Part I Overview Information

Issuing Organization

Council of State and Territorial Epidemiologists (CSTE) at www.cste.org/

Participating Organizations

Centers for Disease Control and Prevention (CDC), at http://www.cdc.gov/

Components of Participating Organizations

Influenza Division, National Center for Immunization and Respiratory Diseases (NCIRD/CDC), at http://www.cdc.gov/ncidod/

Title: Influenza Population-Based Hospitalization Surveillance Project (IHSP)

Table of Contents

Part I Overview Information

Part II Full Text of Announcement

Section I. Funding Opportunity Description
1. Background
2. Objectives
3. Methods

Section II. Award Information
1. Mechanism(s) of Support
2. Funds Available

Section III. Eligibility Information
1. Eligible Applicants
2. Cost Sharing or Matching

Section IV. Application and Submission Information
1. Content and Form of Application Submission
2. Submission Dates and Times
   A. Submission, Review and Anticipated Start Dates

B. Submitting an Application
C. Application Processing

Section V. Application Review Information
1. Criteria
2. Review and Selection Process

Section VI. Award Administration Information
1. Award Notices
2. Recipient Rights and Responsibilities
3. CDC/Influenza Division Rights and Responsibilities
4. CSTE Responsibilities
5. Collaborative Responsibilities

Part II - Full Text of Announcement

Section I. Funding Opportunity Description

---

1. Background

The development of supplemental surveillance methods is a joint project of CSTE and CDC based on CSTE Position Statements (All position statements, including 06-ID-04, available at www.cste.org).

The Emerging Infections Program (EIP) Influenza Hospitalization Surveillance Project, a population- and case-based program, began in 2004, amid a severe pediatric influenza season, to collect information on children (<18 years of age) hospitalized with laboratory-confirmed influenza. In early 2006, surveillance activities expanded to include adults so that currently all-age hospitalization surveillance is being conducted in 11 metropolitan areas in 10 EIP states that represent 7% of the US population. Currently EIP is the only population-based hospitalization surveillance system that provides timely data to the Centers for Disease Control and Prevention (CDC).

Influenza Hospitalization Surveillance uses hospital laboratory, admissions, infection control practitioner databases/logs, or review of reportable conditions databases to identify cases. Cases are residents of pre-identified catchment areas (counties or cities) with community-acquired laboratory confirmed influenza infection who are hospitalized during influenza season. Medical chart reviews of all cases are conducted to collect clinical and epidemiologic information. Influenza vaccination status is obtained through a hierarchical review of sources: medical chart, vaccination registries, primary care provider records and lastly by interview of patient, proxy or parents.

In Spring 2009 a novel influenza A (H1N1) virus emerged and infected people in North America. The first human case of novel influenza A infection identified in the US occurred in areas outside the current EIP catchment counties. To be able to monitor the spread of pandemic influenza and future seasonal influenza hospitalizations, a greater geographic and demographic representation of population-based influenza hospitalization surveillance is desired. In addition, the EIP are also engaged in influenza research activities and would benefit from having wider participation of other sites that conduct surveillance using the same methods.

The purpose of this RFA is to fund up to 7 states to participate in laboratory-confirmed, population-based, all ages, influenza hospitalization surveillance for one year.

The goal of the Population-Based Influenza Hospitalization project is to continue the monitoring of influenza hospitalization using the same methodology as EIP but across a larger geographic and diverse population than is currently being monitored.

2. Objectives

Applicants must address all seven of these objectives:

1. Ability to calculate hospitalization rates that can be examined by race/ethnicity, sex or age group in a timely manner.
2. Describe the temporal trends of laboratory-confirmed influenza hospitalization, including by influenza subtype.
3. Describe characteristics of persons hospitalized with severe influenza illness.
4. Describe the clinical features and course of influenza disease (e.g., severe illness and influenza-associated complications) among persons hospitalized with influenza.
5. Examine risk and protective factors for severe sequelae of influenza infections, including co-morbid conditions and statin medications.
6. Examine etiologic agents associated with severe bacterial illness, including pneumonia among influenza-infected adults.
7. Establish the completeness of case ascertainment by this population-based hospitalization surveillance system.

3. Methods

Project Period.
This FOA refers to surveillance activities to be conducted from October 1, 2010 through April 30, 2011with the funding period from June 1, 2010 – May 31, 2011. Reporting will be required as per the EIP protocol and may be adjusted accordingly depending on the severity of the season.

Hospitalization is defined as an admission to an inpatient ward of the hospital. Patients who are admitted to and discharged from the hospital on the same day are considered hospitalized. An overnight stay is not required. Emergency room and outpatient visits are not hospitalizations. However, if the person is admitted to an inpatient ward directly following an emergency room or outpatient visit then he/she should be considered hospitalized. In this situation, date of admission should be the date the patient was admitted to the ward, not first seen in the emergency department or outpatient clinic.

The methods section of applications must address each of the following:

A. Community-acquired influenza infection case definition

For the purposes of this surveillance system, a case patient is defined as a person who is/has:

1. A resident of a pre-identified geographic area (i.e., county or city)
2. Admitted to a hospital where catchment area residents are likely to receive care in from October 1 2010-April 30 2011 (the hospital may be located outside the catchment area but catchment area residents are known to travel for hospitalization to such hospitals)
3. Admission date: 14 days or less *after* a positive influenza test
   or
   3 days or less *before* a positive influenza test

4. Evidence (i.e., a laboratory report in the current hospital record, a written note in the admission H&P of an influenza positive test before admission, a laboratory report from another hospital, report from infection control practitioner, or a verbal report from a primary care provider's office) of a positive influenza test by at least one of the following methods:
    a. Viral culture
    b. Immunofluorescence antibody staining (Direct [DFA] or indirect [IFA])
    c. Reverse transcriptase polymerase chain reaction (RT-PCR)
    d. A commercially available rapid diagnostic test for influenza
    e. Serologic testing

    OR

    e. A positive, unspecified influenza test noted in the medical chart (e.g., a written note in the admission H&P or discharge summary)

    PCR testing is the preferred test method. Sites that can support this type of testing should indicate in their application.

B. Nosocomial-acquired influenza infection case definition

Criteria A1, 2 and 4 above apply. The final definition of a nosocomial case will be determined during one or more conference calls among all participating sites prior to the start of the 2010-11 influenza season.

C. Exclusion criteria

- Initial hospital admission more than 14 days after positive influenza test

Section II. Award Information

1. Mechanism(s) of Support

CSTE will manage all matters related to financial support for this project. CSTE will award recipients by distributing 25% of the contract amount for year 1 to recipients upon contract initiation. The remainder of the funds (75%) will be distributed at varying intervals during the award period to best meet the need of individual recipients. State health departments are responsible for allocating appropriate amounts to compensate appropriate providers and to supplement the state public health laboratories for the duration of the pilot project. Contracts will not be automatically renewed yearly and are subject to availability of funds.

2. Funds Available

The CDC and CSTE intend to commit up to $700,000 to support up to 7 applications. CSTE will award applicants between $75,000 to $100,000 per site. Because the nature and scope of the proposed project will vary from application to application, the size of each award may vary. Although the financial plans provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the number of applications received.

CSTE receives funding for this project through the Centers for Disease Control and Prevention (CDC) cooperative agreement number 1U38HM000414. Funds awarded to contractors under this announcement are subject to the laws, regulations and policies governing the U.S. Public Health Service grant awards. All estimated funding amounts are subject to availability of funds.

Section III. Eligibility Information

1. Eligible Applicants

Eligible applicants are state or large local health departments with the following characteristics:

- Proven ability to conduct population-based, laboratory confirmed influenza hospitalization surveillance including identification of catchment area (ie, counties or cities from which population estimates can be obtained for rate calculations)
- Provided age-specific (<12mo, 1-4 years, 5-14 years, 15-24 years, 25-44 years, 45-64 years and ≥65 years) hospitalization rates obtained from laboratory-confirmed influenza hospitalization surveillance conducted during the pandemic.
- Willingness to report case level information as identified from the case report form during each scheduled data transmission to CDC.
- Ability to engage hospitals and their staff (eg, infection control practitioners, medical records staff, etc) in which eligible case patients will be hospitalized to:
    - Identify cases that meet case definition in a timely manner.
    - Ensure complete case ascertainment Hospitals need to be chosen carefully to avoid missed cases and underestimation of age-specific hospitalization rates.
    - Establish if there are any infection control policies in place for influenza by hospital.
    - Try to facilitate PCR testing among all or a sample of hospitalized cases.
- Willingness and proven ability to actively engage their hospital counterparts to ensure timely and complete reporting of cases.
- Routinely collect case level data from all patients that meet case definition. Sources of data to include medical charts, and possibly community healthcare providers and from telephone interview of patient, parents or proxy
- Enter case data into a standardized data collection database provided by CDC or send data extracts that match the format of the standardized database; local data will always be available to each participating site
- Adhere to the data reporting schedule for all participating sites
- Correct data identified from routine data quality feedback reports in a timely manner
- Participate in monthly and ad hoc calls among all participants
- Submit a plan, including the methods, for evaluation of case ascertainment completeness.
- Public health laboratory willingness to assist with RT-PCR testing for some or all cases.
- Ability, willingness and interest participate in this project for at least one year.
- Ability to count laboratory confirmed influenza deaths in the hospitalization surveillance catchment area.

2. Cost Sharing or Matching

Cost sharing, matching, or cost participation is not required for this project.

Section IV. Application and Submission Information

State health departments interested in participating in the Influenza Population-Based Hospitalization Surveillance Project should submit an application addressing the objectives and

eligibility requirements stated in Section 1, Part 2 and Section III, Part 1, respectively. Applications should be submitted by the State Epidemiologist in collaboration with appropriate staff from the state health department and state public health laboratory, if appropriate.

1. Content and Form of Application Submission
Applications should include the following headings in the order listed and should address the issues included under each heading:

- **Contact information**: **Contact information**: State Epidemiologist, primary coordinator/contact, influenza surveillance coordinator, and laboratorian, plus any additional contributors. Information should include email, mailing address (no PO boxes) and phone number. All correspondence will be sent to the primary contact listed. ½ page limit
- **Surveillance Experience**: The state's surveillance experience that demonstrates the ability to successfully participate in this pilot project. Applicants should illustrate their proven ability to conduct population-based, laboratory confirmed influenza hospitalization surveillance including identification of catchment area (i.e., counties or cities from which population estimates can be obtained for rate calculations). In addition, applicants should illustrate proven ability to actively engage their hospital counterparts to ensure timely and complete reporting of cases. Details may also include a description of an experienced surveillance officer or other staff member who will oversee the project's progress. 2 page limit.
- **Laboratory**: The willingness of the public health laboratory to engage in this project. Ability to perform RT-PCR and viral culture for influenza (including subtyping) that is consistent with CDC standards. 1 page limit.
- **Methods**: The methods according to those described in the objectives outlined in Section 2. 2-4 page limit
- **IRB**: Human subject review process for the state if necessary. ½ page limit.
- **Budget**: Proposed budget used to recruit hospitals, stimulate active surveillance among participating hospitals, collect hospital information, supplement additional influenza laboratory testing, transportation of increased numbers of specimens, personnel time, attendance for one individual to attend the June 2010 required meeting in Atlanta, and/or other supplemental costs needed to successfully implement the Influenza Population-Base Hospitalization Surveillance Project. 2 page limit.

  For further assistance, technical questions, or inquiries about the application, contact Jennifer Lemmings at CSTE (770-458-3811 or jlemmings@cste.org). CSTE and CDC will be available to speak to potential applicants to discuss technical or administrative questions. All questions and answers will be made available to all potential applicants.

2. Submission Dates and Times

2. A. Submission, Review and Anticipated Start Dates

Letter of Intent Receipt Date: April 30, 2010 (*not required but strongly encouraged*)

Application Submission Receipt Date: May 14, 2010

Mandatory follow-up interview conference call for highly qualified applicants: May 24, 2010

Anticipated Award Date: June 1, 2010 (A portion of the financial award will be made available at this time and sites will begin working with CDC and CSTE on refinement of protocols, IRB submission materials, and training of sites so active surveillance begins on October 1, 2010.)

2. B. Submitting an Application

A completed letter of intent should be sent by email, mail or fax to the Council of State and Territorial Epidemiologists by April 30, 2010:

Jennifer Lemmings
Epidemiology Program Director
Council of State and Territorial Epidemiologists
2872 Woodcock Blvd., Suite 303
Atlanta, GA 30341
770-458-3811 (phone)
770-458-8516 (fax)
jlemmings@cste.org

Completed applications should be sent to the Council of State and Territorial Epidemiologists at the above address by May 14, 2010.

Completed applications should be sent to the Council of State and Territorial Epidemiologists at the above address. The receipt deadline is May 14, 2010. Two copies of each application should be submitted by mail and applications must not contain any staples. Submitted appendices should be kept at a minimum and may not be reviewed as part of the application process. Inquires about successful receipt of application by CSTE will be sent only upon request by email to jlemmings@cste.org.

2. C. Application Processing

All applications received will be reviewed by June 1, 2010. Applications will be reviewed based on criteria described in Section V.

Section V. Application Review Information

---

1. Criteria

Only the review criteria described below will be considered in the review process.

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Completeness of applications, such that all of the content described in Section I, Part II and Part III; Section III, Part 1; and Section IV, Part 1 are addressed.
- Ability to identify sufficient numbers of cases that meet case definition from October 1, 2010 through April 30, 2011.

- Support of the state public health laboratory to perform RT-PCR and viral culture for influenza diagnosis using methods consistent with CDC.
- Adequate personnel to meet requirements for case identification, chart abstraction, data entry and case reporting in a timely manner.
- Sites with experience conducting this type of population-based, laboratory-confirmed hospitalization surveillance during the 2009-10 pandemic should indicate
- Applications proposed must be done in the United States or its territories.

2. Review and Selection Process

Eligible applications that are complete will be evaluated for scientific and technical merit by CDC/Influenza Division and CSTE in accordance with the review criteria stated above. Funding awards will be made based upon the quality of the submitted proposal and the ability of the applicant to meet the stated objectives, including sending one surveillance officer to the June 24 Atlanta meeting.

Section VI. Award Administration Information

1. Award Notices

- Applicants will be notified via email or phone no later than June 1, 2010. Any delays in award notification will be shared with all applicants.

2. Recipient Rights and Responsibilities

Each recipient state public health department and state public health laboratory will have primary responsibility for the following:

- Providing scientific and management oversight for the overall project, including research design and conduct, data collection and reporting, quality control, and collaborations with other awardees, CDC, and CSTE.
- Appointing a staff member to serve as the surveillance officer for this project.
- Obtaining the appropriate human subjects clearances at local sites if required.
- Working with CSTE and CDC scientists to refine protocols and data collection instruments.
- Performing laboratory tests and reporting data as specified in the study protocols.
- Participating in conference calls with project scientists to collaborate on the development of the protocols and providing progress updates.
- Providing appropriate training for providers participating in the project.
- Providing written progress reports and invoices to CSTE as required in the contractual agreement.
- Send one surveillance officer to a June 24 2010 meeting in Georgia

3. CDC/Influenza Division Responsibilities

CDC/Influenza Division will have substantial programmatic involvement as described below:

- If IRB review is deemed necessary at the state level, CDC will assist the state in the development of a research protocol that will be acceptable for local site IRB review and approval.
- CDC will provide the reporting case report form database. CDC, CSTE, and the states selected for this project will together finalize the forms.
- CDC will provide feedback reports that monitor timeliness and completeness of reporting and interim summary data.
- CDC will work with awarded applicants as needed to determine appropriate methods to define the patient population.
- CDC will ensure appropriate training for personnel from state health departments, as requested by the site.
- Provide technical assistance and guidance to awarded applicants.

4. CSTE Responsibilities

During the established grant period, CSTE is responsible for:

- Monitoring the terms of the contract agreement between the recipient and CSTE.
- Collecting invoices from the recipient and paying invoices according to the terms of the contract agreement between the recipient and CST
- Providing information about the progress of the program to the CSTE Executive Committee and to CDC.
- Reviewing and distributing progress reports and the final report with CDC.
- Providing technical expertise when requested.
- Participate and staff PCC meetings (See Section VI, Part 5).

5. Collaborative Responsibilities

CSTE and CDC in conjunction with the State Health Department Contacts for all awarded projects will establish a Planning and Coordination Committee (PCC). Each state contact will be a member of the PCC and will participate in its activities. A CDC staff member will serve as a member of the PCC. CSTE to coordinate and schedule such meetings. The PCC will function to:

- Establish goals, promote collaboration, and coordinate among members of the PCC
- Provide guidance to investigators regarding project implementation and sustainability for the duration of the influenza season.
- Finalize methods, procedures and timelines for case completeness evaluation (an assessment of case ascertainment).
- Develop analytic tools to help sites maintain data quality.
- Evaluate monthly progress of all funded project activities.
- CSTE and CDC will conduct site visits to answer questions, provide guidance and assure that methods followed are consistent among all participating sites and document the findings/recommendations in a site visit report.