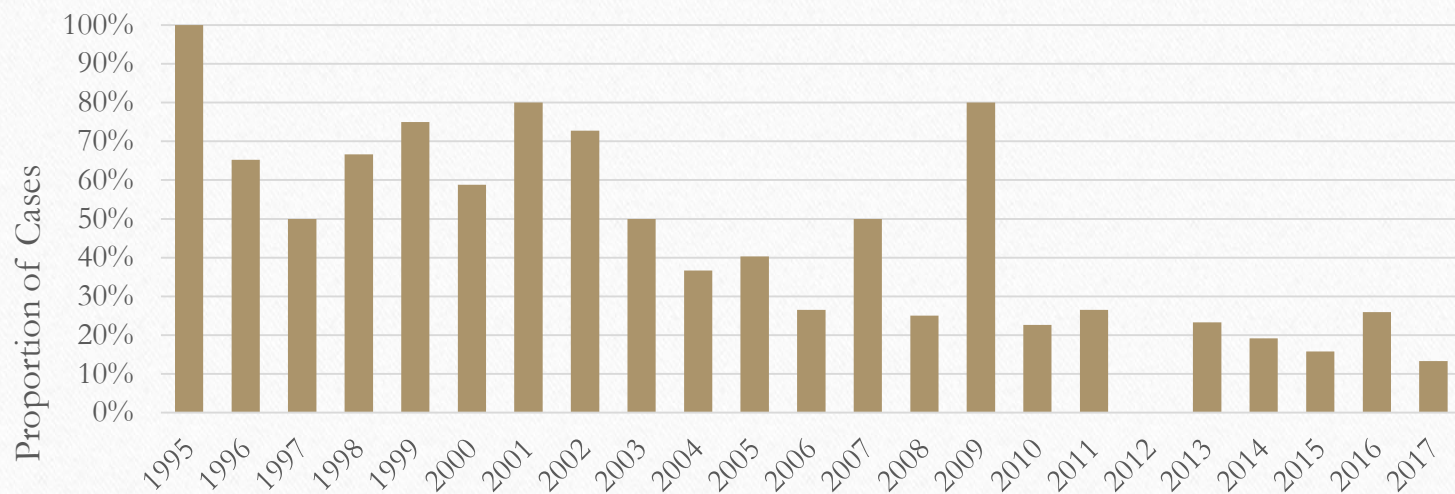
# Pertussis in Kern County



# Pertussis in Kern County



# Proportion of Pertussis Cases <1 year





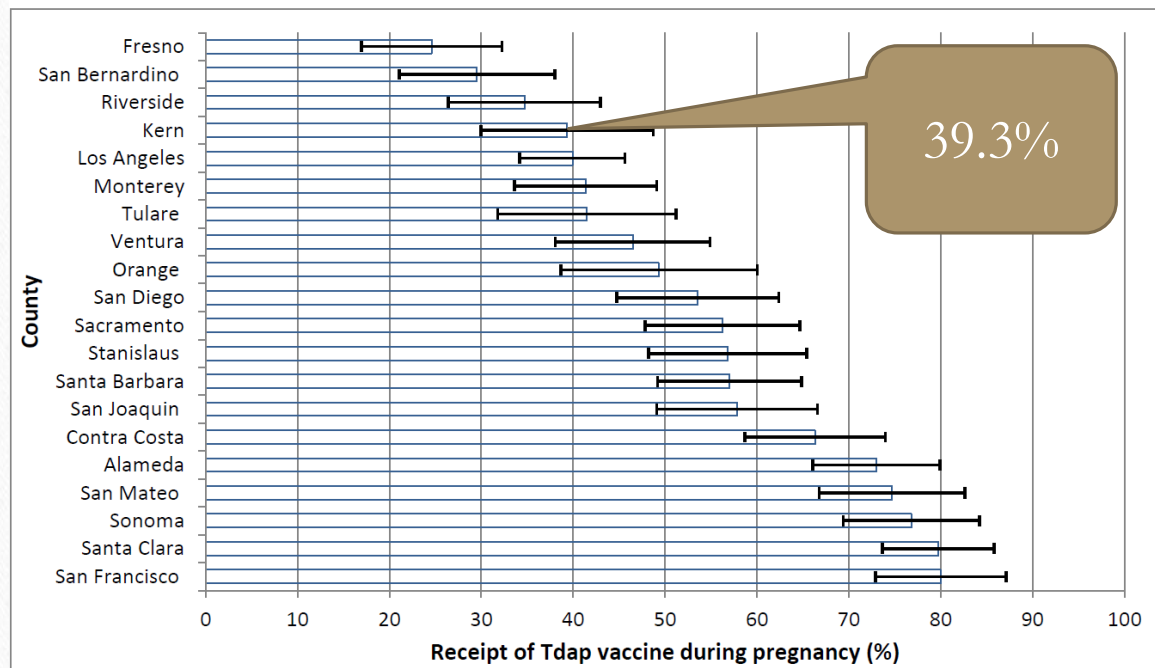
# DTap and Tdap Vaccination Rates

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|                              | Kern  | California |
|------------------------------|-------|------------|
| Kindergarten (DTap )         | 96.2% | 96.9%      |
| 7 <sup>th</sup> Grade (Tdap) | 97.6% | 98.3%      |

# Statewide Maternal Tdap Survey 2015

**Figure 4.** Receipt of Tdap vaccine during pregnancy among women with a live birth in 2015, by the 20 counties with the highest number of births. MIHA 2015



# Push for Further Evaluation

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- Kern high rate of infant pertussis
- Repeat offender prenatal care providers
- Low rate of maternal Tdap
- Death of infant in 2016

# Methods

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- Surveyed providers at OB/Gyn offices (including NP)
- Each individual provider was surveyed, when possible
  - Some clinics had standard protocols/standing orders
- Preliminary data only includes Bakersfield providers (outlying areas are in process of being surveyed)
- In-person interview or paper survey
- Provider/patient resource packet distributed

# Main Questions

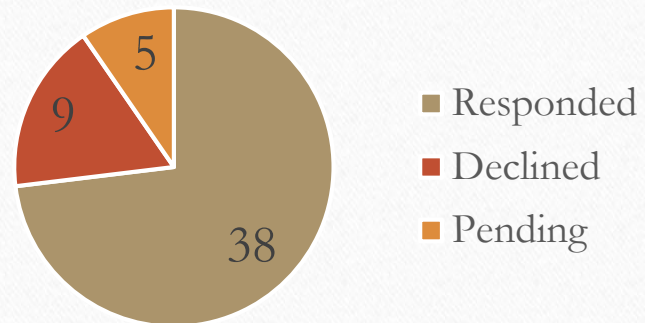
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- Do you recommend Tdap at every pregnancy?
- Do you stock Tdap vaccine in office?
- When do you recommend Tdap administration (gestational week)?
- What support from the health department would help you vaccinate pregnant patients?

# Preliminary Response

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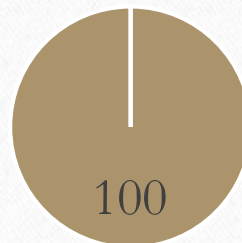
- 52 surveys distributed
- 38 responses received
- 9 surveys declined
- 5 pending



# Preliminary Results

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Do you recommend Tdap vaccination to every pregnant patient during each pregnancy?

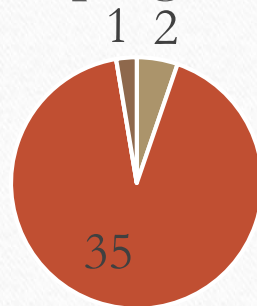


- Yes
- No

# Preliminary Results

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At which gestational week(s) do you recommend pregnant patients receive Tdap?



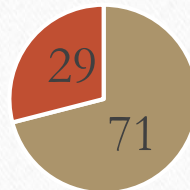
- < 27 weeks
- 27-36 weeks
- 36+ weeks
- Postpartum



# Preliminary Results

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Do you stock Tdap vaccine and offer vaccination to pregnant patients in your office/facility?



■ Yes  
■ No

# Preliminary Results

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Provider self-identified needs:

- Patient information/training materials
- Free vaccinations
- Ability to refer pregnant patients to Public Health Department for vaccine administration

# Other Survey Questions

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- Where/how do you refer patient?
- How do you confirm/document receipt of vaccine?
- How do you document declinations?
- Do you re-recommend after declination?
- What systems are in place to discuss vaccination with patients?

# More Coming Soon!

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- Additional providers
- More in-depth analysis

# Thank You!

- 
- Lauri McAllister

MPH Candidate

American Public University

# Questions?

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- Kimberly Hernandez

Kern County Public Health Services Department

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[hernankim@kerncounty.com](mailto:hernankim@kerncounty.com)

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# SGF Tdap Guidelines

# SGF Prenatal Tdap Program

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- **25,000 doses of Tdap** (Adacel<sup>®</sup>, single dose vials) available now
- **Purpose:** To jumpstart provider offices not offering Tdap to patients
- **Eligible patients:** pregnant women who are uninsured or Medi-Cal beneficiaries
- **Eligible sites** must have (a/an):
  - Written protocol for immunizing pregnant women with Tdap vaccine
  - On-site clinical staff experienced in administering vaccine to adults
  - Plan to continue to offer and bill for Tdap
  - Acceptable refrigerator-only units (see [eziz.org](http://eziz.org))
  - Designated staff as clinic liaison to health department
  - Agreement to report at each LHD check-in



# Evaluation

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- 1, 3 and 6 month follow up to check on progress of dose administration and to collect successes and barriers
- The intent of the surveys are to generate a better understanding of how providers can sustain a prenatal Tdap program

# FAQs

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- Can the doses be offered for cocooning?
  - Not at this time
- Are for-profit providers eligible for these doses?
  - Yes, but we are unable to ship directly to any for-profit sites; you will need to coordinate with the provider on pick up/drop off of doses
- Is there a maximum number of doses a provider can receive?
  - No. The suggested limit is 100 doses/order but we leave that up to your discretion. We recommend you start with a smaller amount and then offer additional doses if they can show they ordered vaccine as well. Remember: the intent of the “starter kits” is to start a sustainable prenatal Tdap program in offices

# SGF Tdap Guidelines Summary

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1. LHDs ensure site meets all program requirements
2. Provider signs MOU and is enrolled
3. **First order:** Suggested limit of 100 Tdap doses!
4. **Second order:** Order Tdap doses *and* “match” with your own private supply

LHDs interview sites 1 month, 3 months, and 6 months after initial order, then send completed questionnaires to [Rebeca.Boyte@cdph.ca.gov](mailto:Rebeca.Boyte@cdph.ca.gov).

## Is your Practice Ready for the Next Pertussis Epidemic?

Ask us about how to receive FREE Tdap Vaccines



Your patients are counting on **you** for protection

Contact [Name, phone #, email] at [Name of LHD] by [X date] to learn more.

Would this be helpful?

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# Announcements

# Intern to the Rescue

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- Are you one of the high-incidence pertussis counties? (LA, SD, Orange, Riverside, Fresno, San Bernardino, Santa Clara, Contra Costa, Alameda, Sacramento)
- Do you need help identifying providers who need Tdap?
- Our intern may be able to help!
- Email: [Rebeca.Boyte@cdph.ca.gov](mailto:Rebeca.Boyte@cdph.ca.gov)

# Reminder: ACOG Antepartum Records

The American College of Obstetricians and Gynecologists  
ACOG Antepartum Record

DATE: \_\_\_/\_\_\_/\_\_\_ ID #: \_\_\_\_\_  
Hospital of Delivery: \_\_\_\_\_

Name: LAST FIRST MIDDLE

Newborn Care Provider: \_\_\_\_\_ Referred By: \_\_\_\_\_  
Primary Care Provider/Group: \_\_\_\_\_ Address: \_\_\_\_\_  
Final EDD: \_\_\_\_\_

Birth Date: \_\_\_/\_\_\_/\_\_\_ Age: \_\_\_\_\_ Race: \_\_\_\_\_ Marital Status: \_\_\_\_\_ Address: \_\_\_\_\_  
Education (Last Grade Completed): \_\_\_\_\_ Sex:  M  F  See  Z \_\_\_\_\_  
Language: \_\_\_\_\_ Ethnicity: \_\_\_\_\_ Phone: \_\_\_\_\_ (1) \_\_\_\_\_ (2) \_\_\_\_\_  
Partner: \_\_\_\_\_ Phone: \_\_\_\_\_ Policy #: \_\_\_\_\_  
Father of Baby: \_\_\_\_\_ Phone: \_\_\_\_\_ Emergency Contact: \_\_\_\_\_ Phone: \_\_\_\_\_

Total Preg: \_\_\_\_\_ Full Term: \_\_\_\_\_ Premature: \_\_\_\_\_ Ab. Induced: \_\_\_\_\_ Ab. Spontaneous: \_\_\_\_\_ Ectopic: \_\_\_\_\_ Multiple Births: \_\_\_\_\_ Living: \_\_\_\_\_

**Menstrual History**

LMP:  Oligo  Anovula (Month known) Duration: \_\_\_\_\_ Days Frequency: \_\_\_\_\_ Days Menarche: \_\_\_\_\_ (Age Child)  
 Unknow  Normal Amount/Duration Prior Menses: \_\_\_\_\_ Date Conception:  Yes  No Hcg: \_\_\_\_\_

**Past Pregnancies (Last Five)**

| Date Month/Year | GA Weeks | Length of Labor | Birth Weight | Sex | Type of Delivery | Asses | Place of Delivery | Birthweight Duration | Lactation Counsel Needed Yes/No | Comments/Complications |
|-----------------|----------|-----------------|--------------|-----|------------------|-------|-------------------|----------------------|---------------------------------|------------------------|
|                 |          |                 |              |     |                  |       |                   |                      |                                 |                        |
|                 |          |                 |              |     |                  |       |                   |                      |                                 |                        |
|                 |          |                 |              |     |                  |       |                   |                      |                                 |                        |
|                 |          |                 |              |     |                  |       |                   |                      |                                 |                        |
|                 |          |                 |              |     |                  |       |                   |                      |                                 |                        |

**Medical History**

| Detail Positive Remarks include Date & Treatment |   | Detail Positive Remarks include Date & Treatment        |   |
|--|---|---|---|
| p*   | † | p*  | † |
| 17. Dermatologic Disorders                       |   | 18. Operative/Injections (Year & Reason)                |   |
| 18. Allergic (Food, Seasonal, Environmental)     |   | 19. Gyn history (Year & Reason)                         |   |
| 19. Neurologic/Oncology                          |   | 20. Anesthetic Complications                            |   |
| 20. Thyroid Dysfunction                          |   | 21. History of Blood Transfusions                       |   |
| 21. Breast Disease/Breast Surgery                |   | 22. Intestine   |   |
| 22. Pulmonary (COPD, Asthma)                     |   | 23. Art (BP, Cholesterol)                               |   |
| 23. Heart Disease                                |   | 24. History of Abnormal Pap                             |   |
| 24. Hypertension                                 |   | 25. History of STI                                      |   |
| 25. Cancer                                       |   | 26. Psychiatric Issues                                  |   |
| 26. Hematologic Disorders                        |   | 27. Depression/Postpartum Depression                    |   |
| 27. Anemia                                       |   | 28. Trauma/Violence                                     |   |
| 28. Gastrointestinal Disorders                   |   | 29. Tobacco (Current, Cigarette, ENDS, Vapes) (MMT/Day) |   |
| 29. Rheumatoid Disease                           |   | 30. Alcohol (AMT/MW)                                    |   |
| 30. Kidney Disease (I)                           |   | 31. Drug Use (including Cocaine) (Last/Now)             |   |
| 31. Deep Vein Thrombosis                         |   |   |   |
| 32. Diabetes (Type 1 Or Type 2)                  |   |   |   |

Prepreg Prog \*Vacc Use

ANTEPARTUM RECORD (FORM A, P)

- Available as single copies
- Please send email: [Rebeca.Boyte@cdph.ca.gov](mailto:Rebeca.Boyte@cdph.ca.gov) indicating desired quantity.

| Immunizations   | Yes (Month/Year)<br>___/___ | No | If No, Vaccine Indicated?* | Immunizations                  | Yes (Month/Year)<br>___/___ | 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

# WIC Resource from ECBT



## Vaccines 101: Information for WIC Staff

Booklet:

[http://www.ecbt.org/images/articles/Final\\_2017\\_Vaccines\\_101\\_for\\_WIC\\_Staff\\_Guide.pdf](http://www.ecbt.org/images/articles/Final_2017_Vaccines_101_for_WIC_Staff_Guide.pdf)

Archived Webinar:

<http://s95168213.onlinehome.us/Webinars/WIC2017/2017ImmunizationWebinarForWICStaff.mp4>



# Questions?

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