Influenza Incidence Surveillance Project (IISP)
APPLICATION

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/

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Part I – Overview Information

Overview

The Influenza Incidence Surveillance Project (IISP) is a collaboration between CSTE and the CDC Influenza Division to support expansion of influenza and respiratory surveillance at state and local health departments to inform the outpatient disease burden of influenza and other respiratory viruses. For the 2016-2017 influenza surveillance year, CSTE seeks to determine the incidence of medically-attended acute respiratory illness (ARI) including influenza-like illness (ILI) and the extrapolated incidence of ARI and ILI associated with influenza and other respiratory viruses. Collection of patient influenza vaccination status will be emphasized, and confirmation preferred.

Part II Full Text of Announcement

Section I. Application Description

1.1 Background

Tracking the incidence of influenza and other respiratory viruses allows for disease burden comparisons across predominant circulating viruses, seasonal epidemics, geographic regions, as well as alerts public health officials of increases beyond usual seasonal activity, and improves non-specific, syndromic measures of disease. Further, the burden of influenza disease in the United States can vary widely from year to year, and is influenced by the characteristics of circulating viruses, the timing of the season, and vaccine effectiveness and coverage. To estimate the influenza disease burden each year, CDC uses data collected through several national surveillance systems conducted by state and local health departments. Building from inpatient, outpatient, and virologic surveillance, mathematical models are used to estimate the disease burden and the impact of influenza immunization programs. Incorporation of other respiratory viruses can further strengthen these models and broaden the utility of the data to inform a more complete picture of acute respiratory illness.

The outpatient setting poses many challenges for estimating disease burden, most importantly the difficulty in defining the population under surveillance and the non-specific nature of commonly used case definitions. The influenza-like illness case definition is commonly used for influenza surveillance due to the high positive predictive value during periods of circulation, although influenza illness is often clinically indistinguishable from illness due to other respiratory pathogens. Current outpatient national surveillance programs are not directly linked, prevention estimation of both the volume of patient visits for respiratory illness and the proportion attributable to influenza.

The IISP was initiated in 2009 to monitor the age-specific incidence of medically-attended ILI among health care providers with patient populations of estimated size, which allow for incidence calculation. Health care providers with a primary care focus tracked ILI patient visits and collected specimens from a subset of patients which were tested for influenza at the state or local health department. Surveillance was expanded in 2010-11 to include more broadly defined ARI and testing for other respiratory viruses. In subsequent years, the program has maintained testing for the most common respiratory viruses, but surveillance for broadly defined ARI became optional. For the 2016-17 season, CSTE seeks proposals that incorporate an expansion of activities to include more broadly defined ARI and is open to any state or large local health department. Funding awards are dependent on commitment and compliance with core activities, expansion to incorporate a broader case definition, multi-pathogen testing, and influenza vaccination confirmation activities as outlined in the guidance of the current FOA.

1.2 Objectives

1. Determine the incidence of medically-attended ARI and/or ILI.
2. Collect specimens from a subset of ARI and ILI patients to calculate the proportion of medically-attended ARI and ILI patients with laboratory-confirmed influenza and other respiratory viruses.
3. Calculate the incidence of laboratory-confirmed influenza and other respiratory viruses among ARI and ILI patients.
4. Collect clinical and epidemiologic information of ARI and ILI patients to describe the patterns of respiratory disease.

1.3 IISP Methods and Guidance

To maximize the comparability of data across awarded sites, some detailed methods are outlined in the following section. Alternatives to the outlined methods are permitted, but should maintain compatible data. A data dictionary will be provided.

Funding and Surveillance Period

The funding period is from July 1, 2016 – June 30, 2017. The surveillance period is from September 1, 2016 – May 31, 2017. If possible, surveillance would be continued ideally through July 31, 2017, but it is not required.

Recruitment of Health Care Providers and Clinics

1. Provider/Clinic Characteristics

Participating IISP sites are responsible for recruiting ≥5 health care providers or clinics willing to comply with the methods outlined in the FOA. Ideally, all providers within a clinic would participate; however, individual health care providers may be recruited. The combination of all clinics/providers participating must represent all age groups for the site. For example, applicants may include pediatric clinics combined with family practice or geriatric practices, etc. Providers must be able to enumerate or estimate the patient panel (at-risk population size) by age group. This will serve as an approximation of a population for incidence calculation. Recommended provider characteristics:

- Allow acute care visits: providers or clinics that triage acutely ill patients to non-participating clinicians or urgent care clinics, or providers that generally do not see acutely ill patients should not be recruited.
- Small to moderate practice size is recommended (weekly patient volume of 100-150 patients). Larger clinics may be considered, but must have the ability to maintain methodology across multiple staff.

Due to the large amount of work required by the health care providers to track all-cause and ARI/ILI patient visits (if directly counting) and to collect specimens with the included case report form, we urge the consideration of incentives. Provider agreements or contracts are recommended.

2. Population Estimation (aka source population, at-risk population)

Each provider must be able to provide an accounting of the number of individual patients under their care by age group. Ways to enumerate the patient population:

- Total number of patients registered with the provider.
- Average number of **unique persons** who have been seen by the provider in a given year (3 years of data desired for making this estimation). This is NOT the same as the number of patient visits each year, since in any given year people may come more than once or they may not have a visit.

Surveillance Methods

Case definitions applied to patients presenting with illness onset <**7 days** from the clinical visit:

- Acute respiratory infections (ARI): patients of all ages with at least 2 of the following: rhinorrhea, nasal congestion, sore throat, cough, fever.
- Influenza-like illness (ILI): patients aged ≥2 years of age with fever AND cough AND/OR sore throat
    - patients aged <2 with a measured or reported fever AND >1 additional ARI symptom (cough, sore throat, rhinorrhea, congestion)

NOTE: Patients do not need to have qualifying symptoms at the time of visit; reported fever or other symptoms with onset ≤7 days prior to clinic visit qualifies the patient for inclusion.

1. Weekly Aggregate Data Reporting (sample form in Appendix A)

- For each week, providers should report the number of ARI visits by age group and propose methods to determine the count or proportion of ARI cases that meet the ILI case definition. Applications may include aggregate reporting of ILI patients only, but may be less competitive than more comprehensive proposals.
- Age groups are designated as follows (years): <1, ≥1 - <2, ≥2 - <5, ≥5 - <18, ≥18 - <25, ≥25 - <50, ≥50 - <65, ≥65
- Patients with ARI and/or ILI may be identified through chief complaints, ICD-10 codes, other electronic sources, or direct identification. **Appendix B** identifies a listing of suggested ICD-10 codes. Proposals should describe the methods and provide any specific listing of ICD-10 codes or chief complaints that will be used to identify ARI/ILI patient visits. Methods to compare patients identified by electronic sources and patients identified by clinical staff for specimen collection should be included.

2. Specimen Collection

Providers should collect a respiratory specimen from a non-biased sample ARI/ILI patients. Non-biased sampling requires that specimen collection NOT be based on clinical suspicion of influenza or other respiratory pathogen infections, but rather by meeting surveillance case criteria. Proposals should outline methods to directly identify patients that meet ARI and/or ILI criteria and indicate the number of specimens that will be collected. Proposed strategies should include sufficient sampling to ensure that the proportion of ARI patients who meet ILI criteria can be calculated. Potential strategies and sample size considerations are given in **Appendix C**, but do not preclude proposals with alternative methods.

- The type of specimen collected is at the discretion of the provider. The preferred specimens are paired nasal and throat swabs, nasopharyngeal swabs, nasal washes, and nasal aspirates; however, a single throat swab (oropharyngeal) or nasal swabs is acceptable.
- Patient refusal is expected, thus specimen collection should continue until the proposed number of specimens have been collected.
- Providers MUST NOT select patients based on suspicion of influenza.

3. Patient Data Collection (sample form in Appendix D)

Demographic and clinical data is collected on sampled patients. A data dictionary will be provided including data formats required for reporting and an indication of mandatory and optional data elements.

- **Demographic data**: a minimum of non-personally identifiable variables with previously established associations with respiratory illness or health care seeking is included: age, race, ethnicity, and gender.
- **Clinical data**: a minimum of non-identifiable variables with established associations with respiratory illness or health care seeking is included. There are questions for the patient and questions for the clinician.
    - Patient questions: date of illness onset, reported symptoms since illness onset, and use of antipyretics in the past 6 hours (only needed if clinician measuring temperature).
    - Clinician questions: type of specimen collected, measured temperature, influenza antiviral prescribing, patient diagnosis, severity of illness, referral to hospital, and rapid testing conducted.
- **Vaccination history**: all patients should be asked about influenza vaccination receipt for the current season; 2015-16 vaccine until 2016-17 vaccine is available. Type of vaccine is optional, but asked to distinguish LAIV from injected. There is no expectation of differentiating types of injected vaccines.

4. Specimen Testing

The state, city or county PHL should process and test specimens.

- Reagents and qualifying ancillary reagents for influenza testing is provided by CDC at no cost to validated public health laboratories. Influenza testing should be conducted using the CDC IVD kit including influenza A (subtypes 2009 H1N1, H3) and influenza B (genotypes Yamagata and Victoria) and results reported within 2 weeks of specimen collection.
- Multi-pathogen testing should be conducted on all specimens collected for at least the following viruses: RSV, adenovirus, parainfluenza viruses 1-3, human metapneumovirus, rhinovirus. Additional respiratory pathogens to consider testing routinely: coronaviruses, parainfluenza virus 4, enteroviruses, and bacterial pathogens.
- Assays for respiratory pathogens may be determined by the PHL, but must include molecular methods.
- Frequency of reporting multi-pathogen at the discretion of the PHL, but should be within 1 month of collection.

5. Influenza Vaccination Verification

For the 2016-17 season, verification of influenza vaccination is a high priority, but not required. Applicants should describe the method that will be used, which may be dependent on IRB regulations, data quality and availability. For example, immunization registries are not required in all states.

Section II. Award Information

1. Mechanism(s) of Support

CSTE will manage all matters related to financial support for this project. CSTE will provide fixed-funding contracts to each of the sites. Funds will be distributed upon contract initiation (25%) and on October 1 (25%), February 1 (25%), and June 30 (25%). In all cases, funds will only be reimbursed upon receipt of invoice from the applicant as well as sufficient progress as determined by CSTE made toward the activities of the IISP project as outlined in this FOA and contract agreement with CSTE. 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 provide support for up to 8 sites. CSTE will award successful applicants with a maximum of $140,000 per site. Eligibility for the maximum award amount will be contingent upon inclusion of molecular-based testing for influenza and other respiratory pathogens. 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: 5U38 OT000143. The development of supplemental surveillance methods is a joint project of CSTE and CDC based on previous CSTE Position Statements. All position statements, including 06-ID-04, are 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.

Section III. Eligibility Information

1. Eligible Applicants

Applicants should clearly describe their ability to meet the objectives and methods listed in Sections 1.2 and 1.3. State, territorial, large city/county* public health agencies. *A large local public health agency is defined as a city or county health department serving a population of one million residents or greater.

2. Cost Sharing or Matching

Cost sharing, matching, or cost participation is required only for activities that overlap with other CDC funded programs to avoid duplicate funding. For example, if a personnel is fully funded by the Epidemiology and Laboratory Capacity Grant, the same individual cannot receive extra salary through IISP.

Section IV. Application and Submission Information

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. Page limits noted are strongly encouraged, but will not affect the review if it is necessary to exceed.

- Contact information: Principle Investigator (PI) and Surveillance Officer(s) (SO). The PI will serve as the primary contact for this project. Applicants should also indicate who will function as the primary laboratory investigator. Information should include email, mailing address (no PO boxes) and phone number. **1 page limit**
- Surveillance Experience: Applicants should describe their surveillance experience and that of any additional participating institutions that demonstrates their ability to successfully participate in this project and achieve the goals outlined. Details may include previous participation in IISP or other relevant studies or surveillance programs, example(s) of possible providers/clinics or capable of increased surveillance activities, and/or a description of an experienced surveillance coordinator or other staff member who will oversee the project's progress. **1 page limit.**
- Methods: Applicants should describe their proposed methods according to those described in the objectives and methods outlined in Sections 1.2 and 1.3. Applications should include at least the following:
    - Describe methods that will be used to identify and recruit health care providers for the project.
    - Describe the methods for determining the patient population.
    - Describe aggregate data that will be collected, and case definitions that will be used to identify patients.
    - Describe methods to compare patients identified by electronic sources and patients identified by clinical staff for specimen collection.
    - Describe the patient specimen and data collection methods, including patient sampling strategy and data elements to be collected (a sample form may be used to demonstrate data elements).
    - Describe the methods by which data will be reported by providers/clinics to the health department and how specimens will be transferred or shipped to the public health laboratories for testing.
    - Describe the methods or mechanism to provide incentives for provider's participation.
    - **4 page limit**
- Laboratory test methods: Applicant should describe the testing algorithm for influenza and other respiratory pathogens, addressing the ability to handle increased numbers of specimens and storage space. Applicants should also describe the expected frequency of specimen testing and result reporting from the laboratory to project coordinators and to CDC. **2 page limit – do not include the instructions or package inserts for assays**
- IRB: Human subject review process for the applicant if necessary. **½ page limit**
- Letters of Support: A letter of support from at least three providers or an organization representing providers or clinics is required and must address commitment to participate and ability to integrate protocol. **1 page limit per letter**
- Budget: Vague budgets may not be considered. Proposed budget should be reasonable and include the amount of funding needed and how it will be appropriated to personnel time, supplies for participating providers, epidemiology, coordination, and laboratory testing, services such as information technology or specimen shipping, and for provider/clinic incentives for participation. **No limit**

For further assistance, technical questions, or inquiries about the application, contact Monica Schroeder at CSTE (770-458-3811 or mschroeder@cste.org). CSTE and CDC will be available to speak to potential applicants to discuss administrative and technical questions. Upon request, all questions and answers will be made available to all potential applicants during the application process.

2. Submission Dates and Times

A completed letter of intent should be sent by email to CSTE by **March 25, 2016**:

Monica Schroeder
Associate Research Analyst
Council of State and Territorial Epidemiologists
2872 Woodcock Blvd., Suite 250
Atlanta, GA 30341
770-458-3811 (phone) | 770-458-8516 (fax)
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Submission, Review and Anticipated Start Dates
Letter of Intent Receipt Date: March 25, 2016 (required)
Application Submission Receipt Date: May 13, 2016
Award notification date: June 8, 2016
*subject to change based on the availability of funding
Budget Period: July 1, 2016-June 30, 2017

Submitting an Application
An electronic copy of the completed application should be submitted electronically to mschroeder@cste.org by May 13, 2016. All application materials must be submitted in one electronic file attachment. Applications must be received by CSTE no later than 11:59pm Eastern on May 13, 2016. Applications received after this deadline may not be reviewed.

The receipt deadline for all application components is 11:59pm Eastern on May 13, 2016.
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 mschroeder@cste.org .

Application Processing
All applications received will be reviewed by June 8, 2016. Applications will be reviewed based on criteria described in Section V.

Section V. Application Review Information

1. Criteria and Prioritization

The scientific merit of the proposed project as determined by the objective review panel will be based on the following criteria and associated weights:

Maximum points

Completeness and appropriateness of the application: 15

- Completeness of applications, such that all of the content described in Section 1, Parts 2 and 3, Section III, Part 1, and Section IV, Part 1 are addressed.
- The extent to which the budget is reasonable and consistent with the purpose of the announcement and the proposed objectives for the program. Budget addresses: personnel time, laboratory costs, provider incentive costs.
- Letters of support from providers and public health laboratory included.

Ability to comply with data collection methods: 40

- Ability to identify and enroll ≥5 providers of a manageable patient volume who can define their patient population and are willing to participate in data and specimen collection. The combination of providers enrolled should represent all age groups.
- Ability to collect aggregate patient visit and ARI and/or ILI count data by eight age groups.
- Ability to collect or estimate weekly counts for both ARI and ILI.
- Ability to collect non-biased specimens from patients with ARI at a sufficient volume to sub-classify patients with ILI – or collects specimens from subsets of ARI and ILI patients – and make robust calculations of the percent of patients positive for influenza and other respiratory viruses by age group.
- Ability to collect non-biased specimens from patients with ARI or ILI at a sufficient volume to make robust calculations of the percent of patients positive for influenza and other respiratory viruses by age group.

State public health laboratory capacity: 30

- Ability of the state public health laboratory to perform influenza testing.
- Ability of the state public health laboratory to perform multi-pathogen testing for respiratory viruses.
- Adequate personnel and facilities at the public health laboratory to handle increased volumes of specimens for testing and ability to maintain timeliness in producing and reporting test results.

Demonstrated success in surveillance activities (previous IISP/other surveillance experience): 15

- Ability to enroll providers/clinics in surveillance with consistent participation, including reporting and/or specimen collection.
- Collected and test a sufficient volume of specimens relative to patient populations and surveillance goals.
- Ability to engage in timely data collection, specimen testing, and reporting.

Grand Total: 100

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 8, 2016. Award date is subject to change based on the availability of funding and any delays in award notification will be shared with all applicants.

2. Recipient Responsibilities

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

- Providing scientific and management oversight for the overall project at participating provider sites, including surveillance design and conduct, data collection and reporting, quality control, and collaborations with other awardees, CDC, and CSTE.
- Obtaining the appropriate human subjects clearances at local sites if required.
- Working with CDC scientists to refine protocols and data collection instruments.
- 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 and submission of samples and data.
- 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.
- Agreement to abide by the collaborative guidelines described in the Data Use Agreement (Appendix E).

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
- 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.
- Abide by the collaborative guidelines described in the Data Use Agreement.
- Providing CSTE staff to support the day to day activities of the IISP project at both CSTE and CDC.

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 Appendices A and B. 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.
- Abide by the collaborative guidelines described in the Data Use Agreement (Appendix E).

5. Collaborative Responsibilities

CSTE and CDC in conjunction with the recipient contacts for all awarded projects will continue participation in 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 if required.
- 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 if required.

Appendix A

SAMPLE

Weekly Report Form of ARI & ILI Counts

REPORTS OF ACUTE RESPIRATORY INFECTIONS (ARI)
& INFLUENZA-LIKE ILLNESS (ILI)

2016-2017 Influenza Incidence Surveillance Project

«ID»

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

Total Patient Visits								
Age (yrs)	**<1**	**1-2**	**2-4**	**5-17**	**18-24**	**25-49**	**50-64**	**≥65**
# Visits								
Number of Patients with ARI and ILI								
Age (yrs)	**<1**	**1-2**	**2-4**	**5-17**	**18-24**	**25-49**	**50-64**	**≥65**
# ARI Visits								
# ILI Visits *(subset of ARI)*								

Symptom	**ARI (all ages)**	**ILI (<2 years)**	**ILI (≥2 years)**
Fever	Any two symptoms	✓ Has fever plus	✓ Has fever plus
Sore throat		Any one other symptom	Cough and/or Sore throat
Cough			
Rhinorrhea			
Congestion			

Appendix B – ICD-10 Code List

CODE GROUP	ICD10	CONDITION
General symptoms	R50	Fever of other and unknown origin
	R50.8	Other specified fever
	R50.9	Fever, unspecified
Symptoms involving respiratory system and other chest symptoms	R05	Cough
Dyspnea and respiratory abnormalities	R06.0	Dyspnea
	R06.2	Wheezing
Acute respiratory infections	J02	Acute pharyngitis
	J02.0	Streptococcal pharyngitis
	J02.1	Acute pharyngitis due to other specified organisms
	J02.2	Acute pharyngitis, unspecified
	J03	Acute tonsillitis
	J03.0	Streptococcal tonsillitis
	J03.8	Acute tonsillitis due to other specified organisms
	J03.9	Acute tonsillitis, unspecified
	J04	Acute laryngitis and tracheitis
	J04.0	Acute laryngitis
	J04.1	Acute tracheitis
	J04.2	Acute laryngotracheitis
	J05	Acute obstructive laryngitis croup and epiglottitis
	J05.0	Acute obstructive laryngitis croup
	J05.1	Acute epiglottitis
	J06	Acute upper respiratory infections of multiple and unspecified sites
	J06.0	Acute laryngopharyngitis
	J06.8	Other acute upper respiratory infections of multiple sites
	J06.9	Acute upper respiratory infection, unspecified
	J20	Acute bronchitis
	J20.0	Acute bronchitis due to Mycoplasma pneumoniae
	J20.1	Acute bronchitis due to Haemophilus influenzae
	J20.2	Acute bronchitis due to streptococcus
	J20.3	Acute bronchitis due to coxsackievirus
	J20.4	Acute bronchitis due to parainfluenza virus
	J20.5	Acute bronchitis due to respiratory syncytial virus
	J20.6	Acute bronchitis due to rhinovirus
	J20.7	Acute bronchitis due to echovirus
	J20.8	Acute bronchitis due to other specified organisms
	J20.9	Acute bronchitis, unspecified
	J21	Acute bronchiolitis
	J21.0	Acute bronchiolitis due to respiratory syncytial virus
	J21.1	Acute bronchiolitis due to human metapneumovirus
	J21.8	Acute bronchiolitis due to other specified organisms
	J21.9	Acute bronchiolitis, unspecified
	J22	Unspecified acute lower respiratory infection
Pneumonia and influenza	J12	Viral pneumonia, not elsewhere classified
	J12.0	Adenoviral pneumonia
	J12.1	Respiratory syncytial virus pneumonia

	J12.3	Parainfluenza virus pneumonia
	J12.81	Human metapneumovirus pneumonia
	J12.89	Other viral pneumonia
	J12.9	Viral pneumonia, unspecified
	J13	Pneumonia due to Streptococcus pneumoniae
	J14	Pneumonia due to Haemophilus influenzae
	J15	Bacterial pneumonia, not elsewhere classified
	J15.0	Pneumonia due to Klebsiella pneumoniae
	J15.1	Pneumonia due to Pseudomonas
	J15.20	J15.2Pneumonia due to staphylococcus
	J15.211	Pneumonia due to methicillin suscep staph
	J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
	J15.29	Pneumonia due to other staphylococcus
	J15.3	Pneumonia due to streptococcus, group B
	J15.4	Pneumonia due to other streptococci
	J15.5	Pneumonia due to Escherichia coli
		Pneumonia due to other Gram-negative bacteria
	J15.7	Pneumonia due to Mycoplasma pneumoniae
	J15.8	Other bacterial pneumonia
	J15.9	Bacterial pneumonia, unspecified
	J16	Pneumonia due to other infectious organisms, not elsewhere classified
	J16.0	Chlamydial pneumonia
	J16.8	Pneumonia due to other specified infectious organisms
	J17	Pneumonia in diseases classified elsewhere
	J18.0	Bronchopneumonia, organism unspecified
	J18	Pneumonia, organism unspecified
	J18.1	Lobar pneumonia, unspecified
	J18.2	Hypostatic pneumonia, unspecified
	J18.8	Other pneumonia, organism unspecified
	J18.9	Pneumonia, unspecified
Pneumonia and influenza	J09	Influenza due to certain identified influenza viruses
	J11	Influenza, virus not identified
	J11.0	Influenza with pneumonia, virus not identified
	J11.1	Influenza with other respiratory manifestations, virus not identified
	J11.8	Influenza with other manifestations, virus not identified
	J10	Influenza due to other identified influenza virus
	J10.0	Influenza with pneumonia, other influenza virus identified
	J10.1	Influenza with other respiratory manifestations, other influenza virus identified
	J10.8	Influenza with other manifestations, other influenza virus identified

APPENDIX C – Examples of specimen sampling strategies

Goal: Ability to collect non-biased specimens from patients with ARI at a sufficient volume to sub-classify patients with ILI – or collects specimens from subsets of ARI and ILI patients – and make robust calculations of the percent of patients positive for influenza and other respiratory viruses by age group.

Sample size consideration:

IISP data suggest an approximate ratio of 2-3 ARI patients to each ILI patient, but may be lower in pediatric practices. Time of year, type of practice, and age of patients presenting to the clinic have may lead to variation in the ratio.

Overall, approximately 10-15% of ARI patients are expected to test positive for influenza over the year. Among ILI patients, approximately 25-30% of specimens are expected to test positive.

Strategies used by IISP sites:

Oversampling ARI:

Aggregate counts of ARI by age group may be electronically identified. Providers collect a larger number of specimens from all ARI patients and use the reported symptoms to determine the proportion of patients sampled that meet ILI criteria. Specimen test volume is higher using this method, but collection of specimens is systematic and easy to implement. The proportion of all ARI patients sampled that meet ILI criteria can be used to extrapolate the aggregate ILI counts from the electronically identified ARI counts.

Complete sampling of clinic:

Providers collect specimens from all ARI patients and use the collection of symptoms to distinguish ARI from ILI patients. The distribution and counts of ARI and ILI are inherent. This method is best in small clinics. Specimen volume may be higher, but methods could be adjusted to a sampling method if necessary.

Estimating the expected number of specimens:

- Previous years of IISP data have shown that for the small/moderate sized providers in an average severity influenza season (2010-11 and 2012-13), the number of specimens collected from ILI patients by a site ranged from 669 to 115 (median 375), with an average of 116 specimens per provider.
    - Small volume providers are encouraged to ensure that the maximum number of specimens possible are not actually observed: 5-6 providers per site x 10 specimens per provider per week = 50-60 specimens per week possible = 2000 *(no IISP site has ever experienced or approached this volume of ILI specimens!).*

Appendix D **2016-2017 Influenza-like Illness Surveillance**
SAMPLE Patient Information Collection Form

Please collect specimens from XXXXXXXX patients seen each week who meet the following case definitions AND have illness <u>onset in the past 7 days</u>:

ARI

✔ **Two of any: cough, sore throat, rhinorrhea, congestion, or measured or self-reported fever**

ILI

Age >2 years:
- ✔ **Measured or self-reported fever**
- ✔ **Cough or sore throat**

Age <2 years:
- ✔ **Measured or self-reported fever**
- ✔ **Cough, sore throat, rhinorrhea or congestion**

Demographic Information			
Provider ID #:		**PatientID #:**	**Date of Visit:** _____/_____/_____ MM DD YYYY
State:	**Sex:** ☐ Male ☐ Female	**Age:** _____ ☐ Days ☐ Months ☐ Years	**Date of birth**: _____/_____/_____ MM DD YYYY
Race: ☐ White ☐ Black ☐ Asian ☐ Native Hawaiian/Pacific Islander ☐ American Indian/ Alaska Native ☐ Not Specified/Unknown			**Ethnicity:** ☐ Non-Hispanic or non-Latino ☐ Hispanic or Latino ☐ Not Specified/Unknown

Clinical Visit Information	
Specimen Type: ☐ Nasal swab ☐ Nasopharyngeal swab (NP) ☐ Oropharyngeal (OP)/throat swab ☐ Nasal wash/aspirate	**Date of illness onset:** _____/_____/_____ MM DD YYYY
Symptoms within the past 4 days: ☐ Fever ☐ Cough ☐ Sore throat ☐ Rhinorrhea ☐ Congestion ☐ Myalgia ☐ Chills ☐ Headache ☐ Ear ache ☐ Anorexia ☐ Malaise/fatigue ☐ Vomiting ☐ Diarrhea ☐ Wheezing ☐ Conjunctivitis ☐ Other: _____	
Measured temperature *(if available)*: _____°F	**Antipyretics taken in past 6 hours**? ☐ Yes ☐ No ☐ Unknown *(such as ibuprofen, aspirin, acetaminophen)*
Patient diagnosis: _____	
Received antivirals for this illness? ☐ Yes ☐ No ☐ Unknown	
Severity of illness *(according to the health care provider's clinical judgment)*: ☐ Mild ☐ Moderate ☐ Severe	
Was this patient referred for hospitalization with this illness? ☐ Yes ☐ No ☐ Unknown	

Rapid test results (blank assumes not done):

Influenza:	☐ Influenza A	☐ Influenza B	☐ Negative
Streptococcus A:	☐ Positive	☐ Negative	
RSV:	☐ Positive	☐ Negative	
Other: _____	☐ Positive	☐ Negative	

Influenza Vaccination Information
Received the 2015-16 influenza vaccine >2 weeks prior to illness? ☐ Yes ☐ No ☐ Unknown
If yes, type of vaccine: ☐ Injected (flu shot) ☐ Nasal spray ☐ Unknown

Appendix E **Data Sharing Guiding Principles**

1. **Primary Multi-Site Investigations**
    - Primary multi-site investigations are those designed to accomplish the core surveillance objectives as stated in the funding opportunity announcement
    - CDC investigators, as listed in the funding opportunity announcement, will lead the primary multi-site investigations to accomplish the core surveillance objectives. They will work closely with the steering committee to ensure that high quality results are generated and will be responsible for running the project and writing the final publication.

2. **Steering Committee**
    - A steering committee will be comprised of the participating sites, CDC and CSTE. The steering committee is responsible for deciding secondary multi-site and single-site investigations will be pursued.

3. **Process for Selecting Proposed Investigations:**

    a. Submission of Secondary Multi-Site Investigation

    Written proposal should be submitted electronically to the CSTE project officer. The proposed work must not already be a part of core surveillance objectives as stated in the funding opportunity announcement or contained within a proposal for which permission was already granted. Proposals should include the following sections

    1. Title
    2. Investigator(s)
    3. Background
    4. Public health rationale
    5. Primary objective(s)
    6. Methods
    7. Analysis plans
    8. Table Shells
    9. Timeline
    10. References
    11. Proposed journal/publication and other presentations, such as conferences

    b. Review and Approval of Proposals

    Each submitted proposal (including title and the lead author) will be distributed to the members of the steering committee for review. Within one week, the steering committee will discuss the proposal on a conference call or via email. Following the discussion, any concerns will be submitted to the lead author who will then have one week to address them. The steering committee will then vote on the final approval of the proposal. Once approval is granted, communication of project approval will be sent to the lead author. Significant changes in a concept or in the variables to be analyzed will require resubmission of the proposal.

    c. Data and Specimen Requests

    Once a proposed investigation is approved, the lead investigator should communicate with CDC to start collaboration in investigation design, creation of analytical datasets, selection of banked specimens, and data analysis.

    d. Submission of a Single-Site Investigation Proposal

    Written proposals should be submitted electronically to the CSTE project officer. The proposed work must not already be a part of core surveillance objectives as stated in the funding opportunity announcement or contained within a proposal for which permission was already granted. Proposals should be in the form of a descriptive summary including the following:

    1. Statement of intent
    2. Investigators
    3. Methods

4. Timeline
5. Proposed journal/publication and other presentations, such as conferences

4. Publications

e. Review of Abstracts, Presentations, Publications

All abstracts, posters, manuscripts, and presentations resulting from secondary multi-site investigations must be reviewed by the steering committee (including CSTE and CDC) before any presentation to a formal scientific meeting or prior to submission for publication. At least 4 weeks should be anticipated for the steering committee review. The CDC disclaimer needs to be on all publications with CDC authors and acknowledgement of CSTE's agreement of funding.

Abstracts, manuscripts, and presentations resulting from single-site analysis also require steering committee review in order to decide the funding line. If the CDC and CSTE do not agree with the results or conclusions of the publication, it will be necessary to add to the funding line that the conclusions do not represent the position of the CDC or CSTE.

All final abstracts and manuscripts must be reviewed by CDC prior to submission for publication with any CDC co-author.

Presentation or manuscript submissions which do not have prior steering committee approval and CDC clearance may result in a denial of access to data. In addition, presentation or submission of unapproved manuscripts could be subject to withdrawal from committee or journal review.

Publications and presentations shall be in compliance with the rules and procedures of the disclosure set forth in the Privacy Act. Confidential or proprietary information of another party shall not be disclosed without the prior written consent of the individual or institution. Privacy Act compliance and documentation of written disclosure consents are the responsibility of each institution involved in the publication.

f. Credit and Authorship

All publications and presentations should acknowledge that the data were collected through "Influenza Incidence Surveillance Project". All publications and presentations should credit participating institutions, CSTE and the CDC.

Each co-author should follow the uniform requirements published by the International Committee of Medical Journal Editors (ICMJE). Each author should contribute to (1) conception and design, or analysis and interpretation of data; (2) drafting the publication or revising it critically for important intellectual content; and (3) approve the final version of the publication.

On secondary multi-site publications, each site, CSTE and the CDC will determine its co-author(s). Each site, CSTE and the CDC can specify more than one co-author. Each site, CSTE and the CDC may decline authorship on a multi-site publication. If necessary, the steering committee will be the arbiter of the final authors list for a publication. Acknowledgements on a manuscript may include more than one person per site. On single site publications, decision will be made between the site, CSTE and CDC whether there should be at least one CDC and/or CSTE co-author.