Prenatal Tdap Workgroup
January 17, 2018

Immunization Branch
California Department of Public Health
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
Prenatal immunization with Tdap is Safe
Summary

• 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

- 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.

https://www.cdc.gov/pertussis/pregnant/research.html
Multiple human studies consistent with the safety of prenatal Tdap immunization

- 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

- 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]

Prior FDA Label framework - basis for 2005 Tdap labels
“Only if clearly needed”

<table>
<thead>
<tr>
<th>Pregnancy Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td><strong>No risk in controlled human studies:</strong> Adequate and well-controlled human studies have failed to demonstrate a risk to the fetus</td>
</tr>
<tr>
<td>B Boostrix, 2005</td>
<td><strong>No risk in other studies:</strong> 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</td>
</tr>
<tr>
<td>C Adacel, 2005</td>
<td><strong>Risk not ruled out:</strong> 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.</td>
</tr>
<tr>
<td>D</td>
<td><strong>Positive evidence of risk:</strong> 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.</td>
</tr>
<tr>
<td>X</td>
<td><strong>Contraindicated in pregnancy:</strong> 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.</td>
</tr>
</tbody>
</table>
Transition in FDA Labeling for Use in Pregnancy 2014 - present

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
Transition in FDA Labeling for Use in Pregnancy 2014 - present

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
Summary

• 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
Vaccine Injury Compensation Program

• 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

Kimberly Hernandez, MPH
Kern County Public Health Services Department
Prenatal Tdap Working Group Meeting
January 17, 2018
Pertussis in Kern County
Pertussis in Kern County

Number of Cases

<1 year  Total Cases
Proportion of Pertussis Cases <1 year
### DTap and Tdap Vaccination Rates

<table>
<thead>
<tr>
<th></th>
<th>Kern</th>
<th>California</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kindergarten (DTap)</td>
<td>96.2%</td>
<td>96.9%</td>
</tr>
<tr>
<td>7th Grade (Tdap)</td>
<td>97.6%</td>
<td>98.3%</td>
</tr>
</tbody>
</table>
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

- Fresno: 39.3%
Push for Further Evaluation

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

- 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

• 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

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

- Responded
- Declined
- Pending
Preliminary Results

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

100

Yes

No
Preliminary Results

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

- < 27 weeks
- 27-36 weeks
- 36+ weeks
- Postpartum
Preliminary Results

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

- Yes: 29
- No: 71
Preliminary Results

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

- 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!

- Additional providers
- More in-depth analysis
Thank You!

- Lauri McAllister
  MPH Candidate
  American Public University
Questions?

• Kimberly Hernandez  
Kern County Public Health Services Department  
(661) 868-0407  
hernankim@kerncounty.com
SGF Tdap Guidelines
SGF Prenatal Tdap Program

• **25,000 doses of Tdap** (Adacel®, 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)
  • Designated staff as clinic liaison to health department
  • Agreement to report at each LHD check-in
Evaluation

• 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

• 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

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.
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.
Announcements
Intern to the Rescue

- 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
Reminder: ACOG Antepartum Records

• Available as single copies
• Please send email: Rebeca.Boyte@cdph.ca.gov indicating desired quantity.
WIC Resource from ECBT

Vaccines 101:
Information for WIC Staff


Archived Webinar: [http://s95168213.onlinehome.us/Webinars/WIC2017/2017ImmunizationWebinarForWICStaff.mp4](http://s95168213.onlinehome.us/Webinars/WIC2017/2017ImmunizationWebinarForWICStaff.mp4)
Questions?

Rebeca Montealegre Boyte
510-620-3762
Rebeca.Boyte@cdph.ca.gov