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PERTUSSIS CASES IN TEENS REACH HIGHEST LEVEL IN NEARLY 4 DECADES NEW VACCINE TO PROTECT ADOLESCENTS: FDA-APPROVED BOOSTRIX[®]

(TETANUS TOXOID, REDUCED DIPHtheria TOXOID AND ACELLULAR PERTUSSIS VACCINE, ADSORBED)

The number of reported cases of pertussis continues to escalate across the United States, particularly among teens. Pertussis (whooping cough) is a highly contagious respiratory tract infection caused by *Bordetella pertussis*. In contrast to other infectious diseases for which a vaccine is available, nearly 26,000 cases of pertussis were reported to the Centers for Disease Control and Prevention (CDC) in 2004—a 121% increase over 2003¹ and the highest number of case reports in over four decades. According to Gary S. Marshall, MD, Professor of Pediatrics, University of Louisville School of Medicine, (Louisville, KY), “these figures are almost certainly underestimated because pertussis is severely underreported and underdiagnosed and the true incidence of the disease in the U.S. may be greater than one million cases per year.”

Although the risk of pertussis among infants remains a substantial clinical problem due to the complications in this age group, Dr. Marshall says that the pattern of infection has shown that, “the largest number of cases is occurring among adolescents. The number of reported cases that were recorded in 2004 among adolescents represented about 38% of all cases.” This number translates into an incidence rate of 23.86/100,000, which is 1.4-fold higher than the rate reported in 1- to 4-year-olds, nearly 2-fold higher than that reported in 5- to 9-year-olds, and 7-fold higher than the rate reported in persons 20 years of age and older.

Pertussis is the only vaccine-preventable disease for which children are routinely vaccinated that is on the rise. Why is this happening? According to Dr. Marshall, “The simple answer is we know that immunity to pertussis wanes with time.” The protection from childhood vaccination generally begins to diminish 5 to 10 years following the last vaccine dose (given at approximately 4 to 6 years of age).^{2,3} “This waning immunity leaves adolescents between the ages of 10 and 19 vulnerable to pertussis,” said Dr. Marshall. “Overall, cases of pertussis have increased 20-fold in the last 30 years.”

Reported Case Profiles, 2004
by Age, Weeks 1-52¹

Age	No. of Cases	%	Incidence per 100,000
<6 mos	2622	(10)	136.46
6-11 mos	611	(2)	31.8
1-4 yrs	2562	(10)	16.89
5-9 yrs	2417	(9)	12.58
10-19 yrs	9802	(38)	23.86
20+ yrs	7158	(28)	3.52
Unknown	655	(3)	
Total*	25827	(100)	8.9

*Total age incidence per 100,000 calculated from 25,172 cases with age reported.

States where there is an extensive and well-established surveillance program can provide a more complete picture of recent epidemiological trends. For example, between 1989 and 1998, the crude incidence of pertussis in Massachusetts increased from 3.2/100,000 to 12.8/100,000.⁴ More importantly, while the incidence of pertussis remained relatively stable among infants and children ≤10 years of age, the incidence among adolescents increased more than 9-fold.⁴ In addition, during the years from 2000 through 2003, there were 120 outbreaks of pertussis in Massachusetts, most of which (87%) were detected in schools.⁵

This increase in adolescent cases has become a critical issue and a great concern to the public health and medical authorities. Adolescents do not generally exhibit the classic signs of the disease, making it difficult to recognize. Adolescents and older individuals are an important reservoir for potentially serious infections in the very young who are either unvaccinated or whose vaccination schedule has not been completed. The risk that infected adolescents pose to infants is underscored by the observation that up to 90% of susceptible household contacts develop clinical disease following exposure to an index case.⁶

Many epidemiologists and infectious disease experts have advocated the addition of a booster vaccination against pertussis in adolescents as a rational way to combat the increased incidence of the disease. Dr. Marshall agrees. "The obvious, important thing here is that we now have vaccines that are capable of boosting immunity to pertussis among adolescents. We didn't have this before, as the infant pertussis vaccine could not be used as of age seven. BOOSTRIX is one of these vaccines that have been approved for use in adolescents." Since the direct and indirect costs of pertussis are substantial, a targeted vaccination program has the potential to be cost-effective. According to Dr. Marshall, "on average, a teenager with the illness can be sick for 100 days, with many visits to the physician and many visits to an emergency department." Is it cost effective to vaccinate all of these kids in terms of balancing the cost for the vaccine versus the money we save preventing the disease? "Yes. Most of the analyses show this is a very cost-effective thing to do. By universally immunizing teenagers we would save money in terms of preventing medical costs, preventing societal costs, and preventing other cases of pertussis, especially in infants that could result in the very high cost of death." It has been estimated that among adolescents, the costs of pertussis could total \$3.2 billion over a 10-year period. A recent pharmacoeconomic analysis has concluded that vaccination for all adolescents 10 to 19 years of age could prevent 0.4 million to 1.8 million cases of adolescent pertussis, saving \$0.3 billion to \$1.6 billion over 10 years.⁷

In June 2005, the Advisory Committee on Immunization Practices (ACIP) to the CDC recommended universal Tdap booster vaccination in place of the currently-given tetanus-diphtheria (Td) booster for adolescents 11 and 12 years

of age.⁸ The ACIP further recommended adolescents 13 to 18 who missed the 11 to 12 year dose of Td, and those 11 to 18 who have already been vaccinated with Td, receive a dose of Tdap to further protect against pertussis, as long as five years have elapsed.⁸

A new combination vaccine, BOOSTRIX®, has recently been approved by the US Food and Drug Administration for booster administration in adolescents. BOOSTRIX contains the same diphtheria toxoid, tetanus toxoid and pertussis antigens as Infanrix® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) and Pediarix® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine Combined), but with reduced quantities of those antigens. BOOSTRIX can be used as a single dose for active booster immunization against diphtheria, tetanus and pertussis in individuals 10 to 18 years of age. Replacing the routine tetanus-diphtheria booster with BOOSTRIX adds needed pertussis protection to the routine tetanus-diphtheria vaccine.

Important Safety Information

In clinical studies, adverse events included pain, redness and swelling at the injection site, headache, fatigue and gastrointestinal symptoms. As with other vaccines, rare adverse events may occur. As with any vaccine, vaccination with BOOSTRIX may not protect 100% of susceptible individuals. Hypersensitivity to any component of BOOSTRIX is a contraindication.

As the number of reported pertussis cases continues to rise, the use of a Tdap vaccine such as BOOSTRIX at the ACIP-recommended early adolescent visit, may be an effective strategy to prevent this serious and highly contagious disease among adolescents in the United States,^{9,10} and may possibly

reduce community outbreaks of pertussis.⁴ According to Gary Marshall, "Now is the time for clinicians to proactively vaccinate all teens in their practice with Tdap."



Please see brief summary of prescribing information for BOOSTRIX on adjacent page.

For more information about BOOSTRIX or GlaxoSmithKline, contact 1-888-825-5249 or visit the company's Web site at www.GSKVaccines.com.

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