

**DIRECT AWARD NOTIFICATION**

**Emerging Infections Program**  
**ARRA 317 Immunizations**

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### **Emerging Infections Program - ARRA 317 Immunizations**

<b>BACKGROUND:</b>	<p>The Georgia Department of Community Health (DCH) was created in 1999 (Senate Bill 241) with the responsibility for insuring over two million people in the State of Georgia to maximize the State’s health care purchasing power, to coordinate health planning for state agencies, and to propose cost-effective solutions to reducing the numbers of uninsured. Within the Department, the Division of Public Health is responsible for disease control and prevention, the reduction of avoidable injury-related deaths and disabilities, and the promotion of healthy lifestyles. The three basic functions of public health include assessing the health status of the population; assuring that people have the resources and skills necessary to remain healthy; and establishing and implementing sound public health policy.</p>
<b>PROGRAM BACKGROUND:</b>	<p>The American Recovery and Reinvestment Act of 2009, Public Law 111-5 (ARRA) was signed into law on February 17, 2009. The Prevention and Wellness Fund section of ARRA provides funding to the Office of the Secretary (OS) of the Department of Health and Human Services (HHS) to carry out activities in support and enhancement of CDC’s immunization program. In this ARRA-317 Immunizations supplement to the CDC Emerging Infections Cooperative Agreement, CDC is proposing to evaluate the effectiveness of 2 vaccines in the 10 EIP sites, including Georgia:</p> <ol style="list-style-type: none"><li>1) PCV-13, a new vaccine against Streptococcus pneumoniae, a common cause of otitis media, bacteremia, pneumonia, and meningitis and the most common vaccine-preventable bacterial cause of death; and,</li><li>2) MCV-4, the meningococcal conjugate vaccine that was licensed for use in the United States in 2005.</li></ol> <p>The Prevention and Wellness Fund section of ARRA provides funding to the Office of the Secretary (OS) of the Department of Health and Human Services (HHS) to carry out activities in support and enhancement of CDC’s immunization program. ARRA 317 immunization funding will be awarded on behalf of the OS through CDC’s Emerging Infections Program (EIP) cooperative agreement to the 10 current EIP sites, including Georgia and should be used to support staff and infrastructure needed to conduct 2 new vaccine effectiveness studies.</p>

<p><b>PROGRAM DESCRIPTION:</b></p>	<p>The purpose of the overall EIP cooperative agreement is to assist in local, state, and national efforts to prevent, control, and assess the public health impact of emerging infectious diseases including vaccine- preventable diseases. The EIPs are a network of 10 State health departments (including Georgia) working with collaborators in laboratories, healthcare facilities, and academic institutions. Although the project takes place in Georgia, similar projects will occur simultaneously in the other 9 EIP sites. CDC is proposing to evaluate the effectiveness of PCV13 and MCV-4 in the EIP sites. The EIP Network is optimal for conducting this evaluation because of the scale and complexity and the Network’s past experience with successfully performing similar evaluations.</p> <p>A new pneumococcal conjugate vaccine that covers 13 serotypes (PCV-7 serotypes plus 1, 3, 5, 6A, 7F, and 19A) is in final stages of FDA review and may be licensed in late 2009 for infant use and replace the currently used PCV-7 vaccine. Vaccine licensure will be based on immunologic non-inferiority rather than clinical trials to evaluate vaccine efficacy. Ongoing active pneumococcal surveillance and post-licensure studies of vaccine effectiveness will provide critical data to assess the impact of the new vaccine. In addition, <i>Neisseria meningitidis</i> (the meningococcus) is an important and potentially devastating human pathogen responsible for meningitis and fulminant sepsis, often in otherwise healthy adolescents and young adults. Mortality approaches 15% in the U.S. and significant morbidity, including loss of digits and limbs, deafness and other neurologic deficits, may leave survivors severely handicapped. In the U.S., most meningococcal disease is caused by serogroups B, C, and Y, with a rare case of serogroup W135. In 2005, a quadrivalent meningococcal conjugate vaccine (MCV-4 containing serogroups A, C, Y, W135) was licensed for use in the U. S. The vaccine was recommended by ACIP for all adolescents aged 11-18 years and other persons aged 2-55 years at increased risk for meningococcal disease. The vaccine was FDA approved based upon non-inferiority of the immune response to MCV-4 compared to a previously available meningococcal polysaccharide (non-conjugate) vaccine rather than by clinical efficacy trials. Only limited data are available on the effectiveness of MCV-4 in protection against invasive meningococcal disease and the duration of protection.</p> <ol style="list-style-type: none"> <li>1) The GRANTEE will comply with all ARRA requirements (see ARRA Division A Title XVI);</li> <li>2) The GRANTEE will comply with the following Health and Human Services (HHS) Grant Policy requirements for purchasing and maintenance of equipment, as defined as tangible nonexpendable personal property, including exempt property, charged directly to the award having a useful life of more than one year and an</li> </ol>
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	<p>acquisition cost of \$5000 or more per unit, (See 45 CFR Part 74 Grant Requirements);</p> <p>3) The GRANTEE agrees to:</p> <ul style="list-style-type: none"> <li>• Work closely with CDC and other EIP sites to develop protocols, study instruments (e.g. chart abstraction forms, questionnaires, vaccine record forms), secure electronic data entry, and transmission systems to support a PCV-13 vaccine effectiveness study.</li> <li>• Conduct active, population-based laboratory surveillance for invasive pneumococcal disease (IPD) in residents of the 20-county Atlanta Metropolitan Statistical Area (MSA) to identify all cases of IPD and identify eligible cases for enrollment in the PCV-13 vaccine effectiveness study.</li> <li>• Extend the current study to establish the rate of pneumococcal nasopharyngeal (NP) carriage and determine the serotype distribution and antimicrobial resistance patterns among carriage isolates in young children in Atlanta at the Children’s Healthcare of Atlanta (CHOA) Emergency Department.</li> <li>• Work closely with CDC and other EIP sites to develop protocols, study instruments (e.g. chart abstraction forms, questionnaires, vaccine record forms), secure electronic data entry, and transmission systems to support the MCV-4 vaccine effectiveness study.</li> <li>• Conduct active, population-based laboratory surveillance for invasive meningococcal disease statewide to identify all cases and identify eligible cases for enrollment in the MCV-4 vaccine effectiveness study.</li> </ul>
<p><b>AWARD JUSTIFICATION:</b></p>	<p>This ARRA funding was awarded through CDC’s Emerging Infections Program (EIP) <u>only</u> to the 10 EIP sites, including Georgia. The Georgia Division of Public Health has contracted with the Atlanta Research and Education Foundation (AREF) to conduct Emerging Infections Program activities in the Atlanta MSA since first receiving EIP funding from CDC in 1996. AREF has developed the extensive experience and infrastructure necessary to support this system, including the retention of many of the original staff who are highly trained and experienced in the implementation of active surveillance methodologies, vaccine effectiveness studies, and project protocols associated with the Emerging Infections Program. The Principal Investigator at AREF has overseen the system for 14 years and has attended all CDC’s annual meetings related to leading this project. Staffing continuity is critical to the continued success</p>

	of the EIP since the AREF EIP Team has developed extensive relationships over the last 14 years with many hospital and community partners necessary for efficient implementation of the ARRA-funded PCV-13 and MCV-4 vaccine effectiveness studies.
<b>AWARD(S):</b>	<b>TOTAL DIRECT AWARD FUNDS AVAILABLE: \$528,719.</b>
<p style="text-align: center;"><b><u>TO SUBMIT INQUIRIES TO THIS DIRECT AWARD NOTIFICATION</u></b>  Contact Romero Stokes, DCH Grant Compliance Monitor at <a href="mailto:rstokes@dch.ga.gov">rstokes@dch.ga.gov</a>  no later than <b>2:00 on Friday, November 20, 2009.</b></p>	