

REAL WORLD EVIDENCE

Understanding the Pentacel Pivotal Study and a Retrospective Cohort Study on DTaP Combination Use and Adherence

DTaP = diphtheria, tetanus, and acellular pertussis.

INDICATION

Pentacel [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine] is indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease due to *H influenzae* type b. Pentacel is approved for use as a 4-dose series in children 6 weeks through 4 years of age (prior to fifth birthday).


IMPORTANT SAFETY INFORMATION

Contraindications to vaccination with Pentacel include: a severe allergic reaction (e.g., anaphylaxis) after a previous dose of Pentacel, any ingredient of Pentacel, or any other diphtheria toxoid-, tetanus toxoid-, pertussis antigen-containing vaccine, inactivated poliovirus vaccine, or *Haemophilus influenzae* type b vaccine; encephalopathy within 7 days after a previous dose of a pertussis antigen-containing vaccine with no other identifiable cause; or a progressive neurologic disorder.

Carefully consider benefits and risks before administering Pentacel to persons with a history of: fever $\geq 105^{\circ}\text{F}$, hypotonic-hyporesponsive episode, or persistent, inconsolable crying lasting ≥ 3 hours within 48 hours after a previous pertussis antigen-containing vaccine; seizures within 3 days after a previous pertussis antigen-containing vaccine; or adverse events after a previous dose of Pentacel or receipt of any other tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information
([49281-0511-05](tel:49281-0511-05)).

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 **Pentacel**[®]
Diphtheria and Tetanus Toxoids and
Acellular Pertussis Adsorbed, Inactivated
Poliovirus and Haemophilus b Conjugate
(Tetanus Toxoid Conjugate) Vaccine

Pentacel Pivotal Study Study Design^{1,2}

A 2-stage, randomized multicenter study of 1939 healthy infants (P3T06) compared the safety and immunogenicity of the combination vaccine DTaP₅-IPV/Hib, Pentacel (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, and Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine) with that of its separately administered equivalent vaccines (diphtheria, tetanus, 5-component acellular pertussis vaccine [DTaP₅, DAPTACEL[®]], inactivated poliovirus vaccine [IPV, IPOL[®]], and *Haemophilus influenzae* type b vaccine [ActHIB[®]]).

- In the infant-series portion of the study, 1939 infants previously given 1 dose of Hep B were randomized to 1 of 4 groups:
 - 3 consistency lots of DAPTACEL[®] coadministered with IPOL[®] and ActHIB[®] vaccines (control group), or 1 lot of Pentacel at 2, 4, and 6 months of age
- Subsequently, 849 of these study participants were given a fourth dose of DAPTACEL[®] and ActHIB[®] vaccines or a fourth dose of Pentacel at 15 to 16 months of age

IMMUNOGENICITY¹

Antibody levels at or above the following prespecified thresholds were considered seroprotective:

- Diphtheria and tetanus: ≥ 0.01 and ≥ 0.1 IU/mL (minimum and standard thresholds, post-dose 3) and ≥ 0.1 and ≥ 1.0 IU/mL (standard and long-term thresholds, post-dose 4)
- Poliovirus: $\geq 1:8$ for poliovirus types 1, 2, and 3
- Anti-Hib PRP: ≥ 0.15 and ≥ 1.0 mcg/mL (minimum and long-term protection thresholds)
- Pertussis: the pertussis immune responses (GMCs and seroconversion rates) 1 month following the third and fourth doses were compared between the 2 groups. Seroconversion was defined as a 4-fold rise in antibody level (post-dose 3/pre-dose 1 or post-dose 4/pre-dose 1)

SAFETY ASSESSMENTS¹

- Parents or guardians recorded occurrence and intensity of any injection-site and systemic reactions on diary cards from day 0 through 3 days after each vaccination

DAPTACEL[®] (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) Intramuscular Injection; IPOL[®] Poliovirus Vaccine Inactivated (Monkey Kidney Cell); ActHIB[®] [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)].

GMC = geometric mean concentration; Hep B = hepatitis B; Hib = *Haemophilus influenzae* type b; IPV = inactivated poliovirus; PRP = polyribosyl ribitol phosphate.

IMPORTANT SAFETY INFORMATION (cont'd)

If Guillain-Barré syndrome has occurred within 6 weeks following receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Pentacel.

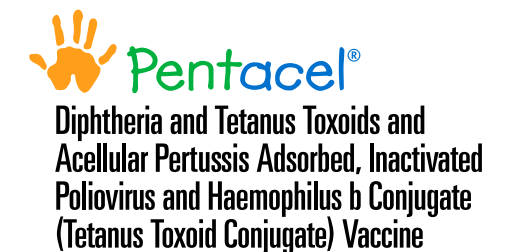
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Pentacel Pivotal Study Vaccination Schedules¹

SCHEDULE WITH PENTACEL	2 MONTHS	4 MONTHS	6 MONTHS	15-16 MONTHS
	Pentacel	Pentacel	Pentacel	Pentacel
	PCV7	PCV7	PCV7	
	Hepatitis B vaccine		Hepatitis B vaccine	

SCHEDULE WITHOUT PENTACEL	2 MONTHS	4 MONTHS	6 MONTHS	15-16 MONTHS
	DAPTACEL [®]	DAPTACEL [®]	DAPTACEL [®]	DAPTACEL [®]
	IPOL [®]	IPOL [®]	IPOL [®]	ActHIB [®]
	ActHIB [®]	ActHIB [®]	ActHIB [®]	
	PCV7	PCV7	PCV7	
	Hepatitis B vaccine		Hepatitis B vaccine	

PCV7 = pneumococcal conjugate vaccine.



Pentacel Pivotal Study Immunogenicity¹

Diphtheria and tetanus seroprotection rates following Pentacel [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine] were not inferior to DAPTACEL[®] after doses 3 and 4. One month following the third dose of study vaccines, more than 99% of participants in Pentacel and DAPTACEL[®] + IPOL[®] + ActHIB[®] groups achieved neutralizing antibody levels of $\geq 1:8$ for poliovirus types 1, 2, and 3.

One month following doses 3 and 4 of Pentacel or DAPTACEL[®] + IPOL[®] + ActHIB[®] in US infants vaccinated at 2, 4, 6, and 15-16 months of age*†

PERTUSSIS ANTIBODY RESPONSES:	Post-Dose 3		Post-Dose 4	
	Pentacel N=143	DAPTACEL [®] + IPOL [®] + ActHIB [®] N=481-485	Pentacel N=113	DAPTACEL [®] + ActHIB [®] N=127-128
Anti-PT % achieving 4-fold rise ^a GMC (EU/mL)	95.8 ^b 102.62 ^b	87.3 61.88	93.8 ^c 107.89 ^c	91.3 100.29
	N=218-318	N=714-1016	N=230-367	N=237-347
Anti-FHA % achieving 4-fold rise ^a GMC (EU/mL)	81.9 ^d 73.68 ^d	60.9 29.22	88.4 ^e 107.94 ^e	79.3 64.02
Anti-PRN % achieving 4-fold rise ^a GMC (EU/mL)	74.2 ^d 36.05 ^d	75.4 43.25	92.7 ^e 93.59 ^f	98.3 186.07
Anti-FIM % achieving 4-fold rise ^a GMC (EU/mL)	91.7 ^d 268.15 ^d	86.3 267.18	93.5 ^e 553.39 ^e	91.6 513.54

*Per Protocol Immunogenicity population for anti-FHA, anti-PRN, and anti-FIM.

†Non-random subset of per Protocol Immunogenicity population for anti-PT. See text for further information on the subset evaluated.

^aFold rise was calculated as post-dose 3/pre-dose 1 antibody level or post-dose 4/pre-dose 1 antibody level.

^bPercent achieving 4-fold rise or GMC post-dose 3 Pentacel vaccine not inferior to post-dose 3 DAPTACEL[®] vaccine (upper limit of 95% CI for GMC ratio [DAPTACEL[®]/Pentacel] <1.5 and upper limit of 95% CI for differences in rates [DAPTACEL[®] minus Pentacel] <10%).

^cPercent achieving 4-fold rise or GMC post-dose 4 Pentacel vaccine not inferior to post-dose 4 DAPTACEL[®] vaccine (upper limit of 95% CI for GMC ratio [DAPTACEL[®]/Pentacel] <1.5 and upper limit of 95% CI for differences in rates [DAPTACEL[®] minus Pentacel] <10%).

^dPercent achieving 4-fold rise or GMC post-dose 3 Pentacel vaccine not inferior to post-dose 3 DAPTACEL[®] vaccine (upper limit of 90% CI for GMC ratio [DAPTACEL[®]/Pentacel] <1.5 and upper limit of 90% CI for differences in rates [DAPTACEL[®] minus Pentacel] <10%).

^ePercent achieving 4-fold rise or GMC post-dose 4 Pentacel vaccine not inferior to post-dose 4 DAPTACEL[®] vaccine (upper limit of 90% CI for GMC ratio [DAPTACEL[®]/Pentacel] <1.5 and upper limit of 90% CI for differences in rates [DAPTACEL[®] minus Pentacel] <10%).

^fNon-inferiority criterion is not met for GMC post-dose 4 Pentacel vaccine relative to post-dose 4 DAPTACEL[®] vaccine (upper limit of 90% CI for GMC ratio [DAPTACEL[®]/Pentacel] = 2.25, which exceeds the non-inferiority criterion of <1.5).

IMPORTANT SAFETY INFORMATION (cont'd)

For infants and children with a history of previous seizures, an antipyretic may be administered (in the dosage recommended in its prescribing information) at the time of vaccination with Pentacel and for the next 24 hours.

Apnea following intramuscular vaccination has been observed in some infants born prematurely.

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Pentacel Pivotal Study Anti-PRP Seroprotection Rates and GMCs¹

One month following 3 doses of Pentacel or separate DTaP + IPV + ActHIB[®] administered at 2, 4, and 6 months of age

ANTI-PRP SEROPROTECTION RATES AND GMCs:	Pentacel	DAPTACEL [®] + IPOL [®] + ActHIB [®]
	N=365	N=1128
% achieving anti-PRP ≥ 0.15 mcg/mL	92.3 ^a	93.3
% achieving anti-PRP ≥ 1.0 mcg/mL	72.1 ^a	70.8 ^a
Anti-PRP GMC (mcg/mL)	2.31 ^b	2.29

^aPercent achieving specified level following Pentacel vaccine not inferior to ActHIB[®] vaccine (upper limit of 90% CI for difference in rates [ActHIB[®] minus Pentacel] <10%).

^bNon-inferiority criterion not prespecified.

Safety: Adverse Reactions and Systemic Reactions

Percentage of children with selected solicited adverse reactions by severity occurring within 0-3 days of injection

INJECTION SITE REACTIONS	Pentacel				DAPTACEL [®]			
	Dose 1 N=465-467	Dose 2 N=451	Dose 3 N=438-440	Dose 4 N=387-396	Dose 1 N=1400-1404	Dose 2 N=1358-1359	Dose 3 N=1311-1312	Dose 4 N=376-380
Redness >5 mm (%)	7.1	8.4	8.7	17.3	6.2	7.1	9.6	16.4
Swelling >5 mm (%)	7.5	7.3	5.0	9.7	4.0	4.0	6.5	10.3
Tenderness ^a Any (%)	47.5	39.2	42.7	56.1	48.8	38.2	40.9	51.1
Increased Arm Circumference >5 mm (%)	-	-	-	33.6	-	-	-	30.6

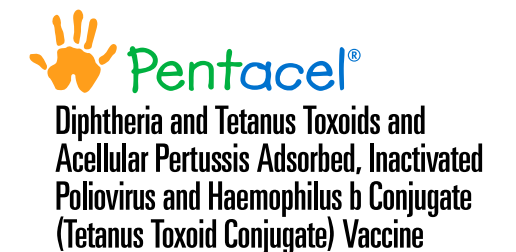
SYSTEMIC REACTIONS	Pentacel				DAPTACEL [®] + IPOL [®] + ActHIB [®]			DAPTACEL [®] + ActHIB [®]
	Dose 1 N=466-467	Dose 2 N=451-452	Dose 3 N=435-440	Dose 4 N=389-398	Dose 1 N=1390-1406	Dose 2 N=1346-1360	Dose 3 N=1301-1312	Dose 4 N=379-381
Fever ^{b,c} $\geq 38.0^{\circ}$ C (%)	5.8	10.9	16.3	13.4	9.3	16.1	15.8	8.7
Decreased Activity/Lethargy ^d Any (%)	45.8	32.7	32.5	24.1	51.1	37.4	33.2	24.1
Inconsolable Crying Any (%)	59.3	49.8	47.3	35.9	58.5	51.4	47.9	36.2
Fussiness/Irritability Any (%)	76.9	71.2	68.0	53.5	75.8	70.7	67.1	53.8

^aAny: mild, moderate, or severe; mild: subject whimpers when site is touched; moderate: subject cries when site is touched; severe: subject cries when leg or arm is moved.

^bFever is based upon actual temperatures recorded with no adjustments to the measurement route.

^cFollowing doses 1-3 combined, the proportion of temperature measurements that were taken by axillary, rectal, or other routes, or not recorded were 46.0%, 53.0%, 1.0%, and 0%, respectively, for Pentacel vaccine, and 44.8%, 54.0%, 1.0%, and 0.1%, respectively, for DAPTACEL[®] + IPOL[®] + ActHIB[®]. Following dose 4, the proportion of temperature measurements that were taken by axillary, rectal, or other routes, or not recorded were 62.7%, 34.4%, 2.4%, and 0.5%, respectively, for Pentacel vaccine, and 61.1%, 36.6%, 1.7%, and 0.5%, respectively, for DAPTACEL[®] + ActHIB[®].

^dModerate: interferes with or limits usual daily activity; severe: disabling, not interested in usual daily activity.



DTaP Combination Vaccine Use and Adherence^{3,4}

A retrospective cohort study, sponsored by Sanofi, comparing adherence among recipients of DTaP-containing combination vaccines* and recipients of stand-alone DTaP vaccines*



STUDY DESIGN

A retrospective cohort study of privately insured children born between 2009 and 2016 who received ≥ 1 DTaP-containing vaccine and had ≥ 24 months of enrollment from birth, retrospectively identified in a large national claims database.



OBJECTIVES

- Assess adherence to the recommended DTaP immunization schedule (ie, completion of the 4-dose series and timely receipt of doses received), stratified by DTaP-containing vaccine use (combination, stand-alone,* or a mixture of both)
- Among children who completed the 4-dose series, assess the association of combination vaccine use with timely receipt of all 4 doses, relative to stand-alone vaccine use
- Describe the associations of potential confounding factors with completion[†] and timely[‡] receipt



STUDY POPULATION

412,441 children were included in the final cohort:

Group 1: n=167,084 (40.5%)

- Children in Group 1 were those who received DTaP-containing combination vaccines only
- Of the Group 1 children, 58,318 (14.1%) were additionally classified as Group 1: DTaP-IPV/Hib subgroup (Pentacel)

Group 2: n=184,015 (44.6%)

- Group 2 children were those who received a mixture of DTaP-containing combination vaccines and stand-alone DTaP-containing vaccines

Group 3: n=61,342 (14.9%)

- Group 3 children were those who received stand-alone DTaP vaccines only
- In all 3 groups, just over half of the children in each group were male
- The majority of children were White, followed by Hispanic, Asian, Black, and unknown
- The majority of the cohort was classified as being above the federal poverty level

*DTaP combination vaccines: quadrivalent and pentavalent. DTaP stand-alone vaccines: trivalent. Children who received 3 doses of Pediarix + 1 stand-alone as their fourth dose remained classified under the combination vaccine recipient group.³

[†]Receipt of 4 doses of DTaP-containing vaccines within 20 months of life.³

[‡]All received DTaP-containing vaccine doses were administered ≤ 2 months after the respective recommended age.³

IMPORTANT SAFETY INFORMATION (cont'd)

Syncope (fainting) may occur in association with administration of injectable vaccines including Pentacel. Procedures should be in place to avoid injury from fainting.

Please see Important Safety Information throughout.
Please see accompanying full Prescribing Information ([49281-0511-05](https://www.accessdata.fda.gov/drugsatfda_docs/ind/2013/012873Orig1s01.pdf)).

LIMITATIONS

While the data in this study allowed the assessment of adherence across a large population, some limitations were also identified.

- Findings may not be generalizable to the overall US population due to participant requirements, including:
 - Private insurance
 - ≥ 24 months of continuous enrollment
- These requirements maximized the probability that receipt of the full 4-dose series could be confirmed, and minimized the potential for misclassification
- The database also lacked a true birthdate, and instead a child's enrollment was used as a proxy for birthdate. While there may be some degree of measurement error, validation of this proxy suggested that it was sufficiently accurate and it is unlikely that there were any substantial implications on findings
- Lastly, in order to be classified into either the combination or stand-alone group, the child must have received at least 1 DTaP-containing dose of the respective type. However, children classified as mixed recipients had to have received at least 2 different DTaP-containing doses, either 1 stand-alone or 1 combination dose. It is important to note, as it may have biased the findings specific to the mixed-recipient group, since there were no children who received only 1 dose within this group

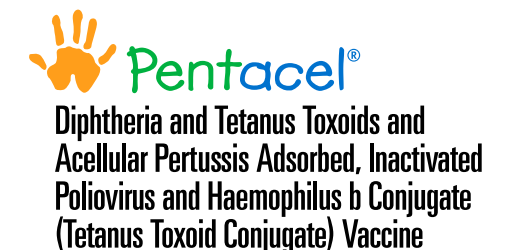
ASSOCIATIONS OF CONFOUNDING FACTORS

Completion

- No significant association between gender and completion were observed
- Black children were approximately 24% less likely to complete the 4-dose series, and Hispanic children were approximately 30% less likely, relative to White children
- No significant association between socioeconomic status and completion was observed

Timely receipt

- Males were approximately 2% less likely to receive their respective doses on time
- Black children were approximately 22% less likely to receive their respective doses on time, and Hispanic children were approximately 27% less likely, relative to White children
- Children above the 400% federal poverty level were approximately 8% more likely to receive their doses on time, relative to children below the 400% federal poverty level



DTaP Combination Vaccine Use and Adherence³

A retrospective cohort study, sponsored by Sanofi, comparing adherence among recipients of DTaP-containing combination vaccines and recipients of stand-alone DTaP vaccines

Completion and timely receipt of the 4-dose series was highest among combination vaccine recipients compared to stand-alone recipients³

COMPLETION

Percentage of children classified as complete vs incomplete*

Children in the group that received combination vaccines only were **nearly 3X as likely** to complete the 4-dose series, relative to stand-alone recipients (OR 2.93 [95% CI, 2.88-2.99])

- From Group 2 (mixed), **73%** (n=133,803/184,015) completed their 4-dose series

TIMELY RECEIPT

Percentage of children classified as timely vs delayed receipt[†]

Children in the group that received combination vaccines only were **more than 4X as likely** to have received their doses on time, relative to stand-alone recipients (OR 4.12 [95% CI, 4.04-4.21])

- From Group 2 (mixed), **70%** (n=129,282/184,015) received their doses on time

CI = confidence interval; OR = odds ratio.

*24% (n=40,830/167,084) of patients in Group 1 were incomplete. 27% (n=50,212/184,015) of patients in Group 2 were incomplete. 49% (n=29,784/61,342) of patients in Group 3 were incomplete.¹

[†]19% (n=31,626/167,084) of patients in Group 1 received delayed doses. 30% (n=54,733/184,015) of patients in Group 2 received delayed doses. 49% (n=30,045/61,342) of patients in Group 3 received delayed doses.¹

IMPORTANT SAFETY INFORMATION (cont'd)

The most common local and systemic adverse reactions to Pentacel include redness, swelling, and tenderness at the injection site; fever, fussiness, and abnormal crying. Other adverse reactions may occur.

Vaccination with Pentacel may not protect all individuals.

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Among those who completed the 4-dose series, children who received Pentacel [Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus, and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine] were more likely to receive their doses on time, compared to stand-alone recipients³

TIMELY RECEIPT

Percentage of children classified as timely vs delayed receipt, among those who completed the 4-dose series^{3,4}

In a supplemental analysis, children in the group that received Pentacel vaccines only were **nearly 2.5X as likely** (calculations were made to address label age groups) to receive their respective doses on time, compared with stand-alone recipients (OR 2.49 [95% CI, 2.34-2.66]).*

*3.2% (n=1743/54,282) of patients in Group 1 received delayed doses. 7.9% (n=2499/31,558) of patients in Group 3 received delayed doses.³

DISCUSSION^{3,5}


Delay in vaccine receipt relates to an increased risk of pertussis. One of the benefits of combination vaccines, including Pentacel for 4 doses, is their association with a patient staying on track with the Advisory Committee on Immunization Practices recommended immunization schedule.

- Several prior studies investigated the relationship between adherence to the immunization schedule and combination vaccines. Although not explicitly investigated, this study found that significant disparities were observed in adherence to the recommended schedule
 - Black and Hispanic children were significantly less likely to complete the 4-dose series and receive doses on time, relative to White children
 - Socioeconomically deprived children were significantly less likely to receive doses on time
- A fundamental strength of this study was the use of electronic claims data from a large national claims database to accurately measure vaccine use, leading to relative accuracy and completeness of vaccination records
- While these findings do not necessarily establish a causal relationship between the receipt of combination vaccines and improved adherence, it was observed that administering combination vaccines may aid in timely receipt of the first 3 doses and increase the likelihood of receiving all recommended doses at a given visit
- Of course, failure to receive all recommended doses goes beyond the type of vaccine received, and includes parental attitudes and beliefs or general vaccine hesitancy



Read the DTaP combination vaccine use and adherence study

<https://doi.org/10.1016/j.vaccine.2021.01.009>

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Carefully consider benefits and risks before administering Pentacel to persons with a history of: fever $\geq 105^{\circ}\text{F}$, hypotonic-hyporesponsive episode, or persistent, inconsolable crying lasting ≥ 3 hours within 48 hours after a previous pertussis antigen-containing vaccine; seizures within 3 days after a previous pertussis antigen-containing vaccine; or adverse events after a previous dose of Pentacel or receipt of any other tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Pentacel.

For infants and children with a history of previous seizures, an antipyretic may be administered (in the dosage recommended in its prescribing information) at the time of vaccination with Pentacel and for the next 24 hours.

Apnea following intramuscular vaccination has been observed in some infants born prematurely.

Syncope (fainting) may occur in association with administration of injectable vaccines including Pentacel. Procedures should be in place to avoid injury from fainting.

The most common local and systemic adverse reactions to Pentacel include redness, swelling, and tenderness at the injection site; fever, fussiness, and abnormal crying. Other adverse reactions may occur.

Vaccination with Pentacel may not protect all individuals.

Please see Important Safety Information throughout.


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References: **1.** Pentacel. Prescribing Information. NDC No. 49281-511-05. Sanofi Pasteur Limited. **2.** Guerra AF, et al. Safety and immunogenicity of a pentavalent vaccine compared with separate administration of licensed equivalent vaccines in US infants and toddlers and persistence of antibodies before a preschool booster dose: a randomized, clinical trial. *Pediatrics*. 2009;123(1):301-312. **3.** Loiacono MM, Pool V, van Aalst R. DTaP combination vaccine use and adherence: a retrospective cohort study. *Vaccine*. 2021;39(7):1064-1071. **4.** Loiacono MM, Pool V, van Aalst R. DTaP combination vaccine use and adherence: a retrospective cohort study. *Vaccine*. 2021;39(7)(suppl 1):1-9. doi:10.1016/j.vaccine.2021.01.009 **5.** Rane MS, Rohani P, Halloran ME. Association of diphtheria-tetanus-acellular pertussis vaccine timeliness and number of doses with age-specific pertussis risk in infants and young children. *JAMA Netw Open*. 2021;4(8):e2119118. doi:10.1001/jamanetworkopen.2021.19118

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