

2008-R-17

**CIO Name:** National Center for Immunization and Respiratory Diseases (NCIRD)

**Project Title:** Monitoring hospitalizations and outpatient visits for pneumonia and other non-invasive pneumococcal diseases by using national databases

**Project Description and Objectives:**

*Streptococcus pneumoniae* causes an estimated one third of community-acquired pneumonia (CAP), resulting in 175,000 hospitalizations annually in the United States. After routine use of the 7-valent pneumococcal conjugate vaccine (PCV7) in young children, substantial reductions in the incidence of invasive pneumococcal disease have been documented in both children and adults due to direct and indirect vaccine effects. Recent studies also suggest that the PCV7 immunization program has reduced pneumonia hospitalizations and related national health care expenditures in young children and possibly in young adults. The 23-valent pneumococcal polysaccharide vaccine (PPV23) has generally not been found to show effectiveness against non-bacteremic pneumococcal pneumonia.

New, expanded-valent pneumococcal conjugate vaccine formulations for children and adults are currently being developed, tested for safety and immunogenicity and are expected to be licensed within a few years. National data on trends in pneumonia hospitalizations are needed in determining the potential future impact and cost-effectiveness of these new vaccines. Surveillance systems are therefore needed to monitor the direct and indirect effects of new pneumococcal vaccines on pneumonia in children and adults. On the other hand, increasing rates of invasive disease caused by pneumococcal serotypes not included in the conjugate vaccine have been documented following PCV7 introduction. Although to date these increases have been small compared with the overall reductions in invasive disease, this "serotype replacement" phenomenon has the potential to decrease the vaccine's observed population effects on pneumonia over time.

The purpose of this project is to develop a reproducible methodology for monitoring and reporting trends in the population effects of the national PCV7 childhood immunization program on pneumonia hospitalizations and

outpatient visits in all age groups as well as other non-invasive pneumococcal-related syndromes (e.g., otitis media) in children. These trends should also be correlated with national immunization coverage estimates.

The impact of immunization programs in open populations may be greater than initially observed in controlled trials as it is generally not possible to assess indirect vaccine effects in these studies. Therefore, alternative data sources are needed to complement the information available from controlled studies and post-licensure active, population-based surveillance systems for invasive pneumococcal disease. This project will address several knowledge gaps regarding the national impact of pneumococcal immunization program and could be useful for public health agencies designing national immunization programs and developing immunization recommendations. Several population-based national databases are available for evaluating changes in pneumonia hospitalization rates and outpatient visits following introduction of PCV7. This type of assessment of impact of interventions and public policies requires accuracy and validity of the captured data, extensive programming, and the application of advanced statistical methods.

The objectives of this cooperative agreement are to:

1. Evaluate the overall national impact of childhood PCV7 immunization program on trends in pneumonia hospitalizations, mortality and outpatient visits in all age groups;
2. Develop and implement a monitoring system to track and report annual trends in pneumonia;
3. Use initial data from this system to prepare for monitoring the effects of future introduction of extended-valent pediatric and adult pneumococcal conjugate vaccines, and to estimate the potential effect of these new vaccines on pneumonia rates

**Awardee Activities:**

1. Designing the studies, in collaboration with CDC, for monitoring systems and developing definitions for outcomes
2. Using the Nationwide Inpatient Sample (NIS), National Ambulatory Medical Care Survey (NAMCS), and National Hospital Ambulatory Medical Care Survey (NHAMCS) databases to evaluate trends in pneumonia hospitalizations and outpatient visits

3. Obtaining and analyzing the datasets, using extensive programming and computational resources, for review by CDC
4. Ensuring accuracy and validity of the captured data
5. In consultation with CDC, develop the final project report and disseminate the project findings in scientific publications

**CDC Activities:**

CDC personnel will provide technical and subject matter expertise and will participate in development of the study design, data review and preparation of reports for presentation and publication.

**Special Requirements:**

1. The type of assessment described in this cooperative agreement requires accuracy and validity of the data, extensive programming, and application of advanced statistical methods.
2. The investigators should have extensive experience in using NIS, NAMCS, and NHAMCS databases and should use all these databases in evaluating the impact of immunization programs and policies through assessment of disease burden trends.
3. Experience should be demonstrated by a track record of previous successful collaborative projects and published reports in evaluating impact of immunization programs and disease burden.

**Additional Review Criteria:** None

**Funding Preferences:**

The investigators who have experience in working with NIS, NAMCS and NHAMCS databases and will use these databases in this project will be given preference for funding over to those high-ranking proposals that do not fulfill these criteria.

**Other Information:** None

**Project Period Length:** No more than 2 years

**Approximate Total Project Period Funding:** \$300,000 (This amount is an estimate, and is subject to availability of funds and **includes direct and indirect costs, excluding the additional academic partner administrative costs.**)

**Approximate Average Award:** \$150,000 (This amount is for the first 12-month budget period, and **includes both direct and indirect costs, excluding the additional academic partner administrative costs.**)

Approximate Number of Awards: 1

NOTE: Please note that applications must not exceed either the stated Project Period Length or the Approximate Total Budget Period funding per year. Applications in excess of these limits will be considered non-responsive and therefore will not be reviewed.