

# Cocooning Efforts in California During the 2010 Pertussis Epidemic



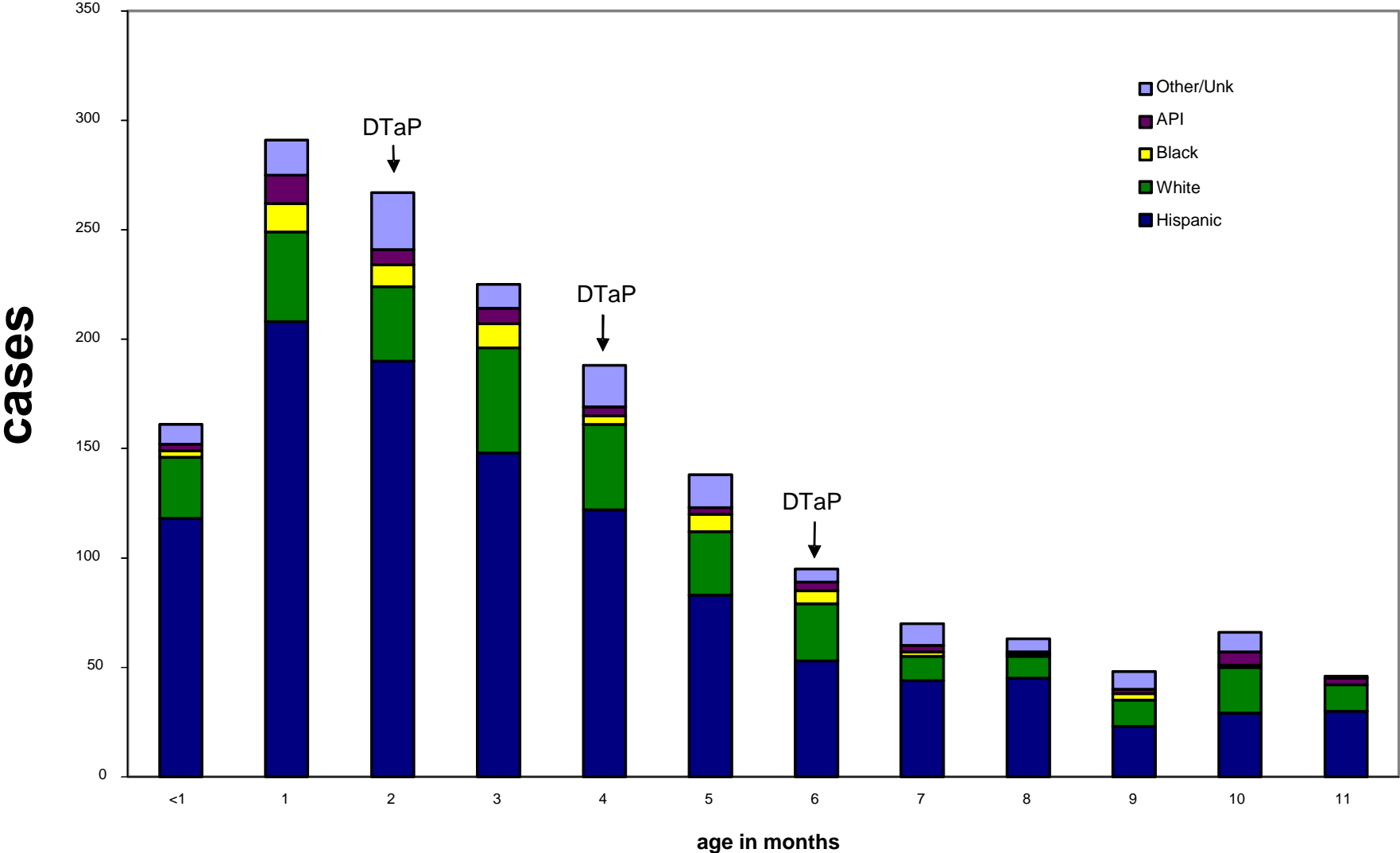
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# Background – Pertussis in Infants

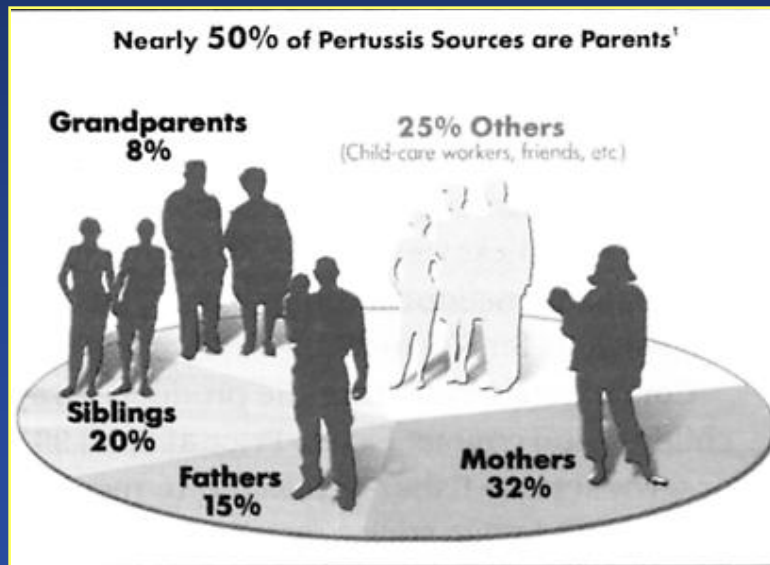
- Most severe disease occurs in infants <3 months of age
  - >60% of infected infants <1 year are hospitalized
  - All pertussis deaths in California since 1998 have been in infants  $\leq 3$  months of age
- U.S. infants do not start the DTaP series until 2 months of age per ACIP recommendations (series may start at 6 weeks in the setting of an outbreak)
- The incidence of pertussis is up to 20-fold higher in infants too young to have completed the primary immunization series ( $\leq 6$  months of age)
- California birth cohort in 2009: 526,774

# Infant pertussis cases by age in months and race/ethnicity – California, 2010



# Who Transmits Pertussis to Infants?

- Adults are likely to transmit pertussis to infants
  - Among 264 known source-cases:
    - ✓ Almost 50% were parents, most often mothers
    - ✓ 51% were adults >19 years of age



Bigard KM, et al. Infant pertussis: who was the source? *Pediatr Infect Dis J* 2004; 23(11):985-989.

Wendelboe AM, et al. Transmission of *Bordetella pertussis* to young infants. *Pediatr Infect Dis J* 2007; 26(4):293-299.

deGreeff SC et al. Pertussis disease burden in the household: how to protect young infants. *Clinical Infectious Diseases* 2010; 50(10):1339-1345.

# “Cocooning”

- Tdap was licensed in the U.S. in 2005
- In 2005, the Global Pertussis Initiative (GPI) used the term “cocoon strategy” and recommended immunization of family members and close contacts of newborns in countries where it was economically feasible
- The GPI report cited a modeling prediction that the incidence of pertussis among infants  $\leq 3$  months of age could be decreased by 70% if households of newborns had 90% vaccine coverage and vaccine efficacy = 90%

Van Rie A and Hethcote HW. Adolescent and adult pertussis vaccination: computer simulations of five new strategies. *Vaccine* 2004;22:3154–3165

# Cocooning in the U.S.

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- In 2006, the Advisory Committee on Immunization Practice (ACIP) recommended Tdap for adults who have or anticipate having close contact with an infant <12 months of age
  - Women of childbearing age (preconception or immediately postpartum)
  - Other close contacts of infants <12 months of age
- Increased pertussis incidence in California was recognized in early April 2010; cocooning was seen as a possible mitigation tool, but no data were available on whether California birth hospitals were vaccinating postpartum women

# Postpartum Tdap Survey

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- In April 2010, a birthing hospital postpartum Tdap survey was conducted in California
- Survey was distributed to Infection Preventionists and Labor and Delivery Managers at California hospitals with >50 births/year in 2009 (n=261)
- Primary questions
  - Does hospital have a policy to provide Tdap for postpartum women or other infants contacts and if so, when was it implemented?
  - What are the barriers to initiating or implementing a Tdap vaccination policy?

# Tdap Survey Results – April 2010

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- Only 25% of California birthing hospitals had a postpartum Tdap policy
- 11% of facilities with an NICU had a policy to offer vaccine to parents/siblings of NICU patients
- 38% of facilities with an emergency department offered Tdap for wound management
- 26% offered Tdap to healthcare personnel
  - As of September 1, 2010, all California hospitals and outpatient healthcare facilities were required to offer Tdap to healthcare personnel covered under Cal/OSHA's aerosol-transmissible disease standard

# Barriers to Hospital Postpartum Tdap Programs

- Primary barrier cited was reimbursement
  - U.S. hospitals typically contract with payers for labor and delivery costs; costs are “bundled,” i.e., set charge for all costs regardless of actual expenses incurred
  - Adding an additional service that is not contracted for (such as Tdap) results in no reimbursement for the service
- Why not add Tdap to contract?
  - Payers looking for most competitive contracts
  - Hospitals have incentive to keep costs low

# Other Barriers

- Even if a postpartum Tdap policy was present, Tdap uptake was often suboptimal
  - Staff busy; unable to effectively educate new mothers about pertussis and on the need for Tdap vaccine
  - Patient immunization records unavailable; hospital policies typically prohibited administering Tdap within two years of Td or giving a second dose of Tdap; if unsure would not give Tdap
- Hospitals had difficulty vaccinating other infant contacts who were not patients, e.g., household and family members of postpartum women
  - Medical-legal concerns over vaccinating non-patients
  - Some hospitals with a Tdap “champion” were able to operationalize methods of vaccinating non-patients

# Postpartum Tdap Conclusions

- Efforts by hospitals to vaccinate postpartum women and other non-patient infant contacts require a multi-faceted, multi-disciplinary approach for successful implementation
- The necessary infrastructure and education requires investment of financial resources and staff time
- A champion for the program is critical



# 2010 Community-Wide Barriers to Tdap Administration

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- Tdap cost and reimbursement issues
- ACIP recommendations on the interval between Td and Tdap confusing to providers; patient uncertainty about date of last Td led to missed opportunities for Tdap
- Tdap not licensed in U.S. for those aged 7-9 or older than 64; no pertussis containing vaccine for these age groups
- Differing recommendations on the use of Tdap in pregnant women by ACIP, the American Academy of Pediatrics (AAP) the American College of Obstetricians and Gynecologists (ACOG)
- Emergency departments unfamiliar with the use of Tdap for wound management

# How the California Department of Public Health (CDPH) Addressed Tdap Barriers

- May 2010 – offered hospitals free Tdap for postpartum women and other infant contacts, including families of NICU infants; offer expanded to community health centers due to hospital difficulty in vaccinating non-patients
- Emergency departments encouraged to use Tdap
- Worked with payers re: Tdap reimbursement
- Recommended accelerated DTaP schedule for infants (first dose at age six weeks)
- July 2010 – issued expanded recommendations on the use of Tdap



# News Release

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

## FOR IMMEDIATE RELEASE

July 19, 2010

### **CDPH Broadens Recommendations for Vaccinating Against Pertussis: Immunization Key to Controlling Whooping Cough**

“...Pediatricians are extremely concerned about the pertussis epidemic in California,” said Kris Calvin, Chief Executive Officer of the American Academy of Pediatrics, California. “We appreciate and fully support CDPH’s efforts.” Family physicians are equally concerned. “The new recommendations will help tremendously in addressing pertussis prevention,” said Jack Chou, M.D., president of the California Academy of Family Physicians. “We support the efforts of the California Department of Public Health.”

...Through July 13 of this year, 1,496 cases of pertussis were reported, a five-fold increase from the same period last year when 304 cases were reported...Five infants, all under three months of age, have died from pertussis this year. Unimmunized or incompletely immunized young infants are particularly vulnerable...

# July 2010 CDPH Tdap Recommendations

- To address barriers related to ACIP Tdap recommendations, CDPH recommended:
  - Immunizing anyone  $\geq 10$  years of age who had not yet received Tdap, especially
    - ✓ women of childbearing age, preferably before, or else during or immediately after pregnancy
    - ✓ others with close contact with young infants
    - ✓ includes persons  $>64$  years of age
    - ✓ wound management (to replace Td)
  - Using Tdap for under-immunized 7-9 year olds
  - No minimum interval needed between Td and Tdap



# Postpartum Tdap Effectiveness Study

- Birthing hospital postpartum Tdap policy survey data were used to conduct a postpartum Tdap effectiveness study
- Study question: Is postpartum Tdap vaccination an effective strategy to reduce transmission of *B. pertussis* to young infants?
- Matched pertussis cases <4 months of age born from 2006-2009 to birth certificate data to identify hospital of birth



# Postpartum Tdap Effectiveness Study: Methods

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- Calculated annual rate of pertussis among infants born in each hospital (# cases/total births)
- Ordinary Least Squares regression analysis used to estimate the impact of a postpartum Tdap vaccination policy on pertussis among infants born in the facility
  - Controlled for hospital location (county) and year to account for natural variation in disease incidence across years

# Postpartum Tdap Effectiveness Study: Results

- 744 infants <4 months of age were reported with pertussis in 2006-2009
  - 585 (77%) hospitalized
  - 12 (1.6%) died
  - Hospital of birth identified for 620 infants (93%)
  - Overall rate of infant pertussis was 34.4 cases/100,000 births
    - ✓ Incidence rate ranged from 21.7 in 2007 to 55.7 in 2009, consistent with statewide trends

# Postpartum Tdap Effectiveness Study: Results

- 239 (92%) birthing hospitals responded to survey
  - 51 (21%) had implemented a postpartum Tdap policy by the end of 2009
  - The first Tdap policy was implemented in January 2007
  - 188 (79%) “control” hospitals had no policy or were in the process of initiating a policy
- 183 (70%) of facilities had at least one infant from the birth cohort diagnosed with pertussis at <4 months of age (median=2, range 0-21)

# Results, continued



- Presence of a postpartum Tdap policy was associated with a significant decline in pertussis incidence of 28.1 cases/100,000 ( $p < 0.01$ )
- Overall 2009 pertussis incidence was lower in hospitals with a Tdap policy
  - Hospitals with Tdap policy:  
42.1 cases/100,000 births (95% CI 30.2-54.0)
  - Hospitals without a Tdap policy:  
62.1 cases/100,000 births (95% CI 54.1-70.2)

# Data Limitations

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- 2010 data not included; will continue analysis when 2010 birth certificate data are available
  - If there is a true effect, it should be seen in 2010
- Incidence only calculated by year – will attempt to break down incidence by month in future analysis to account for hospitals that established a Tdap policy mid-year
- Vaccine uptake in facilities with a Tdap policy was unknown
- Maternal vaccination status for infant cases unknown

# Discussion

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- A decline in pertussis incidence was observed in hospitals with a postpartum Tdap vaccination policy suggesting that vaccinating new mothers may reduce transmission to infants
- Although recommended in 2006, most California birthing hospitals had not implemented a postpartum Tdap policy by 2009 and in hospitals with policies, Tdap uptake may have been suboptimal
- A follow-up hospital survey has been initiated to determine how many postpartum women and other infant contacts were vaccinated and whether Tdap programs are continuing

# Updated Hospital Tdap Survey, Preliminary Results, August 2011

- 77 hospital respondents:
  - 65 (85%) had ever had a postpartum Tdap policy; most policies were implemented in 2010
  - 37 (73%) administered Tdap if no immunization record available per CDPH recommendation
  - 33 (64%) enrolled in free Tdap program
  - 20 (36%) vaccinated non-patient infant contacts
  - Most responding hospitals continuing to vaccinate postpartum women even though free Tdap program has ended, but half of those vaccinating other infant contacts have stopped

# Prenatal Care Provider Survey – Preliminary Results, August 2011

- 53 respondents:
  - 41 (79%) vaccinate any patients
  - 34 (90%) use Tdap
  - 27 (71%) vaccinate pregnant women with Tdap
    - ✓ 19 (83%) started vaccinating pregnant women after the July 2010 CDPH recommendations
    - ✓ Most vaccinate in 2<sup>nd</sup> and 3<sup>rd</sup> trimesters only
    - ✓ Most pregnant women accept Tdap (88%)
- 32 (94%) vaccinate pregnant women for influenza
- 50% of practices were enrolled in the U.S. Vaccines for Children Program

# Conclusions

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- Tdap reimbursement is a barrier to postpartum Tdap vaccination programs in U.S. hospitals
- Even if Tdap is free, postpartum Tdap programs may not achieve high immunization rates
- Administrative/cost barriers may prevent hospital immunization of non-patient infant contacts
- Although cocooning may reduce the incidence of infant pertussis and should be encouraged, difficulty in implementing such programs in the U.S. may limit their full potential



# Cocooning vs. Community Vaccination



- Community vaccination as a strategy to protect infants may also fail to achieve goals
  - Current estimates suggest that only 6% of U.S. adults had received Tdap by 2009 leaving a very large pool of susceptibles
  - Even if large numbers of adults could be vaccinated, vaccine efficacy is suboptimal and immunity from vaccination (or disease) is continually waning resulting in a need for revaccination
  - Herd immunity levels required to interrupt transmission estimated at >90%; sustaining this level of immunity would be difficult

# Cocooning vs. Community Vaccination

- Data limited on the efficacy of using a cocooning strategy to protect infants or of protecting infants by increasing overall vaccination rates in the community
- Cocooning has the following advantages:
  - Targeted use of resources
  - Family members most likely to transmit pertussis to vulnerable infants; may be more effective way to prevent transmission to those at highest risk for morbidity and mortality



# Community Vaccination – Natural Experiment

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- New California school law effective July 2011
- All 3 million students entering 7-12<sup>th</sup> grades in 2011-2012 are required to have a dose of pertussis-containing vaccine or have a personal beliefs exemption; in subsequent years, newly entering 7<sup>th</sup> grade students will have the requirement
- Current Tdap coverage in California adolescents estimated at 53%, similar to national estimate of 55.6%
- Will this help reduce community-wide transmission?
- Because of the 2010 epidemic rates are likely to be lower in subsequent years regardless of mandate



# Scientific Gaps

- DTap and Tdap vaccine efficacy – possible need for change in schedule, need to determine Tdap revaccination interval
- Community vaccination efficacy – do adolescent Tdap mandates reduce the number of infant cases?  
Cocooning efficacy and feasibility – continue to recommend, but pursue other strategies that more directly protect infants
  - Vaccination of pregnant women to protect infants via transplacental transfer of maternal antibodies;
  - Need to revaccinate during each pregnancy?
  - Vaccination of infants at birth



# Questions?

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# Rationale for Recommendations

- The safety of Tdap in children 7 through 9 years suggested by two studies; Tdap licensed in Canada to age four years
- Local and systemic events after ADACEL® vaccination less frequent in adults <65 than adolescents, suggesting the safety of Tdap in older populations (FDA Clinical Briefing Document)
- Td is safely given to pregnant women; no theoretical risk of harm to mother or fetus exists from Tdap - AAP recommends use in pregnancy; not a contraindication for ACIP and ACOG, but preconception or postpartum administration preferred
- Tdap given after previous Td or DTaP is well tolerated at intervals of 1-18 months; there is no minimum interval between doses for all the stated intervals in ACIP guidance

Halperin et al. *Pediatr Infect Dis J* 2006;25:195-200, Scheifele et al. *Pediatr Infect Dis J* 2005;24(12): 1059-1066, Beytout et al. *Hum Vaccines* 2009;5(5): 315-321.

# Tdap for Healthcare Personnel

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- Per the Cal/OSHA aerosol-transmissible disease standard, employees who may be exposed to aerosol-transmissible diseases must be offered Tdap free of charge if they haven't already received it
- Susceptible employees must also be offered measles, mumps, rubella, and varicella vaccines and all employees must be offered influenza vaccine each year
- Employees should be offered Tdap unless they can provide written documentation of a prior dose
- No minimum interval between the last dose of Td