

proportion of young children and adolescents who receive all vaccines that have been recommended for universal administration for at least 5 years.)

The specific goals of this project include:

- Enhancing methods to evaluate the burden of pertussis disease across age groups.
- Developing improved methods for pertussis surveillance that could be applied in other areas.
- Evaluating the effectiveness of pertussis vaccination by linking disease surveillance with immunization registry data on vaccination coverage.
- Developing a study site that could be used to assess the impact of an adolescent/adult pertussis vaccine program.

Measurable outcomes of the program will be in alignment with the goals listed above.

Background

The number of reported cases of pertussis in the United States has increased steadily from a historic low of 1,010 cases in 1976 to 7,867 cases in 2000. Despite high vaccination coverage in infants and children, pertussis is the only vaccine-preventable disease that has a reported increase in overall cases and infant mortality in the United States over the past decade. Adolescents and adults suffer significant morbidity; 12 percent to greater than 30 percent of persons with cough illness of at least one to two weeks duration have evidence of pertussis infection. The mean duration of cough in adolescents and adults has been estimated to be approximately eight weeks. It has been hypothesized that the incidence of pertussis in adolescents and adults is increasing and that this age group is a reservoir for circulation of *Bordetella pertussis* and transmission to infants, who have the highest morbidity and mortality.

The use of pertussis-containing vaccines has evolved since the first vaccine was licensed in the United States in 1914. Since becoming available in a combined vaccine with diphtheria and tetanus toxoids (DTP) in 1948, the vaccine has been widely used for routine childhood immunization. In 1991, acellular pertussis vaccine (DtaP) was introduced in the United States for the fourth and fifth booster dose. In 1997, DTaP was recommended for the entire five dose series (primary series plus booster doses) for children under six years of age. DTaP manufacturers and types have varied during their short history. Currently there are three different DTaP formulations (and one

DTaP-HepB-IPV) available in the United States. Many children receive more than one formulation of DTaP over the five dose vaccine series. Because the efficacy of products may differ, evaluating product specific vaccine efficacy requires good data on the specific vaccine administered; these data may be available in a vaccination registry.

The current passive surveillance system for pertussis lacks sensitivity. Pertussis incidence is thought to be underestimated by at least one to two orders of magnitude in some age groups. Diagnostic criteria and reporting of pertussis vary significantly from state to state and from year to year. Outbreak investigations and the occurrence of periodic epidemic years can also markedly affect reporting. For example, among adolescents aged 15–19 years, the reported national incidence was 3.6 per 100,000 in 1999. By contrast, the reported incidence rate for adolescents aged 15–19 years in Massachusetts (which uses serologic testing for diagnosis in persons over the age of 11) was 65.6 per 100,000 in 1999. In the epidemic year 1996, Massachusetts reported an incidence rate of 103 per 100,000 for adolescents in the same age group. Current data for pertussis in adults is even more limited. Thus, the variability in diagnostic testing and reporting makes the interpretation of the true incidence and trends in pertussis challenging.

A better understanding of the age distribution, transmission, and disease burden is critical to implement and evaluate an adolescent/adult immunization program in the United States. The ability to link immunization registry data to disease surveillance is also critical to evaluate vaccine efficacy and to assess trends in vaccine coverage and disease burden.

C. Eligible Applicants

Applications may be submitted by public and non-profit private organizations and by governments and their agencies.

Note: Title 2 of the United States Code Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

D. Availability of Funds

Approximately \$325,000 is available in FY 2003 to fund one award. It is expected that the award will begin on or before September 15, 2003 and will be made for a 12-month budget period. The overall project period is five years with funding in years two through five dependent on availability of funds and

satisfactory progress achieving project goals.

Recipient Financial Participation

Matching funds are not required for this program.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities. The intention is for the Recipient and the CDC to work jointly and in collaboration in developing, executing and reporting on this project.

1. Recipient Activities

The following section describes the expected activities of the recipient:

a. Establish population-based active surveillance for pertussis in geographic area with a well-defined population of at least 200,000 persons. Reporting sources should include all sites that provide inpatient and outpatient care to children, adolescents, and young adults. These include but are not necessarily limited to hospitals; emergency departments; pediatric, family practice, and internal medicine physician offices; public health clinics; urgent care centers; schools; and college health centers. Methods should be implemented to assure timely reporting of suspected pertussis cases, potentially including routine periodic contacts with reporting sources. Data should be collected from all suspected cases such that the descriptive epidemiology, risk factors, clinical course, therapy, and outcome of infection can be determined.

b. Enhance availability and use of laboratory testing to confirm the diagnosis of pertussis.

A range of laboratory tests should be available to confirm a pertussis diagnosis (e.g., culture, polymerase chain reaction (PCR), and serology). Strategies to facilitate widespread testing should be implemented. These may include educating reporting sources of the value and availability of testing, providing tests at no cost to the patient; facilitating transport of clinical specimens to the laboratory; and timely reporting of results.

c. Enhance the quality and scope of immunization registries in the surveillance area.

Activities to enhance quality include enrolling non-participating providers by facilitating ease of participation, and educating providers regarding the advantages of participation.

d. The applicant is also invited to propose a methodology for a pertussis