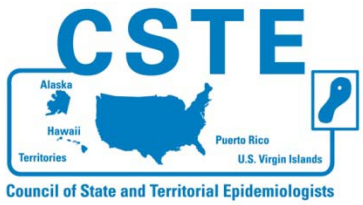

Part I Overview Information

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 Incidence Surveillance Project

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Part II Overview Information

Section I. Funding Opportunity Description

1. Background

Influenza incidence varies with each seasonal epidemic and influenza A and B viruses cause differential disease by age, as evidenced by 2009 pandemic influenza A (H1N1) virus (pH1N1). Tracking the incidence of influenza allows for disease burden comparisons across predominant circulating virus types, seasonal epidemics, geographic regions, alerts public health officials of increases beyond usual seasonal activity, and improves measures of influenza that are currently non-specific, including influenza-like illness (ILI) and acute respiratory infections (ARI) .

The Influenza Incidence Project (IIP) monitors the age-specific incidence of medically-attended ILI and influenza-associated ILI in real time throughout the influenza season. During the first year of the IIP, a convenience sample of 38 providers in 8 states or jurisdictions with defined patient populations reported weekly the number of ILI cases and total number of patient visits. Specimens were collected for rapid antigen testing from all ILI patients. Specimens were collected for influenza PCR testing from the first 10 ILI patients each week; demographic and clinical data were also collected. PCR testing allowing for influenza detection verification, viral subtyping, and calculation of rapid antigen assay sensitivity and specificity. Data collection began October 4th, 2009 with success. The IIP reported the incidence of ILI and laboratory-confirmed influenza throughout the season.

The purpose of this FOA is to fund up to 4 additional state or local health agencies to participate in the Influenza Incidence Surveillance Project. The surveillance project will provide support for activities to determine and report real time, locality-specific weekly incidence of ILI and laboratory confirmed influenza among persons seeking medical care for acute respiratory infection for one full year. This project will also test protocols that could meet some of the needs for increased surveillance during a pandemic, such as timely test result confirmation from state laboratories.

2. Objectives

Applicants must address all three of these required objectives:

1. Determine the incidence of medically attended ARI and ILI
2. Determine the incidence of laboratory-confirmed influenza in health care seeking populations
3. Determine the etiologic agents among patients with ILI

3. Methods

Applicants must verify the ability to conduct surveillance consistently with current protocols:

Project Period.

Reporting is weekly to CDC. This FOA refers to surveillance activities to be conducted from August 1, 2010 through July 30, 2011 with the initial funding period from June 1, 2010 – May 31, 2011 (renewable based on availability of funds).

Case Definitions.

Influenza-like illness (ILI)

Patients aged >2 years: cases presenting with fever ≥100°F AND cough and/or sore throat in the absence of a known cause other than influenza.
Children aged <2 years: cases presenting with fever ≥100°F and at least one respiratory symptom including cough, sore throat, coryza, runny nose, anorexia chills, myalgia or malaise.

Note: report of fever as opposed to measured fever is sufficient for the case definition requirements.

Acute respiratory infections (ARI)

Recent onset of at least two of the following: rhinorrhea or nasal congestion, sore throat, cough (with or without fever or feverishness)

Surveillance.

1. *Determine the incidence of medically attended ARI and ILI.*
    - Recipients would be responsible for recruiting 5-6 providers with a weekly patient volume of approximately 100-150 patients to conduct the following:
        - Estimate the patient panel (total number of patients managed by the provider in one year).
        - Report the following weekly **(Appendix A)**:
            - All patient visits by age group (<1 year, 1-4 years, 5-17 years, 18-24 years, 25-64 years and ≥65 years).
            - ARI visits by age group

- ILI visits by age group (this will be a subset of the ARI patients)

2. *Determine the incidence of laboratory-confirmed influenza in health care seeking populations.*
    - Recipients would be responsible for recruiting providers to conduct the following:
        - Provider will obtain a nasal wash, nasal, or nasopharyngeal specimen from patients with ARI seen during the week
        - conduct rapid testing (supplied at no cost through CSTE) on all ARI patients and report the results by age group **(Appendix A)**
        - From the first 10 patients with ILI each week, providers will collect either a second specimen or split the specimen used for rapid testing for PCR testing.
        - Collect brief patient demographic and clinical data on the same 10 patients sampled (**Appendix B**).

    NOTE: Undue burden is not expected given an average ILI count of 6 patients during the peak of the influenza season among providers that see 100-150 total patients per week as reported through ILINet.

3. *Determine the etiologic agents attributable to influenza negative ILI.*
    - State Public Health Laboratory will process and test specimens collected by providers such that influenza incidence may be reported throughout the season.
    - Testing should be conducted within 2 weeks using a multiplexed PCR respiratory virus panel. Pathogens in the panel should include:
        - Non-specific Influenza A, A subtypes, H1 and H3, and influenza B
        - RSV
        - Adenovirus
        - Parainfluenza viruses 1-3
        - Human metapneumovirus
        - Rhinovirus
    - Reporting to CDC is weekly, but may lag by 1 – 2 weeks behind the report ARI and ILI activity.

The methods section of applications proposed to meet the objectives must address each of the following:

Health Department Methods:

1. Applications must describe the methods that will be used by the grantee to identify and recruit approximately 5 – 6 providers for the project.
2. Describe the methods by which data reporting and specimen transfer will occur between providers, laboratories, health departments, and the CDC.
3. Describe the methods of data handling including linkage of laboratory test results and accompanying specimen information, and reporting to CDC.
4. Describe the methods or mechanism to provide incentives for provider's participation.

a. Suggest an incentive commensurate with the time required by staff for participation (est. 2-3 hrs per week).

Laboratory Methods:

1. Applications should include the expected frequency of specimen testing and result reporting from the laboratory to project coordinators. In addition, applications should include a timeline for reporting of results to CDC.
2. Describe the PCR methods used for viral detection.
3. Include methods for storage of specimens tested at the health department until the close of the surveillance period.

Provider Methods:

1. Providers must have the ability to determine their patient panel, i.e., the number of patients they manage. This will serve as an approximation of a population for which incidence may be calculated.
2. The combination of providers enrolled should represent all age groups.
3. To ensure sufficient numbers without creating burden, providers should see a patient volume of approximately 100 and 150 patients per week.
4. For providers that identify ILI patients through electronic sources, the following ICD-9 codes are suggested but may be dependent on coding practices:
    a. Fever (780.6) with cough (786.2) and/or sore throat (including acute pharyngitis (462) and throat pain (784.1)), or influenza diagnoses (487).
    b. The set of codes used should demonstrate the same timing and magnitude of ILI activity in previous seasons.
    c. Recipients must validate ILI patients identified electronically with those identified and sampled by providers. Data for sampled patients not identified electronically must be collected.

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. Recipients are responsible for allocating appropriate amounts to support activities including compensation for providers and to supplement the state public health laboratories for the duration of the project. Contracts will not be automatically renewed yearly and are subject to availability of funds.

2. Funds Available

CSTE intends to commit up to $880,000 to support up to 4 applications. CSTE will award successful applicants with approximately $175,000-$220,000 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. 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, is available at www.cste.org). Funds awarded 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

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1. Eligible Applicants

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

- Ability to enroll approximately 5-6 providers that each see between 100 and 150 total patients per week (e.g. family practitioners, internists, pediatricians, health plans and emergency departments) to provide sufficient numbers of patients and ILI cases to allow for an adequate degree of precision for the incidence estimates
- Willing to report ILI and influenza data each week and corresponding influenza laboratory results to CDC.
- Ability to identify and recruit providers for the duration of funding with the following characteristics:
    - Reliable provider willing to adhere to the project methods.
    - Able to easily integrate age-specific ARI and ILI tallying into their routine.
    - Providers must collectively serve all age groups.
    - Able to submit ILI reports to the CDC at least once a week.
    - Able to enumerate their patient population over the entire year.
    - Able and willing to collect specimens from ILI patients and submit to the health department for influenza testing.
    - Able and willing to conduct rapid testing of all ARI patients.
- Public health departments willing and able to provide incentives to providers to ensure participation.
- Public health laboratory capable of completing multiplexed PCR for influenza diagnosis and of handling increased testing capacities.
- Public health laboratory committed to conduct influenza testing within two weeks from specimen collection from ILI cases.
- Willing to participate in this project for at least one year.
- This announcement is eligible for application by all state and large city local health agencies.

2. Cost Sharing or Matching

Cost sharing, matching, or cost participation is required only to the extent that funding is available to only supplement a portion of the laboratory costs needed for the additional laboratory testing required for this project.

Section IV. Application and Submission Information

Public health departments interested in participating in the Influenza Incidence 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 influenza surveillance coordinators and the State Epidemiologist in collaboration with appropriate staff from the public health department and state public health laboratory. State influenza surveillance coordinators should serve as the point of contact at the state public health department. Appropriate senior staff responsible for influenza surveillance in local health agencies will serve as the point of contact and submitter for local health agencies applying for funding.

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**: Primary coordinator, 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 coordinator listed. ½ page limit
- **Surveillance Experience**: Surveillance experience that demonstrates the ability to successfully participate in this project. Example(s) of possible providers who are capable of increased surveillance required for this project. Details may also include a description of an experienced surveillance coordinator or other staff member who will oversee the project's progress. 1 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. Ability to handle increased numbers of specimens for influenza testing, two week testing timeframe, and storage space. Include a timeline for testing specimens and reporting results. A letter of support from the public health laboratory must be included with the application. 1 page limit plus letter of support.
- **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 applicant if necessary. ½ page limit.
- **Budget**: Proposed budget used to compensate providers, supplement additional influenza laboratory testing, transportation of increased numbers of specimens, and/or other supplemental costs needed to successfully implement the Influenza Incidence Project. Describe the mechanism to be used by the recipient to get funds to the state

public health laboratory and to providers. The submitted budget should contain three primary categories 1) epidemiology costs such as personnel time 2) laboratory costs such as cost of reagents and 3) provider incentive costs. The budget should not include the estimated cost of the rapid antigen kits; rather the budget should include an estimated number of kits needed between August 1, 2010 and May 31, 2011. 2-4 page limit.

- **Letter of Support**: A letter of support from up to three providers is required. 1 page limit per letter and must address commitment to participate and ability to integrate protocol.

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 administrative and technical questions. All questions and answers will be made available to all potential applicants during the application process.

2. Submission Dates and Times

2. A. Submission, Review and Anticipated Start Dates

Letter of Intent Receipt Date: April 23, 2010 (*not required but strongly encouraged*)

Application Submission Receipt Date: May 14, 2010

Mandatory follow-up interview conference call for highly qualified applicants: TBD May 21, 2010

Award notification date: June 1, 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 CSTE and CDC on refinement of protocols, IRB submission materials, and training of sites so active surveillance begins on August 1, 2010.)

Required in person award recipient meeting: TBD at the CSTE Annual Conference (June 6 – June 10, 2010)

2. B. Submitting an Application

A completed letter of intent should be sent by mail or fax to the Council of State and Territorial Epidemiologists by April 23, 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. 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 May 21, 2010. Applications will be reviewed based on criteria described in Section V.

Section V. Application Review Information

1. Criteria

The review criteria described below will be considered in the review process:

- Scientific merit of the proposed project as determined by the objective review panel
- Completeness of applications, such that all of the content described in Section I, Part II, Section III, Part 1 and Section IV, Part 1 are addressed.
- Ability to enroll sufficient numbers of providers that see between 100 and 150 patients per week, can define their patient population and are willing to participate in ARI and ILI data and specimen collection from August 1, 2010 through July 30, 2011.
- Ability of the state public health laboratory to perform PCR for influenza diagnosis using methods consistent with CDC.
- Adequate personnel and facilities at the state public health laboratory to handle increased volumes of specimens for testing and ability to maintain timeliness in producing and reporting test results.
- Willingness to submit a subset of influenza isolates and original clinical material to the CDC.
- Letters of support from state public health laboratory (1) and up to 3 providers.
- Acknowledgement of collaborative efforts between local sentinel providers, the public health department, the state public health laboratory, and the CDC.
- 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 CSTE and CDC/Influenza Division in accordance with the review criteria stated within this announcement. Funding awards will be made based upon the quality of the submitted proposal and the ability of the applicant to meet the objectives stated above.

Section VI. Award Administration Information

1. Award Notices

- Applicants will be notified via email or phone by June 1, 2010. Any delays in award notification will be shared with all applicants.

2. Recipient Rights and Responsibilities

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

- Providing scientific and management oversight for the overall project at participating sentinel provider sites, including surveillance design and conduct, data collection and reporting, quality control, and collaborations with other awardees, CDC, and CSTE.
- Appointing a coordinator to serve on the Planning and Coordination Committee (see section VI.5. Collaborative Responsibilities), preferably the state/local influenza surveillance coordinator.
- Obtaining the appropriate human subjects clearances at local sites if required.
- Working with CDC scientists to refine protocols and data collection instruments.
- Performing laboratory tests and reporting data as specified in the surveillance protocols.
- Provide a mechanism of transporting specimens from sentinel provider sites to the state public health laboratory.
- Participating in monthly conference calls with project staff 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 that describe performance milestones and invoices to CSTE as required in the contract agreement.
- Initiate a formal agreement with providers to ensure participation, submission of samples and data, to prohibit charging patients for the cost of rapid antigen tests.
- Agreement to participate in in-person meetings as determined by CSTE and CDC (up to two per year) and may be a state site visit, state hosted all participating sites meeting, or CSTE/CDC hosted meeting.

3. 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 CSTE.
- Providing information about the progress of the program to the CSTE Executive Board and to CDC.
- Reviewing and distributing progress reports and the final report with CDC.
- Providing technical expertise.
- Participate and staff the Planning and Coordination Committee (PCC) meetings (See Section VI, Part 5).
- Fund travel of PCC members to in person meetings and technical consultations. Convene an independent review panel of experts to provide an objective review of the submitted applications.

4. CDC/Influenza Division Responsibilities

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

- If IRB review is deemed necessary at the state/local level, CDC will assist the recipient in the development of a research protocol that will be acceptable for local site IRB review and approval.
- CDC will provide technical advice concerning laboratory methods for the diagnosis of influenza if needed and may perform or suggest quality control testing of the laboratory methods used to diagnosis influenza at each funded site.
- CDC will provide the reporting mechanism and maintain a database for all project related data including ILI and patient visit tallies and the specimen related case report form.
- CDC will work with awarded applicants as needed to determine appropriate methods to define the patient population.
- CDC will provide templates for data collection forms, which are found in the Appendix, Parts 1-3. Forms include those that could be used for daily ILI reporting and for reporting of influenza testing results. CDC and the applicants selected for this project will together finalize the forms.
- CDC will ensure appropriate training for personnel from state health departments, including appropriate laboratory personnel before the start of the project.
- Participate on an independent review panel convened by CSTE to provide an objective review of the submitted applications.

5. Collaborative Responsibilities

CSTE and CDC in conjunction with the recipient contacts for all awarded projects will establish a Planning and Coordination Committee (PCC). Each recipient 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 and schedule its first meeting. The PCC will function to:

- Establish goals, promote collaboration, share best practices, and coordinate surveillance activities among members of the PCC
- Provide guidance to investigators regarding project implementation and sustainability for the duration of the influenza season.
- Evaluate monthly progress of all funded project activities
- Meet by phone at least once per month and up two twice per year for an in person meeting. CSTE will provide travel support.
- Members of the PCC may be required to travel to other PCC health agencies up to twice a year to provide or receive technical support. CSTE will provide travel support.

Appendix A: DRAFT Weekly Report Form of ILI Counts

REPORTS OF INFLUENZA-LIKE ILLNESS (ILI) AND RAPID ANTIGEN TEST RESULTS

2010-2011 Influenza Incidence Project

Provider ID

Report for the 7-day period ending ___/___/___
(Period includes Sunday through Saturday)

☐ **Check if Revised Report**

Total Patient Visits (ILI + Non-ILI)								
Age (yrs)	**<1**	**1-2**	**2-4**	**5-17**	**18-24**	**25-49**	**50-64**	**≥65**
# Visits								
Number of Patients with ILI and Rapid Antigen Test Results								
Age (yrs)	**<1**	**1-2**	**2-4**	**5-17**	**18-24**	**25-49**	**50-64**	**≥65**
# ARI Visits								
# ILI Visits *(subset of ARI)*								
# Flu A (+)								
# Flu B (+)								
Negative								
Not Tested								

Acute Respiratory Illness: Recent onset of at least two of the following: rhinorrhea or nasal congestion, sore throat, cough (with or without fever or feverishness)

Influenza-like Illness: Fever -AND- cough and/or sore throat (in the absence of a known cause).

Influenza-like Illness in children <2 years: Fever and any indication of respiratory illness

Appendix B. DRAFT TO BE FINALIZED BY RECIPIENT

Specimen Collection Form

STATE USE ONLY – DO NOT SEND INFORMATION *IN THIS SECTION* TO CDC		
Last Name: _____	First Name: _____	County: _____ __
Address:	City:	State, Zip:

(Required only for 1st 10 ILI patients each week)

Provider ID #: _____	**Date of Visit: _____**		
Patient Demographic, Medical and Vaccination Information			
State:	County:	Zip Code:	State ID #:
Age: _____ ☐ Days ☐ Months ☐ Years	Sex: ☐ Male ☐ Female	Date of illness onset: _____/_____/_____ MM DD YYYY	
Symptoms: ☐ Fever ☐ Cough ☐ Sore Throat ☐ Rhinorrhea ☐ Myalgia ☐ Coryza ☐ Ear ache ☐ Anorexia ☐ Chills ☐ Malaise/Fatigue ☐ Vomiting ☐ Diarrhea ☐ Abdominal pain ☐ Other:			
Did the patient receive antivirals for this illness?		☐ Yes ☐ No ☐ Unknown	
Did the patient receive influenza vaccine during the current season (before illness)?		☐ Yes ☐ No ☐ Unknown	
Rapid Test Results: ☐ Influenza A ☐ Influenza B ☐ Negative ☐ Not Tested			

Please submit specimen collection form with specimen to <Health Department contact information>.