“Cocooning” and Tdap vaccination

Jennifer L. Liang, DVM, MPVM

On behalf of the Pertussis Vaccines Work Group

Advisory Committee on Immunization Practices
June 25, 2015
Evaluating Tdap vaccination of close contacts of infants

- Tdap vaccine
  - Second dose of Tdap
  - Effectiveness

- Pertussis in young infants

- Strategies to prevent pertussis in young infants
  - ACIP recommendations

- Evaluating the impact of “cocooning”

- Vaccinating during pregnancy

- WG conclusions

- Discussion
Tdap VACCINE
Response to Second Tdap at 5- or 10-yr Interval
Safety and Immunogenicity

- **Safety**
  - Generally comparable after first Tdap
  - Majority of local and systemic adverse events: mild to moderate; self-limited
  - Of few serious adverse events reported, none related to second Tdap
  - Rates comparable at the 5- and 10-year interval

- **Immunogenicity**
  - Tetanus and Diphtheria ~100% seroprotection
  - Pertussis
    - Response at 5- and 10-year intervals similar
    - Comparable to historic and contemporaneous first dose

Halperin 2011; Knuf 2010; Booy 2010, Halperin 2012, Mertsola 2010
Sanofi Pasteur – revaccination with Adacel

Adults administered 9-11 years after previous Tdap

- U.S. study completed
  - Presented to WG and ACIP (2013)
- Canadian study will finish later this year
- Plans to submit to FDA
GSK Revaccination Studies for Boostrix

- GSK is conducting clinical studies in the US for revaccination after prior vaccination with Boostrix
  - GSK recently completed a revaccination study of young adults, 20-28 years old, who were initially vaccinated 10 years earlier when they were adolescents (11-18 years old).
  - Revaccination study in adults, 28-73 years old who were initially vaccinated approximately 9 years ago, when they were 19-64 years old, began this year.
- Plans to submit the data to the FDA for consideration of a label update for BOOSTRIX will be dependent on pertussis epidemiology and ACIP recommendations.
### Estimates of Tdap vaccine effectiveness in adolescents

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**Tdap duration of protection among populations born during 1998-2000, that only received acellular vaccines, Washington and Wisconsin, 2012**

**Vaccine Effectiveness (VE)**

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<th>Time since Tdap</th>
<th>VE, % (95% CI)</th>
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<th>Year of Tdap Receipt</th>
<th>VE, % (95% CI)</th>
<th>Wisconsin²</th>
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<td>&lt; 1 year</td>
<td>73.1 (60.3-81.8)</td>
<td></td>
<td>2012</td>
<td>75.3 (55.2-86.5)</td>
<td></td>
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<td>1 - &lt; 2 years</td>
<td>54.9 (32.4-70.0)</td>
<td></td>
<td>2011</td>
<td>68.2 (60.9-74.1)</td>
<td></td>
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<td>2 - &lt; 4 years</td>
<td>34.2 (-0.03-58.0)</td>
<td></td>
<td>2010</td>
<td>34.5 (19.9-46.4)</td>
<td></td>
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<td></td>
<td>2009/2008</td>
<td>11.9 (-11.1-30.1)</td>
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Tdap Vaccination: Unclear Effect on Preventing Transmission

- Vaccinated person’s symptoms not as severe – may be less likely to transmit

- Australian cocooning evaluation
  - Moderate reduction in risk of pertussis in infants – parents vaccinated at least 4 weeks before infant disease onset
  - Effect seen for mothers vaccinated post-partum
    - Unclear if infant disease risk lower because of impact on transmission or lack of exposure

- Baboon model
  - Acellular pertussis vaccines protect against disease but not infection
  - Bacterial colony counts comparable to unvaccinated animals
  - Transmitted pertussis to other cohoused baboons

PERTUSSIS IN YOUNG INFANTS
Reported pertussis incidence by age group: 1990-2014*, United States

*2014 data are provisional.

SOURCE: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System
Hospitalizations and Deaths in Infants <12 Months of Age, % Total Cases, 2004-2014*, United States

* 2014 data are provisional and subject to change

Source: CDC, National Notifiable Diseases Surveillance System and Supplemental Pertussis Surveillance System
STRATEGIES TO PREVENT PERTUSSIS IN YOUNG INFANTS
2005 ACIP Cocooning Recommendation: A new strategy

- Vaccinating all close contacts of infants aged less than 12 months with Tdap to reduce the risk of transmission of pertussis to these infants
  - Ideally at least 2 weeks before contact with the infant.
  - Parents, siblings, grandparents, child-care providers and health-care personnel
  - Pregnant women vaccinated immediately post-partum
Shifting the time of mother’s Tdap dose: postpartum to pregnancy

- Provides earlier benefit to mother, thereby potentially providing indirect protection to infant at birth
- High levels of transplacental maternal antibodies in infants of mothers vaccinated during pregnancy
  - Likely provides direct immunity to infant
ACIP maternal Tdap recommendations
Preventing infant pertussis

2011
- During pregnancy (if not previously received Tdap)
  - Preferably during the third or late second trimester
- Post-partum dose – if not during pregnancy and not previously received Tdap

2012
- During each pregnancy, irrespective of prior Tdap history
  - Between 27 and 36 weeks gestation, but may be given at any time
- Post-partum dose if not vaccinated during pregnancy and if previously not received Tdap
- “Cocooning”
  - Guidance will be forthcoming on revaccination of persons who anticipate close contact with an infant, including postpartum women who previously have received Tdap
EVALUATING THE IMPACT OF COCOONING
"Cocooning" strategy in practice
Operational success

- Primarily hospital-based, targeting post-partum period
- Educating providers and patients
- Postpartum dose
  - Standing orders
- Vaccinating close contacts
  - On-site clinic
  - Convenient clinic hours
  - Free Tdap

Cocooning strategy in practice
Operational challenges

- **Logistical**
  - Target potential contacts during short period of time
  - Additional staffing for education and vaccine administration
  - Inability to verify vaccine history
  - Hospitals not set up to treat outpatients

- **Financial**
  - Operational costs of program
  - Funding to offer free vaccine
  - Billing and reimbursement

- **Program sustainability**

How complete is the cocoon around infants?

- In 2012, 26% Tdap coverage in adults aged 19–64 years who reported living with an infant aged <1 year

- Tdap uptake highest in postpartum mothers

- Limited success in vaccinating fathers or other family members
  - Knowledge gap about pertussis and vaccine
  - Household size impacts ability to vaccinate all members
  - If no on-site clinic available, numerous barriers to receive Tdap
    - Delay vaccination to later date
    - Locating where to get vaccinated

Conflicting evidence on the effectiveness of postpartum dose in preventing infant pertussis

- California, 2010: pertussis incidence in infants born at hospitals with a postpartum Tdap policy was lower compared to hospitals without postpartum Tdap policy suggesting that vaccinating new mothers may protect infants.¹

- Another study compared pre-intervention to post-intervention period found no impact of postpartum Tdap on infant disease.²


Unclear and inconclusive evidence on effectiveness of cocooning in preventing infant pertussis

**United States**

- **Hospital-based evaluation**
  - Observed no impact in reduction of infant pertussis, but cautious interpretation
    - Limited by design, small numbers, changing recommendations

- **Emerging Infections Program (EIP)**
  - Numbers too limited to assess effectiveness
  - Assessed completeness of cocoon
    - 9 (4.5%) fully vaccinated cocoons; 5/9 mother only

**Australia**

- Moderate reduction in risk of pertussis in infants – parents vaccinated at least 4 weeks before infant disease onset

Changing pertussis epidemiology – shift in source of transmission to infants

- Previously, parents commonly identified as source
  - Mothers most often

- More recently, siblings identified as most common source
  - Having a sibling was a risk factor for infant pertussis
  - Source of infection study (CDC, unpublished)
    - 2006-2013 a source of infection for 44% of identified infant pertussis cases
    - 66%-85% of identified sources were classified as family members
      - Siblings most commonly identified (35.5%)

VACCINATING DURING PREGNANCY
Agreement of high effectiveness of maternal pertussis vaccination -- United Kingdom

Observational study

- Vaccine screening method
- For infants <3 mths of age at onset of pertussis

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<th>Timing of maternal vaccination</th>
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<tr>
<td>91% (83-95)</td>
<td>At least 28 days before birth</td>
</tr>
<tr>
<td>38% (-95-80)</td>
<td>0-6 days before or 1-13 days after birth</td>
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Case-Control study

- Cases: infants <2 mths of age at onset pertussis infection
- 58 cases, 55 controls
  - Mothers vaccinated during pregnancy: 10 cases (17%) and 39 controls (71%)
- Unadjusted VE = 91% (77%-97%)
- Adjusted* VE = 93% (81%-97%)

* Adjusted by sex, geographical area, and birth period

Tdap coverage among pregnant women from various sources, United States

- **Vaccine Safety Datalink sites**
  - 13.7% (2012)

- **Michigan Medicaid**
  - 14.3% (2011-2013)

- **Internet Panel Survey of pregnant women, during flu season**
  - 22.9% (2014-2015 flu season)

CDC. Internet Panel Survey. Women aged 18–49 years pregnant at any time since August of prior year (e.g. 2014 for the April 2015 survey) were recruited in a general population internet panel operated by Survey Sampling International.
WG Assessments
Vaccinating close contacts of infants with Tdap

- Implementation and sustainability of “coccooning” programs remain a challenge
- Lack of data evaluating effectiveness/impact of strategy
- Inconclusive evidence that additional doses for close contacts, including postpartum, would be beneficial in prevention of disease and transmission of pertussis to infants
  - Even if additional Tdap doses recommended, this would not address the shift to siblings as source of pertussis to infants
- Vaccinating women during pregnancy is optimal strategy to prevent infant pertussis
Available evidence does not support changes to the current ACIP Tdap recommendation for close contacts of infants, including the postpartum dose for women.

Focus on current pertussis vaccination program

- Maintain high level of DTaP coverage
- Sustain Tdap coverage in adolescents
- Improve adult Tdap coverage
- Vaccinate women during pregnancy
**Factsheets for Healthcare Professionals**

**Provide the best prenatal care to prevent pertussis**

**Strategies for healthcare professionals**

**5 Facts about Tdap and Pregnancy**

1. **Tdap during pregnancy provides the best protection for mother and infant.**
   - Recommended and administer or refer your patients to receive Tdap during every pregnancy.
   - Optimal timing is between 27 and 36 weeks’ gestation to maximize the maternal antibody response and passive antibody transfer to the infant.
   - Fewer babies will be hospitalised for and die from pertussis when Tdap is given during pregnancy rather than during the postpartum period.

2. **Postpartum Tdap administration is NOT optimal.**
   - Postpartum Tdap administration does not provide immunity to the infant, who is most vulnerable to the disease’s serious complications.
   - Infants remain at risk of contracting pertussis from others, including siblings, grandparents, and other caregivers.
   - It takes about 2 weeks after Tdap receipt for the mother to have protection against pertussis, which means the mother is still at risk for catching and spreading the disease to her newborn during this time.

3. **Coconing alone may not be effective and is hard to implement.**
   - The term “coconing” means vaccinating anyone who comes in close contact with an infant.
   - It is difficult and can be costly to make sure that everyone who is around an infant is vaccinated.

4. **Tdap should NOT be offered as part of routine preconception care.**
   - Protection from pertussis vaccines does not last as long as vaccine experts would like, so Tdap is recommended during pregnancy in order to provide optimal protection to the infant.
   - If Tdap is administered at a preconception visit, it should be administered again during pregnancy between 27 and 36 weeks gestation.

5. **Tdap can be safely administered earlier in pregnancy if needed.**
   - Pregnant women should receive Tdap anytime during pregnancy if it is indicated for wound care or during a community pertussis outbreak.
   - If Tdap is administered earlier in pregnancy, it should not be repeated between 27 and 36 weeks gestation; only one dose is recommended during each pregnancy.

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**Making a strong vaccine referral to pregnant women**

**Strategies for healthcare professionals**

**Making the Referral**

Begin each referral with a vaccine recommendation that includes information on why the vaccine is beneficial and safe for mother and baby. Tailoring your message with scientific data or personal anecdotes may help convey the vaccine’s importance to individual patients.

Provide information on where patients can get the vaccine(s) you recommend. For help locating vaccines in your area, the HealthMap Vaccine Finder is available at: http://vaccine.healthmap.org.

Always write a patient-specific prescription. This will help your patients obtain the vaccine at another location where a prescription may be required.

Anticipate questions on why patients cannot get vaccinated in your office. For example, if you stock flu vaccine, but not Tdap, be prepared to explain why you offer one vaccine but not the other.

Re-emphasize vaccine importance. Remember to emphasize the fact that just because you do not stock a specific vaccine in your office does not mean it is not important. It is less important than other vaccines you do stock, or that you have concerns about its safety.

Have a plan in place to answer questions from other immunization providers who are concerned with vaccinating your pregnant patients. Questions should be answered promptly, as it is likely your patient is with them at the time they contact you.

**Vaccines Routinely Recommended for Pregnant Women**

It is safe for the flu vaccine and Tdap vaccine to be given to pregnant patients at the same time.

**Flu Vaccine**
- Is recommended for pregnant women and safe to administer during any trimester.
- Is the best way to protect pregnant women and their babies from the flu, and prevent possible flu-associated pregnancy complications.
- Is safe and can help protect the baby from flu for up to 6 months after birth. This is important because babies younger than 6 months of age are too young to get a flu vaccine.

**Tdap Vaccine**
- Is recommended during every pregnancy, ideally between 27 and 36 weeks gestation.
- When given during pregnancy, boosts antibodies in the mother, which are transplacentally transferred to her unborn baby. Third trimester administration optimizes neonatal antibody levels.
- Helps protect infants, who are at greatest risk for developing pertussis and its life-threatening complications, until they are old enough to start the childhood pertussis vaccine series.

[www.cdc.gov/pertussis/pregnant](http://www.cdc.gov/pertussis/pregnant)
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2. Postpartum Tdap administration is NOT optimal.
   - Postpartum Tdap administration does not provide immunity to the infant, who is most vulnerable to the disease’s serious complications.
   - Infants remain at risk of contracting pertussis from others, including siblings, grandparents, and other caregivers.
   - It takes about 2 weeks after Tdap receipt for the mother to have protection against pertussis, which means the mother is still at risk for catching and spreading the disease to her newborn during this time.

3. Cocooning alone may not be effective and is hard to implement.
   - The term “cocooning” means vaccinating anyone who comes in close contact with an infant.
   - It is difficult and can be costly to make sure that everyone who is around an infant is vaccinated.

4. Tdap should NOT be offered as part of routine preconception care.
   - Protection from pertussis vaccines does not last as long as vaccine experts would like, so Tdap is recommended during pregnancy in order to provide optimal protection to the infant.
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5. Tdap can be safely administered earlier in pregnancy if needed.
   - Pregnant women should receive Tdap anytime during pregnancy if it is indicated for wound care or during a community pertussis outbreak.
   - If Tdap is administered earlier in pregnancy, it should not be repeated between 27 and 36 weeks gestation; only one dose is recommended during each pregnancy.

Strongly recommend Tdap to your patients during the 3rd trimester of each pregnancy.

Making a strong vaccine referral to pregnant women

**Making the Referral**

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Tailoring your message with scientific data or personal anecdotes may help convey the vaccine’s importance to individual patients.

Provide information on where patients can get the vaccine(s) you recommend. For help locating vaccines in your area, the HealthMap Vaccine Finder is available at: http://vaccine.healthmap.org.

Always write a patient-specific prescription. This will help your patients obtain the vaccine at another location when a prescription may be required.

Anticipate questions on why patients cannot get vaccinated in your office. For example, if you stock flu vaccine but not Tdap, be prepared to explain why you offer one vaccine but not the other.

Re-emphasize vaccine importance. Remember to emphasize the fact that just because you do not stock a specific vaccine in your office does not mean it is not important. It is less important than other vaccines you do stock, or that you have concerns about its safety.

Have a plan in place to answer questions from other immunization providers who are concerned with vaccinating your pregnant patients. Questions should be answered promptly, as it is likely your patient is with them at the time they contact you.

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3. Co-cooking alone may not be effective and is hard to implement.
   - The term “co-cooking” means vaccinating anyone who comes in close contact with an infant.
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4. Tdap should NOT be offered as part of routine preconception care.
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Get Reimbursed for Tdap Vaccination

Coding and billing are known barriers to administering vaccines during pregnancy. Correct coding enables an office to report these activities to third-party payers and receive appropriate reimbursement for these services.

- ACOG’s Tdap Toolkit provides coding and billing information for Tdap: www.acog.org/TdapToolKit

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February 2015
Fact Sheet and Posters for Pregnant Women

**Free to download**

**Limited quantities free for order**
What We Are Asking Partners To Do

- **GIVE STRONG RECOMMENDATIONS** for whooping cough vaccine (Tdap) in the 3rd trimester of each pregnancy

- **ASK HEALTHCARE PROFESSIONALS** to include *Born with Protection* campaign materials in prenatal information packets
  

- **ENCOURAGE** pregnant women to ask their doctor or midwife about whooping cough vaccine

- **PROMOTE** CDC’s Tdap during pregnancy website and materials through your social media channels
  
  [www.cdc.gov/pertussis/pregnant](http://www.cdc.gov/pertussis/pregnant)
More Ways to Get Involved!

- REMIND prenatal healthcare professionals that whooping cough outbreaks are happening across the U.S.

- RAISE AWARENESS among prenatal healthcare professionals that:
  - 3rd trimester vaccination every pregnancy offers the best protection for baby
  - Postpartum Tdap administration is NOT optimal
  - Cocooning alone may not be effective and is hard to implement

- DIRECT pregnant women to CDC information about Tdap during pregnancy
  - www.cdc.gov/pertussis/pregnant

- COLLABORATE with us to expand the campaign’s reach