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Estimates of pertussis vaccine effectiveness in United States air force pediatric dependents

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ABSTRACT

Background: Pertussis vaccination compliance is critical for reduction in the prevalence of disease; however, the current acellular pertussis vaccine may not provide sufficient protection from infection. This study examined acellular pertussis vaccine effectiveness (VE) for Air Force dependents less than 12 years of age.
Methods: We conducted a case-control study among Air Force pediatric dependents from 2011 to 2013, comparing cases with positive pertussis test results to controls who received the same lab tests with a negative result. Our study population was categorized by age group and vaccination status based on the Centers for Disease Control and Prevention recommended pertussis vaccination schedule. VE was calculated with respect to vaccination status and pertussis lab results.
Results: We compared 27 pertussis laboratory positive cases with 974 pertussis laboratory negative controls, 2 months to <12 years old. Comparing completely vaccinated to non-vaccinated patients, the overall VE was 78.3% (95% confidence interval (CI): 48.6, 90.8; $p < 0.001$). VE was highest among those 15 months to <6 years old: 97.6% (95% CI: 78.5, 99.7; $p < 0.001$). Children 6 to <12 years old had the lowest VE: 48.5% (95% CI: −74.0, 84.7; $p = 0.28$). Comparing partially vaccinated patients to nonvaccinated patients yielded 64.2% (95% CI: −7.2, 88.1; $p = 0.06$) overall VE.
Conclusions: Acellular pertussis vaccination was effective at preventing laboratory confirmed pertussis among our Air Force pediatric dependent population, with highest protection among completely vaccinated, young children. Older children received the lowest amount of protection. Partial vaccination had near significant protection. Our overall calculated pertussis VE corroborates other pertussis VE studies looking at similar age groups.

1. Introduction

Prior to the development of pertussis vaccination, the highest incidence of reported cases in the United States (U.S.) occurred in 1934, with 260,000 cases (205.7 cases per 100,000 people) [1–3]. In response, the whole-cell pertussis vaccine was developed and licensed in the U.S. for use in children beginning in the mid-1940s, leading to a 99% rate decline by 1970 [2]. By 1976 the Centers for Disease Control and Prevention (CDC) reported the lowest number of pertussis cases in the U.S., 1010 cases (0.5 cases per 100,000 people [2,3]). However, since 1976, pertussis has been on a cyclical increase, a trend never before seen in the post-vaccine era [4]. The acellular formulation was developed in 1991, eventually replacing the whole cell formulation in the U.S. and subsequently reducing vaccine adverse events [2]. By 2012 48,277 cases (15.4 cases per 100,000 people) of pertussis were reported in the U.S [5,6]. Though diverse, heterogeneous trends of pertussis incidence have been observed globally over the past 20 years, increasing trends have been observed in several developed countries [7]. In 2012, Canada and the United Kingdom reported 14.1 cases per 100,000 people and 19.0 cases per 100,000 people [8,9], respectively. Additionally the same year, Australia witnessed one of the highest global incidence rates of pertussis (108.4 cases per 100,000 people) [8,9].

The Advisory Committee on Immunization Practices (ACIP) recommends vaccination with diphtheria, tetanus toxoids, and

Abbreviations: ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; CI, confidence interval; ClinChem, Clinical Chemistry Database; DFA, direct fluorescent antibody; DTaP, diphtheria, tetanus toxoids, and acellular pertussis; MTF, medical treatment facility; OR, odds ratio; PCR, polymerase chain reaction; Tdap, tetanus, diphtheria toxoids, and acellular pertussis; U.S., United States; USAF, United States Air Force; VE, vaccine effectiveness; VPD, vaccine preventable disease.

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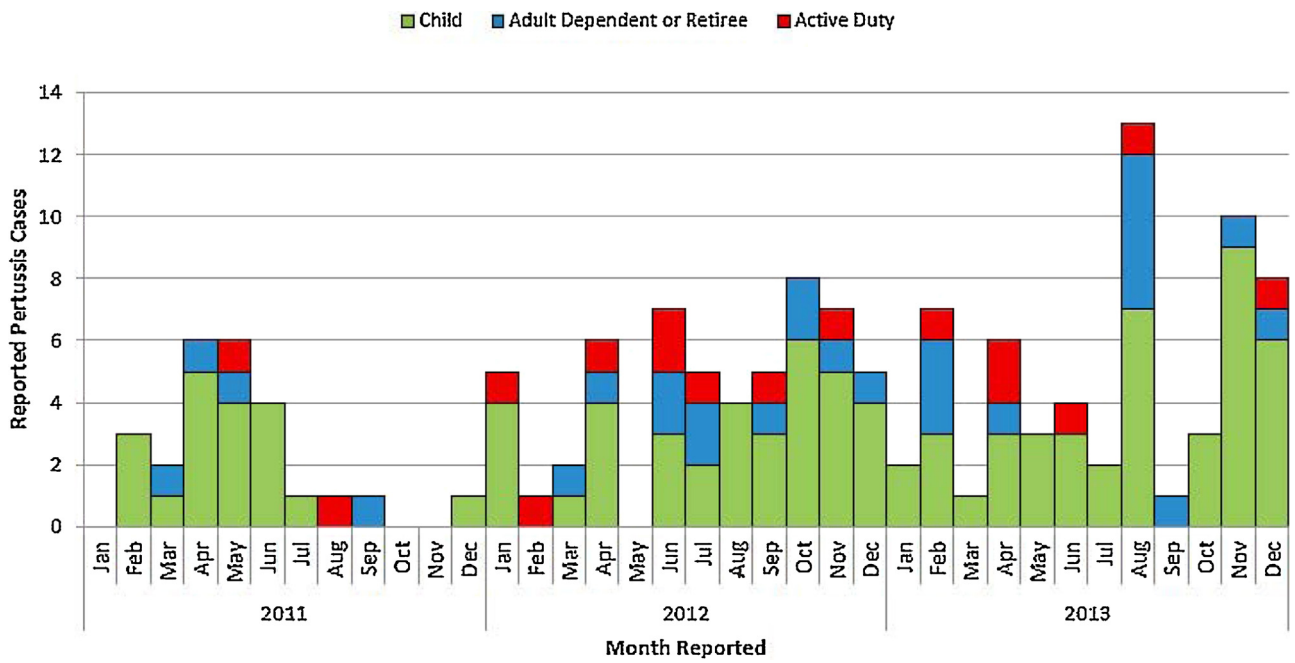

Fig. 1. Reported pertussis cases at USAF medical treatment facilities, 2011–2013.

acellular pertussis (DTaP) sequentially for children at 2 months, 4 months, 6 months, 15 to 18 months, and 4 to 6 years of age [10]. Globally, the World Health Organization recommends three doses of pertussis vaccine during the first year of life, followed by one booster dose between the ages of 1–6 years old, with a preference at 2 years of age [11]. Current members serving in the U.S. Air Force (USAF) (active duty, Guard, and Reserve) are required to receive one dose of Tdap during basic training (if lacking documentation of previous vaccine) or a one-time dose of Tdap in place of a tetanus booster during adulthood [12]. Spouses and children of USAF service members are requested to follow the ACIP pertussis vaccination guidelines.

Studies in the general U.S. population exploring the benefits of acellular vaccines have observed an overall pertussis vaccine effectiveness (VE) ranging from 51% to 89% [13–15]. Data collected through routine passive surveillance from the Air Force Reportable Event Surveillance System, an electronic repository of reportable diseases, detected an increased number of pertussis cases during 2012–2013 (55 and 60 cases, respectively) when compared to cases reported in 2011 (25 cases, Fig. 1). These cases of pertussis were most frequently observed in children (dependents) of USAF service members, although adult members (both service members and spouses) contributed to the case reporting. This study examines and further characterizes pertussis VE from 2011 to 2013 for USAF dependents younger than 12 years of age. The protocol for this study was reviewed and approved as exempt by the Air Force Research Laboratory Institutional Review Board.

2. Materials and methods

A test-negative study was conducted to examine the effectiveness of acellular pertussis vaccination against laboratory-confirmed pertussis cases within the population. This method has been described elsewhere [16,17]. Briefly those who seek care for respiratory illnesses are different than those who do not with regard to both their exposure (vaccination vs. no vaccination) and disease status (positive disease known vs. unknown). The test negative study design minimizes these classification biases by only utilizing controls who seek medical care if they develop a pertussis-like illness since the incidence of non-pertussis disease is assumed similar between vaccinated and unvaccinated subjects.

USAF dependent children 2 months to less than 12 years old who were seen at any USAF medical treatment facility (MTF) from January 1, 2011, to December 31, 2013, were eligible to be included in the study. Laboratory data were derived from the Clinical Chemistry database (ClinChem), a Department of Defense database composed of laboratory results. ClinChem variables included individual demographics (gender, age, and beneficiary type) and pertussis laboratory data. ClinChem data were linked to the TriCare® enrollment database to obtain service member's (sponsor's) rank, service branch, and pay grade. TriCare® is health insurance coverage for military and their family members (dependents). The Military Personnel Database is a Department of Defense database containing demographic personnel data. Sponsor's race and ethnicity were identified through Military Personnel and used as proxies for dependent's race and ethnicity. Finally, the Air Force Complete Immunization Tracking Application database, a USAF database containing vaccination-related data, was queried to identify vaccination (DTaP and Tdap) histories. This was matched to individuals who received any pertussis laboratory testing during the study timeframe. Data were de-identified prior to study commencement by replacing Social Security numbers with unique study identification numbers.

Per the 2012 *Armed Forces Reportable Medical Events: Guidelines & Case Definitions* [18], a case was defined as any study patient with confirmed *Bordetella pertussis* infection identified through polymerase chain reaction (PCR), direct fluorescent antibody (DFA), or culture from a clinical specimen tested between January 1, 2011, and December 31, 2013. Controls included all negative *B. pertussis* test results submitted for testing during the same timeframe as cases. Patients born before 2002 were excluded from the study because of unavailability of complete vaccination histories. Infants less than 2 months of age at the time of their pertussis lab test were too young to receive vaccination and therefore were excluded from the study.

The final study population was categorized by vaccination status and age based on the CDC-recommended pertussis vaccine schedule [10]. DTaP (Tripedia®, Infanrix®, Trihibit®, Daptacel®,