Effectiveness of 5-Pertussis-Component Tetanus, Diphtheria, and Acellular Pertussis ($Tdap_5$) Vaccination in Pregnancy at Preventing Infant Pertussis*

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KEY TAKEAWAYS

- $Tdap_5$ vaccination during pregnancy reduced infant pertussis by *96% in the first 2 months* and *55.8% in the first 12 months of life*
- $Tdap_5$ vaccination during pregnancy continued to provide protection against pertussis throughout the first year of life, even after infants received their own DTaP vaccinations

BACKGROUND

Pertussis poses the greatest burden on infants <6 months (incidence: 76.5 per 100,000 in US, 2019); between 2004 & 2016, *85.5% of pertussis* deaths occurred in infants <2 months old

Although DTaP vaccination may be initiated at 6 weeks of age, it is routinely scheduled at 2 months, leaving young infants particularly vulnerable during this interval. To address this critical gap, ACIP in 2012 recommended that all pregnant women receive Tdap vaccination during 27–36 weeks of gestation during each pregnancy irrespective of prior vaccination history

Multiple Tdap formulations are available for use during pregnancy, and most effectiveness studies have focused on protection of infants before their first DTaP dose at 2 months of age

OBJECTIVE

The primary objective of this study was to evaluate the effectiveness of $Tdap_5$ vaccination during pregnancy in preventing PCR-confirmed pertussis disease in infants during the *first 2 and 12 months of life*

STUDY CONDUCT

Study design

Retrospective observational cohort study conducted within KPNC hospitals

Pertussis confirmed by centralized PCR; follow-up from birth to 2 and 12 months

Vaccines

Maternal vaccine: $Tdap_5$ (contains 5 pertussis components; Adacel, Sanofi), ≥ 14 days before delivery

Infant vaccination: DTaP at 2, 4 and 6 months of age

Study duration

1st Jan 2010 – 31st Dec 2019

Follow-up through 31st March 2020

Inclusion criteria

- Full-term infants (≥ 37 weeks gestation)
- Born at KPNC hospitals
- Mothers enrolled at KPNC throughout their pregnancy

Exclusion criteria

Infants were excluded if their mothers:

- Received a non-$Tdap_5$ acellular pertussis vaccine (i.e., $Tdap_3$ or unknown Tdap product)
- Were not continuously enrolled during pregnancy

OUTCOMES

Primary Endpoint:

Incidence of PCR-confirmed pertussis in infants from birth to

- 2 months of age (before DTaP eligibility)
- 12 months of age (through primary DTaP series)

Secondary Endpoint:

- Vaccine effectiveness at each infant DTaP dose (0, 1, 2, 3 doses)
- Effectiveness by timing of maternal vaccination

RESULTS

Participants and Main Baseline Characteristics

263,809 of 389,457
Full-term infants were eligible

- **$Tdap_5$-vaccinated mothers (14+ days before birth)** (n= 170,799)
- **Unvaccinated mothers** (n= 88,304)

- Baseline characteristics showed increasing $Tdap_5$ uptake over the study period
- Maternal vaccination coverage increased from <25% (2010–2012, prior to ACIP expanded guideline) to 44% by 2013 and *92% by 2019*
- Starting in 2013, nearly all the $Tdap_5$ was administered at 27 to 36 weeks' gestation, in line with ACIP recommendations

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Pertussis Incidence by Maternal Tdap$_5$ Vaccination Status

Maternal Tdap$_5$ vaccination status	2-month follow-up		12-month follow-up	
	No. of pertussis cases	Rate per 100,000 PY	No. of pertussis cases	Rate per 100,000 PY
Overall	19	42.9	135	55.9
Unvaccinated during pregnancy	17	114.6	91	110.4
Vaccinated >14 days before birth	1	3.5	43	27.8

** Please refer to the paper for the full dataset*

Maternal Tdap$_5$ vaccination during pregnancy was associated with substantially lower pertussis incidence in infants during the first 2 months and the first year of life

Effectiveness of Tdap$_5$ and DTaP in preventing infant pertussis

Tdap$_5$ vaccination during pregnancy, administered at least 14 days before delivery, reduced pertussis risk in infants compared with infants born to unvaccinated mothers (Figure 1):

- *96.0%* (95% CI: 64.6–99.6; P= 0.004) during the *first 2 months of life*
- *55.8%* (95% CI: 27.1–73.2; P= 0.001) during the *first 12 months of life*

During the first 12 months of life, infant DTaP vaccine effectiveness increased with each dose irrespective of maternal vaccination status (Figure 2):

- *58.1%* (95% CI: 21.3–77.7) *after the first dose*
- *76.8%* (95% CI: 54.7–88.1) *after the second dose*
- *92.9%* (95% CI: 86.3–96.3) *after the third dose*

Tdap$_5$ vaccination during pregnancy reduced the risk of pertussis by *62.0%* in infants who had protection from 1 DTaP dose (95% CI: 3.6–85.0; P= 0.04), *65.4%* in infants who had 2 DTaP doses (95% CI: -336.4–37.4; P= 0.31) and *68.8%* in infants who had 3 DTaP doses (95% CI: 24.4–87.2; P= 0.01). Infant protection prior to their first DTaP dose was *78.2%* (95% CI: 34.9–92.7; P=0.006) from Tdap$_5$ vaccination of the mother

Tdap$_5$ vaccination during pregnancy continued to offer protection even after infants received DTaP, without interfering with infant DTaP vaccine effectiveness

Figure 1: Vaccine Effectiveness of Maternal Tdap$_5$ Vaccination in Preventing Pertussis

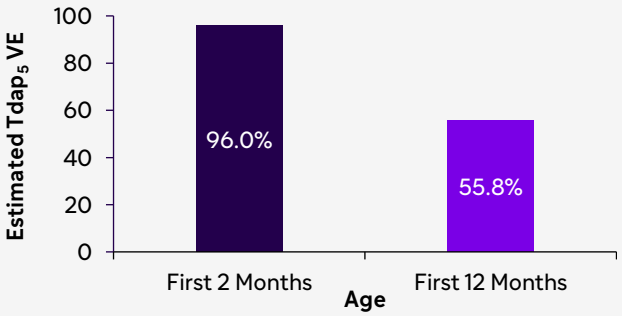
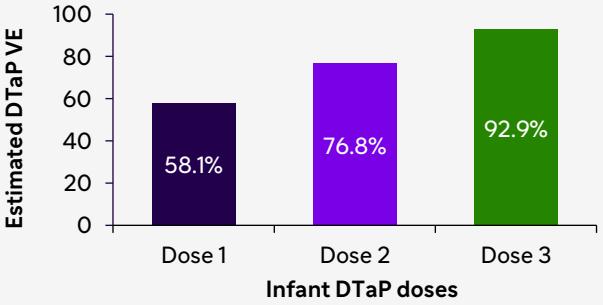


Figure 2: Vaccine Effectiveness of Infant DTaP and Maternal Tdap$_5$ in Preventing Pertussis



** Please refer to the paper for the full dataset*

LIMITATIONS

- *Few pertussis cases:* Limited number of cases during the study period led to wide CIs
- *Testing bias:* Only included infants tested for pertussis; may underestimate true incidence
- *Limited power for timing analysis:* Most vaccinations occurred during recommended window (27–36 weeks)
- *Generalizability:* Findings may not apply to populations with different vaccination coverage or pertussis exposure risk

CONCLUSION

Maternal Tdap$_5$ vaccination during pregnancy was highly effective in protecting infants against pertussis before they received their own DTaP vaccination and continued to provide additional protection even after infants were vaccinated with DTaP through the first year of life

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†D.M. is employed by Sanofi and holds shares in the Sanofi group of companies as part of his employee remuneration.

Abbreviations: ACIP, Advisory Committee on Immunization Practices; AI/AN, American Indian or Alaskan native; CI, confidence interval; DTaP, diphtheria, tetanus, and acellular pertussis; KPNC, Kaiser Permanente Northern California; n, numbers; PCR, polymerase chain reaction; PY, person-years; Tdap, tetanus, diphtheria, and acellular pertussis; Tdap5, 5-pertussis-component Tdap vaccine; US, United States of America; VE, vaccine effectiveness.

Reference: Hsiao A, et al. *Am J Obstet Gynecol*. Published online November 21, 2025. doi:10.1016/j.ajog.2025.11.025.

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