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CME Information

CME Released: 07/09/2010; Valid for credit through 07/09/2011

Target Audience

This article is intended for primary care clinicians, infectious disease specialists, and other specialists who provide care to patients at risk for pertussis infection.

Goal

The goal of this activity is to provide medical news to primary care clinicians and other healthcare professionals in order to enhance patient care.

Learning Objectives

Upon completion of this activity, participants will be able to:

1. Describe the vaccine efficacy of Tdap booster in the prevention of pertussis in children.
2. Describe the usefulness of serologic testing to identify pertussis.

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From Reuters Health Information CME Tdap Vaccine Protects Against Pertussis During Outbreak CME

News Author: Karla Gale, MS

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July 9, 2010 — The Tdap vaccine — a tetanus, reduced-dose diphtheria, and acellular pertussis booster — effectively protected adolescents during a pertussis outbreak in the U.S. Virgin Islands, investigators reported online June 25th in *Clinical Infectious Diseases*.

Tdap's licensure in 2005 was based on serological surrogate end points rather than direct vaccine efficacy data. In this study, the first published evaluation in an outbreak setting, Tdap was 65.6% effective.

The outbreak occurred in the autumn of 2007 at a nursery through 12th grade school on St. Croix. With 51 confirmed or probable cases among 499 students, the attack rate was 10%. Coughs lasted up to four months or more, with a median duration of 38 days.

According to senior author Dr. Stacey W. Martin, from the U.S. Centers for Disease Control and Prevention, Atlanta, Georgia, and colleagues, all but three cases occurred in grades six through 12, with an overall attack rate in those classes of 17%. The highest incidence was in the 10th grade (38%).

Among students age 11 and older, overall Tdap coverage was 12%. There were two confirmed or probable cases among 33 vaccinated students (6.1%) and 41 among 233 not vaccinated (17.6%, relative risk 2.9). The vaccine's effectiveness was not statistically significant ($p = 0.092$) due to limited sample size.

Local authorities collected nasopharyngeal aspirates or swab samples for culture and for pertussis polymerase chain reaction (PCR) testing from students whose cough had started no more than 14 days earlier. They also collected blood samples from students with any duration of cough. During the convalescence phase in winter 2008, nasopharyngeal specimens were again collected from kids with cough, and all students age 11 and over were offered serological testing regardless of cough history.

In confirmed cases, *Bordetella pertussis* was isolated in culture or patients had positive PCR or serological test results. Clinical cases (cough for at least 14 days along with whoop, post-tussive vomiting and/or paroxysmal cough) that were not laboratory-confirmed were classified as probable.

Because the Advisory Committee on Immunization Practices recommends Tdap vaccination only for adolescents and adults up to age 65, the research team limited its vaccine efficacy analyses to the 287 students age 11 and older.

Among 162 students who provided clinical specimens, six had culture-confirmed cases. These six also had the only positive results on PCR and convalescent serology.

The authors report that geometric mean concentrations (GMC) of anti-pertussis IgG varied in the serum samples obtained in the convalescent period, from 107.2 ELISA Units/mL in 40 patients with confirmed or probable cases, to 20.2 EU/mL in 45 students with a history of cough not meeting the case definition, and 29.4 EU/mL in 72 students with no history of cough ($p < 0.001$ comparing cases with noncases).

They also note that only 26 of 40 case patients had positive convalescent serological test results, and one had indeterminate results.

On the other hand, 12 of 72 noncoughing students also had positive serological test results, indicating "evidence of asymptomatic infection and the potential for unrecognized transmission."

The investigators also point out that serology results identified 20 patients who didn't present for testing until they'd been coughing for more than two weeks. These students didn't provide nasopharyngeal specimens, but if they had, the tests would likely have been negative because of the timing. Given the usefulness of serology in these cases, the authors recommend that the Council of State and Territorial Epidemiologists include serological testing in its case definition.

"Higher Tdap coverage rates are needed to minimize the negative impacts of waning immunity, imperfect (vaccine effectiveness) and high secondary transmission rates," the research team concludes.

Clin Infect Dis. 2010;51:315-321.

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Clinical Context

In the March 30, 2007, issue of *MMWR. Morbidity and Mortality Weekly Report*, McNabb and colleagues reported that 53% of pertussis cases in 2006 occurred in children at least 15 years old. According to Kretsinger and colleagues in the December 15, 2006, issue of *MMWR. Recommendations and Reports: Morbidity and Mortality Weekly Report*, a combined vaccine, Tdap, was recommended for all adolescents and adults up to age 65 years. In the March 2006 issue of *Pediatrics*, it was noted that approval of Tdap use was based on serologic responses in adolescents and adults.

This study of a pertussis outbreak assesses the vaccine effectiveness of Tdap and whether serologic testing is useful to detect pertussis.

Study Highlights

- A pertussis outbreak occurred from September 30, 2007, to December 19, 2007, at a nursery through 12th grade school in the US Virgin Islands.
- Written, telephone, and in-person surveys were obtained from parents for students below grade 7 and from students in grade 7 or above.
- All students were screened for cough.
- Vaccine effectiveness analysis was conducted on 287 students at least 11 years old.
- Specimen collection occurred at 2 periods: December 18, 2007, to December 19, 2007, and January 17, 2008, to February 21, 2008.
- From December 18, 2007, to December 19, 2007, students with cough less than 14 days prior were offered pertussis PCR, culture, and serologic testing. Students with cough more than 14 days were offered serologic testing.
- From January 17, 2008, to February 21, 2008, students with cough less than 14 days were offered pertussis PCR and culture testing. All students at least 11 years old were offered serologic testing.
- A PCR result was considered positive if both insertion sequence 481 and pertussis toxin subunit 1 nucleic acid sequences were amplified.
- A serologic test result was considered positive if concentration of IgG antibody against pertussis toxin was at least 94 ELISA units/mL and indeterminate for recent infection if IgG concentration was at least 49 and less than 94 ELISA units/mL.
- Serum samples were acute if obtained up to 14 days from cough onset and convalescent if obtained more than 14 days from cough onset.
- Students were considered vaccinated if Tdap was received before the pertussis outbreak and unvaccinated if no Tdap was received or if Tdap was received 2 weeks before the end of the outbreak.
- Clinical cases were defined by cough for at least 14 days plus whoop, paroxysms, or post-tussive vomiting.
- Confirmed cases were defined by any cough plus *B pertussis* isolation or clinical cases plus *B pertussis* by PCR or serologic testing.
- Probable cases were defined by clinical cases not confirmed by laboratory testing.
- 266 students aged at least 11 years had complete data.
- 162 students (56%) aged at least 11 years gave specimens.
- Confirmed or probable pertussis occurred in 51 of 499 students (attack rate, 10%): 27 confirmed and 24 probable cases.
- Of 6 students with positive culture results, all were PCR positive and had positive convalescent serology results, but 2 had indeterminate acute serology results, and 2 had negative acute serology results.
- Of 40 students with clinical or culture-confirmed cases, 26 had positive convalescent serology test results, 1 had indeterminate results, and 13 had negative results.
- Convalescent serologic results were higher in students with clinical or culture-confirmed pertussis vs students with cough or students without cough (GMC, 107.2 vs 20.2 vs 29.4 ELISA/mL, respectively; $P < .001$).
- Most pertussis occurred in grades 6 to 12, with the peak attack rate of 38% in 10th graders.
- The most common pertussis symptom was paroxysmal cough in 77%, followed by whoop (46%) and post-tussive vomiting (35%).
- Median cough duration was 38 days (range, 14 - 127 days).
- Pertussis incidence did not differ by sex, race, or ethnicity.
- 31 (12%) of students aged at least 11 years received Tdap.
- Confirmed or probable pertussis occurred in 41 (18%) of unvaccinated students vs 2 (6%) of vaccinated students (relative risk, 2.9).
- Vaccine effectiveness was 65.6% for confirmed or probable pertussis (95% confidence interval, -35.8% to 91.3%; $P = .092$) and 70.6% for laboratory-confirmed pertussis (95% confidence interval, -110.3% to 95.9%; $P = .180$).

- Study limitations included limited sample size and the need for additional studies as Tdap use increases.

Clinical Implications

- In children at least 11 years old, Tdap vaccine appears to provide protection against pertussis with a vaccine efficacy of approximately 66%.
- In children at least 11 years old, convalescent-phase serology test results are significantly higher in patients with clinical or culture-confirmed pertussis vs those with cough who do not meet the pertussis case definition or those without cough.

CME Test

According to the study by Wei and colleagues, which of the following percentages *most* accurately describes the apparent efficacy of Tdap vaccine in the prevention of pertussis?

- 15%
- 35%
- 50%
- 65%
- 85%

A 12-year-old child with cough is suspected to have pertussis. Which of the following statements is *most* accurate?

- Serology test results are similar for children with culture-confirmed pertussis and those with no cough
- Serology test results are higher for children with culture-confirmed pertussis vs those without cough
- Serology test results are lower for children with culture-confirmed pertussis vs those without cough
- Serology test results are not useful for detecting pertussis
- Serology testing is recommended instead of culture testing for pertussis

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