National PBM Drug Monograph
Tetanus-Diptheria-Pertussis Vaccine (Adacel™ or Tdap)
VHA Pharmacy Benefits Management-Strategic Healthcare Group
And The Medical Advisory Panel

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) at its recent meeting (October 26 and 27, 2005) in Atlanta, voted to recommend that adults 19 to 64 years of age be vaccinated with a newly licensed adult booster tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (whooping cough) vaccine adsorbed or Tdap. (1)

Under the ACIP recommendation, the Tdap vaccine would replace the currently recommended tetanus-diphtheria vaccine that is used as the adult booster vaccine. The new vaccine helps protect adults from pertussis, an illness with severe and prolonged cough. It also reduces the risk of transmitting pertussis to infants.

The ACIP recommended that adults receive a booster dose of Tdap vaccine against tetanus, diphtheria and pertussis if they have not received a tetanus and diphtheria (Td) booster dose in ten or more years. Adults should receive a single dose of Tdap to replace a single dose of Td. Pertussis affects an estimated 600,000 adults every year, aged 20 to 64 years, and can result in weeks of coughing, cracked ribs from severe coughing spells, pneumonia, and other complications.

Tdap should also be given to adults who will have close contact with an infant less than 12 months of age, ideally at least one month before beginning close contact with infants. In situations when it is important to protect against pertussis, intervals shorter than 10 years since the last Td vaccination may be used. A 2-year interval between Td and Tdap is suggested to reduce the risk of reactions following vaccination.

Healthcare personnel working in hospital or ambulatory care facilities and involved direct patient care should receive Tdap as soon as possible if they have not already done so. However, a 2-year interval between Td and Tdap is suggested to reduce the risk of reactions following vaccination. In those healthcare personnel not working in direct patient care or in settings other than hospitals or ambulatory care should receive a single dose of Tdap according to the routine recommendation and interval guidance for use of Tdap in adults.

Since Tdap has not been evaluated in persons 65 years of age and older and has not been licensed for use in this age group, ACIP recommends a Td booster every 10 years in these individuals and as indicated for wound management. This recommendation will be updated as new information become available.

In addition, those individuals with contraindications to pertussis containing vaccines will continue to receive Td boosters as indicated.

MAP RECOMMENDATIONS

1. Adacel® or Tdap vaccine should be added to the VA National Formulary to be utilized as the adult booster vaccine, to replace the Td booster, in patients aged 19-64 years if they have not received a Td booster in 10 or more years.
2. Patients 65 years and older will continue to receive the Td booster every 10 years or as indicated for wound management.
3. The Td booster will be used as the adult booster vaccine in patients with contraindications to pertussis containing vaccines.
4. A National workgroup through the Office of Public Health and Environmental Hazards is developing a plan for immunizing VA employees with Tdap. However, the group will await final recommendations from the CDC prior to immunizing employees on a large scale.

INTRODUCTION

Pertussis (whooping cough) is a disease of the respiratory tract, most often caused by *B pertussis*. This gram-negative coccobacillus produces a variety of biologically active components, though their role in pathogenesis is not clearly defined. Widespread use of pertussis vaccines among infants and children younger than 7 years of age led to a gradual decline in reported cases from the late 1940s through the 1970s. From 1980 through 2003, the number of pertussis cases reported annually in the US has increased, with adolescents and adults accounting for a substantial percentage of the reported cases. (2,3)

In the United States, immunization against pertussis, tetanus and diphtheria became widespread in the late 1940s and resulted in a decrease in the incidence of morbidity and mortality from these diseases. Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP) vaccines were first available for use in infants in the US in 1996 and have been routinely recommended for all doses of the vaccination series for infants and children <7 years of age since 1997. (4)

PHARMACOLOGY

Protection against disease attributable to *C tetani* is due to the development of neutralizing antibodies to tetanus toxin. A serum tetanus antitoxin level of at least 0.01 IU/mL, measured by neutralization assay, is considered the minimum protective level. A level ≥0.1 to 0.2 IU/mL has been considered as protective. Protection against disease attributable to *C diphtheriae* is due to the development of neutralizing antibodies to diphtheria toxin. A serum antitoxin level of 0.01 IU/mL is the lowest level giving some degree of protection. Antitoxin levels of at least 0.1 IU/mL are generally regarded as protective. Levels of 1.0 IU/mL have been associated with long-term protection. There is no standardized, well-accepted serologic or laboratory correlate of protection for pertussis.
A consensus was reached at the 1997 meeting of the Vaccines and Related Biological Products Advisory Committee that clinical endpoint efficacy studies of acellular pertussis vaccines among adolescents or adults were not required for Tdap licensure in these age groups. Rather, the efficacy of the pertussis components of Tdap administered to adolescents and adults could be inferred using a serologic bridge to infants vaccinated with pediatric DTaP during clinical endpoint efficacy trials for pertussis. For each Tdap product, the immune response (geometric mean antibody concentration [GMC]) of adolescents to each vaccine pertussis antigen after a single dose of Tdap was compared with the immune response of infants after three doses of pediatric DTaP that included the same pertussis components as the Tdap being assessed .

FDA APPROVED INDICATIONS

ADACEL vaccine is indicated for active booster immunization for the prevention of tetanus, diphtheria and pertussis as a single dose in persons 11 through 64 years of age. The use of ADACEL vaccine as a primary series, or to complete the primary series, has not been studied.

VA FORMULARY ALTERNATIVES: None

DOSAGE AND ADMINISTRATION

ADACEL vaccine should be administered as a single injection of one dose (0.5 mL) by the intramuscular route. There are no data to support repeat administration of ADACEL vaccine. The use of ADACEL vaccine as a primary series or to complete the primary series for tetanus, diphtheria, or pertussis has not been studied. For individuals planning to travel to developing countries, a one-time booster dose of ADACEL vaccine may be considered if more than 5 years has lapsed since receipt of the previous dose of diphtheria toxoids, tetanus toxoids or pertussis-containing vaccine.

Each dose of ADACEL vaccine (0.5 mL) contains the following active ingredients:
tetanus toxoid (T) 5 Lf
diphtheria toxoid (d) 2 Lf
detoxified pertussis toxin (PT) 2.5 µg
filamentous hemagglutinin (FHA) 5 µg
pertactin (PRN) 3 µg
fimbriae types 2 and 3 (FIM) 5 µg

CONCOMITANT ADMINISTRATION WITH OTHER VACCINES

Hepatitis B Vaccine

The concomitant use of ADACEL vaccine and hepatitis B (Hep B) vaccine (Recombivax HB®, 10 µg per dose using a two-dose regimen, manufactured by Merck and Co., Inc) was evaluated in a multi-center, open-labeled, randomized, controlled study that enrolled 410 adolescents, 11-14 years of age inclusive. One group received ADACEL and Hep B vaccines concurrently (N = 206). The other group (N = 204) received ADACEL vaccine at the first visit, then 4-6 weeks later received Hep B vaccine. The second dose of Hep B vaccine was given 4-6 weeks after the first dose. Serum samples were obtained prior to and 4-6 weeks after ADACEL vaccine administration, as well as 4-6 weeks after the 2nd dose of Hep B for all subjects. No interference was observed in the immune responses to any of the vaccine antigens when ADACEL and Hep B vaccines were given concurrently or separately. (5)

Trivalent Inactivated Influenza Vaccine

The concomitant use of ADACEL vaccine and trivalent inactivated influenza vaccine (TIV, Fluzone®, manufactured by Aventis Pasteur Inc., Swiftwater, PA) was evaluated in a multi-center, open-labeled, randomized, controlled study conducted in 720 adults, 19-64 years of age inclusive. In one group, subjects received ADACEL and TIV vaccines concurrently (N = 359). The other group received TIV at the first visit, then 4-6 weeks later received ADACEL vaccine (N = 361). Sera were obtained prior to and 4-6 weeks after ADACEL vaccine, as well as 4-6 weeks after the TIV. The immune responses were comparable for concurrent and separate administration of ADACEL and TIV vaccines for diphtheria (percent of subjects with seroprotective concentration ≥0.1 IU/mL and booster responses), tetanus (percent of subjects with seroprotective concentration ≥0.1 IU/mL), pertussis antigens (booster responses and GMCs except lower PRN GMC in the concomitant group, lower bound of the 90% CI was 0.61 and the pre-specified criterion was ≥0.67) and influenza antigens (seroprotection and seroconversion rates). Although tetanus booster response rates were significantly lower in the group receiving the vaccines concurrently versus separately, greater than 98% of subjects in both groups achieved seroprotective levels of ≥0.1 IU/mL. (5)

EFFICACY

Adacel® (diptheria-tetanus-pertussis) vaccine has been assessed in adolescents and adults for efficacy and safety. A total of 4480 healthy individuals between the ages 11-64 years of age were randomly assigned to receive either dT (diptheria-tetanus) vaccine or Tdap vaccine. Antibody titers to diphtheria and tetanus toxoids for Tdap and Td were measured in sera collected from subsets of adolescents and adults, before and 28 days after vaccination. For pertussis antigens, titers in sera from Tdap vaccines were assessed vs those from infants who received analogous pediatric diphtheria-tetanus-acellular pertussis vaccine (DTaP) in a previous efficacy trial. Safety was assessed via solicited local and systemic reactions for 14 days and adverse events for 6 months following vaccination. For both Tdap and Td, more than 94% and nearly 100% of vaccinees had protective antibody concentrations of at least 0.1 IU/mL for diphtheria and tetanus, respectively. Geometric mean antibody titers to pertussis toxoid, filamentous hemagglutinin, pertactin, and fimbriae types 2 and 3 exceeded (by 2.1 to 5.4 times) levels in infants following immunization at 2, 4, and 6 months with DTaP. Local and systemic adverse effects were similar in both groups. (6)

SAFETY (please refer to package insert for detailed listing)

Contraindications: Known hypersensitivity to vaccine or any of its components. Both of the following are contraindications to use of any pertussis containing vaccine. As a result, Td booster can be used if vaccination planned and as indicated.

1) Encephalopathy (e.g. coma, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of a pertussis containing vaccine.
2) Progressive neurological disorder, uncontrolled epilepsy, or progressive encephalopathy. Pertussis vaccine should not be administered to individuals with these conditions until a treatment regimen has been established, the condition has stabilized, and the benefit clearly outweighs the risk.

Precautions and Reasons to Defer Vaccination:

1) Guillain-Barre syndrome ≤ 6 weeks after a previous dose of tetanus toxoid-containing vaccine. If vaccination is planned, careful consideration should be given to the potential risks and benefits of providing a tetanus-toxoid containing vaccine.
2) Progressive neurologic disorder; including progressive encephalopathy, or uncontrolled epilepsy until condition is stabilized. These are precautions to use of pertussis vaccination. Tdap preferred but Td can be used.
3) Vaccination should be generally deferred in the setting of acute illness with or without fever, history of an Arthus reaction (severe local reaction with systemic symptoms) following a previous dose of tetanus-toxoid containing vaccine. If fever or seizures are thought to be due to vaccination then this is not a contraindication to continuation with the pediatric vaccination series.

Frequencies of Other Solicited Injection Site Reactions and Fever and other Adverse Events for Adolescents and Adults, Days 0-14, Following a Single Dose of ADACEL Vaccine or Td Vaccine (6,7)

Adverse Event		Adolescents 11-17 years		Adults 18-64 years	
		Adacel (n=1,184) (%)	Td (n=792) (%)	Adacel (n=1,752) (%)	Td (n=573) (%)
Injection Site Pain	**Any**	77.8†	71.0	65.7	62.9
	Moderate‡	18.0	15.6	15.1	10.2
	Severe§	1.5	0.6	1.1	0.9
Injection Site Swelling	**Any**	20.9	18.3	21.0	17.3
	Moderate‡				
	1.0 to 3.4 cm	6.5	5.7	7.6	5.4
	Severe§				
	≥3.5 cm	6.4	5.5	5.8	5.5
	≥5 cm (2 inches)	2.8	3.6	3.2	2.7
Injection Site Erythema	**Any**	20.8	19.7	24.7	21.6
	Moderate‡	5.9	4.6	8.0	8.4
	1.0 To 3.4 cm				
	Severe§	6.0	5.3	6.2	4.8
	≥3.5 cm				
Fever	**≥38.0°C (≥100.4°F)**	5.0†	2.7	1.4	1.1
	≥38.8°C to ≤39.4°C (≥102.0°F to ≤103.0°F)	0.9	0.6	0.4	0.2
	≥39.5°C (≥103.1°F)	0.2	0.1	0	0
Headache	Any	43.7	40.4	33.9	34.1
	Moderate‡	14.2	11.1	11.4	10.5
	Severe§	2.0	1.5	2.8	2.1
Body ache	Any	30.4	29.9	21.9	18.8
	Moderate‡	8.5	6.9	6.1	5.7
	Severe§	1.3	0.9	1.2	0.9
Tiredness	Any	30.2	27.3	24.3	20.7
	Moderate‡	9.8	7.5	6.9	6.1
	Severe§	1.2	1.0	1.3	0.5
Chills	Any	15.1	12.6	8.1	6.6
	Moderate‡	3.2	2.5	1.3	1.6
	Severe§	0.5	0.1	0.7	0.5
Sore Swollen Joints	Any	11.3	11.7	9.1	7.0
	Moderate‡	2.6	2.5	2.5	2.1
	Severe§	0.3	0.1	0.5	0.5
Nausea	Any	13.3	12.3	9.2	7.9
	Moderate‡	3.2	3.2	2.5	1.8
	Severe§	1.0	0.6	0.8	0.5
Lymph Node Swelling	Any	6.6	5.3	6.5	4.1
	Moderate‡	1.0	0.5	1.2	0.5
	Severe§	0.1	0.0	0.1	0.0
Diarrhea	Any	10.3	10.2	10.3	11.3
	Moderate‡	1.9	2.0	2.2	2.7
	Severe§	0.3	0.0	0.5	0.5

Vomiting	Any Moderate‡ Severe§	4.6 1.2 0.5	2.8 1.1 0.3	3.0 1.0 0.5	1.8 0.9 0.2
Rash	Any	2.7	2.0	2.0	2.3

* Sample size was designed to detect >10% differences between ADACEL and Td vaccines for events of 'Any' intensity.
† ADACEL vaccine did not meet the non-inferiority criterion for rates of 'Any Pain' in Adolescents compared to Td Vaccine rates (upper limit of the 95% CI on the difference for ADACEL vaccine minus Td vaccine was 10.7% whereas the criterion was <10%). For 'Any' fever the non-inferiority criteria was met, however, 'Any' fever was statistically higher in adolescents receiving ADACEL vaccine.
‡ Interfered with activities, but did not necessitate medical care or absenteeism.
§ Incapacitating, prevented the performance of usual activities, may have/or did necessitate medical care or absenteeism.

LOOK-ALIKE/SOUND-ALIKE POTENTIAL

As part of a pilot program, the VA PBM and Center for Medication Safety queried a multi-attribute drug product search engine for similar sounding and appearing drug names based on orthographic and phonological similarities, as well as similarities in dosage form, strength and route of administration. By incorporating similarity scores as well as clinical judgment, it was determined that the following drug names may pose as potential sources of drug name confusion.

Drug Name	Potential Name Confusion	Potential Severity	Probability
Adacel (Tdap)	Daptacel (DTaP)	Moderate	Frequent
Td Vaccine	Tdap	Moderate	Frequent
DDAVP	Tdap	Moderate	Remote
ADALAT	ADACEL	Moderate	Uncommon
AMARYL	ADACEL	Severe	Uncommon
ASACREL	ADACEL	Minor	Remote
ATACAND	ADACEL	Moderate	Uncommon
ADDERALL	ADACEL	Moderate	Uncommon
ADVICOR	ADACEL	Minor	Uncommon

COST

Adacel® (tetanus toxoid, reduced diptheria toxoid and acellular pertussis adsorbed or Tdap) is only available direct purchase from Sanofi Pasteur NDC: 49281-0400-10, $250.94 per box of 10 vial/ doses on FSS contract. = $25.09 per dose.

Decavac ® (tetanus and diptheria toxoids adsorbed or Td) is available thru McKesson NDC: 49281-0291-10, $124.90 per box of 10 pfs on contract (big 4). = $12.49 per dose.

TETANUS/DIPTHERIA TOXOIDS VACCINE USAGE IN VHA FY 05

VA Product	Total Rxs	Day30Rxs	Total Qty	Uniques
DIPHTHERIA TOXOID 2UNT/TETANUS TOXOID 5UNT/0.5ML ADSORBED INJ	4,667	5,330	4,652	4,642
DIPHTHERIA TOXOID/TETANUS TOXOID ADSORBED (ADULT) INJ	6,720	7,420	4,737	6,624
DIPHTHERIA TOXOID/TETANUS TOXOID ADSORBED (PEDIATRIC) INJ	1	1		1
DIPHTHERIA TOXOID/TETANUS TOXOID ADSORBED INJ	110	116	105	109
DIPHTHERIA TOXOID/TETANUS TOXOID TOTAL	**11,498**	**12,867**	**9,494**	**11,366**
DIPHTHERIA TOXOID/PERTUSSIS VACCINE/TETANUS TOXOID	9	25	9	9
TETANUS TOXOID ADSORBED INJ	1,107	1,246	1,094	1,100
TETANUS TOXOID FLUID INJ	74	75	72	74
TETANUS TOXOID TOTAL	**1,181**	**1,321**	**1,166**	**1,174**

RECOMMENDATIONS

Adacel® should be added to the VANF and be utilized as the adult booster vaccine for adults aged 19 to 64 years against tetanus-diptheria and pertussis. Per recent ACIP recommendations, the Tdap vaccine will replace

the currently recommended Td booster in that age group. The ACIP recommended that adults receive a booster dose of Tdap vaccine against tetanus, diphtheria and pertussis if they have not received a tetanus and diphtheria (Td) booster dose in ten or more years. Adults should receive a single dose of Tdap to replace a single dose of Td.

Healthcare personnel working in hospital or ambulatory care facilities and involved direct patient care should receive Tdap as soon as possible if they have not already done so. However, a 2-year interval between Td and Tdap is suggested to reduce the risk of reactions following vaccination. In those healthcare personnel not working in direct patient care or in settings other than hospitals or ambulatory care should receive a single dose of Tdap according to the routine recommendation and interval guidance for use of Tdap in adults.

ACIP has noted that Tdap is not licensed for use in individuals 65 years of age and older since Tdap was not studied in this age group. These recommendations will be updated, as new data are available. In the meantime, patients 65 years and older should receive a Td booster every 10 years and for wound management as indicated. In addition, those with contraindications to pertussis containing vaccines could continue to receive Td boosters as indicated.

Prepared by Lisa Korman, PharmD and Reviewed by Matthew Goetz, M.D.

REFERENCES

1. CDC: Preventing Diptheria, Pertussis, Tetanus in Adolescents: Use of Tetanus Toxoid and Reduced Diptheria Toxoid and Reduced Acellular Pertussis Vaccine-ACIP Recommendations. MMWR Feb 23 2006;Vol 55.
2. CDC. Pertussis - United States, 1997-2000. MMWR 2002;51(4):73-92.
3. CDC. Summary of notifiable diseases - United States, 2003. MMWR 2005;52(54):28,72.
4. CDC. Pertussis vaccination: Use of acellular pertussis vaccines among infants and young children. Recommendations of the ACIP. MMWR 1997;46(RR-7):1-25.
5. Data on file at Aventis Pasteur Limited.
6. Pichichero, ME, Rennels MB, Edwards KM, et al; Combined Tetanus, Diphtheria, and 5-Component Pertussis Vaccine for Use in Adolescents and Adults. JAMA. 2005;293:3003-3011.
7. Product Package Insert for Adacel®. January 2006.

Appendix 1: Published clinical trial

<table>
<tr><th>Study</th><th>Inclusion/ exclusion criteria</th><th>Dose</th><th>Outcome Assessment</th><th>Results</th></tr>
<tr>
<td>Pichichero, ME, Rennels MB, Edwards KM

Combined Tetanus, Diphtheria, and 5-Component Pertussis Vaccine for Use in Adolescents and Adults

Adolescents (11-17): n=2053 (1232 Assigned to Receive Tdap)- 606 of 1232 Assigned to Receive Tdap Randomly Selected to Participate in Immunogenicity Study

Adults (18-64): n=2427 (1821 Assigned to Receive Tdap)- 908 of 1821 Assigned to Receive Tdap Randomly Selected to Participate in Immunogenicity Study

JAMA. 2005;293:3003-3011</td>
<td>A prospective, randomized, modified double blind, comparative trial Participants were randomized to receive Tdap or Td (3:2 for adolescents; 3:1 for adults). To ensure adequate distribution across groups, enrollment was stratified by age (11-13, 14-17, 18-28, 29-48, and 49-64 years; block size was 10 for adolescents and 8 for adults).

Inclusion: 11- 64 years of age, in good health, with temp < than 38.0°C. Exclusion: receipt of any DPT containing vaccines within 5 years; diagnosis of pertussis within 2 years; allergy or sensitivity to any vaccine component, including previous vaccine reactions; acute respiratory illness; daily use of oral NSAIDs; receipt of blood products or immunoglobulins within 3 months; and any immunodeficiency, malignancy, significant underlying disease, neurological impairment, or pregnancy.</td>
<td>Tdap contained 2.5 µg of pertussis toxoid; 5 µg of filamentous hemagglutinin ; 3 µg of pertactin; 5 µg of fimbriae types 2 and 3; 2 Limit of flocculation (Lf) of diphtheria toxoid; 5 Lf of tetanus toxoid; 1.5 mg of aluminum phosphate (0.33 mg aluminum); and 0.6% 2-phenoxyethanol per 0.5-mL dose. The control vaccine, Td, was a licensed product containing 2 Lf of diphtheria toxoid; 5 Lf of tetanus toxoid; 1.5 mg of aluminum phosphate (0.33 mg aluminum); and 0.01% thimerosal as a preservative per 0.5-mL dose.</td>
<td>Antipertussis, anti–filamentous hemagglutinin, anti–fimbriae types 2 and 3, antipertactin IgG, and antitetanus antibody titers were determined by an enzyme-linked immunosorbent assay (ELISA) method. Results for pertussis antibodies were calculated in ELISA units per milliliter (EU/mL) by comparison with in-house standard antisera of assigned unitage, calibrated to the US Human Reference Lots 3 or 4. Pertussis antibody response comparisons were made using serum samples collected at 7 months of age, following immunization at 2, 4, and 6 months of age, from infant participants in an efficacy trial using analogous pediatric diphtheria-tetanus 5-component-acellular pertussis vaccine (DTaP; Daptacel, Sanofi Pasteur Limited).</td>
<td>Immunogenicity Findings in the Per-Protocol Population*
<table>
<tr><th></th><th colspan="2">Adolescents 11-17y</th><th colspan="2">Adults 18-64y</th></tr>
<tr><th></th><th>Tdap (n=527)</th><th>Td (n=516)</th><th>Tdap (n=743)</th><th>Td (n=510)</th></tr>
<tr><td>Seroprotection >0.1 IU/mL, No./total (%)
Diptheria
Tetanus</td><td>
526/527 (99.8)
527/527 (100.0</td><td>
515/516 (99.8)
516/516 (100)</td><td>
697/741 (94.1)
742/742 (100)</td><td>
482/507 (95.1)
508/509 (99.8)</td></tr>
<tr><td>Booster response rates, No./total (%)†
Diptheria
Tetanus
Pertussis Toxin</td><td>
501/527 (95.1)
483/527 (91.7)
482/524 (92.0)</td><td>
489/515 (95)
471/516 (91..3)</td><td>
646/739 (87.4)
468/742 (63.1)
624/739 (84.4)</td><td>
422/506 (83.4)
340/509 (66.8)</td></tr>
<tr><td>Geometric mean titers (95% CI)
Diptheria (IU/ml)
Tetanus (IU/ml)
Pertussis Toxin (EU/ml)</td><td>
8.46 (7.56-9.48)
12.87 (12.28-13.48)
309.26 (283-337)</td><td>
7.10 (6.43-7.83)
14.35 (13.6-15.09)
15.61 (13.89-17.54)</td><td>
2.49 (2.17-2.85)
7.65 (7.28-8.0)
178.84 (164.24-194.74)</td><td>
2.37 (2.0-2.7)
8.18 (7.6-8.75)
13.16 (11.71-14.79)</td></tr>
</table>
Abbreviations: CI, confidence interval; ELISA, enzyme-linked immunosorbent assay; EU/mL, ELISA units per milliliter; Td, tetanus-diphtheria vaccine; Tdap, tetanus-diphtheria 5-component acellular pertussis vaccine.
*For all comparisons, Tdap vaccine met predefined noninferiority criteria vs Td vaccine based on 95% CIs around the differences in seroprotection rates.
†Percentages based on participants for whom evaluable data were available. Up to 4 participants per group had missing data for an individual measurement.</td>
</tr>
</table>

Table 2. Antibody Responses to Pertussis Antigens*

	Antigens, EU/ml GMT (95% CI)			Tdap/D Tap GMT Ratio (95% CI)	
	Tdap Adolescents (n=527)	Tdap Adults (n=741)	Dtap Infants 2-6 mos (n=80)	Adolescents	Adults
Pertussis Toxin					
Prevaccination	14.46 (12.95-16.14)	12.54 (11.46-13.73)	5.24 (4-6)	2.76 (2-3.7)	2.39 (1.8-3.2)
Postvaccination	309.26 (283-337)	178.84 (164-194)	86.55 (71-105)	3.57 (2.8-4.5)	2.07 (1.58-2.7)
Filamentous hemagglutinin					
Prevaccination	19.49 (17.51-21.69)	18.13 (16.69-19.68)	5.21 (4.18-6.49)	3.74 (2.81-4.99)	3.48 (2.68-4.52)
Postvaccination	214.83 (200.34-230.37)	192.91 (180.72-205.93)	39.95 (34.62-46.10	5.38 (4.46-6.49)	4.83 (3.94-5.92)
Pertactin					
Prevaccination	10.01 (8.93-11.24	8.45 (7.65-9.34)	2.15 (1.85-2.49)	4.67 (3.46-6.30)	3.94 (2.89-5.36)
Postvaccination	344.52 (313.28-378.87	341.89 (306.19-381.75)	108.12 (91.41-127.88)	3.19 (2.48-4.10)	3.16 (2.25-4.44)
Fimbriae types 2 and 3					
Prevaccination	25.80 (23.49-28.33)	28.56 (26.12-31.23)	13.26 (11.23-15.67)	1.94 (1.52-2.50)	2.15 (1.63-2.84)
Postvaccination	1792.40 (1603.74-2003.24	852.72 (762.82-953.20)	341.10 (270.23-430.56)	5.25 (3.90-7.09)	2.50 (1.77-3.54)

Abbreviations: CI, confidence interval; ELISA, enzyme-linked immunosorbent assay; EU/mL, ELISA units per milliliter; GMT, geometric mean titer; Td, tetanus-diphtheria vaccine; Tdap, tetanus-diphtheria 5-component acellular pertussis vaccine.
*Based on number of participants with evaluable data for each antigen. For all comparisons, Tdap vaccine met predefined noninferiority criteria.