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Waning protection following 5 doses of a 3-component diphtheria, tetanus, and acellular pertussis vaccine

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ABSTRACT

Background: The effectiveness of diphtheria, tetanus, and acellular pertussis (DTaP) vaccines wanes substantially after the 5th dose given at ages 4–6 years, but has not been described following 5 doses of the same type of DTaP vaccine. We investigated waning effectiveness against pertussis in California over nearly 10 years, which included large pertussis outbreaks, following 5 doses of GSK DTaP vaccines ($DTaP_3$).

Methods: We conducted a case-control study (NCT02447978) of children who received 5 doses of DTaP at Kaiser Permanente Northern California from 01/2006 through 03/2015. We compared time since the 5th dose in confirmed pertussis polymerase chain reaction (PCR)-positive cases with pertussis PCR-negative controls. We used logistic regression adjusted for calendar time, age, sex, race, and service area to estimate the effect of time since the 5th DTaP dose on the odds of pertussis. Our primary analysis evaluated waning after 5 doses of $DTaP_3$. We also examined waning after 5 doses of any type of DTaP vaccines.

Results: Our primary analysis compared 340 pertussis cases diagnosed at ages 4–12 years with 3841 controls. The any DTaP analysis compared 462 pertussis cases with 5649 controls. The majority of all DTaP doses in the study population were $DTaP_3$ (86.8%). Children who were more remote from their 5th dose were less protected than were children whose 5th dose was more recent; the adjusted odds of pertussis increased by 1.27 per year (95% CI 1.10, 1.46) after 5 doses of $DTaP_3$ and by 1.30 per year (95% CI 1.15, 1.46) after any 5 DTaP vaccines doses.

Conclusions: Waning protection after $DTaP_3$ was similar to that following 5 doses of any type of DTaP vaccines. This finding is not unexpected as most of the DTaP vaccines administered were $DTaP_3$. Following 5 doses of $DTaP_3$ vaccines, protection from pertussis waned 27% per year on average.

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1. Introduction

Pertussis vaccines derived from whole *Bordetella pertussis* organisms and combined with diphtheria, tetanus toxoid (DTwP) were available from the 1940s and were effective [1], but were also associated with safety concerns [2], which ultimately led to the development of acellular pertussis vaccines combined with diphtheria, tetanus toxoid (DTaP) [3]. By the late 1990s, the United States (US) had switched from DTwP to DTaP vaccines for all recommended doses [4,5].

The Advisory Committee on Immunization Practices (ACIP) recommends 5 doses of the DTaP vaccine at ages 2, 4, 6 and 15–18 months, followed by a 5th dose given between ages 4 and 6 years. Data regarding the efficacy, safety, and immunogenicity

Abbreviations: ACIP, Advisory Committee on Immunization Practices; BISG, Bayesian Improved Surname Geocoding Method; DTaP, Diphtheria, Tetanus, and acellular Pertussis vaccine; CI, confidence interval; $DTaP_3$, GSK 3-component pediatric acellular pertussis vaccines; DTwP, Diphtheria, Tetanus, and whole-cell Pertussis vaccine; FDA, Food and Drug Administration; KPNC, Kaiser Permanente Northern California; OR, odds ratio; PCR, polymerase chain reaction; Tdap, reduced-antigen-content Tetanus, Diphtheria, and acellular Pertussis vaccine; US, United States; VE, vaccine effectiveness.

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of using vaccines from multiple brands in a DTaP vaccination series are lacking; therefore, the Food and Drug Administration (FDA) and ACIP recommend immunizing with the same DTaP vaccine brand throughout the entire immunization series. If the prior vaccine brand cannot be determined or is not available, ACIP recommends using any of the licensed DTaP vaccines. In the US, there are currently 2 available DTaP vaccines, a 3-component DTaP vaccine (GSK) and a 5-component DTaP vaccine (Sanofi Pasteur) [6].

Despite high levels of vaccine coverage among children and adolescents, an increase of pertussis incidence has been observed since 1980s, with peaks arising every 3–5 years [7]. California experienced its largest pertussis outbreak in more than 50 years in 2010–2011, followed by an even larger outbreak in 2014–2015. Although not the only factor, waning of vaccine effectiveness (VE) following 5 DTaP doses plays a central role in recent outbreaks [7–14]. We reported that during California's 2010 pertussis outbreak, protection from pertussis following the 5th dose of DTaP from any manufacturer waned on average 42% each year [10].

To our knowledge, studies to date have not evaluated waning after 5 DTaP doses of the same type of acellular pertussis vaccine or manufacturer. It is not known whether waning after 5 doses of the same brand of DTaP in children vaccinated according to the US schedule is similar to the DTaP waning reported following 5 doses of DTaP from multiple manufacturers [10,11,13,14].

This study assessed the durability of protection against pertussis following California's 2010 and 2014 pertussis epidemics in children who received 5 doses of 3-component DTaP vaccines ($DTaP_3$; *Pediarix*, *Kinrix* and/or *Infanrix*, GSK) in Kaiser Permanente Northern California (KPNC), according to the US schedule.

2. Methods

2.1. Setting

KPNC is an integrated health care delivery system which provides care to approximately 3.5 million members. KPNC operates 49 medical clinics and 21 hospitals, including pharmacies and laboratories. KPNC electronic databases capture vaccinations, laboratory tests, and inpatient, emergency room, and outpatient diagnoses. KPNC's single centralized laboratory has identified *Bordetella pertussis* and *Bordetella parapertussis* using polymerase chain reaction (PCR) since 2005. PCR results are categorized as positive for *Bordetella pertussis*; positive for *Bordetella parapertussis*; or negative for both. PCR kits were supplied by *Roche* from December 2005–May 2009 and by *Cepheid* from May 2009 onwards [10].

Within KPNC, DTaP (replacing DTwP) was introduced for the 5th dose in 1991, the 4th dose in 1992, the 3-dose primary series in 1997, and all 5 childhood doses by 1999. Persons born before 1999 either received all DTwP vaccines or a mix of DTwP and DTaP vaccines.

2.2. Study population

This was a case-control study (NCT02447978) in which we selected cases and controls from all KPNC members from January 1, 2006 through March 31, 2015 (conclusion of the 2014 California pertussis epidemic). We included all KPNC members during the study period who met the following criteria: (1) were born in 1999 or later; and (2) received 5 doses of DTaP vaccines in KPNC between 1 and 84 months of age, with the doses distributed as follows: 3 doses between 1 and 11 months, 1 dose between 12 and 46 months, and 1 dose between 47 and 84 months.

We excluded persons who received reduced-antigen-content pertussis (Tdap) vaccine before the PCR test, who received any pertussis-containing vaccine between the 5th dose and the PCR test, who received a PCR test within 2 weeks of the 5th DTaP dose, and children who were not KPNC members for greater than 3 months between the 5th DTaP dose and PCR test. We applied the same exclusion criteria for cases and controls, and excluded individuals as controls if they were an earlier case. Finally, we excluded persons who were older than 12 years of age who had not yet received Tdap or who met the other exclusion criteria above.

Cases: We included as potential cases all individuals who tested pertussis PCR-positive and parapertussis negative during the study period and who had received either 5 doses of $DTaP_3$ or 5 doses of DTaP vaccines regardless of type or manufacturer ("any DTaP") before testing PCR-positive, depending on the study objective.

Controls: We utilized two control groups. The first control group ("PCR-negatives") consisted of persons who tested PCR-negative for both pertussis and parapertussis and who received 5 doses of either $DTaP_3$ or any DTaP vaccines before testing PCR negative. The second control group ("KPNC-matched controls") consisted of all KPNC members of the same sex, age (year and quarter of birth), race or ethnic group (7 groups; 6 for reported, 1 for imputed), and medical clinic as each pertussis case and who were members on the date the matched case tested PCR-positive (anchor date). We retained all KPNC-matched controls (no sampling) who received 5 doses of either $DTaP_3$ or any DTaP vaccines prior to their anchor date.

PCR-negative controls were intended to be comparable to the cases with regard to propensity to seek care and to get the PCR test when symptomatic. However, this comparison group is vulnerable to "collider bias" [15,16] such that the test negative individuals could differ from the cases with respect to unmeasured selection factors. For this reason, we also used the larger comparison groups of KPNC-matched controls who were not vulnerable to this particular bias. We used the PCR-negative comparison group for our primary analysis because we were most concerned about biases related to healthcare seeking behaviors. Collider bias was of less concern because our study population all received 5 doses of DTaP and the timing of the 5th dose seemed unlikely to be driven by confounders.

2.3. Sensitivity analyses

To better put the current results into the context of our prior study on DTaP waning, we also identified an additional study population described previously ("any 5th DTaP") [10]. Individuals in "any 5th DTaP" met all the above criteria, with the exception of the stringent DTaP vaccine history requirements. The "any 5th DTaP" vaccine requirement was receipt of any type of DTaP vaccine in KPNC between 47 and 84 months of age (considered the 5th DTaP dose).

2.4. Statistical analysis

This study had two primary aims. The first was to estimate the waning of $DTaP_3$ protection against pertussis infection by comparing time since the 5th $DTaP_3$ dose between cases and PCR-negative controls who had all received 5 doses of $DTaP_3$ vaccines. The second was to estimate the waning of DTaP protection against pertussis infection by comparing time since the 5th DTaP dose between cases and PCR-negative controls who had all received 5 doses of "any DTaP" for their childhood vaccination series.

The secondary aims were the same except that waning protection following the 5th DTaP dose was estimated by instead comparing cases to KPNC-matched controls.

We fit conditional logistic regression models to examine cases versus controls in relation to time since the 5th DTaP dose. We modeled time since the 5th DTaP dose as a continuous variable

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