2019 Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)

CDC-RFA-CK19-1904

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Estimated Publication Date:

March 1, 2019

Contents

Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notifications Emails" link to ensure they receive notifications of any changes to **CDC-RFA-CK19-1904.**

Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC) / Agency for Toxic Substance and Disease Registry (ATSDR)

B. Funding Opportunity Title:

Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)

C. Announcement Type: New - Type 1

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For this purpose, research is defined at https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf. Guidance on how CDC interprets the definition of research in the context of public health can be found at http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf.

D. Agency Funding Opportunity Number:

CDC-RFA-CK19-1904

E. Catalog of Federal Domestic Assistance (CFDA) Number:

93.323

F. Dates

1. Due Date for Letter of Intent (LOI):

N/A

2. Due Date for Applications:

Applications are due on May 10, 2019, 11:59 p.m. Eastern Standard Time, on www.grants.gov

3. Date for Informational Conference Call:

An informational call will be held approximately two weeks after posting. The date and time for this call is March 14, 2019 at 3:00 p.m. ET.
Dial-in number: (773) 756-0169 (toll) or (800) 857-4945 (toll free)
Passcode: 3092790

G. Executive Summary

1. Summary Paragraph

The Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Notice of Funding Opportunity (NOFO) builds upon the program that was initiated in 1995 as one of the key activities under CDC's plan to address emerging infectious disease threats. The purpose

of this NOFO is to protect the public health and safety of the American people by enhancing the capacity of public health agencies to effectively detect, respond, prevent and control known and emerging (or re-emerging) infectious diseases. This is accomplished by providing financial and technical resources to (1) strengthen epidemiologic capacity; (2) enhance laboratory capacity; (3) improve information systems; and (4) enhance collaboration among epidemiology, laboratory, and information systems components of public health departments.

a. Eligible Applicants:
Limited competition

b. NOFO Type:
Cooperative Agreement

c. Approximate Number of Awards:
64

d. Total Period of Performance Funding:
$1,000,000,000

Approximately $200M awarded annually

e. Average One Year Award Amount:
$3,125,000

f. Total Period of Performance Length:
5

g. Estimated Award Date:
08/01/2019

h. Cost Sharing and / or Matching Requirements:
N/A

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

The goal of the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) program is to reduce illness and related deaths caused by a wide range of infectious disease threats. The ELC Program provides annual funding, strategic direction and technical assistance to domestic jurisdictions for core capacities in epidemiology, laboratory, and health information technology activities. In addition to strengthening core infectious disease capacities nationwide, this cooperative agreement also supports a myriad of specific infectious disease programs.

In the last five years, CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) extramural funding has increased from $109 million in FY 2013 to $302 million in FY 2017. This increase coincides with increased responsibilities at the state and local level for emerging infectious disease control, notably for emergency responses to Ebola and Zika, and for expanded investment to curb antibiotic resistant infections and modernize public health laboratory capacity. Ebola and Zika funding began as one-time emergency funding, while antibiotic resistance funding is expected to reoccur annually, and base vector-borne disease funding is beginning to grow. Together with food- and water-borne disease program growth, these investments have moved from capacity building to program delivery. In other infectious disease areas, capacity building is still the focus of investments.

b. Statutory Authorities

Public Health Service Act Sections 301(a) [42 U.S.C. 241(a)] and 317(k) (2) [42 U.S.C. 247b (k) (2)], as amended, and the Patient Protection and Affordable Care Act (PL 111-148), Title IV, Sections 4002 and 4304 (Prevention and Public Health Fund).

c. Healthy People 2020

The ELC supports the following activities aligned with Health People 2020 Topics and Objectives: Food Safety, Health Communication and Health Information Technology, Healthcare Associated Infections, Immunization and Infectious Diseases, Public Health Infrastructure, and Respiratory Diseases.

d. Other National Public Health Priorities and Strategies

ELC supports CDC Agency priorities, including Healthcare Associated Infections (HAI) and Food Safety. Other National Public Health Priorities and Strategies are defined in individual project attachments.

e. Relevant Work

This ELC NOFO builds upon the program that was initiated in 1995 as one of the first key activities under CDC's plan to address emerging infectious disease threats. Previous ELC cooperative agreement announcement numbers include CI04-040, CI07-701, CI07-702, CI10-1012, CK12-1201, and CK14-1401. The program has grown to become one of CDC's key nationwide cooperative agreements for supporting state and local infectious disease control capacity for 1) cross-cutting epidemiology, laboratory and health information systems, 2) infectious disease programs (Food and Water, Healthcare Associated Infections/Antimicrobial Resistance, and Vector-borne), and 3) disease-specific projects. This also builds upon special funding allocations in the previous NOFO that helped to enhance epidemiology, laboratory, and health information systems to specific disease and health threats.

2. CDC Project Description

a. Approach

CDC-RFA-CK19-1904

OVERALL ROADMAP FOR THE EPIDEMIOLOGY AND LABORATORY CAPACITY FOR PREVENTION AND CONTROL OF EMERGING INFECTIOUS DISEASES (ELC)

The ultimate goal of the ELC is to **prevent the transmission of future outbreaks of known and emerging (or re-emerging) infectious diseases while reducing the exposure to current infectious disease threats**. We achieve this by enhancing the capacity of public health agencies to effectively detect, respond to, control, and prevent known and emerging (or re-emerging) infectious diseases threats.

Core Areas/Strategies *ELC provides funding to recipients to implement these strategies.*	**Short-term** *ELC recipients produce these outputs as a result of implementing the strategies.*	**Mid-term** *As a result of the outputs, ELC recipients will achieve these outcomes.*	**Long-term** *As a result of achieving the mid-term outcomes, these longer term outcomes will be achieved.*
1. Surveillance, Detection and Response • 1a: Enhance workforce capacity • 1b: Enhance investigation and outbreak response • 1c: Improve surveillance and reporting • 1d: Strengthen laboratory testing for response • 1e: Enhance laboratory testing for surveillance and reporting • 1f: Improve laboratory coordination and outreach to improve efficiency • 1g: Enhance coordination between epi-lab-HIT • 1h: Advance electronic information exchange implementation • 1i: Sustain and/or enhance information systems **2. Prevention and Intervention** • 2a: Implement public health interventions and tools • 2b: Develop/advance policies to improve public health capabilities	Effective public health workforce prepared to respond to infectious disease threats Investigations conducted Best practices for outbreak management in place Surveillance of infectious disease conducted Best fit and/or modern laboratory diagnostic techniques and capabilities in place Laboratory operations are maintained and improved Coordination between laboratories within the state and/or within laboratory networks are	Improved understanding of the epidemiology and incidence of infectious diseases Improved surveillance • Improved completeness of data • Improved timeliness of reporting • Increased distribution and use of data to public health partners Improved efficiencies between laboratories and their networks, use of public health resources Infectious disease data is automated and efficiently transmitted Electronic mechanisms for data exchange are in place	More efficient and accurate public health reporting More rapid detection of cases and outbreaks More timely, complete and effective investigation efforts: • Response to outbreaks • Investigation of outbreaks • Implementation of control measures Improved use of data to: • Inform response and control • Improve public health practice • Inform program and policy development • Develop and implement public health best practices and/or guidelines Public and healthcare providers adopt appropriate practices to

• 2c: Implement health promotion strategies **3. Communications, Coordination and Partnerships** • 3a: Coordinate and engage with partners • 3b: Information dissemination	improved Increased interoperability between information systems and entities Integrated surveillance systems Development, implementation and evaluation of strong public health interventions Partnerships and collaborations formed	Increased awareness among: • Public regarding infectious disease risks and protective actions • Providers regarding appropriate public health actions Enhanced coordination on prevention and control of infectious diseases between partners	protect themselves and the public from infectious diseases

i. Purpose

The purpose of the activities supported through this NOFO is to protect the public health and safety of the American people by enhancing the capacity of public health agencies to effectively detect, respond, prevent and control known and emerging (or re-emerging) infectious diseases. ELC is CDC's national funding strategy to support state, local, and territorial health departments to battle infectious disease threats in the U.S. This is accomplished by providing financial and technical resources to support the implementation of three core areas; (1) surveillance, detection and response, (2) prevention and intervention, and (3) communications, coordination and partnerships. Any surveillance data collection efforts should leverage existing tools and systems and should adhere to national data and technology standards to support interoperability of system- to-system data exchange.

ELC resources may support each of these individually however, it is only through integration that these complementary core areas are optimized.

ii. Outcomes

As reflected in the ELC Overall Roadmap, recipients are expected to show measurable progress made toward the outcomes for this five-year period of performance. Each of ELC's Cross-Cutting, Program and disease-specific Projects focus on achieving one or more of the outcomes from the ELC Overall Roadmap (see 2. CDC Project Description, a. Approach section above). Each program and project have specified this information in the 'Outcomes' section of each project attachment. As such, the specific outcomes recipients are expected to demonstrate progress for will depend on the Programs or Projects funded.

The mid-term outcomes will also be achieved during this period of performance: (1) Effective public health workforce better prepared to respond to infectious disease threats; (2) Improved understanding of the epidemiology and incidence of infectious diseases; (3) Improved surveillance: Improved completeness of data, Improved timeliness of reporting, Increased distribution and use of data to public health partners; (4) Improved efficiencies between laboratories and their networks/use of public health resources; (5) Infectious disease data is automated and efficient; (6) Electronic mechanisms for data exchange are in place; (7) Increased awareness of: Public regarding infectious disease risks and protective actions, Providers regarding appropriate public health actions.

Long term, ELC will contribute to: (1) More efficient and accurate public health reporting; (2) More rapid detection of cases and outbreaks; (3) More timely, complete and effective investigation efforts: Response to outbreaks, Investigation of outbreaks, and Implementation of control measures; (4) Improved use of data to: Inform public health response and control, Improve public health practice, Inform program and policy development, Develop and implement public health best practices and/or guidelines; (5) Public and healthcare providers adopt appropriate practices to protect themselves and the public from infectious diseases.

iii. Strategies and Activities

Applicants should apply for programs and projects that will support identified infectious disease detection, prevention, and control needs in their jurisdictions. Note that each program and project has a separate attachment (in Part III, Section B. Program and Project Detailed Guidance Attachments) which details sub-activities, funding strategies other key criteria. Applicants may apply to any program or project, depending on jurisdiction-specific needs. Furthermore, the planning and preparation of your response to this NOFO, and implementation and monitoring/evaluation of all ELC activities must be coordinated via your established ELC Governance Team.

This Cooperative Agreement is organized into three major sections of content:

Section I: Cross-cutting Emerging Infectious Disease Capacity, Systems and Leadership

A. Cross-Cutting Epidemiology and Laboratory Capacity
B. ELC Leadership, Management and Administration
C. Health Information Systems Capacity
D. Impact and Evaluation
E. Cross-Cutting Emerging Issues: Enhanced Surveillance, Investigation Response and Reporting, Surge Efforts and Interventions

Section II: Emerging Infectious Disease Programs

F. Foodborne, Waterborne, Enteric, and Environmentally Transmitted Diseases: Surveillance, Detection, Response, Reporting, and Prevention
G. Healthcare-associated Infections and Antibiotic Resistance Program

G1. Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship
G2. Antibiotic Resistance Laboratory Network (AR Lab Network)

H. Vector-borne Diseases: Building Comprehensive Programs to Identify, Diagnose, Report, Prevent, and Respond

Section III: Disease-Specific Projects

I. Mycotics: Detecting and Preventing Fungal Infections
J. Binational Border Infectious Disease Surveillance (BIDS) Program
K. Global Migration, Border Interventions and Migrant Health
L. Prion Surveillance
M. Rabies Surveillance
N. Parasitic Diseases Surveillance
O. Enhanced Vaccine-Preventable Disease (VPD)
P. Legionnaires' Disease Prevention
Q. Influenza Surveillance and Diagnostic Testing
R. Non-Influenza Respiratory Diseases: Diagnostics, Reporting, and Surveillance
S. Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity
T. Gonococcal Isolate Surveillance Project (GISP)
U. Syphilis and HIV Prevention Through Social, Sexual and Phylogenetic Networks
V. Human Papillomavirus Surveillance Among Men
W. Infants with Congenital Exposure: Surveillance and Monitoring to Emerging Infectious Diseases and Other Health Threats

As described above, ELC is a complex Cooperative Agreement with cross-cutting and large infectious disease programs, as well as a myriad of disease-specific projects. Within each program or project section, the activities will be grouped by key strategies that link back to the mid- and long-term outcomes (see below and Roadmap in Section 2.a). Programs and Projects will vary in the number of strategies applied, and specific activities associated with these strategies are described in the program and project attachments within this NOFO.

1. Surveillance, Detection and Response

1a: Enhance workforce capacity

1b: Enhance investigation and outbreak response

1c: Improve surveillance and reporting

1d: Strengthen laboratory testing for response

1e: Enhance laboratory testing for surveillance and reporting

1f: Improve laboratory coordination and outreach to improve efficiency

1g: Enhance coordination between epi-lab

1h: Advance electronic information exchange implementation

1i: Sustain and/or enhance information systems

2. Prevention and Intervention Strategies

2a: Implement public health interventions and tools

2b: Develop/advance policies to improve public health capabilities

2c: Implement health promotion strategies

3. Coordination and Partnerships

3a: Coordinate and engage with partners

3b: Information dissemination

In this NOFO Programs and Projects have outlined a path to meet minimum expectations, expand or enhance these capacities, and even provide leadership amongst other jurisdictions. Each Program or Project section will include an activities summary table, grouping the activities by three tiers:

Tier 1: Core required activities within the program

Tier 2: Enhanced or expanded activities

Tier 3: Advanced activities, Regional Activities, Centers of Excellence or similar

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

Funding to support the ELC program as a whole should complement and be closely coordinated, with other CDC programs related to improving surveillance for, and response to, infectious diseases, for example the Emerging Infections Program (EIP) and the Public Health Emergency Preparedness (PHEP) cooperative agreements. Recipients should have a coordinated understanding and approach to all health information systems strengthening and enhancements occurring across the ELC portfolio. ELC recipients should also be aware of, and are strongly encouraged to use, resources designed as management tools that improve efficiency and promote sustainability of Public Health Labs (PHLs) and their services. Two of these resources have been developed in a collaborative fashion between CDC and the Association of Public Health Laboratories (APHL) under the Laboratories Efficiencies Initiative (LEI): (1) the LEI Informatics Self-Assessment Tool for Public Health Laboratories and (2) the online National PHL Test Service Directory.

Each Program or Project has its own description of required or suggested collaborations if applicable. This information may be found in Part III, Section B. Program and Project Detailed Guidance Attachments.

b. Internal coordination for effective ELC portfolio management

Since 2012, all ELC recipients were required to implement a governance structure for the management and oversight of the portfolio of ELC activities in their jurisdiction. All ELC recipients are required to maintain an active ELC Governance Team comprised of a Principal Investigator and representatives from epidemiology, laboratory, and health information systems (the PI may serve as a representative for one of these areas). Representatives on the Governance Team should be positioned within the organization such that they may make strategic recommendations and decisions about the activities supported with ELC resources. Members are expected to communicate with other staff regarding various aspects of ELC activities within the jurisdiction.

Building upon previous year's successes and challenges, the role of this Team is to work together to assure sufficient and appropriate oversight and integration of the ELC Cooperative Agreement planning and implementation.

c. With organizations not funded by CDC:
Each program or project that appears in Part III of this NOFO has its own program guidance that provides collaboration (if applicable) information specific to that CDC program. This information may be found in Part III, Section B. Program and Project Detailed Guidance Attachments.

2. Target Populations
Each program or project that appears in Part III of this NOFO has its own program guidance that provides a target population (if applicable) information specific to that CDC program. This information may be found in Part III, Section B. Program and Project Detailed Guidance Attachments.

a. Health Disparities
Recipients are encouraged to consider underserved populations (e.g., rural, tribal, and ESOL populations, people with disabilities) throughout their ELC portfolio of activities, especially where infectious disease health disparities and high health burdens exist. Each program or project that appears in Part III of this NOFO has its own program guidance that provides additional information about Health Disparities (if applicable) to that CDC program. This information may be found in Part III, Section B. Program and Project Detailed Guidance Attachments.

iv. Funding Strategy
The dollar amounts listed below are the estimated total annual funding, and number of awards expected for each program or project. More detail on each program or project's funding strategy may be found in Part III. Section B. Program and Project Detailed Guidance Attachments.

Section I: Cross-cutting Emerging Infectious Disease Capacity, Systems and Leadership

A. Cross-Cutting Epidemiology and Laboratory Capacity $25,600,000; 64 awards
B. ELC Leadership, Management and Administration $8,000,000 to $11,000,000; 40-50 awards
C. Health Information Systems Capacity $32,000,000; 64 awards
D. Impact and Evaluation $600,000; 5 awards

E. Cross-Cutting Emerging Issues: Enhanced Surveillance, Investigation Response and Reporting, Surge Efforts and Interventions (estimated) up to $500,000; up to 64 awards

Section II: Emerging Infectious Disease Programs

F. Foodborne, Waterborne, Enteric, and Environmentally Transmitted Diseases: Capacity Building for Surveillance, Detection, Response, Reporting, and Prevention $33,000,000; 56-59 awards
G. Healthcare-associated Infections and Antibiotic Resistance Program
   G1. Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship $28,000,000; 57 awards
   G2. Antibiotic Resistance Laboratory Network (AR Lab Network) $2,250,000; up to 56 awards
H. Vector-borne Diseases: Building Comprehensive Programs to Identify, Diagnose, Report, Prevent, and Respond $16,000,000; 60 awards

Section III: Disease-Specific Projects

I. Mycotics: Detecting and Preventing Fungal Infections $600,000; 20 awards
J. Binational Border Infectious Disease Surveillance (BIDS) Program $750,000; 1-4 awards
K. Global Migration, Border Interventions and Migrant Health $230,000; 3-5 awards
L. Prion Surveillance $500,000; 7 awards
M. Rabies Surveillance $125,000; 2 awards
N. Parasitic Diseases Surveillance $100,000; 10 awards
O. Enhanced Vaccine-Preventable Disease (VPD) $6,400,000; 64 awards
P. Legionnaires' Disease Prevention $3,000,000; 25 awards
Q. Influenza Surveillance and Diagnostic Testing $8,100,000; 57 awards
R. Non-Influenza Respiratory Diseases: Diagnostics, Reporting, and Surveillance $750,000; 10-15 awards
S. Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity $5,164,038; 8 awards
T. Gonococcal Isolate Surveillance Project (GISP) $660,000; 25 awards
U. Syphilis and HIV Prevention Through Social, Sexual and Phylogenetic Networks $1,400,000; 2 awards
V. Human Papillomavirus Surveillance Among Men $375,000; 3 awards
W. Infants with Congenital Exposure: Surveillance and Monitoring to Emerging Infectious Diseases and Other Health Threats $3,000,000; 4-9 awards

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Measurement Strategy

The purpose of evaluation and performance measurement is to help CDC and ELC recipients monitor the extent to which activities planned were successfully completed, demonstrate how capacity building activities contribute towards program outcomes, and inform decisions about future programming that drive continuous program improvement for more efficient and effective program performance.

Each of the ELC Program or Projects require a detailed Evaluation and Performance Measurement Strategy described in their individual attachment (i.e., requirements for reporting of performance measures.).

In addition, an overall Data Management Plan (DMP) is required for each recipient. Funds provided under this cooperative agreement may be used to support activities that assure compliance with CDC's DMP. A DMP is required if the NOFO involves the collection or generation of public health data. The goal of the policy is to ensure public access to federally funded public health data. This specifically requires the development of Data Management Plans (DMPs) for ELC activities that includes collection of public health data. DMPs should be as complete as possible but CDC can work jointly with ELC recipients within the first 6 months after award to finalize them. Additional details and resources for developing a DMP can be found in Part II, D. 18. Data Management Plan in this NOFO.

ii. Applicant Evaluation and Performance Measurement Plan

If needed, ELC will work with recipients during the first six months of the period of performance to finalize an evaluation and performance measurement plan to monitor the progress of the activities implemented and outcomes achieved. Each ELC program or project attachment illustrates its specific requirements for the NOFO.

c. Organizational Capacity of Recipients to Implement the Approach

The successful ELC recipient must have a demonstrated core organizational capacity in order to effectively conduct the activities for which awards are made. This organizational capacity includes skill sets such as program planning and performance management, partnership development, evaluation, performance monitoring, financial reporting, budget management and administration, personnel management (including developing staffing plans, developing and training workforce and developing a sustainability plan). Specific expectations around capacity may be found in Part III, Section B. Program and Project Detailed Guidance Attachments. Applicants also must be fully capable of managing the required procurement efforts, including the ability to write and award contracts in accordance with 45 CFR §75.

d. Work Plan

Each project the applicant is applying for (see Part III, Section B. Program and Project Detailed Guidance Attachment) must include a work plan. Work plans should be detailed and should focus on the first year of the period of performance with only a high level plan for subsequent years. Work plans should demonstrate alignment among the outcomes, strategies, activities, timelines, and staffing/collaborations. Additional information on performance measures, data sources, and target population can also be included. Specific expectations for the Work Plans may be found in Part II, Section D10. Project Narrative, and Part III, Section B. Program and Project Detailed Guidance Attachments.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients. REDCap may be utilized to assist with programmatic documentation of performance.

f. CDC Program Support to Recipients

In a cooperative agreement, CDC and recipients share responsibility for successfully implementing the award and meeting identified outcomes. The following are potential areas of substantial involvement, others may also be included:

1. Technical assistance in the following: evaluation, performance measurement, work plan development, program planning, and specific subject matter expertise for ELC Program or Projects.
2. National coordination of activities where appropriate.
3. Targeted Electronic Data Exchange (EDX) technical assistance to public health departments and public health labs.

B. Award Information

1. Funding Instrument Type:

Cooperative Agreement

CDC's substantial involvement in this program appears in the CDC Program Support to Recipients section.

2. Award Mechanism:

U50

3. Fiscal Year:
2019

4. Approximate Total Fiscal Year Funding:
$200,000,000

5. Approximate Period of Performance Funding:
$1,000,000,000, subject to the availability of funds.

6. Total Period of Performance Length:
Five years

7. Expected Number of Awards:
64

8. Approximate Average Award:
$3,125,000, subject to availability of funds.

9. Award Ceiling:
None

10. Award Floor:
None

11. Estimated Award Date:
August 1, 2019

12. Budget Period Length:
12 months

13. Direct Assistance
Direct Assistance (DA) is available for this NOFO

Extremely limited opportunities for DA may be available through this NOFO.
An official state, local or territorial government applicant may request that CDC provide DA as a part of the grant awarded through this NOFO. Recipients may request that CDC provide DA to support assignment of federal staff through CDC fellowships (e.g., Epidemic Intelligence Officers, Laboratory Leadership Service Fellows). If your request for DA is approved as a part of your award, CDC will reduce the funding amount provided directly to you as a part of your award. The amount by which your award is reduced will be used to provide DA; the funding shall be deemed part of the award and as having been paid to you, the recipient. Additional information about available DA may be found in Part III, Section B. Program and Project Detailed Guidance Attachments.

C. Eligibility Information

1. Eligible Applicants

Only current ELC recipients under CK14-1401 are eligible to apply for this announcement. This includes the departments of health for all US states, 6 of the largest locals (Chicago, District of Columbia, Houston, Los Angeles County, New York City, Philadelphia) and all of our US territories and affiliates in the Caribbean and Pacific (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Puerto Rico, Republic of Palau, US Virgin Islands).

2. Additional Information on Eligibility

Specific ELC Programs and Projects may have additional eligibility requirements associated with them. If so, these will be noted in the project-specific attachments.

3. Justification for Less than Maximum Competition

The Epidemiology and Laboratory Capacity for the Prevention and Control of Infectious Diseases (ELC) is a cooperative agreement to build the governmental public health system capacity to address emerging infectious disease prevention, detection, and response of our nation. Capacity built and sustained in health departments with jurisdictional authority for public health helps prevent disease through better surveillance of known and emerging infectious diseases, which leads to more rapid response to disease outbreaks and better development, implementation and evaluation of public health interventions.

The ELC program targets partnerships with states, and some of the nation's largest local health departments, U.S. territories and affiliates because these governmental organizations are constitutionally empowered and are responsible for the protection of the health and welfare of their respective communities. Governmental public health agencies execute this responsibility through their unique access to health information, laboratory samples, and their legal powers to investigate diseases through interactions with patients, the health care system, other governmental agencies (e.g., environmental agencies, emergency response agencies), and the law enforcement abilities of state and local government. In addition to these legal authorities, eligible applicants must have functional infectious disease detection, prevention, and control programs; and already existing public health outbreak response infrastructure and capacity. Established capacity and infrastructure to detect, prevent and control infectious disease outbreaks are critical requirements, to enable recipients to act expeditiously to implement the activities in this cooperative agreement.

Since 2012, under CK12-1201 the ELC has supported public health capacity building activities in all US states, 6 of the largest locals (Chicago, District of Columbia, Houston, Los Angeles County, New York City, Philadelphia) and all of our US territories and affiliates in the Caribbean and Pacific (American Samoa, Commonwealth of the Northern Mariana Islands, Federated States of Micronesia, Guam, Puerto Rico, Republic of the Marshall Islands, Republic of Palau, US Virgin Islands). State recipients are required to document their partnerships and support for local health departments that are not receiving federal funds directly, and award amounts to states take into account the needs of the local jurisdictions

within the state. For local jurisdictions, these health departments represent the largest population centers and align with related public health programs, including the Public Health Emergency Preparedness (PHEP) program and the Public Health Crisis Response cooperative agreement. By aligning these three programs, local jurisdictions can best leverage existing capacities and coordinate efforts both for public health emergencies and for ongoing infectious disease response efforts. These governmental entities continue to be critical partners to respond to infectious disease threats across the nation. Under CK12-1201, ELC recipients were required to build local infrastructure for the coordination of all future ELC-funded programs. The infrastructure and relationships built in funded jurisdictions through ELC since 2012 are a critical prerequisite to the achievement of program goals, to sound fiscal stewardship, and to maximize the benefit to the Nation's public health in 2019-2024.

The ELC is approved to limit eligibility for CK19-1904 to only those governmental public health agencies previously funded to ensure successful progress in meeting ELC program outcomes. There are significant programmatic needs, which only the prior-funded 64 jurisdictions have the legal authorities, intergovernmental relationships, and capacity for adequately addressing. Should this request to limit eligibility not be approved, the intended outcomes under the ELC Cooperative Agreement, CK19-1904, are at significant risk of not being completed due to entrance of additional site that lack the responsibilities, authorities, and technical capability necessary to be successful. Such an outcome would jeopardize the nation's system for responding to infectious disease threats.

4. Cost Sharing or Matching

No. Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

a. Data Universal Numbering System:

All applicant organizations must obtain a Data Universal Numbering System (DUNS) number. A DUNS number is a unique nine-digit identification number provided by Dun & Bradstreet (D&B). It will be used as the Universal Identifier when applying for federal awards or cooperative agreements. The applicant organization may request a DUNS number by telephone at 1-866-705-5711 (toll free) or internet at http://fedgov.dnb.com/webform/displayHomePage.do. The DUNS number will be provided at no charge.

If funds are awarded to an applicant organization that includes sub-recipients, those sub-recipients must provide their DUNS numbers before accepting any funds.

b. System for Award Management (SAM):
The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as an recipient. All applicant organizations must register with SAM, and will be assigned a SAM number. All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at *www.SAM.gov.*

c. Grants.gov:
The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov. All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	Data Universal Number System (DUNS)	1. Click on http://fedgov.dnb.com/webform 2. Select Begin DUNS search/request process 3. Select your country or territory and follow the instructions to obtain your DUNS 9-digit # 4. Request appropriate staff member(s) to obtain DUNS number, verify & update information under DUNS number	1-2 Business Days	To confirm that you have been issued a new DUNS number check online at (http://fedgov.dnb.com/webform) or call 1-866-705-5711
2	System for Award Management (SAM) formerly Central Contractor Registration (CCR)	1. Retrieve organizations DUNS number 2. Go to www.sam.gov and designate an E-Biz POC (note CCR username will not work in SAM and you will need to have an active SAM account before you can register on grants.gov)	3-5 Business Days but up to 2 weeks and must be renewed once a year	For SAM Customer Service Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220

3	Grants.gov	1. Set up an individual account in Grants.gov using organization new DUNS number to become an authorized organization representative (AOR) 2. Once the account is set up the E-BIZ POC will be notified via email 3. Log into grants.gov using the password the E-BIZ POC received and create new password 4. This authorizes the AOR to submit applications on behalf of the organization	Same day but can take 8 weeks to be fully registered and approved in the system (note, applicants MUST obtain a DUNS number and SAM account before applying on grants.gov)	Register early! Log into grants.gov and check AOR status until it shows you have been approved

2. Request Application Package

Applicants may access the application package at www.grants.gov.

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov. If Internet access is not available, or if the online forms cannot be accessed, applicants may call the CDC OGS staff at 770-488-2700 or e-mail OGS ogstims@cdc.gov for assistance. Persons with hearing loss may access CDC telecommunications at TTY 1-888-232-6348.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed or postmarked by)

N/A

b. Application Deadline

Applications are due on May 10, 2019, 11:59 p.m. Eastern Standard Time, on www.grants.gov

An informational call will be held approximately two weeks after posting. The date and time for this call is March 14, 2019 at 3:00 p.m.

Dial-in number: (773) 756-0169 (toll) or (800) 857-4945 (toll free)
Passcode: 3092790

5. CDC Assurances and Certifications

All applicants are required to sign and submit "Assurances and Certifications" documents indicated at http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjjmaa))/Homepage.aspx.

Applicants may follow either of the following processes:

- Complete the applicable assurances and certifications with each application submission, name the file "Assurances and Certifications" and upload it as a PDF file with at www.grants.gov
- Complete the applicable assurances and certifications and submit them directly to CDC on an annual basis at http://wwwn.cdc.gov/grantassurances/(S(mj444mxct51lnrv1hljjjmaa))/Homepage.aspx

Assurances and certifications submitted directly to CDC will be kept on file for one year and will apply to all applications (ELC or others) submitted to CDC by the applicant within one year of the submission date.

Risk Assessment Questionnaire Requirement

CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR 75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.

CDC requires all applicants to complete the CDC Risk Questionnaire, OMB Control Number 0920-1132 annually. The questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts

Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g.. equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

LOI is not requested or required as part of the application for this NOFO.

8. Table of Contents

There is no page limit. The table of contents is not included in the project narrative page limit.

9. Project Abstract Summary

(Maximum 1 page)

A Project Abstract is not required for submission of the application.

10. Project Narrative

2019 ELC Project Narrative Guidance:

The ELC application must be written according to the following outline. The entire application should contain a single, overarching 'Background & Overview' (see sections a. i-iv in this section below, for more detail). Applications must include a Project Approach for each ELC program and project applied for that includes a problem statement, justification, and applicant capacity (see section b in this section below, for more detail). Each Project Approach must be succinct, easily understood, and in the order outlined in this section, which will be reflected in the application template tools distributed by ELC. The Project Approaches must address outcomes and activities to be conducted over the next budget period,

but should also address the entire period of performance as identified in Part III, Section B. Program and Project Detailed Guidance Attachments.
ELC highly recommends recipients use the application template tools provided by ELC for NOFO submission. These tools will capture all required information for each ELC program and project and will be distributed to applicants at the time this NOFO is published.

a. Background & Overview (Only one per application)**:** Applicants must provide a description of relevant background information that includes the context of the problem. Specifically:

i. **Jurisdictional Overview and Main Challenges**: Provide information on the jurisdiction's population size, demographic characteristics, and morbidity and mortality related to infectious diseases (e.g., priority infectious diseases in the jurisdiction).

ii. **Structure and Organization:** Provide an overview of the structure of jurisdiction's health department (e.g. centralized, decentralized, hybrid) and where leadership involved in this ELC Cooperative Agreement reside within the health department's structure and describe the current process for supporting local public health concerns (including tribal governments within the jurisdiction, if applicable) and associated health departments. Next, describe challenges or limitations expected across organizational (especially as it relates to the integration of epidemiology, laboratory and health IT), fiscal, administrative, and/or programmatic areas in the jurisdiction. Also include measures to overcome these challenges, to achieve full implementation of the activities proposed in this application. This could include references to resources being requested through ELC's new "Leadership, Management and Administration" project. Describe plans to ensure adequate planning and implementation of activities (e.g., hiring, contracting, procurement, collaborations, etc.) are quickly executed with rigorous tracking and oversight to avoid delays and reduce the potential for unobligated funds remaining at the end of the budget and period of performance.

iii. **ELC Program Leadership, Governance, Integration, and Tracking and Reporting:**

i. **ELC Governance Team:** Each recipient shall maintain an active ELC Governance Team that consists of three individuals who have leadership roles for the health department in epidemiology, laboratory, and health information systems (i.e., one person representing each area); plus the Principal Investigator (PI) if the PI is someone other than one of the three above individuals (the Team thus will include 3 or 4 persons). Persons appointed to the Governance Team should have authority over their respective areas (e.g., the State Laboratory Director, State Epidemiologist, IT/Informatics Director or persons specifically designated and empowered by these authorities). The required role of this Team is to work together to assure sufficient and appropriate oversight and integration of epidemiology, laboratory, and health information systems in the jurisdiction's ELC planning and implementation.

For this section of the Background narrative:

1. List the ELC Governance Team members, including name, position/title, and contact information.
2. Provide as an attachment to this application, Statement of the ELC Governance Team, signed by all Governance Team members, explicitly stating their agreement to serve on the Team and confirming their understanding and support of the overall content of the application.

ii. Epidemiology, laboratory and health information systems integration. For the FY 2019-2023 period of performance, provide a plan to document efforts to maintain and/or strengthen epidemiology, laboratory and health information systems integration. Include a clear description of the process for engaging the jurisdiction's ELC Governance Team during the course of the ELC period of performance for general oversight, planning, review and agreement on annual continuation applications, review and agreement on significant ELC process actions such as carryover, redirection, and supplemental requests, etc. This should include periodic regular meetings of the Governance Team to discuss ELC plans, activities, awards, progress report, evaluation and performance measures, etc. Strong applications will include the shared decision-making process of the ELC Governance Team. Plan to make the Governance Team available for quarterly conference calls with CDC ELC staff.

iv. **Local engagement:** CDC's ELC Cooperative Agreement depends upon health departments working with local stakeholders to meet local needs and for larger health departments to request resources for other health departments within their jurisdiction. In this section, please describe the engagement with local health departments that will assist in achieving goals described earlier in this narrative (including tribal governments within the jurisdiction, as applicable). This discussion should include information on how collaboration between the state health department and the local health departments will help assess and mitigate gaps; including needs related to financial and technical assistance available from ELC that could be requested for the local health department by the state.

v. **Programs/Projects:** List of the Program/Project component activities being addressed in the application.

vi. **Success Stories**: Please provide stories, using the ELC Success Story template available on REDCap, to capture recent accomplishments that highlight the impact of the ELC Cooperative Agreement in the jurisdiction. They will be used to educate stakeholders, decision makers, and policymakers about the impact of ELC.

vii. **DMP**: A Data Management Plans (DMP) is required if the NOFO involves the collection or generation of public health data. The goal of the policy is to ensure public access to federally funded public health data. This specifically requires the development of DMPs for ELC activities that includes collection of public health data. One overall DMP is requested per application. DMPs should be as complete as possible but CDC can work jointly with ELC recipients within the first 6

months after award to finalize them. They can be updated as appropriate throughout the life cycle of the data.

b. Project Approach (for each ELC Program or Project):

i. **Problem Statement:** Applicants must describe core information around the needs of the jurisdiction or populations being served relative to the specific ELC program or project. The core information must help reviewers understand how the applicant's response to the NOFO will address the public health problem and support public health priorities (See Part III, Section B. Program and Project Detailed Guidance Attachments).

ii. **Justification:** Explain the importance of the proposed activities, including why its implementation would address specific gaps mentioned in the 'Problem Statement,' and advance and/or improve public health in the jurisdiction. For each ELC program or project applied for, applicants must provide a clear and concise description of the strategic approach they will to use to achieve the period of performance outcomes.

iii. **Applicant Capacity:** Describe the current resources, processes, and steps planned to implement this activity and achieve expected milestones.

- **Current Capacity:** For each program or project component applied, address the recipient's current capacity to successfully implement the proposed strategies and activities. If the recipient was funded for a project component in previous funding periods, capacities attained during these periods (including describing staff and other infrastructure already in place that will be built upon) should be reported.
- **Major Achievements:**
  - Describe major activities conducted in past periods of performance, the progress of those activities, and significant milestones accomplished as a result of those activities.
  - If applicable, describe any barriers encountered, and how the barriers were addressed during implementation of these activities.

iv. **Evaluation Plan for 2019:** If needed, ELC will work with recipients during the first six months of the period of performance to finalize an evaluation and performance measurement plan to monitor the progress of the activities implemented and outcomes achieved.

Applicants must provide an overall recipient evaluation and performance measurement plan for each program/project. This plan must address the following points:

- Identify key program staff who will participate in collecting and reporting performance measurement data.
- Demonstrates experience and capacity to implement the evaluation plan.
- Describe your plans and ability to collect data and report on the performance measures listed in the 2019 Notice of Funding Opportunity.

- Discuss how you and your program staff will use (e.g., to inform program improvement, identify gaps, program management, etc.) and share performance measurement data collected.
- If applicable: Discuss any barriers or challenges expected for collecting data (i.e., responding to performance measures), and reporting on results. Describe how these potential barriers would be overcome. In addition, applicants may also describe other measures to be developed or additional data sources and data collection methods that applicants will use to evaluate their activities and outcomes.

c. Work Plan (comprised of an implementation plan for each activity in ELC Program or Project)

The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement. Applicants should include the following detail on implementation plans for each ELC program or project activity:

i. **Purpose:** Describe in 2-3 sentences specifically how the work plan will address the problem as described in the component program's or project's 'Problem Statement.'

ii. **Outcomes:** Clearly identify the expected outcomes to be achieved by the end of the period of performance. Refer to outcomes listed in the component program's or project's 'Outcomes' section. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (i.e., increase, decrease, maintain, complete) (see Overall Roadmap in Part II, 2. CDC Project Description a. Approach). In addition to the period of performance outcomes required by CDC, applicants should include any additional outcomes they anticipate.

iii. **Milestones:** For each ELC program or project applied for, applicants must provide a clear and concise description of the period of performance milestones. Briefly introduce the activity(ies) being proposed and describe what the expected outputs (e.g., milestones) and outcomes will be over the first 12-month budget period. Also provide a brief discussion of what will be achieved (i.e., expected outputs and outcomes) over the entire five-year period of performance (see Part III, Section B. Program and Project Detailed Guidance Attachments). Finally, include a Work Plan (described in detail below Section D. Application and Submission Information; Section 11: Work Plan)

iv. **If applicable, describe collaborations** with programs and organizations either internal or external to CDC and describe the extent to which the strategies and activities will target specific population(s) in their jurisdiction.

d. Budget Narrative (One for each ELC Program and Project)

Applicants must submit a discrete and separate itemized budget and budget narrative for each ELC program or project they are applying for. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and

consistent with the purpose, outcomes, and program strategy outlined in the project narrative.
Be sure to consider and include requests for travel that are required for proposed activities. Please include travel for ELC Governance Team members and a financial representative to the ELC Annual Meeting. Travel that is approved and funded by CDC will be considered a required activity. The budget must include:

- Salaries and wages
- Fringe benefits
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

For guidance on completing a detailed budget, see Budget Preparation Guidelines at: https://www.cdc.gov/grants/documents/Budget-Preparation-Guidance.pdf

Applicants must submit a Budget Summary. Please name this file "Budget Narrative Summary" and upload it as a PDF file at www.grants.gov. A detailed Budget request and accompanying justification should be submitted using the ELC template. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect cost rate is a provisional rate, the agreement must have been made less than 12 months earlier. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

1. Collaborations
Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the collaboration requirements as described in Part III, Section B. Program and Project Detailed Guidance Attachments.

2. Target Populations and Health Disparities
Applicants must describe the specific target population(s) in their jurisdiction and explain how activities will achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program. Applicants must address specific Target Populations and Health Disparities requirements described in Part III, Section B. Program and Project Detailed Guidance Attachments.

c. Applicant Evaluation and Performance Measurement Plan
Performance measures for each program or project are included in Part III, Section B. Program and Project Detailed Guidance Attachments.

- The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see http://www.hhs.gov/ocio/policy/collection/.

11. Work Plan

The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement. See Part II, Section D. 10 Project Narratives, above, for more detail on Work Plan requirements for each activity within ELC Programs and Projects.

12. Budget Narrative

Applicants must submit a discrete and separate itemized budget and budget narrative for each ELC project they are applying for. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. See Part II, Section D. 10 Project Narratives, above, for more detail on Budget Narrative requirements for each ELC Program and Project.

13. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds.

Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded. Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 2 CFR 200 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.

- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

14. Intergovernmental Review

The application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order 12372, which established a system for state and local intergovernmental review of proposed federal assistance applications. Applicants should inform their state single point of contact (SPOC) as early as possible that they are applying prospectively for federal assistance and request instructions on the state's process. The current SPOC list is available: https://www.whitehouse.gov/wp-content/uploads/2017/11/SPOC-Feb.-2018.pdf

15. Pilot Program for Enhancement of Employee Whistleblower Protections

Pilot Program for Enhancement of Employee Whistleblower Protections: All applicants will be subject to a term and condition that applies the terms of 48 Code of Federal Regulations (CFR) section 3.908 to the award and requires that recipients inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

16. Copyright Interests Provisions

This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

17. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient. These requests are reviewed by the Grants Specialist on a case-by-case basis.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
    - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
    - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See Additional Requirement (AR) 12 for detailed guidance on this prohibition and additional guidance on lobbying for CDC recipients.
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.
- In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).

18. Data Management Plan

An overall Data Management Plan (DMP) is required for each recipient. Funds provided under this cooperative agreement may be used to support activities that assure compliance with CDC's DMP. A DMP is required if the NOFO involves the collection or generation of public health data. The goal of the policy is to ensure public access to federally funded public health data. This specifically requires the development of DMPs for ELC activities that includes collection of public health data. DMPs should be

as complete as possible but CDC can work jointly with ELC recipients within the first 6 months after award to finalize them.

They can be updated as appropriate throughout the life cycle of the data. DMPs should include:

- Descriptions of the data to be produced
- How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
- Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represents, and potential limitations for use
- Plans for archival and long-term preservation of the data, or explanation of why long-term preservation and access cannot be provided.

The DMP may be submitted as a checklist, paragraph, or other format, as currently, HHS/CDC does not have a standardized DMP template or checklist due to PRA requirements. However, below are DMP examples that applicants can refer to as they develop their DMP:

- University of California: http://dmp.cdlib.org/
- USGS: http://www.usgs.gov/datamanagement/plan/dmplans.php
- ICPSR:http://www.icpsr.umich.edu/icpsrweb/content/datamanagement/dmp/plan.html

19. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. All application attachments must be submitted to www.grants.gov using a PDF file format. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option. Courtesy copies of the completed application templates should be uploaded into each respective recipient's ELC REDCap workspace.

If Internet access is not available or if the forms cannot be accessed online, applicants may contact the OGS TIMS staff at 770- 488-2700 or by e-mail at ogstims@cdc.gov, Monday through Friday, 7:30 a.m.–4:30 p.m., except federal holidays. Electronic applications will be considered successful if they are available to OGS TIMS staff for processing from www.grants.gov on the deadline date.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be

generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or the Grants.gov Online User Guide.

http://www.grants.gov/help/html/help/index.htm?callingApp=custom#t=Get_Started%2FGet_Started.htm

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: Paper submissions will not be accepted. If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit an electronic copy of the application Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Applications submitted using this method will not be considered without prior GMS/GMO approval.

If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application.

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by CDC Office of Grants Services. Complete applications will be reviewed for responsiveness by the Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

An objective merit review utilizing subject matter experts (SMEs) will be conducted to evaluate complete and responsive applications according to the criteria listed in the three broad sections below. At minimum, the review will be conducted by program staff in the National Center for Zoonotic and Emerging Infectious Diseases (NCEZID), the National Center for Immunization and Respiratory Diseases (NCIRD), and the Center for Surveillance, Epidemiology and Laboratory Services (CSELS).

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

i. Background	Maximum Points:

Background and overview (one for entire ELC application)
 	
• Fully describes (see section D. 10. Project Narrative for more detail):
  o Jurisdictional overview
  o Structure and organization
  o ELC Program Leadership, Governance, Integration, and Tracking and Reporting.
  o Local engagement
  o List of programs/projects applied for
  o Impact communicated in success stories
  o Data management plan (DMP)
• Provides plan to document efforts to maintain and/or strengthen epidemiology, laboratory and health information systems integration.
• Clear description of process to engage the recipient's ELC Governance Team during the course of the ELC period of performance for general oversight, planning, review and agreement on annual continuation applications, review and agreement on significant ELC process actions
	15 points

i. Approach	Maximum Points:
Project approach and work plan (one for each ELC Program or Project) • Fully describes (see section D. 10. Project Narrative for more detail): o Problem statement	40 points

- Justification
- Work plan (comprised of an implementation plan for each activity in ELC Program or Project)

- Presents outcomes that are consistent with the period of performance outcomes described in the CDC Project Description and Roadmap.
- Describes an overall strategy and activities consistent with the CDC Project Description and ELC Overall Roadmap.
- Describes strategies and activities that are achievable, appropriate to achieve the outcomes of the project, and evidence-based (to the degree practicable).
- Shows that the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the period of performance outcomes.
- Presents a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC.

ii. Evaluation and Performance Measurement	Maximum Points:

Evaluation and Performance Measurement Plan (one for each ELC Program or Project) 20 points

- Identify key program staff who will participate in collecting and reporting performance measurement data.
- Demonstrates experience and capacity to implement the evaluation plan.
- Describe your plans and ability to collect data and report on the performance measures listed in the 2019 Notice of Funding Opportunity.
- Discuss how you and your program staff will use (e.g., to inform program improvement, identify gaps, program management, etc.) and share performance measurement data collected.
- If applicable: Discuss any barriers or challenges expected for collecting data (i.e., responding to performance measures), and reporting on results. Describe how these potential barriers would be overcome. In addition, applicants may also describe other measures to be developed or additional data sources and data collection methods that applicants will use to evaluate their activities and outcomes.
- Measures developed are relevant and impactful for the specific program or project in this NOFO

iii. Applicant Capacity	Maximum Points:

Applicant capacity to implement approach (one for each ELC Program or Project) 25 points

- Describe the current resources, processes, and steps planned to implement this activity and achieve expected milestones

- Current Capacity: For each program or project component applied, address the recipient's current capacity to successfully implement the proposed strategies and activities. If the recipient was funded for a project component in previous funding periods, capacities attained during these periods (including describing staff and other infrastructure already in place that will be built upon) should be reported.
- Major Achievements:
    - Describe major activities conducted, the progress of those activities, and significant milestones accomplished as a result of those activities.
    - If applicable, describe any barriers encountered, and how the barriers were addressed during implementation of these activities

Budget

(not scored)

When reviewing budgets, CDC programs must assess whether the budget aligns with the proposed work plan. For additional guidance, check with the CIO extramural program office, GMO, or GMS.

c. Phase III Review

Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;

(2) Quality of management systems and ability to meet the management standards prescribed in this part;

(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;

(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and

(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

2. Announcement and Anticipated Award Dates

Awards will be communicated by the CDC Office of Grants Services via official Notice of Award to be released no later than August 1, 2019.

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed in application and the Program Director.

Any applicant awarded funds in response to this NOFO will be subject to the DUNS, SAM Registration, and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt or by U.S. mail.

2. Administrative and National Policy Requirements

Recipients must comply with the administrative and public policy requirements outlined in 45 CFR Part 75 and the HHS Grants Policy Statement, as appropriate. Brief descriptions of relevant provisions are available at http://www.cdcgov/grants/additionalrequirements/index.html#ui-id-17.

The HHS Grants Policy Statement is available at http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. CDC programs must indicate which ARs are relevant to the NOFO. All NOFOs from the Center for Global Health must include AR-35. The ARs are listed in the Template for CDC programs. Recipients must then comply with the ARs listed in the NOFO. Do not include any ARs that do not apply to this NOFO. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.

The following Administrative Requirements (AR) apply to this project:
Generally applicable ARs:

- AR-7: Executive Order 12372
- AR-9: Paperwork Reduction Act
- AR-10: Smoke-Free Workplace
- AR-11: Healthy People 2010
- AR-12: Lobbying Restrictions
- AR-14: Accounting System Requirements
- AR-24: Health Insurance Portability and Accountability Act
- AR-25: Release and Sharing of Data
- AR-29: Compliance with EO13513, “Federal Leadership on Reducing Text Messaging while Driving,” October 1, 2009
- AR-30: Compliance with Section 508 of the Rehabilitation Act of 1973
- AR-33: Plain Writing Act of 2010
- AR-34: Patient Protection and Affordable Care Act (e.g., a tobacco-free campus policy and a lactation policy consistent with S4207)

For more information on the C.F.R., visit the National Archives and Records Administration at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.

The full text of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards 45 CFR 75, can be found at https://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75.

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the period of performance. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;
- Provides CDC with periodic data to monitor recipient progress toward meeting the NOFO outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the "Agency Contacts" section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	APR is submitted as a part of the continuation application.	Yes
Data on Performance Measures	See Attachments	Yes
Federal Financial Reporting Forms	Interim FFR (or equivalent) reporting of projected unobligated at the end of the budget period is due at the time of the continuation application. Annual FFR due 90 days after the end of the budget period	Yes
Final Performance and Financial Report	90 days after end of period of performance	Yes

Payment Management System (PMS) Reporting	Quarterly reports due January 30; April 30; July 30; and October 30	Yes

a. Recipient Evaluation and Performance Measurement Plan (required)
With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient's monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement:

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.
- How performance measurement will yield findings to demonstrate progress towards achieving
- NOFO goals (e.g., reaching target populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

Evaluation:

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publicly available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- • How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The recipient must submit the APR along with the continuation application www.grantsolutions.gov. Performance measures will be collected per schedules set in the specific program or project areas (see Attachments).

Topics typically covered in this report include but are not limited to:

- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
    - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the Roadmap and work plan.
    - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
    - Recipients must describe success stories.
- **Challenges**
    - Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
    - Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**
    - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.
- **Administrative Reporting** (No page limit)
    - SF-424A Budget Information-Non-Construction Programs. The section Estimated Unobligated Funds should be completed (and all unliquidated obligations projected).
    - Budget Narrative – Must include the content outlined in "Content and Form of Application Submission, Budget Narrative" section. The ELC Budget template should be utilized for the submission of the Budget and accompanying Budget Narrative.
    - Indirect Cost Rate Agreement.

The recipients must submit the Annual Performance Report via www.grantsolutions.gov along with the application for continuation funding. Recipients must report on performance measures for each budget period and update measures, if needed. Measures should be reported upon per the frequency outlined in each program or project description (see Attachments). ELC application and performance measure templates should be used where directed to ensure clear communication of report information.

c. Performance Measure Reporting (required)

CDC Programs and Projects may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC Programs and Projects will collect this information directly, and will specify reporting frequency, data fields, format, and submission information for recipients, at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)

Beginning in budget period 2, an interim FFR (or approved equivalent) that illustrates the projected amount of unobligated funds at the end of the budget period is required to be submitted with the continuation application. The annual FFR form (SF-425) is required and must be submitted no later than 90 days after the end of the budget period. The report must include only those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds, and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) cash transaction data. Failure to submit the required information by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

This report is due 90 days after the end of the period of performance. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.
- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the period of performance, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252 requires full disclosure of all entities and organizations receiving Federal funds including awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, http://www.USASpending.gov.

Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over $25,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf
- https://www.fsrs.gov/documents/ffata_legislation_110_252.pdf
- http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA

G. Agency Contacts

CDC encourages inquiries concerning this NOFO.

Program Office Contact

For **programmatic technical assistance,** contact:

Angelica O'Connor, ELC Program Coordinator
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Atlanta, GA 30333
Telephone: 404.639.7379
Email: AMOConnor@cdc.gov

Grants Staff Contact

For **financial, awards management, or budget assistance**, contact:

Shirley Byrd, Lead Grants Management Specialist
CDC Grants Services Office
2920 Brandywine Road, MS
Atlanta, GA 30341
Telephone: 770.488.2591
Email: SKByrd@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

For all other **submission** questions, contact:
Technical Information Management Section

Department of Health and Human Services
CDC Office of Financial Resources
Office of Grants Services
2920 Brandywine Road, MS E-14
Atlanta, GA 30341
Telephone: 770-488-2700
E-mail: ogstims@cdc.gov

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments applicants can upload as PDF files as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- CDC Assurances and Certifications
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission
- For international NOFOs:
- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC Programs and Projects.

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements

AR: Antibiotic resistance

(ARs): Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO.

To view brief descriptions of relevant provisions, see http://www.cdc.gov/grants/additionalrequirements/index.html. Note that 2 CFR 200 supersedes the

administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assistance Listings (CFDA): A government-wide compendium published by the General Services Administration (available on-line in searchable format as well as in printable format as a .pdf file) that describes domestic assistance programs administered by the Federal Government.

Assistance Listings (CFDA) Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the period of performance. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

CDC Assurances and Certifications: Standard government-wide grant application forms.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the "life" of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. http://www.cdc.gov/grants/additionalrequirements/index.html.

DUNS: The Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is a nine-digit number assigned by Dun and Bradstreet Information Services. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a DUNS number as the Universal Identifier. DUNS number assignment is free. If requested by telephone, a DUNS number will be provided immediately at no charge. If requested via the Internet, obtaining a DUNS number may take one to two days at no charge. If an organization does not know its DUNS number or needs to register for one, visit Dun & Bradstreet at http://fedgov.dnb.com/webform/displayHomePage.do.

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation;

technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Differences in health outcomes and their determinants among segments of the population as defined by social, demographic, environmental, or geographic category.

Health Equity: Striving for the highest possible standard of health for all people and giving special attention to the needs of those at greatest risk of poor health, based on social conditions.

Health Inequities: Systematic, unfair, and avoidable differences in health outcomes and their determinants between segments of the population, such as by socioeconomic status (SES), demographics, or geography.

Healthy People 2020: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: Both the meaningful involvement of a community's members in all stages of the program process and the maximum involvement of the target population that the intervention will benefit. Inclusion ensures that the views, perspectives, and needs of affected communities, care providers, and key partners are considered.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Intergovernmental Review: Executive Order 12372 governs applications subject to Intergovernmental Review of Federal Programs. This order sets up a system for state and local governmental review of proposed federal assistance applications. Contact the state single point of contact (SPOC) to alert the SPOC to prospective applications and to receive instructions on the State's process. Visit the following web address to get the current SPOC list: https://www.whitehouse.gov/wp-content/uploads/2017/11/Intergovernmental_-Review-_SPOC_01_2018_OFFM.pdf

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results. In this NOFO, the logic model is referred to as Overall Roadmap.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA): Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations

of the organization. Nonprofit organizations include institutions of higher educations, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Overall Roadmap: See "Logic Model," for the purposes of this NOFO.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A "program" may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of Performance – formerly known as the project period: The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the period of performance.

Plain Writing Act of 2010: Plain Writing Act of 2010, Public Law 111-274 requires federal agencies to communicate with the public in plain language to make information more accessible and understandable by intended users, especially people with limited health literacy skills or limited English proficiency. The Plain Writing Act is available at www.plainlanguage.gov.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Period of performance - formerly known as the project period: The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award

Period of performance Outcome: An outcome that will occur by the end of the NOFO's funding period.

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation http://www.phaboard.org.

Social Determinants of Health: Conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.

Part III. Program and Project Attachments

A. Program and Project Summaries with Tiered Activities

In this NOFO Programs and Projects have outlined a path to meet minimum expectations, expand or enhance these capacities, and even provide leadership amongst other jurisdictions. This section provides a summary activity table for each program and project, organizing the activities within the following three tiers:

Tier 1: Core Activities

Tier 2: Enhanced or Expanded Activities

Tier 3: Advanced or Regional Activities

Section I: Cross-cutting Emerging Infectious Disease Capacity, Systems, and Leadership

A: Cross-Cutting Epidemiology and Laboratory Capacity

Tier 1: Core Required Activities

- Conduct needs assessments to identify gaps and/or training needs in epidemiology and laboratory activities
- Develop and implement a training plan based on the findings from the needs assessment.
- Enhance skills and maintain pace with novel laboratory and epidemiology techniques by participating in trainings or creating training opportunities for professional development (e.g., forums, seminars, workshops) for staff
- Lead/assist in timely response to outbreak investigations
- Plan for/address surge capacity needs during outbreaks (e.g., establishing investigation teams and/or student workforce or cross training staff)
- Develop, maintain and evaluate the use of communication protocols or guidelines for outbreak response and management
- Develop, implement, review and maintain a plan or strategy for the optimal use of lab supplies and equipment that addresses flexible, changing, and multi-disease purpose needs.
- Collaborate with clinical/private labs for surge, continuity of operations and CIDT issues.

Tier 2: Enhanced or Expanded Activities

- Peer-to-Peer: Visit another ELC jurisdiction to facilitate knowledge sharing
- Implement advanced technologies (e.g., AMD, SaTScans, GIS) for more thorough and accurate detection of infectious diseases
- Improve use of surveillance data by implementing innovative methodologies (e.g., SaTScans , GIS, etc.)
- Improve coordination and exchange of surveillance data with other jurisdictions and partners
- Improve lab throughput, efficiency and proficiency by incorporating use of novel techniques for detection to expand capabilities and improve laboratory throughput, efficiency and proficiency
- Use analytical methods to enhance laboratory operational planning (e.g. Collecting and compiling data on resources needed for processing laboratory samples and estimating the cost/quantify the costs required for processing specimens in different scenarios, using throughput and network models to understand and plan for surge)
- AMD Training Participant
- Implement evidence-based prevention tools and/or interventions (e.g., policy, engineering, service delivery, education, and/or communication campaigns) to achieve improved prevention practices and reduction of disease
- Improve use and/or review of surveillance data for prevention and response (e.g. identifying risk populations to drive interventions, data quality checks, more robust analysis)
- Conduct process and/or outcome evaluations of tools and/or interventions to understand whether intended outcomes and/or effects were achieved and identify opportunities for improvement
- Foster collaboration among city, county, state and federal partners (e.g., workgroups) and other external partners for the purpose of improving outbreak response and management
- Develop communication tools such as public websites that disseminate information regarding emerging and re-emerging disease threats

Tier 3: Advanced or Regional Activities

- Develop and enhance regional laboratory networks for service sharing
- AMD Training Lead
- AMD Regional Bioinformatics

B: ELC Leadership, Management and Administration

Tier 1: Core Required Activities

- Manage ELC activities across all ELC programs and projects
- Actively plan, coordinate and implement ELC activities across epidemiology, laboratory and health informatics interests at health department and within jurisdiction
- Manage financial aspects of ELC Cooperative Agreements, including resource tracking and spending

C: Health Information Systems Capacity

Tier 1: Core Required Activities

- Manage ELC activities across all ELC programs and projects.
- Actively plan, coordinate and implement ELC activities across epidemiology, laboratory and health informatics interests at health department and within jurisdiction.
- Manage financial aspects of ELC Cooperative Agreements, including resource tracking and spending.

Tier 2: Enhanced or Expanded Activities

- Advance electronic data exchange for Public Health Laboratories.
- Advance electronic information exchange between electronic health records and public health.
- Advance electronic information exchange between jurisdictions.
- Collect and use syndromic surveillance data to validate and monitor harmful effects of exposures to diseases and hazardous conditions.
- Implement (if appropriate) new/replacement information systems.
- Enhance existing information system(s) by adding or improving functionality.
- Implement additional innovative enhancements that improve analysis, enable lab-epi collaboration, or increase the sustainability or efficiency of systems.
- Increase HIS capacity to support Advanced Molecular Detection (AMD) activities.

D: Impact and Evaluation

Tier 1: Core Required Activities

- Conduct cost-effectiveness and/or public health impact evaluations (in coordination with CDC) associated with ELC-funded activities.

E: Cross-Cutting Emerging Issues: Enhanced Surveillance, Outbreak Investigation Response and Reporting, Surge Efforts and Interventions

Tier 2: Enhanced or Expanded Activities

- Depending upon current baseline capacity, conduct specimen collection, shipping, case/contact/control interviews and medical record review, and transmit results to CDC to enhance the ability to rapidly respond to outbreaks.

- Depending upon current baseline capacity, enhance the ability of the laboratory to rapidly respond to outbreaks.
- Depending upon current baseline capacity, enhance the ability of the health information system to rapidly respond to outbreaks.

Section II: Emerging Infectious Disease Programs

F: Foodborne, Waterborne, Enteric, and Environmentally Transmitted Diseases: Surveillance, Detection, Response, Reporting, and Prevention

Tier 1: Core Required Activities

- CaliciNet
- National Antimicrobial Resistance Monitoring System (NARMS)
- National Case Surveillance
- National Outbreak Reporting System (NORS)
- OutbreakNet
- PulseNet

Tier 2: Enhanced or Expanded Activities

- CryptoNet and CryptoNet Regional Labs Activities
- *Cyclospora* Genotyping Activities
- FoodCORE Activities
- FoodNet Activities
- NoroSTAT Activities
- National Respiratory and Enteric Virus Surveillance System (NREVSS) Enhanced Activities
- Harmful Algal Bloom Surveillance, Response, and Mitigation
- OutbreakNet Enhanced Activities
- PulseNet Area Laboratories Activities

Tier 3: Advanced or Regional Activities

- Integrated Food Safety Centers of Excellence Activities

G: Healthcare-associated Infections and Antibiotic Resistance Program
G1: Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship and
G2: Antibiotic Resistance Laboratory Network (AR Lab Network)

Tier 1: Core Required Activities

Epidemiology:

- In collaboration with public health laboratories, provide technical expertise and support to clinical laboratories, infection prevention networks, and healthcare facilities.
- Conduct colonization screenings and continue until spread is controlled. Refer to CDC guidance to determine when colonization screening is recommended. Facilitate timely sharing of colonization screening results and incorporate findings in recommendations to affected healthcare facilities and providers.

- Provide technical expertise to healthcare facilities.
- Facilitate timely sharing of laboratory results and incorporate findings in recommendations to affected healthcare facilities and providers.
- Conduct onsite infection control assessments at facilities where targeted organisms or resistance mechanisms have been identified (i.e., as part of the containment described in Strategy I).
- Conduct onsite infection control assessments at facilities where outbreaks have occurred (i.e., as part of response efforts described in Strategy II).
- Provide continued assistance until infection control gaps have been addressed.
- Using elements and guidance provided by CDC, collaborate with public health labs (local, state, and regional) to develop coordinated work plans to improve coordination and information flow.
- Facilitate connections between facilities or clinical laboratories and public health labs to ensure appropriate isolates are forwarded to the regional AR laboratory for targeted surveillance activities
- Identify and use data sources to inform prevention and response activities.
- Identify and implement mechanisms to detect emerging MDROs within the jurisdiction (e.g., sentinel lab/facility surveillance) and to define local and regional epidemiology.
- Use data to inform the HAI advisory committee structure, membership, and priorities. (See Area C for additional guidance for the HAI advisory committee. This activity in Area A refers to how data are used to determine structure, membership, and priorities of the committee. Area C, Strategy IV refers to minimum expectations of the committee.)
- Conduct ongoing onsite assessments and gap mitigation in long length-of-stay, high-acuity facilities (e.g., skilled nursing facilities that provide ventilator care [vSNF], LTACHs) or others (e.g., dialysis facilities, outpatient facilities), based on identified needs (e.g., poor infection control practices), with the goal to improve infection control practices to reduce transmission of selected MDROs or reduce HAIs. Assessments will require direct observation.
- Facilitate core element implementation in designated settings. Core elements should be applied in the setting for which they were designed
- The HAI coordinator should assure HAI prevention through coordination throughout the jurisdiction (including for containment and response); epi-lab collaboration, including but not limited to coordination with the AR Lab Network regional lab, and use of the Targeted Assessment for Prevention; serve on the ELC governance team to monitor HAI program performance and spending; and serve as the primary point of contact for HAI communications with and reporting to CDC.
- The AR/AS expert should provide senior-level expertise (e.g., doctoral level or equivalent experience) in epidemiology and infection prevention with proficiency in AR/AS and data for action, as described in the detailed guidance below.
- Building upon work previously funded through the Ebola supplement, maintain and update as needed an inventory of all healthcare settings in the jurisdiction. Use this inventory to guide outreach for containment, response, and prevention activities.
- Provide education/training on infection control for healthcare facilities on prevention of HAIs and control of targeted MDROs.
- Providing training and support for local health departments in investigations in healthcare settings, control of targeted MDROs, and prevention of HAIs.

- Improve onsite assessment capacity by developing expertise in facility assessment designed to improve infection prevention and control in outpatient or high-acuity, post-acute care settings.
- Identify and engage with partners for prevention activities. Strong applications will define specific roles and responsibilities of the Recipient and those of the partners.
- *Jurisdictions with EIP catchment areas:* Establish plans to share data and findings related to surveillance activities and projects and outbreaks. Funding requests should be of sufficient detail to demonstrate there is no overlap with EIP-funded activities and that ELC funds will not be used for research purposes.
- Assign strategies, roles, and responsibilities of members.
- Update the HAI plan regularly.

Laboratory:

- Increase or sustain laboratory capacity to perform CLIA-compliant organism identification and carbapenemase production testing on Carbapenem-resistant Enterobacteriaceae (CRE), including at least *E. coli*, *Enterobacter*, and *Klebsiella*, and a proportion of Carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) isolates, as recommended by CDC.
- Increase or sustain laboratory capacity to perform CLIA-compliant carbapenem-resistance mechanism testing on CRE (at least *E. coli*, *Enterobacter*, *Klebsiella,* and *Citrobacter*) and a proportion of CRPA isolates for the most common and important resistance mechanisms (e.g., PCR detection of KPC, NDM, VIM, OXA-48-like OR Cepheid CARBA-R panel) as recommended and updated annually by CDC.
- Report testing results to submitting clinical laboratory within two working days of testing completion.
- Store bacterial isolates for a minimum of two years. Transport isolates of interest (as defined or specifically requested by CDC) to AR Lab Network regional lab and/or to CDC for further characterization or to CDC for deposit in a CDC repository.
- Submit data, at least monthly, to CDC via APHL Informatics Messaging Services platform (AIMS) or CDC-provided templates. Participate in data reconciliation confirmation of counts and data quality. Communicate any test results defined as an "alert" by CDC (e.g., novel or high-concern resistance), within one business day to CDC and the state/local HAI/AR epidemiologist(s).
- An AR lab expert should clearly demonstrate expertise in AR testing (particularly focused on AR Lab Network guidance) and data reporting for the jurisdiction
- Train and educate laboratorians and maintain adequate workforce to perform CRE and CRPA testing.
- Coordinate epidemiology and laboratory functions at state, city, county, and local levels, as well as with the AR Lab Network regional lab.
- Using elements and guidance provided by CDC, collaborate with ELC-funded HAI/AR programs to develop and regularly update coordinated work plans to improve communication and information flow that ensure timely detection and response to targeted resistance threats. The plan should include the list of prioritized antibiotic resistant organisms and mechanisms, based on the epidemiology of the jurisdiction. States that participate in the Emerging Infections Program Healthcare-Associated Infections-Community Interface Activity (EIP HAIC) should demonstrate efforts to enhance relationships and collaboration with EIP HAI/AR staff.
- Coordinate connections with clinical laboratories serving the state or jurisdiction to solicit CRE and CRPA isolates from healthcare facilities (including short- and long-term acute care facilities) with specific focus on laboratories that serve high risk settings as defined by or in coordination with CDC. Provide outreach and technical assistance to clinical microbiology laboratories to improve the detection of targeted organisms,

including timely submission and reporting of results. Guidance for targeting laboratories serving high risk settings will be provided by the CDC HAI/AR program.

- Facilitate coordinated connections with clinical laboratories in the state or jurisdiction to solicit isolates requested from the AR Lab Network regional lab for targeted surveillance activities (Tier 3, Strategy 1, Activity b) and for *Candida* activities (Tier 3, Strategy 1, Activity d).
- Develop testing and communication protocols, reporting processes, and IT infrastructure to ensure timely testing and reporting of results to submitting laboratories, state prevention epidemiologists, jurisdictional public health laboratories, and CDC.
- Work with APHL to implement or sustain reporting using APHL Informatics Messaging Services (AIMS) platform.

Tier 2: Enhanced or Expanded Activities

Epidemiology:

- Conduct data validation to inform prevention. Preference for funding will be given to Recipients that will conduct their own validation rather than contracting for services. Recipients are required to identify 2 HAIs that will be validated during a funding year and are encouraged to consider Dialysis Event validation and Long Term Care Facility HAI validation in addition to inpatient HAIs.
- Implement a targeted prevention project addressing MRSA BSIs or CDI, which involve transmission across facilities, based on data-identified need. The goal of this project is to reduce the burden of selected HAIs in facilities with high rates, through implementation of the TAP strategy or a Prevention Collaborative.
- Continue work with partners across settings for prevention of device- and procedure-associated infections (CAUTI, CLABSI, dialysis BSI, surgical site infection) through implementation of the TAP Strategy or other data-driven prevention project.
- Implement targeted project to improve antibiotic use.
- Implement, continue, or enhance an MDRO patient registry. The registry should tie to public health actions, enable tracking of the regional spread of MDROs, and fit into the overall surveillance and response strategy.

Laboratory:

- Increase or sustain laboratory capacity to perform CLIA-compliant routine confirmatory antibiotic susceptibility testing on CRE and a proportion of CRPA isolates, in accordance with CDC guidance. This testing would be in addition to the organism identification, carbapenemase production testing and carbapenem-resistance mechanism testing described under Tier 1.
- Increase or sustain scope of CRE testing to include at least *Citrobacter, Providencia, Proteus,* and *Serratia*, in addition to target genera described under Tier 1.
- Increase or sustain laboratory capacity to conduct reference identification of *Candida* spp. using MALDI-TOF or DNA-based methods.
- Up to five non-regional public health laboratories may be funded to perform coordinated by CDC to support epidemiologic investigations in their state. These labs must be able to demonstrate sequencing capacity and follow guidance and training recommendations put forth by CDC. Sequencing priorities would be set by CDC, in accordance with emerging threats and current WGS capacities. CDC will provide resources and bioinformatics support for analysis of WGS data.

Tier 3: Advanced or Regional Activities

Laboratory:

AR Lab Network regional laboratories

- In collaboration with CDC, provide CLIA-compliant organism identification, antibiotic susceptibility testing, carbapenemase production testing, and molecular detection of resistance mechanisms for new, unusual or emerging AR threats, including isolates suspected of carrying novel resistance mechanisms sent from state and local laboratories within the region.
- Perform targeted surveillance for emerging or changing AR threats (e.g. mobile colistin resistance or carbapenemase genes), as directed by CDC, using lab testing to fill gaps in detection and containment.
- Conduct reference identification and susceptibility testing of *Candida* spp. Regional laboratories will collect isolates from a diverse range of hospitals and other healthcare settings in their region to ensure wide surveillance coverage.
- Sustain/implement specimen storage and isolate transport per CDC guidance or upon request (e.g., isolates which harbor new or unusual resistance, a subset of isolates including representative isolates from outbreaks) for additional characterization and potential inclusion in CDC specimen repositories.
- Submit testing data at least monthly to CDC via APHL Informatics Messaging Services (AIMS) platform.
- Provide regional laboratory support for state-led epidemiologic investigations and HAI/AR prevention efforts focused on carbapenemase-producing organisms (CPOs) by performing molecular tests, including CDC-recommended commercial assay(s), to detect colonization for CPOs.
- At the direction of CDC, laboratories will perform *C. auris* colonization screening testing to support surveillance activities and outbreak investigations occurring within the region
- Implement or sustain CDC-directed reference antibiotic susceptibility testing to new antibiotic agents by broth microdilution (BMD) of pan-resistant or nearly pan-resistant bacteria.
- Perform whole genome sequencing for HAI/AR pathogens to support epidemiologic investigations in the region. Labs must be able to demonstrate sequencing capacity and follow CDC guidance and training recommendations. Sequencing priorities will be determined by CDC, in accordance with emerging threats and current WGS capacities. CDC will provide resources and bioinformatics support for analysis of WGS data.
- Demonstrate surge capacity. Accept specimens for testing from outside of the region when CDC determines that a public health need exists and alternative testing capacity is limited or unavailable.
- Report all colonization screening results to submitters within one day of testing completion. Report all targeted surveillance testing results at least monthly to submitting laboratories and the jurisdictional HAI programs. Submit colonization screening and targeted surveillance data at least monthly to CDC via APHL Informatics Messaging Services platform (AIMS). Participate in data reconciliation confirmation of counts and data quality.
- Train laboratory personnel to demonstrate competency and proficiency for performing all AR tests (available in their test directory.
- A regional epidemiologist should work closely with regional laboratory staff and state HAI/AR epidemiologists throughout the region to recruit and coordinate sample submissions and testing, and use of data for containment and prevention activities, using elements and guidance provided by CDC.
- In collaboration with CDC programs, establish a project plan and protocol for collection of specimens and/or isolates from healthcare facility, other clinical microbiology laboratories, or other settings like sexually-transmitted disease clinics.
- Implement AR-related consultations and results interpretation for facilities, designated outbreak and prevention program staff, and partners, and other network clinical or public health laboratories.

- Offer troubleshooting expertise or training for laboratory personnel conducting AR testing in regional state or local AR lab network funded public health laboratories, as needed/requested.
- Host a regional partnership meeting for state HAI/AR prevention programs and public health laboratories within the region.
- Participate in regularly scheduled conference calls with CDC to discuss AR concerns, emerging issues, protocol plans, etc.
- Develop or sustain processes and IT infrastructure for timely reporting to submitting facilities, state or local public health laboratories, epidemiologists, regional AR prevention partners, and CDC.
- Work with APHL to implement or sustain reporting using APHL Informatics Messaging Services (AIMS) platform and Lab Web Portal for applicable testing. Lab Web Portal should be implemented using sync services and not HL7.
- Establish or sustain laboratory capacity for *N. gonorrhoeae* resistance surveillance by performing AST on up to 5,000 isolates and WGS for up to 1,250 isolates per funded laboratory annually.
- Antibiotic susceptibility testing and serotyping of MDR-*Streptococcus pneumoniae* (up to 500 isolates per year). Funded laboratories will perform whole genome sequencing (WGS) for up to 500 isolates per funded laboratory annually. These WGS data will be used to detect and characterize *S. pneumoniae* isolates with unique antibiotic susceptibility patterns.
- Perform CDC-directed and coordinated public health assessments of emerging or changing epidemiology of *Clostridium difficile* by implementing culture capacity for clinical specimens and environmental specimens. As directed by CDC, apply advanced molecular detection testing to type isolated bacteria and to assess *C. difficile* transmission.

National TB Molecular Surveillance Center

- Establish or sustain laboratory capacity for Mtb 24 locus MIRU-VNTR typing by testing approximately 9,000 isolates in total annually (from all 50 states and U.S. territories). Preference will be given to laboratories that have demonstrated proficiency in 24 locus MIRU-VNTR testing in accordance with methods recommended by CDC's Division of TB Elimination.
- Establish or sustain whole genome sequencing (WGS) of Mtb by sequencing approximately 9,000 isolates in total annually (from all 50 states and U.S. territories). The NextSeq sequencer is the preferred platform for this work. These sequence data will be used to conduct molecular surveillance of antibiotic susceptibility patterns and to strengthen epidemiologic investigations through transmission network analysis. Preference will be given to laboratories that have demonstrated proficiency In WGS testing of M. tuberculosis in accordance with methods recommended by CDC's Division of TB Elimination.
- Implement Mtb sample inventory storage system; prepare subcultures of all submitted isolates and provide transport to CDC within three months of submission for long term storage.

H: Vector-borne Diseases: Building Comprehensive Programs to Identify, Diagnose, Report, Prevent, and Respond

Tier 1: Core Required Activities

- Identify and report nationally notifiable vector-borne disease cases to CDC using standard CSTE case definitions with complete reporting of key variables (using NNDSS, supplemental case report forms or enhanced surveillance platforms, e.g. ArboNET)
- Identify and report blood donations with evidence of vector-borne pathogens (including West Nile virus, Zika virus, *Ehrlichia* and *Anaplasma* spp. and *Babesia* spp.) to CDC
- Identify and report possible transfusion and transplant transmitted infections
- Analyze and interpret vector-borne disease surveillance data
- Report *passively* collected ecologic surveillance data already being collected (e.g. veterinary cases, sentinel animal infections, vector abundance and infection prevalence) for vector-borne disease to the appropriate CDC systems (e.g. ArboNET, MosquitoNET) and local vector control programs.
- Advise local agencies (e.g. mosquito abatement districts, health departments) on surveillance and control of vectors to reduce human disease where appropriate
- Maintain core capacity to perform testing for vector-borne diseases of public health importance to the jurisdiction.
- Participate in annual proficiency testing for vector-borne disease diagnostic testing
- Participate in CDC coordinated national and/or regional vector-borne disease meeting (e.g. ELC annual meeting and/or vector-borne disease focused meeting)
- Participate in relevant meetings and trainings to improve capacity for vector-borne diseases detection, reporting and response
- In coordination with CDC and other partners, investigate and respond to vector-borne disease outbreaks, implement timely control measures, and disseminate findings
- Conduct outreach and educational activities to increase awareness of healthcare providers, public health personnel and the public regarding the risks, clinical manifestations, diagnosis and prevention of vector-borne diseases
- Post jurisdiction specific vector-borne disease surveillance data to health department website

Tier 2: Enhanced or Expanded Activities

- Identify and report non-nationally notifiable vector-borne disease cases to CDC
- Perform expanded analysis and interpretation of vector-borne disease surveillance data to inform public health action
- Investigate and report vector-borne disease cases with new or unusual modes of transmission or clinical manifestations
- *Actively* conduct or coordinate ecologic/vector surveillance and pathogen testing, and report to the appropriate CDC systems (e.g. ArboNET, MosquitoNET)
- Perform or obtain insecticide resistance testing results for mosquitos and submit, coordinate or verify submission of results to national systems (e.g. MosquitoNET). Use data to inform emergency mosquito control activities

- Maintain enhanced capacity to perform testing or confirmation for an expanded number of vector-borne diseases of public health importance to the jurisdiction such as for a panel of arboviral infections and PCR testing for *Ehrlichia* and *Anaplasma* spp.
- Develop and maintain surveillance and response plans for vector-borne diseases (e.g. emerging infections, outbreaks) as appropriate for the jurisdiction
- Prepare up-to-date summaries of vector-borne disease data, and distribute to healthcare providers, public health partners, policy makers and the public

Tier 3: Advanced or Regional Activities

- In coordination with CDC and other ELC-funded jurisdictions, conduct enhanced case investigations and surveillance for vector-borne diseases to: 1) improve estimates of disease incidence and burden; 2) describe clinical features and outcomes; and 3) identify groups at increased risk for infection or disease to target prevention
- Develop and maintain capacity to lead and coordinate complex investigations involving multiple jurisdictions or agencies (e.g., transfusion or transplant-associated transmission, and complex outbreaks)
- Evaluate novel ways to conduct improved public health surveillance and collaborate with CDC to evaluate next generation public health surveillance (including informatics modernization initiatives).
- Develop and maintain capacity to serve as a regional reference laboratory for other states and jurisdictions for advanced and confirmatory vector-borne disease diagnostic testing, including but not limited to plaque reduction neutralization testing
- Develop and implement a comprehensive integrated vector surveillance and control plan
- Collaborate with CDC and other CDC-supported extramural programs to evaluate the effectiveness and feasibility of integrated strategies to prevent, control or reduce the burden of vector-borne diseases (e.g. vaccines, therapeutics, clinical management, vector control or public education).
- Establish and manage regional collaborations with other state and local health departments to improve resource sharing, staffing and capacity for vector-borne disease surveillance and control measures
- Evaluate and modify prevention and control messages as appropriate
- Develop comprehensive vector-borne disease communication plans
- Develop and evaluate innovative communication approaches to improve information reach and retention
- Perform workforce training, intensive public outreach and/or clinician education

Section III: Disease-Specific Projects

I: Mycotics: Detecting and Preventing Fungal Infections

Tier 1: Core Required Activities

- Acquire/maintain laboratory equipment or supplies for fungal diseases testing (note that testing should not be duplicative with *Candida* AR Lab Network testing)

Tier 2: Enhanced or Expanded Activities

- Improve laboratory detection of fungal infections
- Respond to fungal disease outbreaks and report findings to CDC
- Contain or prevent the spread of antifungal-resistant fungal pathogens
- Use CSTE case definitions to conduct surveillance for coccidioidomycosis and histoplasmosis

- Help improve standardized data collection for fungal disease surveillance, including revised case definitions and optional data elements harmonized across states
- Conduct enhanced surveillance for one or more endemic mycoses to better characterize patient characteristics, diagnostics used, clinical illness, and possible exposures
- Conduct active, population-based surveillance for invasive mold infections, including collection of clinical isolates and pathology specimens; states may consider using a case investigation form used by the Emerging Infections Program.
- Implement or improve testing protocols for fungal infectious diseases
- Develop health promotion materials for healthcare providers and the public to increase health literacy about fungal disease prevention (e.g., participate in national Fungal Disease Awareness Week activities)

J: Binational Border Infectious Disease Surveillance (BIDS) Program

Tier 1: Core Required Activities

- Assess the completeness, and data quality of Binational Variables (i.e., Binational Reporting Criteria, Country of Exposure, Country of Usual Residence and Country of Birth) in state and local systems by county
- Train state and local staff on the use of the Binational Reporting Criteria and related variables
- Binational Case Reporting

Tier 2: Enhanced or Expanded Activities

- Integrate the Binational Variables into local and state electronic disease surveillance systems
- Incorporate the Binational Variables into routine case notifications to the National Notifiable Disease Surveillance System
- Implement or enhance human surveillance
- Develop, test, and refine binational information sharing and collaboration protocols
- Assess, enhance, or systematize data collection
- Share best practices through Peer to Peer training or consultation
- Assist local health jurisdictions with binational outbreak investigations
- Train border region epidemiologists/disease investigators, or physicians to improve surveillance and response

K: Global Migration, Border Interventions and Migrant Health

Tier 1: Core Required Activities

- Develop new investigation materials, processes, procedures, or technology that would more quickly and completely detect cases of immediate public health interest among globally mobile populations
- Analyze, report, and share surveillance, epidemiological, or clinical data for globally mobile populations.
- Implement interventions addressing the health needs of refugee and /or immigrant populations at conveyances or at border crossings
- Evaluate the effectiveness of interventions addressing the health needs of refugee and/or immigrant populations
- Enhance staff training and education on port of entry International Health Regulations core capacities (http://www.who.int/ihr/procedures/en)
- Facilitate coordination/exchange of surveillance, epidemiological, or clinical data for globally mobile populations

L: Prion Surveillance

Tier 1: Core Required Activities

- Actively investigate all cases of suspected prion disease reported in state residents; refer out-of-state cases to the health department of patient's residence.
- Within two weeks of a report, actively investigate all cases of suspected prion disease in higher priority cases of suspected prion disease (e.g., suspected cases in persons < 55 years of age, suspected cases of variant CJD or possible human CWD, suspected iatrogenic cases, and suspected case clusters.
- Cross check various data sources to ensure that all cases are identified in the project area. Specific search terms are available from the CDC Prion Group and are listed in the detailed Prion guidance in Part III, section B of this NOFO.
- Utilize human prion disease surveillance to better inform and lessen undue concerns among health professionals and the public.
- Obtain scientific data to support development of evidence based and cost-effective policies
- Work collaboratively with the state wildlife/natural resources department to ascertain the degree of CWD surveillance within the state, conduct chronic wasting disease related education and consider other activities aimed at persons who hunt within the state and those who consume venison provided by hunters.
- Work collaboratively with CDC and other sites funded for enhanced surveillance of CJD and other prion diseases.
- Work collaboratively with the National Prion Disease Pathology Surveillance Center at Case Western Reserve University by maintaining regular contact including at least twice yearly phone or email contact.
- Identify facilities within the state that are able to perform brain autopsy on persons suspected of or clinically diagnosed with a prion disease.
- Develop relationships with the CJD Foundation or comparable patient groups to enhance collaborative work and to educate and provide assistance to family members of persons affected by prion diseases. Conduct outreach with hospitals and facilities that care for persons with prion disease to educate caregivers, including family members and medical personnel, about prion disease-related infection control issues and about the importance of prion disease surveillance and confirming clinically suspected cases.
- Work collaboratively with pathologists, neurologists, funeral and mortuary directors, and other appropriate professionals within the state to ensure these professionals are aware of the state's prion disease surveillance system as well as the prion disease-related resources available to support them, including at CDC, the National Prion Disease Pathology Surveillance Center, the state health department and the CJD Foundation.
- Disseminate data and information on human prion disease within the state (e.g., reports, workshops, grand rounds, etc.)
- Education of infection control practitioners and other relevant staff at hospitals and other facilities about the importance of appropriate infection control regarding human prion diseases

M: Rabies Surveillance

Tier 1: Core Required Activities

- Develop or improve electronic systems that facilitate real-time flow of results between local and state agencies responsible for managing suspect rabies exposure cases

- Develop or improve electronic systems that facilitate electronic laboratory reporting based on standard message mapping guides for national notification of animal rabies
- Improve sharing of laboratory data to help facilitate confirmatory testing of samples between state and federal laboratories
- Improve real-time laboratory data sharing to facilitate coordination of rabies response activities between local, state, and federal agencies

N: Parasitic Diseases Surveillance

Tier 1: Core Activities

- Training in use of diagnostic parasitology tools.
- Expand surveillance for soil transmitted helminth infections
- Maintain or improve the use of appropriate diagnostic parasitology tools for case detection, surveillance and outbreak investigations.

O: Enhanced Vaccine-Preventable Disease (VPD)

Tier 1: Core Required Activities

- VPD surveillance coordinator will serve as the point of contact for VPDs and related conditions for which surveillance is conducted through NNDSS or the ELC Project O CoAg
- Collect case data on key and enhanced variables, as described in CDC guidance
- Provide surveillance data to support evaluations of public health response to meningococcal disease, as appropriate (e.g., risk factors for meningococcal disease, serogroup B meningococcal vaccine effectiveness, retrospective record review to identify cases among the same household)
- Ensure reporting sources follow jurisdiction requirements to inform state/local health departments of varicella outbreaks; for jurisdictions where varicella is not a reportable condition but outbreaks of all etiologies are reportable, processes should be put into place to facilitate reporting of varicella outbreaks
- Develop, implement, and maintain surveillance systems
- Evaluate and enhance surveillance systems based on CDC guidelines
- Conduct regular assessment of surveillance data and implement processes to improve completeness, timeliness, and quality of case data
- Facilitate coordination/exchange of surveillance data with CDC
- For each disease/condition, support maintenance of the availability of appropriate surveillance testing capacity (e.g., culture, serotyping/serogrouping, molecular sequencing) within jurisdiction public health laboratories, VPD Reference Centers (RCs), and/or CDC laboratories
- Implement a flexible plan for use and acquisition of laboratory supplies and testing that addresses changing needs/purposes for each disease/condition
- Collect isolates from confirmed and probable cases of meningococcal disease and test for serogroup and additional molecular characterization
- Support linkage of laboratory specimens, isolates, and results with epidemiologic and clinical case-patient data
- Coordinate activities to increase access to specimens and isolates so that laboratory data are available to inform surveillance activities
- Support and integrate epidemiology, laboratory, immunization, and health information activities

- Support VPD surveillance through coordination between epidemiology, laboratory, immunization, and health information systems (e.g., NNDSS, IIS, electronic lab reports (ELR), electronic case reports (eCR), Health Level 7 (HL7) messages) to enhance use and exchange of electronic data files
- Foster collaboration among city, county, state, federal, and other internal and external partners to improve outbreak and case-based reporting for VPDs and related conditions (e.g., AFM)
- Engage and collaborate with stakeholders by providing surveillance data to inform and support policies and public health evaluations for VPDs and related conditions (e.g., AFM)
- Communicate and coordinate with public health partners to ensure appropriate investigation, testing, and case-based reporting for VPDs and related conditions (e.g., AFM)

Tier 2: Enhanced or Expanded Activities

- Enhance surveillance for severe cases of varicella
- Enhance pertussis surveillance
- Enhance *H. influenzae* surveillance
- Enhance IPD surveillance
- Enhance measles surveillance
- Enhance mumps surveillance
- Enhance surveillance for other vaccine preventable diseases

P: Legionnaires' Disease Prevention

Tier 1: Core Required Activities

- Develop and implement a comprehensive, multi-disciplinary LD outbreak response protocol.
- Attempt to interview all suspect and confirmed legionellosis cases to obtain exposure information (e.g., using a form similar to the SLDSS Case Report Form or the RIBD MMG)
- Report all cases including exposure information to CDC via SLDSS (using a data extract, if possible) or an HL7-based reporting mechanism using the RIBD MMG
- Develop and implement an LD Primary Prevention Strategy

Tier 2: Enhanced or Expanded Activities

- Develop an LD investigative team consisting of epidemiology, environmental health, and laboratory staff
- Participate in RIBD MMG transition
- Perform enhanced surveillance to improve capture of possible sources of exposure.
- Utilize software packages such as SaTScan for geospatial detection of LD clusters and outbreaks
- Operationalize clinical Polymerase Chain reaction (PCR) capacity at the state laboratory
- Become CDC Environmental *Legionella* Isolation Techniques Evaluation (ELITE) member laboratory
- Build internal capacity for analysis of Legionella whole genome sequencing
- Collaborate with hospital and clinical laboratory systems to increase number of respiratory specimens cultured for *Legionella*
- Develop and implement an LD Primary Prevention Strategy
- Evaluate uptake of WMPs in buildings at increased risk
- Prepare and distribute communication materials regarding programmatic activities to relevant audiences

Tier 3: Advanced or Regional Activities

- Evaluate interventions resulting from outbreak investigations. For each investigation, identify and report:

- Evaluate effectiveness of policies and public health approaches to the implementation of industry standards for primary prevention of LD

Q: Influenza Surveillance and Diagnostic Testing

Tier 1: Core Required Activities

- Use standard investigative tools (i.e. influenza-associated pediatric death and novel influenza A case report forms), data sharing tools, and methods
- Participate in influenza outbreak investigations and assist local jurisdictions in large, complex outbreaks
- Identify and maintain an influenza surveillance coordinator
- Recruit, retain, and encourage timely reporting from ILINet providers
- Develop, implement and maintain the components of the U.S. Influenza Surveillance System
- Collect, analyze, and disseminate influenza surveillance data
- Advance meaningful public health use of electronic health records, including exploring the availability and utility of existing sources of electronic influenza morbidity (including influenza hospitalization data) and mortality data
- Facilitate the improvement of influenza surveillance as recommended by the Council of State and Territorial Epidemiologists (CSTE)
- Utilize modern techniques for diagnosis (i.e. real-time RT-PCR) for typing and subtyping of influenza viruses, including detection of novel influenza viruses, year-round
- Identify and maintain a laboratorian who is proficient in influenza diagnostic testing (i.e. PCR methods for influenza virus detection, typing, and subtyping
- Continue to assess your capacity for achieving the guidance and goals within the Right Size Road Map by evaluating and updating your implementation plans for achieving the Right Size objectives.
- Maintain weekly reporting of influenza test results from the U.S. World Health Organization (WHO) collaborating laboratories in your jurisdiction
- Coordinate connections between epidemiology and laboratory functions, at state and local levels
- Implement and maintain electronic mechanisms for exchange of public health information, including the Public Health Laboratory Interoperability Project (PHLIP) system to transmit specimen-level data to CDC each week
- Foster general collaboration and relationship building among city, county, state, and federal partners and other external partners (e.g. CSTE, APHL)
- Coordinate epidemiologic services throughout the state, including developing a collaborating relationship between ELC and FluSurv-NET staff (if applicable)

Tier 2: Enhanced or Expanded Activities

- Systematic surveillance sampling of patients meeting the ILI case definition and presenting to ILINet providers.
- Report level of care (inpatient or outpatient) for patients with specimens tested at the PHL.
- Estimate population served by ILINet providers.

R: Non-Influenza Respiratory Diseases: Diagnostics, Reporting, and Surveillance

Tier 1: Core Activities

- Perform diagnostic testing for non-influenza respiratory viruses in eligible ELC public health state and local laboratories
- Increase or maintain the number of clinical laboratories that report respiratory virus laboratory results to CDC via the National Respiratory and Enteric Virus Surveillance System (NREVSS), either directly or by pass-through from local and state public health departments.
- Establish or improve non-influenza respiratory virus surveillance
- Assist CDC in investigations of deaths associated with RSV among children less than five years of age
- Work with CDC to determine rates of RSV-associated ICU admissions for some or all ages in specific catchment areas
- Report appropriate type-specific respiratory virus results from public health laboratories to CDC via the National Enterovirus Surveillance System (NESS) and/or the National Adenovirus Type Reporting System (NATRS)
- Participate in respiratory illness outbreak investigations and assist local jurisdictions in outbreaks as needed.
- Transmit information regarding non-influenza respiratory virus testing from public health laboratories to CDC via the Public Health Laboratory Interoperability Project (PHLIP) system, including clinical variables when feasible.
- Collaborate with CDC to implement electronic data transfers from clinical or health department laboratories to CDC of respiratory virus laboratory results, including epidemiologic and clinical data when feasible such as age, specimen collection date, illness onset date, location, severity/outcome measures (e.g., hospitalization, ICU admission, death).

S: Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity

Tier 1: Core Required Activities

- Identify and maintain appropriate staffing.
- Maintain and update (as needed) local SURRG project protocols and IT systems to address clinic, laboratory, surveillance, investigation, and data management GC rapid detection and response activities.
- Robust collection of specimens for gonococcal culture and performance of AST
- Conduct timely GC culture and AST via Etest, and maintain associated data
- Ship GC isolates and transmit manifests to the appropriate Antibiotic Resistance Laboratory (ARLN) for confirmatory agar dilution AST and whole genome sequencing.
- Rapidly initiate SURRG case investigations on all patients with elevated ASTs
- Initiate SURRG investigations/partner services/epi investigations on at least an additional 12 seed index cases (with susceptible GC) in the jurisdiction (and their social contacts, sex partners, and sex partners of sex partners as per the SURRG Epi Investigation protocol).
- Conduct routine process and outcome evaluations on core clinic and laboratory activities (e.g. monitor implementation and success of specimen collection criteria for gonococcal culture and AST, transport time, or culture yield by anatomic site).
- Analyze program data for programmatic quality improvement efforts.
- Develop and implement a plan to conduct analyses on GC rapid detection and response epi investigation and partner services activities. These analyses should attempt to 1) document of the impact and value of

conducting local partner services and outbreak response activities, and 2) improve local understanding of GC and resistant GC epidemiology and transmission dynamics. These analyses may include partner services metrics, network information, epi, clinical, AST and/or genomic data.
- To inform and improve GC and ARGC prevention and control efforts more broadly, awardees are required to disseminate (through documentation and/or presentation) lessons learned, best practices, local protocols, or results of programmatic analyses.

Tier 2: Enhanced or Expanded Activities

- Community messaging, workforce development, and training related to rapid response to resistant GC
- Evaluate routinely collected programmatic data related to test-of-cure among persons tested and treated for GC who return for a test-of-cure visits.

T: Gonococcal Isolate Surveillance Project (GISP)

Tier 1: Core Required Activities

- Identify one or more categorical STD clinics and a local public health laboratory in a jurisdiction that will execute the program activities and meet the project period outcomes
- Collect urethral *N. gonorrhoeae* isolates from the first 25 men with symptomatic gonococcal urethritis seen in the STD clinic each month
- Inoculate specimens for culture onto selective media at the STD clinic(s). Subculture gonococcal isolates from the selective primary medium to a non-inhibitory medium in the local public health laboratory, as described in the GISP protocol
- Maintain adequate specimen handling quality control to maximize isolate viability and minimize contamination
- Assign isolates an identifying number, freeze the isolates and ship them monthly to the assigned GISP regional Antimicrobial-Resistance Laboratory Network (ARLN) reference laboratory for antibiotic susceptibility testing
- Maintain and store duplicates of submitted isolates in the local public health laboratory
- Review antibiotic susceptibility test results received from the ARLN laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform patient management and local public health response
- Collect line-listed, coded specified demographic and clinical data elements associated with each isolate and electronically submit to CDC following standardized protocols

Tier 2: Enhanced or Expanded Activities

- Identify one or more categorical STD clinics in the jurisdiction and a local public health laboratory that will execute the program strategies and meet the project period outcomes
- Collect urethral swabs for Gram stain, gonococcal culture and urethral/urine specimens for nucleic acid amplification testing (NAAT) from the first 25 men presenting to the participating STD clinic(s) each month with symptomatic urethritis
- Collect pharyngeal and/or rectal swabs for culture and NAAT from patients (men or women) seen in the participating STD clinic(s) reporting pharyngeal and/or rectal exposure (e.g., men reporting oral sex or receptive anal sex) until 25 cases of gonococcal infection at extragenital sites are identified each month
- Collect cervical swabs for gonococcal culture and NAAT from women undergoing pelvic examinations with concerns of cervicitis, women with known exposures to a GC case and women with a positive NAAT result in

the participating STD clinic(s) until 25 cases of gonococcal genital infections in women are identified each month. A urine specimen for NAAT (rather than a swab) is acceptable

- Inoculate specimens for culture onto selective media at the STD clinic(s). Subculture gonococcal isolates from the selective primary media to a non-inhibitory medium in the local public health laboratory, as described in the eGISP protocol
- Maintain adequate specimen handling quality control to maximize isolate viability and minimize contamination
- Assign isolates a unique identifying number, freeze the isolates and ship them monthly to the assigned eGISP regional Antimicrobial-Resistance Laboratory Network (ARLN) reference laboratory for antibiotic susceptibility testing
- Ship isolates associated with positive gonorrhea NAAT results monthly to the assigned ARLN laboratory for antimicrobial susceptibility testing by agar dilution and possible molecular characterization (including whole genome sequencing)
- Review antibiotic susceptibility test results received from the ARLN laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform local public health response
- Collect line-listed, coded specified demographic and clinical data elements associated with each isolate and electronically submit to CDC following standardized protocols
- Identify and maintain records of all urethral, pharyngeal, rectal, and cervical isolates that are suggestive of *N. meningitidis*
- Ship the identified presumed *N. meningitidis* isolates monthly directly to the CDC Meningitis Branch Laboratory in Atlanta, Georgia for antibiotic susceptibility testing, confirmatory identification, and molecular characterization (including whole genome sequencing
- Maintain adequate specimen handling quality control to maximize isolate viability and minimize contamination
- Review antibiotic susceptibility test results received from the CDC Meningitis Branch Laboratory, describe the epidemiology of *N. meningitidis* in urethral, pharyngeal, rectal and cervical isolates in their jurisdiction to help inform patient management and local public health response
- Collect line-listed, coded specified demographic and clinical data elements associated with each isolate and electronically submit to CDC following standardized protocols

U: Syphilis and HIV Prevention Through Social, Sexual and Phylogenetic Networks

Tier 1: Core Required Activities

- Engage in formative assessment of MSM populations and transgender women with particular attention to local epidemiology and behaviors, social context, service availability, and disease.
- Use network methodological techniques to describe networks seeded from STD clinic patients who are MSM or transgender women who have a recent history of HIV infection or syphilis, or who have a history of repeated syphilis infection.
- Assure the provision of interventions to identify candidates for PrEP/ART and assure linkage to PrEP services, as well as interventions to assure treatment for syphilis.
- Measure all costs related to identification of networks and implementation of network-level interventions
- Participate in discussions about common protocols and common data elements across grantees

- Contribute data to inform models of transmission dynamics

V: Human Papillomavirus Surveillance Among Men

Tier 1: Core Required Activities

- Identify participating health center/s
- Obtain anal specimens from sexually active young adult MSM (N>300 annually).
- Store and ship specimens to CDC for HPV testing
- Obtain relevant surveillance information for each specimen, including at a minimum: age in years, sex (e.g., current gender identity and sex assigned at birth), race/ethnicity, HPV vaccination status (e.g., number of doses administered, with dates and/or intervals), sexual orientation and/or sex of sex partners, number of lifetime sex partners, and HIV status.
- Line-listed de-identified demographic and clinical data elements associated with each specimen will be collected by the awardee and electronically submitted to CDC following standardized protocols.
- Coordinate submission of specimens and surveillance data to CDC for HPV testing and analysis.
- Collaborate with CDC to evaluate changes in HPV prevalence.

Tier 2: Enhanced or Expanded Activities

- Collaborate with CDC to evaluate changes in HPV prevalence

W: Infants with Congenital Exposure: Surveillance and Monitoring to Emerging Infectious Diseases and Other Health Threats

Tier 1: Core Required Activities

- Identify personnel or contractual staff to function as a jurisdictional-level Coordinator who will track and report all follow-up information for infants born to women enrolled in the US Zika Pregnancy and Infant Registry or other surveillance systems for emerging treats.
- Coordinate with birth defects surveillance efforts, the investigation and reporting of possible congenital Zika virus infection and other congenital infection cases with severe clinical manifestations.
- Work with CDC to guide analytic direction and identify prenatal care facilities for prioritized assessments/response
- Identify and report all eligible cases that meet required case definition within 30 days of case identification
- Participate in the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry by collecting follow-up clinical data at designated time points for Registry-eligible pregnant women and infants.
- Develop, maintain and/or enhance surveillance systems for emerging infections
- For emerging infections, describe case inclusion criteria and preliminary case definitions for public health awareness and collaboration
- Analyze, prepare summaries of data (e.g., reports, maps, manuscripts, and presentations), and distribute to medical providers, public health partners, policy makers, and the public
- Coordinate connections between epidemiology and laboratory functions, at state and local levels
- Collaborate with the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry to leverage the existing infrastructure

- Identify and connect with national/local partners to raise awareness and increase provider support and collaboration. Examples include, but are not limited to: professional societies, health care systems, health plans, schools/universities, and community interest groups
- Implement and maintain electronic mechanisms for exchange of public health information
-
- Ensure surveillance systems are modernized and integrated when possible, and linked to mother-child health information is used to assess the impact of congenital infection
- Participate collaboratively to development of best practices for preparing and responding to emerging threats to pregnant women and their infants
- Participate collaboratively to disseminate information on protection of pregnant women and their infants from other emerging infectious diseases, and known health threats to pregnant women/infants such as CMV
- Actively participate in the Data Use Working Group to communicate the public health message to protect mothers and babies
- Participate in the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry by collecting follow-up clinical data at designated time points for Registry-eligible pregnant women and infants

B. Program and Project Detailed Guidance Attachments

This section of the NOFO contains the detailed guidance for each program and project, which details sub-activities, funding strategies other key criteria. Applicants should apply for programs and projects that will support identified infectious disease detection, prevention, and control needs in their jurisdictions. Applicants may apply to any program or project, depending on jurisdiction-specific needs.

Section I: Cross-cutting Emerging Infectious Disease Capacity, Systems, and Leadership

A: Cross-Cutting Epidemiology and Laboratory Capacity

Program Activity Contact Information

Angelica O'Connor; Email: apw1@cdc.gov

Funding Opportunity Description

Background

a. Overview

The Epidemiology and Laboratory Capacity for Prevention and Control of Infectious Diseases (ELC) Cross-cutting Epidemiology and Laboratory program is intended to improve core capabilities of jurisdiction's health departments. Not only does this flexible funding help meet health departments' core public health needs but also supports unanticipated events that could require the redirection of resources to confront rapidly emergent situations. ELC enhances epidemiology and laboratory capacity by supporting personnel to help address capacity deficits, programmatic gaps, and support unanticipated events. Flexible funding has proven to be an effective model for strengthening epidemiology and laboratory capacity among health departments.[1]

b. Healthy People 2020

Public Health Infrastructure Objective 11: Increase the proportion of Tribal and State public health agencies that provide or assure comprehensive laboratory services to support essential public health services

Public Health Infrastructure Objective 13: Increase the proportion of Tribal, State, and local public health agencies that provide or assure comprehensive epidemiology services to support essential public health services

c. Other National Public Health Priorities and Strategies

N/A

CDC Project Description

a. Problem Statement:

Federal resources provided for infectious diseases are often prescriptive, both in terms of the activities they fund and pathogens they target. Yet in many health departments, the core infrastructure in epidemiology, laboratory, and information systems is not robust or flexible enough to meet the challenges of emerging infections optimally. Adding to the complexity of each jurisdiction's infrastructure, unanticipated events may occur that require shifting resources to respond to an emerging or re-emerging disease. To better meet each jurisdiction's specific needs and to be able to transition quickly during unanticipated events, resources need to be allocated in a multi-categorical and flexible way so agencies are better able to address planned-for and unanticipated infectious disease public health threats.

b. Purpose:

The purpose of this Cross-Cutting Epidemiology and Laboratory Capacity program is to provide support to maintain and strengthen infectious disease epidemiology and laboratory capacity so that state public health

[1] Chung, Christina; Fischer, Leah; O'Connor, Angelica; Shultz, Alvin; 2017 "CDC's "Flexible" Epidemiologist: A Strategy for Enhancing Health Department Infectious Disease Epidemiology Capacity." Journal of Public Health Management and Practice. May/Jun;23(3):295-30.1

agencies can effectively respond, prevent and control known and emerging (or re-emerging) infectious diseases. This is intended to address activities for needs that do not clearly fall under specific disease components and/or are cross-cutting, including the basic 'core' elements of an epidemiology and laboratory program for emerging and re-emerging infectious diseases.

c. Outcomes:

- Effective public health workforce prepared to address infectious disease threats, including:
  - Improved workforce knowledge and skills regarding next-generation sequencing (NGS), bioinformatics, and other AMD technologies.
  - Improved NGS capacity in state and local health departments.
- Timelier disease reporting, investigation and initiation of control measures of clusters and outbreaks of infectious diseases
- More effective and targeted interventions to protect public from infectious disease
- Improved use of data to inform public health response and practice, including program and policy development
- Public health laboratories are addressing testing needs more efficiently
- Improved efficiencies between laboratories and their networks, including use of public health resources

Funding Strategy:

In FY 2019, the ELC cooperative agreement has collapsed four separate projects (Cross-Cutting Epidemiology, Cross-Cutting Laboratory, Advanced Molecular Detection, and Public Health Laboratory Sustainability) from previous years into this one program. While the cross-cutting activities have been consolidated under one section, the budgets for the laboratory and epidemiology sections will remain separate to distinguish the unique fiscal needs of each.

Cross-Cutting Epidemiology and Laboratory
Funds should be used for personnel (i.e., multi-disease purpose 'ELC Flexible Epidemiologist', and/or 'Laboratorian'), supplies, travel, systems (e.g. courier / lab networks), statistical software and other requisite support to build and/or maintain epidemiological and laboratory capacity within the jurisdiction.

Requests for cross-cutting leadership, program management, finance, and epi/lab integration staff should be submitted under the ELC's newly established "Leadership" project.

Total availability of funds for cross-cutting epidemiology and laboratory: $22,100,000

- Approximate number of awards given: 64
- Approximate average per award: $345,313; 64 awards

In addition to the above, there is a total of $3,500,000 to support: (1) Advanced Molecular Detection (AMD)-related workforce development through training at the state and local level, (2) Bioinformatics support, and (3) support state and local health department initiatives to extend the use of AMD technologies. See below for details on the funding strategy for AMD related projects to be funded within ELC's Cross-Cutting component.

(1) AMD Workforce Development:

Applicants applying should apply *either* to be a training "lead" *or* "participant":

- ***Training lead:*** Funds should be requested to cover the costs of the training plus any in-state travel expenses for trainers and participants.
  - Approximate number of awards: 7
  - Approximate average per award: $20,000 to $150,000
- ***Training participant***: Funds should be requested for travel and training registration (if applicable). Other costs with accompanying justification will be considered.
  - Approximate number of awards: 20 to 40
  - Approximate average per award: $5,000 to $15,000

(2) Bioinformatics Resource Support Component:

Funds should be requested for staff time (if the bioinformatician is on staff) or, if the health department is contracting with a university for bioinformatics consultation services, the costs of acquiring those services (i.e., the costs of the contract or whatever mechanism is being used); travel costs for work within the region; other costs associated with performing this function.

- Approximate number of awards: 7
- Approximate average per award: $50,000 to $150,000

(3) AMD Capacity Component (i.e., extending the application of AMD technologies):

- Approximate number of awards: 5 to 20
- Approximate average per award: $20,000 to 100,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1a: Enhance Workforce Capacity

a) Conduct needs assessments to identify gaps and/or training needs in epidemiology and laboratory activities

☒Required ☐Optional

b) Develop and implement a training plan based on the findings from the needs assessment.

☒Required ☐Optional

c) Enhance skills and maintain pace with novel laboratory and epidemiology techniques by participating in trainings or creating training opportunities for professional development (e.g., forums, seminars, workshops) for staff

☒Required ☐Optional

d) Peer-to-Peer: Visit another ELC jurisdiction to facilitate knowledge sharing

i. Train a member(s) of your staff by visiting and participating in public health activities with another ELC jurisdiction. Specifics are to be negotiated between the participating ELC

recipients and may involve reciprocal arrangements where host jurisdictions would later be hosted (however, such an arrangement is not a requirement). The ELC program will try to facilitate match-making between recipients.

ii. Travel that is approved and funded by CDC will be considered a required activity.

iii. After the Peer-to-Peer visit is completed a final report, using the ELC template, shall be submitted to the ELC Project Officer.

☐Required ☒Optional

II. Strategy 1b: Enhance investigation and outbreak response

a) Lead/assist in timely response to outbreak investigations

☒Required ☐Optional

b) Plan for/address surge capacity needs during outbreaks (e.g., establishing investigation teams and/or student workforce or cross training staff)

☒Required ☐Optional

c) Develop, maintain and evaluate the use of communication protocols or guidelines for outbreak response and management

☒Required ☐Optional

d) Implement advanced technologies (e.g., AMD, SaTScans, GIS) for more thorough and accurate detection of infectious diseases

☐Required ☒Optional

III. Strategy 1c: Improve Surveillance and Reporting

a) Improve use of surveillance data by implementing innovative methodologies (e.g., SaTScans , GIS, etc.)

☐Required ☒Optional

b) Improve coordination and exchange of surveillance data with other jurisdictions and partners

☐Required ☒Optional

IV. Strategy 1d: Strengthen laboratory testing for response

a) Improve lab throughput, efficiency and proficiency by incorporating use of novel techniques for detection to expand capabilities and improve laboratory throughput, efficiency and proficiency.

☐Required ☒Optional

V. Strategy 1f: Improve laboratory coordination and outreach to improve efficiency

a) Develop, implement, review and maintain a plan or strategy for the optimal use of lab supplies and equipment that addresses flexible, changing, and multi-disease purpose needs.

☒Required ☐Optional

b) Collaborate with clinical/private labs for surge, continuity of operations and CIDT issues.

☒Required ☐Optional

c) Use analytical methods to enhance laboratory operational planning (e.g. Collecting and compiling data on resources needed for processing laboratory samples and estimating the cost[2]/quantify the costs required for processing specimens in different scenarios, using throughput and network models to understand and plan for surge).

☐Required ☒Optional

d) Develop and enhance regional laboratory networks for service sharing. Required elements for those receiving funding, unless otherwise specified:

i. Improve laboratory coordination and outreach/information flow
ii. Share information and data on the test services and informatics capabilities of each PHL participating in a regional network through use of the Public Health Laboratory System Database at https://www.apl.org/programs/research/IRP/Pages/resources/aspx and the Informatics Self-Assessment Tool for Public Health Laboratories (Available at https://www.aphl.org/programs/informatics/Pages/Informatics-Self-Assessment-Tool.aspx)
iii. With network partners, formulate a shared plan and support for developing regional testing capability, including, for example:

- Identification of shared tests and other services between PHLs in the network [Required of the network collectively]
- Development of supportive MOUs or other agreements [Optional for the collective network or subsets of member laboratories]
- Development of capability to support region-wide surge and COOP plans as demonstrated by active test sharing and plans for additional sharing in emergencies [Optional for the collective network or subsets of member laboratories]
- Sharing of training and other resources (e.g., clinical lab survey instruments, biosafety technical materials) that support any of the many functions of PHLs, including quality management systems, testing capabilities and capacity [Optional for the collective network]

☐Required ☒Optional

[2] Adhikari, Bishwa; Carias, Cristina; Washington, Michael; Kahn, Emily; Meltzer, Martin. "A tool to estimate the costs of processing and testing samples in a laboratory." Last updated: April 10, 2018, Version 2.1. If you would like to access this tool, please send an email to vnn9@cdc.gov.

VI. Strategy 1a: AMD Enhanced & Regional Activities

a) AMD Training Participant:

i. Sending staff to be trained at in-person courses and workshops on NGS, bioinformatics, and/or other AMD-related activities.

ii. Enabling staff to participate in webinars and other structured online content.

iii. Participating in needs assessment of AMD workforce as requested by training labs.

iv. Providing evaluation and feedback on training materials and content delivery.

States and localities planning to send staff to participate in regional AMD trainings should apply for this section. ** Regional training networks are consistent with the seven PulseNet regions*

☐Required ☒Optional

b) AMD Training Lead:

i. Hosting new and existing trainings, collaborating with local or regional partners where possible.

ii. Conducting training needs assessment before scheduling regional or local training.

iii. Conducting training evaluations to measure impact of course(s) and perform continuous improvement of training program.

iv. Coordinating training activities with regional training participants.

☐Required ☒Optional

States and localities are encouraged to work with training participants within their region (see note below [*]), and other regional training leads to develop discrete local or regional training plans. Existing training networks (*) are encouraged to apply and are also encouraged to incorporate local or regional resources where possible. Collaboration with universities or other public or private institutions with NGS and bioinformatics capacity to develop trainings is encouraged.

c) AMD Regional Bioinformatics

i. Assist the regional training lead in developing and carrying out training. This may involve, for example, assisting in the development of web-based modules that could be used within the region or nationally

ii. Consult with states and localities in the region on bioinformatics problems. This may involve, for example, performing ad hoc bioinformatics analysis for those states or localities or assisting a staff member in one of their laboratories in doing his or her own analysis.

iii. Coordinate and communicate with regional training leads and participants for bioinformatics technical support

iv. Consult with local or state IT departments regarding IT policies necessary to support AMD implementation.

v. Work with states or localities to resolve IT problems that are limiting the use of AMD technologies.

vi. Assist states and large localities in the region in bioinformatics analysis, either by assisting staff in those organizations or by performing the analysis themselves.

vii. Work with state labs and CDC to find sustainable, affordable solutions to state and local health department AMD-related informatics needs such as storage and cloud computing.

viii. Work with state and local health departments to promote data sharing (where needed and appropriate)

☐Required ☒Optional

** Regional training networks are consistent with the seven PulseNet regions. The lab supporting either the regional training lead or regional bioinformatician for workforce development and bioinformatics resource components may be the same as or may be different from the PulseNet Area Lab servicing the region*

AREA B: PREVENTION AND INTERVENTION

VII. Strategy 2a: Implement public health interventions and tools

a) Improve use and/or review of surveillance data for prevention and response (e.g. identifying risk populations to drive interventions, data quality checks, more robust analysis)

☒Required ☐Optional

b) Implement evidence-based prevention tools and/or interventions (e.g., policy, engineering, service delivery, education, and/or communication campaigns) to achieve improved prevention practices and reduction of disease.

i. Use surveillance data to identify at-risk populations requiring focused intervention

ii. Incorporate social and behavioral science approaches in the development, delivery and evaluation of interventions

iii. Engage community stakeholders with surveillance data to mobilize collaborative action toward prevention.

☐Required ☒Optional

c) Conduct process and/or outcome evaluations of tools and/or interventions to understand whether intended outcomes and/or effects were achieved and identify opportunities for improvement.

☐Required ☒Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

VIII. Strategy 3a: Coordinate and engage with partners

a) Foster collaboration among city, county, state and federal partners (e.g., workgroups) and other external partners for the purpose of improving outbreak response and management

☒Required ☐Optional

b) Develop communication tools such as public websites that disseminate information regarding emerging and re-emerging disease threats

☐Required ☒Optional

Collaborations

a. With CDC-funded programs:

Collaborations with other CDC funded programs is strongly encouraged, especially where this cross-cutting epidemiology project supports emerging disease-specific needs.

b. With organizations external to CDC:

N/A

Target Populations:

N/A

Evaluation and Performance Measurement:

Tier 1 (Measures #1-7)

1. Number of ELC-funded epidemiologists and laboratorians in your jurisdiction that are able to work across areas of infectious disease
2. Top training needs among jurisdictions and those that have been addressed
3. Percentage of reports of selected reportable diseases received by a public health agency within the awardee-required timeframe (PHEP 13.1)
4. Percentage of reports of selected reportable diseases for which initial public health control measure(s) were initiated within the appropriate timeframe (PHEP 13.2)
5. Number of outbreaks investigated by ELC-funded personnel by proportion and type
6. Epidemiology and laboratory coordination – TBD
7. AMD implementation - TBD

Tier 2 (Measures #8-9)

8. Peer-2-Peer Site Visit Report
9. Programs, policies or interventions implemented that were informed by surveillance data

Tier 3 (Measures #10-14)

10. Number of newly shared testing services, activities, or resources, by network member labs in existing shared testing services, activities, or resources (if participating in the laboratory network activity)
11. Workforce Development: Training Lead
    a. Number of individuals participating in AMD Regional Training events
    b. Number of trainings presented (in-person, web-based, or 1-on-1 consultations)
    c. Percentage training evaluations completed within the training region
12. Workforce Development: Training Participant
    a. Percentage of staff who completed AMD regional training or other AMD related trainings
    b. Percentage of staff trained to perform bioinformatics/ NGS data analysis techniques
    c. Percentage of staff able to perform bioinformatics/ NGS data analysis
    d. Number of AMD trainings attended (in-person, web-based, or 1-on-1 consultations with regional AMD Training Lead)

13. Bioinformatics Resource Support Lead
    a. Percentage of staff who completed AMD regional training or other AMD related trainings
    b. Percentage of staff trained to perform bioinformatics/ NGS data analysis techniques
    c. Percentage of staff able to perform bioinformatics/ NGS data analysis
       i. Number of AMD trainings attended (in-person, web-based, or 1-on-1 consultations with regional AMD Training Lead)
14. AMD Capacity Building
    a. Number and proportion of applicants with at least one MiSeq sequencer
    b. Number and proportion of applicants who are actively applying next-generation sequencing to the following public health priorities:
       i. Bacterial foodborne illness (i.e., through PulseNet)
       ii. Antimicrobial-resistant hospital-acquired pathogens (such as CRE)
       iii. Influenza
       iv. Hepatitis C (i.e., by means of the GHOST system)
       v. *Legionella*
       vi. Streptococcal pathogens
       vii. *Mycobacterium tuberculosis*

B: ELC Leadership, Management and Administration
Program Activity Contact Information
Angelica O'Connor; Email: apw1@cdc.gov
Funding Opportunity Description
Background
a. Overview
The Epidemiology and Laboratory Capacity for the Prevention and Control of Infectious Diseases (ELC) Cooperative Agreement has grown enormously since 1995 when it was first enacted with eight jurisdictions, $2 million and a single project. Today's ELC annually awards between $200 and $300 million, has 64 jurisdictions and comprises many different categorical and cross-cutting programs, projects and activities. Through the years, the ELC has become a more integral and visible part of health departments' infectious disease-related activities. However, with greater resources and opportunities, also comes challenges in the areas of leadership, management and administration of the health departments' ELC and program-related activities. As we head into a new 5-year ELC NOFO cycle, this ELC Leadership initiative is intended to strategically provide health departments dedicated resources to optimize their ELC program through enhanced leadership and coordination.
b. Healthy People 2020
N/A
c. Other National Public Health Priorities and Strategies
N/A
CDC Project Description
a. Problem Statement:
Management of the ELC Cooperative Agreement is a challenging task that requires careful attention to detail and coordination across numerous branches within each health department; including epidemiology, environmental, laboratory and health information systems. This management also requires knowledge of technical, administrative and financial elements – some of which may be outside the expertise of senior program staff. In addition, this new 5-year NOFO includes opportunities to engage in robust public health programs to address several emerging infectious disease areas. To be effective in establishing these new initiatives, recipients will need clear and ongoing leadership engagement across their health departments.
b. Purpose:
The purpose of this section is to provide health departments with dedicated resources to assist in the leadership, management, coordination and administration of their ELC Cooperative Agreements.
c. Outcomes:
• Enhanced emerging infectious disease programs in the areas of food- and water-borne disease, healthcare acquired infections and antibiotic resistance, and vector-borne diseases. • Enhanced coordination across ELC, including integration of epidemiology laboratory and health informatics activities. • Improved health department leadership's understanding and management of ELC portfolio. • Reduction in unspent funding through appropriate fiscal management by health departments to support public health activities as proposed.

- Better visibility of impact and success of ELC funded activities at the state and local level.

Funding Strategy:

The resources available in this section should be used primarily for staff (this could include staff secured through contracts) and associated supplies and travel that are directly related to improving the integration, coordination, and fiscally-responsible management of the ELC program. As a new ELC initiative, it is hoped that the initiative will grow over time. In this first year, it is not anticipated that ELC will have the budget to provide a resource for every health department, but through demonstrated success and impact, increased support is a goal.

Very large health departments might be able to make an effective case for multiple resources (e.g. an ELC Program Manager and a Financial administrator) while smaller health departments might want to focus on their most critical areas of need (e.g. internal coordination, project management, financial management, etc.)

- Estimated total availability of funds: $8 to $11 million
- Estimated number of awards given: 40 - 50
- Estimated average per award: $50,000 - $300,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Improve Health Department's ELC Leadership, Management and Administration

a) Manage ELC activities across all ELC programs and projects

i. Further enhance work with health department staff to develop activities within the ELC scope (with special focus on ELC programs such as cross-cutting, foodborne, HAI/AR and vectorborne); monitor implementation and effectiveness of ELC activities and work with CDC to overcome barriers and challenges occurring during implementation of activities.

ii. Participate in Annual Meetings: Attend ELC annual meeting(s) (for epidemiology, laboratory, health informatics and finance staff); and ensure that attendees disseminate pertinent information to others in their jurisdictions who were unable to attend.

iii. Develop and maintain succession and sustainability planning (especially with respect to staff) for the continuation and improvement of ELC activities

☒Required ☐Optional

b) Actively plan, coordinate and implement ELC activities across epidemiology, laboratory and health informatics interests at health department and within jurisdiction

i. Actively seek (through perhaps an epi-lab liaison position) to coordinate ELC activities and data/information pertinent to health department's mission with respect to infectious diseases.

ii. Identify barriers impacting epi / lab integration and develop a plan and timeline for mitigating barriers

iii. Enhanced coordination of ELC-related activities with local health departments within jurisdiction (including tribal governments), including identifying and requesting resources for local needs.

☒Required ☐Optional

c) Manage financial aspects of ELC Cooperative Agreements, including resource tracking and spending

☒Required ☐Optional

Collaborations:

a. With CDC funded programs:

Activities within this section should be coordinated with other CDC programs that support infectious disease-related activities at local health departments. Important programs include CDC's Emerging Infections Program (EIP) and the Public Health Emergency Preparedness Cooperative Agreement (PHEP).

b. With organizations external to CDC:

Local health departments and other public health concerns (e.g. hospitals, vector control districts, etc.) within the jurisdiction's boundaries; other local and state health departments outside of jurisdiction's boundaries; tribes and/or tribal organizations.

Target Populations:

N/A

Evaluation and Performance Measurement:

Awardees are required to demonstrate that measurable progress is being made throughout the project period and share this progress in workgroup and partner conference calls. To indicate progress made toward program outcomes, data will be reported through:

- Bimonthly (every two months) conference calls
- Bimonthly (every two months) written updates to submitted via email prior to conference calls
- Performance Measures for Tier 1 activities

Measure #1

Outcome: Reduction in the percentage of unspent funds by health departments for ELC intended public health purposes

Measure: Unobligated funding identified on grantees Annual Federal Financial Report (FFR)

Measure #2

Outcome: Improved ELC program management, coordination, and implementation of ELC activities

Measure: Quantitative or Qualitative scores on annual ELC technical reviews

Measure: Number and proportion of Cross-cutting Epidemiology and Laboratory program activities on track as recorded on ELC's monitoring portal (REDCap based)

C: Health Information Systems Capacity

Program Activity Contact Information

Jason Hall, ELC Informatics Subject Matter Expert (404) 639-7884
Michele Hoover, Lead Public Health Advisor (404) 498-2705

Funding Opportunity Description

Background

a. Overview

Data are foundational to every public health decision and enable the prevention, detection, and response to health threats. In our current world, data are also ubiquitous, with a growing volume and variety of data sources from both within and outside of traditional health partners. Public health has a unique opportunity to harness these data to make more timely and insight-driven decisions to inform their programs, policies, and investments, but requires robust health information systems infrastructure.

b. Healthy People 2020

Healthy People 2020 Health Communication and Health Information Technology topic area

c. Other National Public Health Priorities and Strategies

These activities are aligned with CDC's public health data strategy and IT transformation efforts. These efforts include components focused on expanding core data, informatics, and IT capacity; advancing interoperable systems and tools; and strengthening and expanding collaboration with and support for partners.

These activities also complement the Centers for Medicare & Medicaid Services Promoting Interoperability (PI) Programs focused on increased accessibility and improved facilitation of data exchange between providers and patients (https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHrIncentivePrograms/).

CDC Project Description

a. Problem Statement:

State and local public health agencies require standardized processes and interoperable systems to access the timely, high quality data that are critical to carrying out key public health functions. However, many are faced with challenges in building the health information systems capacity needed to produce, transmit, manage, and analyze these data in an efficient way. For instance, clinical and laboratory partners often exchange data that are not standardized or via labor-intensive, paper- based methods. In addition, in many jurisdictions, the systems for analyzing and sharing these data are stand-alone, outdated, or functionally deficient.

b. Purpose:

The purpose of the Cross-Cutting Health Information Systems (HIS) Capacity program is to provide jurisdictions the support to maintain, improve, and modernize health information systems infrastructure. Improvements should be forward-thinking and strategic, advancing standards-based electronic data exchange, increasing interoperability, and sustaining and enhancing integrated surveillance information systems.

c. Outcomes:

Mid-Term Outcomes:

- Improved surveillance
    - Improved completeness of data
    - Improved timeliness of reporting

- Increased distribution and use of data to public health partners
- Infectious disease data are automated and efficient
- Electronic mechanisms for data exchange are in place

Long-Term Outcomes:

- More efficient and accurate public health reporting
- More rapid detection of cases and outbreaks
- Improved use of data to
  - Inform public health response and control
  - Improve public health practice
  - Inform program and policy development
  - Develop and implement public health best practices and or guidelines

Funding Strategy:

Funds should be utilized for personnel, travel, supplies, equipment, or contractual support for proposed activities.

- Estimated total availability of funds: $32,000,000
- Estimated number of awards given: 64
- Estimated average per award: $500,000

Distribution of funding for each activity will be dependent on jurisdictional needs, the quality and composition of the application, prior performance, as well as the availability of funds and agency priorities. Funding allocations will be discussed and clarified during the annual grantee meeting. Note that funding for systems development or acquisition costs may not be available through ELC.

Funded jurisdictions are expected to adhere to the requirements of the cooperative agreement (see the CDC Project Description Section (Part II, #2, above). For HIS this includes:

- Identifying a designated person with overall responsibility for HIS activities as well as personnel responsible for each activity;
- Participating in a Technical Assistance (TA) consultation assessment to identify annual TA priorities (jurisdictions may also request EDX Technical assistance at EDX@cdc.gov if needed throughout the project period);
- Participating in ELC HIS implementation, support, and monitoring efforts;
- Working with CDC to measure key aspects of implementation (e.g., reporting the percent of lab report volume received through ELR at least once during the project period); and
- Participating in efforts to define consistent ways to link surveillance data to laboratory findings from public health labs and CDC labs for all conditions.

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1h: Advance Electronic Data Exchange- Public health agencies receive data from and transmit data to many different stakeholders, including laboratories, healthcare, and CDC. This strategy is focused on standardizing and optimizing the exchange of data among these various entities

a) Maintain and enhance Electronic Laboratory Reporting (ELR) to enable public health agencies to receive reports from laboratories in a more efficient electronic format.

i. (Required) Maintain existing ELR transmissions

ii. (Required for jurisdictions below 75%) Increase ELR - propose and execute a plan to increase the volume and percentage of lab reports received through ELR over the next year

iii. Develop and enhance processes so that ELR delivered to health departments enters systems in an automated way (vs. re-keying or manually uploaded).

iv. Develop or enhance ELR data quality and assurance processes to improve timeliness of reporting, adherence to the implementation guide, mapping to standard codes (LOINC/SNOMED), etc. and provide feedback to reporting facilities.

☒Required ☐Optional

b) Support CDC's ability to monitor, control, and prevent diseases and other health threats by standardizing the reporting of surveillance data (required for all reporting jurisdictions).

i. Implement New National Notifiable Disease Surveillance System (NNDSS) Case Notification Messages

(a) Extract, translate and transmit the data for conditions contained in 5 additional finalized HL7 Nationally Notifiable Message Mapping Guides (see https://wwwn.cdc.gov/nndss/case- notification/message-mapping-guides.html for final MMGs) using the new HL7 case notification structure and retire the corresponding legacy formatted transmissions.

(b) Use the CDC NNDSS onboarding process (see https://www.cdc.gov/nmi/ta-trc/index.html) to receive approval for the new HL7-based case notifications before production transmissions are initiated or legacy transmissions are retired (for additional information please see NMI Technical Assistance and Training Resource Center at https://www.cdc.gov/nmi/ta-trc/index.html).

☒Required ☐Optional

c) Collect and use syndromic surveillance data to validate and monitor harmful effects of exposures to diseases and hazardous conditions.

i. Increase coverage and number of facilities submitting syndromic surveillance data to the BioSense Platform according to jurisdictional needs

(a) (Required for any jurisdiction applying for Syndromic Surveillance funding) Onboard new, and maintain existing, data transmissions to the NSSP BioSense Platform for emergency department (ED) and urgent care facilities with messages that include the NSSP priority 1 and 2 data elements.

ii. (Required for any jurisdiction applying for Syndromic Surveillance funding) Participate in the NSSP Community of Practice and other efforts to strengthen syndromic surveillance practice and use. This may include participation in meetings, workshops, and trainings; development of collaborative projects; increase use cases and practical applications by public health programs; share lessons learned and best practices, and providing feedback on the BioSense Platform.

(a) Develop or enhance data quality control and assurance processes

(b) Enhance timeliness of messages sent to jurisdiction systems and to NSSP BioSense Platform.

iii. Enhance completeness and validity of data, focusing on NSSP Priority 1 and 2 data elements.

iv. Develop or enhance syndrome monitoring and response protocols.

v. Develop at least two collaborative projects (one with a CDC program) where syndromic surveillance can be used to address health department surveillance data needs. Projects done in collaboration with CDC should include sharing the syndromic data with the CDC program through the BioSense Platform.

☐Required ☒Optional

d) Advance electronic data exchange for Public Health Laboratories.

i. Create and send ELR based on Promoting Interoperability (formerly Meaningful Use (MU)) standards for all reportable conditions to or within the public health department.

ii. Map local test, result, and specimen source codes to LOINC and SNOMED standards.

iii. Establish electronic test ordering and reporting (ETOR), using HL7 messages, with one or more hospitals or public health labs.

☐Required ☒Optional

e) Advance electronic information exchange between electronic health records and public health.

i. Implement electronic case reporting (eCR)

(a) Develop a project plan and begin implementation of eCR with one or more clinical partners and their EHR vendors for conditions published in the Reportable Condition Trigger Tables (available at https://phinvads.cdc.gov/vads/SearchVocab.action) and use RCKMS for public health reporting decision support.

(b) Develop a project plan and begin implementation of eCR with one or more clinical partners and their EHR vendors for Chlamydia and Gonorrhea. Technical guidance on electronic case reporting for Gonorrhea and Chlamydia is available in a document named “Advancing ECR of STIs: Technical Guidance for Public Health Departments” (available at https://www.phii.org/ECR-STI-report). This document allows jurisdictions to choose different technical architecture of implementation while providing consistent guidance on the science of STI reporting.

ii. Participate in national efforts by engaging in the: 1) discussion and development of eCR standards by participating in the HL7 Public Health Working Group; and 2) development and updates to default reporting specifications and trigger codes by participating in the CSTE RCKMS vetting process

iii. Participate in the Reportable Conditions Knowledge Management System (RCKMS) to author jurisdictional reporting criteria and maintain reporting specifications

☐Required ☒Optional

f) Advance electronic information exchange between jurisdictions.

i. Create the capacity to transfer ELR messages and eCR messages between jurisdictions. These transfers refer to the electronic sending of ELR and case data between two jurisdictions for a lab report or a case that was reported to one jurisdiction but belongs to another jurisdiction

☐Required ☒Optional

II. Strategy 1i: Sustain and enhance information systems- This strategy is focused on ensuring the information systems used to store and manage public health data are maintained and enhanced.

a) Maintain existing information systems (e.g., integrated surveillance information system, LIMS, and syndromic surveillance information system), including the personnel and operating environment/supporting software necessary for them to function.

☒Required ☐Optional

b) Implement (if appropriate) new/replacement information systems.

☐Required ☒Optional

c) Enhance existing information system(s) by adding or improving functionality. Prioritized enhancements are listed below, but other enhancements may be requested.

i. Integrated surveillance information system:

(a) Enhance systems to enable the automated processing and use of eCR (and if desired, Reportability Response) documents.

(b) Transition STD surveillance into the existing or new integrated surveillance information system along with appropriate legacy data migration.

(c) Transition from hard copy reporting to electronic reporting of congenital syphilis (CS) cases. If using a standalone CS database, migrate CS surveillance into an existing integrated information system. States using NBS version 5.3 or newer should use CS module available within the system.

(d) Enhance systems to enable the automated processing and use of ELR, including complete susceptibility findings.

ii. LIMS

(a) Enhance system to enable the automated processing and use of HL7 electronic test orders.

(b) Consult with CDC to evaluate options for implementing and integrating a web portal to support electronic test ordering and reporting (ETOR).

iii. Syndromic surveillance information system

(a) Explore, evaluate, and incorporate new data sources at your jurisdiction that can enhance syndromic surveillance.

☐Required ☒Optional

d) Implement additional innovative enhancements that improve analysis, enable lab-epi collaboration, or increase the sustainability or efficiency of systems. Illustrate projects:

i. Enable lab-epi collaboration by identifying and implementing a universal case identifier (or similar linking variable) to include with laboratory and case data transmission (e.g., patient identifier that links data from health systems; identifier to link PulseNet data to case reports).

ii. Develop systems or tools for public release of public health data.

iii. Explore the efficiencies of moving an existing or new information system to a cloud-based/hosted environment.

iv. Identify software or platforms that enable the integration and visualization of surveillance and laboratory data.

v. Identify solutions to integrate AMD data with surveillance data for analysis or visualization.

☐Required ☒Optional

e) Increase HIS capacity to support Advanced Molecular Detection (AMD) activities.

i. Implement management and analytic software

ii. Increase network bandwidth and computing power and/or use cloud infrastructure to support AMD initiatives

☐Required ☒Optional

Collaborations:

a. With CDC funded programs:

Recipients are expected to coordinate with others across their agency and local health departments in the planning, execution, and management of activities under this ELC program with related efforts funded through the Public Health Emergency Preparedness (PHEP) cooperative agreement and through categorical cooperative agreements (e.g., STD, HIV/AIDS, TB).

b. With organizations external to CDC:

Recipients are encouraged to participate with CDC and its partners in planning, development, implementation, and assessment efforts related to electronic data exchange and integrated surveillance systems. These partners include, among others, the Association of State and Territorial Health Officials (ASTHO), Council of

State and Territorial Epidemiologists (CSTE), Association of Public Health Laboratories (APHL), the National Association of County and City Health Officials (NACCHO), the Public Health Informatics Institute (PHII), and the International Society for Disease Surveillance (ISDS).

Target Populations:

N/A

Evaluation and Performance Measurement:

Measures

Data will be measured and reported quarterly on the ELC Health Information Systems Implementation Support and Monitoring calls, where progress made on recipient activities and toward program outcomes will be monitored and discussed.

- Percent of lab report volume received through ELR
- Number of hospitals and public health labs with established electronic test ordering and reporting (ETOR)
- Percent of conditions for both state and nationally notifiable conditions that use HL7 format
- Percent of emergency departments (EDs) sending HL7 Promoting Interoperability (formerly MU) compliant syndromic surveillance messages to the health department and BioSense Platform
- Percentage of STD case investigations (e.g., Chlamydia, Gonorrhea) auto-created from ELR.

D: Impact and Evaluation
Program Activity Contact Information
Christina Chung, cchung@cdc.gov and Martin Meltzer, qzm4@cdc.gov
Funding Opportunity Description
Background
a. Overview
The overall goal of this ELC funding is to support projects that use quantitative analytic methods to assess the cost-effectiveness and impact of ELC-funded activities on the transmission of infectious diseases. This project will also help to build capacity for these types of evaluations in state and local health departments. Ultimately, results from these assessments may be used to set priorities in the development and implementation of program strategies and activities; and make informed decisions about future program and policy development.
b. Healthy People 2020
Public Health Infrastructure Goal: To ensure that Federal, State, Tribal, and local health agencies have the necessary infrastructure to effectively provide essential public health services.
c. Other National Public Health Priorities and Strategies
N/A
CDC Project Description
a. Problem Statement:
Impact evaluation is a critical component to understanding outcomes related to public health actions. Across jurisdictions, public health agencies often lack the capacity to perform impact evaluation activities (and evaluation activities in general), with resources notably absent in the area of infectious diseases. Data from CSTE's Epidemiology Capacity Assessments suggests that among epidemiologists working at state health departments, the ability to ensure and assist in evaluation of programs, as well as develop program logic models and theories of action, are low. Limited impact evaluation capacity across jurisdictions in infectious disease programs limits CDC's and awardees' ability to articulate the importance of the public health sector, including the understanding of the effectiveness of ELC activities and strategies and opportunities to improve their implementation.
b. Purpose:
The main purpose of this funding will be to conduct impact and cost-effectiveness evaluations of ELC activities to illustrate quantitative impact (e.g. illnesses/hospitalizations averted, lives saved, etc.) to the public, policy makers and government leadership. Conducting these evaluations will also build capacity to assess impact and cost-effectiveness. Finally, these evaluations will help the public health sector collect information to improve the practice and demonstrate the effectiveness of ELC-funded strategies and activities.
c. Outcomes:
• Provide better demonstration of the public health impact of ELC-funded activities at the state and local level. • Provide evidence for making more informed decisions about public health infectious disease activities. • Develop independent state and local leadership capacity to conduct quantitative impact evaluations of infectious disease public health interventions.

Funding Strategy:

Funds should be used to hire a project manager to coordinate this activity. With technical assistance from CDC's Health Economics and Modeling Unit and ELC evaluation specialists, the project manager's job duties will include data collection and analysis, report writing, and presenting results to non-technical audiences as described in section I.a. below. In addition to staff, funding may be used to support trainings, supplies, travel, and other requisite support to implement cost-effectiveness evaluation projects and build impact evaluation capacity within the jurisdiction.

The first year of the project will focus on precisely specifying the evaluation question(s) the recipient will analyze, and should include collecting baseline information (e.g. cost of outbreak response) that will be used later in the analysis. The first year will also focus on workforce development to build state and local capacity for quantitative analysis of impact.

- Estimated total availability of funds: $600,000
- Estimated number of awards given: 5
- Estimated average per award: $120,000

Strategies and Activities:

AREA B: Prevention and Intervention Strategies

I. Strategy 2a: Implement public health interventions and tools

a) Conduct cost-effectiveness and/or public health impact evaluations (in coordination with CDC) associated with ELC-funded activities.

i. Develop a specific analytic proposal

(a) Identify the area to be evaluated with the outcomes (i.e. cases, hospitalizations, deaths averted) of interest, and frame in terms of a specific analytic question.

(b) Identify the primary audience/purpose of the evaluation.

(c) Identify the appropriate methods to answer the specific analytic question.

(d) Identify the data needed to answer the evaluation question (e.g., epidemiologic data, cost data, data about implementation of the activities chosen for evaluation).

ii. Develop impact and cost-effectiveness analytic skills through attending trainings in quantitative data analysis and cost-effectiveness methods.

iii. Collect the data identified in the analytic proposal.

iv. In collaboration, develop a tool and conduct the analysis outlined in the proposal.

v. Develop a report/policy brief/document outlining the results and implications of the analysis

☒Required ☐Optional

Collaborations:

a. With CDC funded programs:

CDC's expectation is that the awardees will continually engage and work with CDC (specifically CDC's Health Economics and Modelling Unit and ELC's Evaluation Specialists) during the implementation of the project. The

ELC program intends to provide both in-person and virtual technical assistance. The awardee will participate on quarterly, at the minimum, group check-in calls and discussions with other awardees.

b. With organizations external to CDC:

Optional. When appropriate, recipients are encouraged to collaborate with others to conduct evaluation activities. Possible partners could be located within health departments, academia, or agencies within the community. If chosen, applicant must provide evidence of prior collaborations with such groups and describe the organization's role in achieving project outcomes, and how the applicant will interact with the program in specific terms. Prior achievements and evidence may be provided as an MOU, MOA, or letters of support.

Target Populations:

N/A

Evaluation and Performance Measurement:

Awardees are required to demonstrate that measurable progress is being made throughout the project period and share this progress in workgroup and partner conference calls. To indicate progress made toward program outcomes, data will be reported through:

- Bimonthly (every two months) conference calls
- Bimonthly (every two months) written updates to submitted via email prior to conference calls
- Performance Measures for Tier 1 activities

The recipient will be expected to develop a report/policy brief/document outlining the results and implications of the analysis.

E: Cross-Cutting Emerging Issues: Enhanced Surveillance, Outbreak Investigation Response and Reporting, Surge Efforts and Interventions

Program Activity Contact Information

Angelica O'Connor; Email: apw1@cdc.gov

Funding Opportunity Description

Background

a. Overview

The CDC's Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) Cooperative Agreement aims to help health departments strengthen core capacity needed to respond to a variety of emerging infectious diseases. This includes the potential provision of additional funding to increase epidemiology, laboratory and health IT support to meet needs during a local, regional or national infectious disease emergency.

b. Healthy People 2020

N/A

c. Other National Public Health Priorities and Strategies

N/A

CDC Project Description

a. Problem Statement:

If the factors giving rise to infectious disease emergencies could be predicted, then those associated emergencies might never occur. Nonetheless, the world of public health is in some state of preparedness or preparation for a variety of outbreaks such as threats related to novel influenza A, expanding arboviral disease vectors, foodborne pathogens, etc. Other types of outbreaks (e.g., SARS in 2002/2003 and fungal meningitis in 2012) may be far less anticipated. However, one commonality between most disease threats is resources available to mitigate them often only become available after the outbreak event occurs and becomes a public health emergency. Due to the unpredictable nature of these infectious disease emergencies and the lag in resources, jurisdictions need a ready mechanism to provide support for a range of infectious disease threats.

b. Purpose:

This potential funding is envisioned to provide additional laboratory, epidemiologic and/or health information systems surge capacity necessary for enhanced surveillance due to factors such as technology change and expanding disease boundaries or surge and response efforts associated with new or emerging infections including outbreak scenarios.

c. Outcomes:

State and local health departments better prepared to respond to new surveillance and response needs (including outbreaks) with more timely and efficient efforts for detection, investigation and implementation of control measures.

Funding Strategy:

Funding may be requested to support (depending on baseline capacity) temporary personnel, additional laboratory or office supplies, specimen shipping costs, and any other supplies needed for an effective response to an emergency or disease threat. Funds may be available on the condition of a local or national disease threat. Please request and have a plan for approximately $500,000 per jurisdiction (small jurisdictions

may request less while very large jurisdictions may request more). **Activities in this section will only be funded should conditions warrant, should funds become available.** Applicants should limit their response to no more than one page.

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1b: Enhance investigation response and reporting

a) Depending upon current baseline capacity, conduct specimen collection, shipping, case/contact/control interviews and medical record review, and transmit results to CDC to enhance the ability to rapidly respond to outbreaks.

☐Required ☒Optional

II. Strategy 1d: Strengthen laboratory testing for response

a) Depending upon current baseline capacity, enhance the ability of the laboratory to rapidly respond to outbreaks.

☐Required ☒Optional

III. Strategy 1j: Maintain and enhance integrated surveillance information

a) Depending upon current baseline capacity, enhance the ability of the health information system to rapidly respond to outbreaks.

☐Required ☒Optional

Collaborations:

a. With CDC funded programs:

Depending on the specifics of the disease threat, jurisdictions are encouraged to work with respective CDC programs if technical assistance is needed. With organizations external to CDC:

b. With organizations external to CDC

N/A

Target Populations:

N/A

Evaluation and Performance Measurement:

Report describing how resources awarded were used to mitigate the disease threat, including activities that were conducted that otherwise would not have been (or conducted faster/more completely).

Section II: Emerging Infectious Disease Programs

F: Foodborne, Waterborne, Enteric, and Environmentally Transmitted Diseases: Surveillance, Detection, Response, Reporting, and Prevention

Program Activity Contact Information

N/A

Funding Opportunity Description

Background

a. Overview

This program of the Division of Foodborne, Waterborne, and Environmental Diseases, in collaboration with the Division of Viral Diseases and the Division of Parasitic Diseases and Malaria, aims to protect public health through the prevention and control of disease, disability, and death caused by foodborne, enteric, waterborne, and environmentally transmitted infections. This section describes the activities necessary for a comprehensive program in a jurisdiction for the detection, investigation and response, reporting, and prevention of illnesses and outbreaks.

This template section is divided into three tiers. Tier 1 strategies and activities cover general surveillance, detection, and response; prevention and intervention; and communications and partnerships. Tier 1 activities apply to nationally notifiable diseases as well as conditions related to food, water, zoonotic, other enteric, and environmental transmission (See Project F Appendix 1). Tier 2 strategies and activities include expanded capacity for specific components of surveillance, investigation, and response. These activities are essential to understand and respond to changes in testing practices; identifying sources of sporadic enteric disease; developing or improving new methods for outbreak detection and response; and improving overall capacity for outbreak detection and response. Tier 3 includes activities for the Integrated Food Safety Centers of Excellence.

All Tier 1 activities must be addressed before applying for additional funds under Tier 2. The program/project areas under each tier are briefly described below.

Tier 1 includes (but activities are not limited to) the following programs. Programs listed may contain both epidemiologic and laboratory components:

CaliciNet: A network of federal, state, and local public health laboratories established to capture norovirus genotyping data from outbreaks, which can link geographically different clusters of illness to a common source, e.g., foodborne outbreak

National Antimicrobial Resistance Monitoring System (NARMS): A national public health surveillance system that tracks antimicrobial resistance in foodborne and other enteric bacteria. The goal of NARMS program is to help protect public health by providing information about emerging bacterial resistance, the ways in which resistance is spread, and how resistant infections differ from susceptible infections.

National Case Surveillance: Collects data from all states on infections due to nationally notifiable diseases as well as conditions related to nationally notifiable foodborne, waterborne, and environmentally transmitted diseases. Information is gathered from both “laboratory-based” and “case-based” surveillance systems.

National Outbreak Reporting System (NORS): National Outbreak Reporting System (NORS) captures all reports of enteric disease outbreaks caused by bacterial, viral, parasitic, chemical, toxin, and unknown agents, as well as foodborne and waterborne outbreaks of non-enteric disease.
OutbreakNet: Provides basic epidemiologic support nationally
PulseNet: National laboratory network that connects foodborne illness cases to detect outbreaks. PulseNet uses DNA fingerprinting, from pulsed-field gel electrophoresis and whole genome sequencing, of bacteria making people sick, to detect thousands of local and multistate outbreaks.

Tier 2 includes the following enhanced programs:
While any Tier 2 section is optional for applicants, if a jurisdiction is applying for a Tier 2 project then all the activities within that project are required.
CryptoNet and CryptoNet Regional Labs: CryptoNet is an enhanced surveillance program that tracks cryptosporidiosis by regular analysis of merged traditional epidemiology data and subtyping data. Cryptosporidiosis subtyping surveillance is conducted using CryptoNet protocols and will use PulseNet infrastructure to support advancement. Regional labs provide support to participants in their region with troubleshooting, surge capacity for subtyping, and training of laboratory and analysis methods.
***Cyclospora* genotyping:** Amplicon-based multilocus sequence typing approach to provide genotyping information for *Cyclospora cayetanensis.*
FoodCORE: FoodCORE is comprised of 10 centers that work together to develop new and better methods to detect, investigate, respond to, and control multistate outbreaks of foodborne diseases. FoodCORE provides support to improve laboratory, epidemiologic, and environmental health capacity.
FoodNet: FoodNet conducts active surveillance in 10 sites aimed at reducing morbidity and mortality due to diseases commonly transmitted by food and understanding sources of these infections. FoodNet goals are to provide the knowledge base to inform national level surveillance and antimicrobial resistance as well as evaluate effectiveness of regulations and interventions aimed at reducing the burden of select foodborne illnesses.
NoroSTAT: A network of sentinel states tasked with improving the timeliness and completeness of reported norovirus outbreaks due to all modes of transmission.
National Respiratory and Enteric Virus Surveillance System (NREVSS) Enhanced: NREVSS Enhanced Conducts clinical laboratory-based norovirus surveillance to track endemic norovirus disease and circulating strains.
One Health Harmful Algal Bloom System (OHHABS): A voluntary reporting system available to state and territorial public health departments and their designated environmental health or animal health partners. OHHABS collects data on HAB events and individual human and animal cases of HAB-associated illnesses. The goal of OHHABS is to collect information to support the understanding and prevention of HAB events and HAB-associated illnesses.
OutbreakNet Enhanced: Provides epidemiologic support to state and local health departments to improve their capacity to detect, investigate, control, and respond to enteric disease outbreaks.
PulseNet Area Labs: Provide support to network participants in their regions with trouble shooting, surge capacity for subtyping, training of laboratory and analysis methods, and coordination of regional calls and meetings.
Environmental Microbiology: Conduct environmental sampling and testing of environmental samples for waterborne disease investigations.

Tier 3 includes the following program:

Integrated Food Safety Centers of Excellence (CoEs): CoEs are headquartered at state health departments that have demonstrated excellence in surveillance and investigation of foodborne illness and outbreaks, and each CoE must partner with at least one academic institution. The CoEs develop tools, deliver trainings, and provide consultations to public health professionals in other states who conduct surveillance and investigation of foodborne illness and outbreaks. CoEs are encouraged to propose additional activities not listed in this guidance that are compatible with program goals, build on current capacity and public health needs, and do not duplicate other efforts

b. Healthy People 2020

Healthy People 2020 Goals for Food Safety include reducing the number of infections caused by key pathogens transmitted commonly through food (FS-1); reducing the number of outbreak-associated infections due to Shiga toxin-producing *E. coli* (STEC), *Campylobacter, Listeria,* or *Salmonella* associated with five food commodity groups (FS-2); preventing an increase in the proportion of nontyphoidal *Salmonella* and *Campylobacter jejuni* isolates from humans that are resistant to antimicrobial drugs (FS-3).

c. Other National Public Health Priorities and Strategies

National Strategy for Combating Antibiotic-Resistant Bacteria (CARB)

CDC Project Description

a. Problem Statement

Foodborne, waterborne, enteric, and environmentally transmitted disease surveillance and outbreak investigations are essential public health functions. Investigations require close collaboration between state, local, and federal agencies. Changes in society, technology, our environment, and microorganisms themselves are affecting the occurrence and complexity of foodborne, waterborne, enteric, and environmental diseases. Strong national surveillance is key to detecting outbreaks, and prompt and effective outbreak investigations and reporting are necessary to identify and remove contaminated products, prevent further illnesses, and focus prevention strategies on critical contamination points. Furthermore, antimicrobial resistance is one of our most serious health threats. Surveillance is critical to detect the emergence and spread of antibiotic resistance and to inform interventions that reduce resistance among bacteria.

b. Purpose

To support and enhance capacity for detection, investigation, control, and reporting of foodborne, waterborne, enteric, and environmentally transmitted disease cases and outbreaks.

c. Outcomes

- More efficient and accurate public health reporting
- More effective public health workforce better prepared to respond to infectious disease threats
- More rapid detection of cases and outbreaks
- Improved surveillance
    - Improved completeness of data
    - Improved timeliness of reporting
    - Increased distribution and use of data to public health partners
- More timely, complete and effective investigation efforts:
    - Response to outbreaks
    - Investigation of outbreaks

- Implementation of control measures
- Improved use of data to:
  - Inform public health response and control
  - Improve public health practice
  - Inform program and policy development
- Coordination between laboratory and epidemiology is improved

Funding Strategy

In developing budgets for the activities described, separate budgets should be developed for laboratory and epidemiology activities. These budgets should include Tier 1 and Tier 2 activities, if a recipient is applying for Tier 2 funding. Tier 3 (CoE) activities should be addressed in a separate budget template.

- Dedicated staff for investigation and reporting
- Resources to transmit surveillance data
- Training of state and local public health staff
- Supplies and equipment to maintain and enhance surveillance and outbreak reporting
- Tier 3 CoE Funding Note: A substantive portion of the CoE budget should be allocated to the academic partner. Detailed justifications must be included in the budget that make it clear how funds will be spent including a breakdown by salary, travel, supplies, etc.

- Estimated total availability of funds: Approximately $33 million
- Estimated number of awards given: 56-59
- Estimated average per award: Approximately $575,000. The average award depends on the project areas and activities in which a jurisdiction participates.

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1a: Enhance Epidemiologic Workforce Capacity

a) Support a sufficiently trained workforce for epidemiologic surveillance and outbreak response capabilities. Maintain supplies, computer equipment, and data entry personnel necessary for surveillance and outbreak reporting.

   i. Ensure staff have sufficient training to conduct the analysis of epidemiologic data related to clusters detected through PulseNet

   ii. Ensure personnel responding to outbreaks have the ability to use the Line List Editor in SEDRIC

   iii. Cross-train and educate staff about waterborne disease to build expertise for detection, investigation, and reporting of waterborne disease outbreaks

☒Required ☐Optional

b) Support a sufficiently trained workforce and associated resources to electronically transmit case surveillance data

i. Integrate data elements into a disease surveillance system, build data entry screens, create data exports, and implement HL7 data transmission

ii. Develop, maintain, or enhance data management systems, working with IT/informatics staff, to enable transmission of data elements specified in Generic Version 2 and Foodborne Diarrheal Diseases MMGs in HL7 format; this includes supporting data migration from legacy systems

☒Required ☐Optional

c) Identify a designated waterborne disease coordinator, a designated NORS point of contact, and at least one point of contact for foodborne, waterborne, zoonotic, and environmentally transmitted enteric disease case surveillance and outbreak response activities.

☒Required ☐Optional

d) Participate in routinely scheduled teleconferences/calls: OutbreakNet/WASH quarterly webinars; NORS quarterly webinars; NARMS quarterly calls; monthly waterborne disease state partner calls; national case surveillance working group calls; and trainings, webinars, etc. for pathogen/program-specific activities including data transmission activities (mapping, page building, etc.)

☒Required ☐Optional

e) Travel at least one epi to the Regional PulseNet/OutbreakNet Meeting (or InFORM Conference)

i. Also consider support for travel to other relevant conferences and trainings (e.g. CSTE, specialized trainings for enteric and/or waterborne diseases)

☒Required ☐Optional

II. Strategy 1a: Enhance Laboratory Workforce Capacity

a) Support a well-trained staff on high quality laboratory processes to laboratory-based surveillance and outbreak response capabilities

i. Ensure staff are trained and when necessary, attend trainings at their area lab or CDC

ii. Ensure staff are certified in required lab procedures (e.g. PFGE/WGS, identification, serotyping, culturing of primary specimens)

iii. Ensure staff are trained and certified to analyze and upload subtyping data to PulseNet or CryptoNet and typing data to CaliciNet national databases

iv. Ensure staff/mechanisms (in-house or via partners) are available for collection of environmental samples (e.g., water [small and large volume], soil, surface, and other samples) for waterborne disease investigations

☒Required ☐Optional

b) Identify at least one designated point(s) of contact for PulseNet, CryptoNet, NARMS laboratory activities, CaliciNet, waterborne laboratory testing, surveillance, and response activities, and *Cyclospora* genotyping

i. Complete, sign and return PulseNet Memorandum of Understanding (MOU) and Terms of Reference (TOR) documents to CDC PulseNet staff, or provide contact information for the state or local public health official(s) responsible for signature of those documents

ii. Complete sign, and return CryptoNet Memorandum of Understanding (MOU) to CDC CryptoNet staff, or provide contact information for the state or local public health official(s) responsible for signature of those documents

iii. Complete, sign and return CaliciNet Memorandum of Understanding (MOU) to CDC CaliciNet staff, or provide contact information for the state or local public health official(s) responsible for signature of those documents

☒Required ☐Optional

c) Participate in regularly scheduled calls, webinars, in-person trainings, etc.

i. Participate in monthly calls (AMD/CARB, etc.) facilitated by PulseNet

ii. Participate in area lab calls administered by PulseNet area labs and/or APHL

iii. Participate in routine (e.g., weekly, monthly, quarterly) CaliciNet meetings between epidemiology and laboratory staff on norovirus outbreaks

iv. Participate in quarterly NARMS conference calls

☒Required ☐Optional

d) Travel at least one PulseNet laboratorian to the Regional PulseNet/OutbreakNet meetings or the InFORM Conference; Travel at least one laboratorian per CaliciNet-certified laboratory to the annual CaliciNet User meeting

☒Required ☐Optional

III. Strategy 1b: Enhance Epidemiologic Investigation and Outbreak Response

a) Implement model practices to improve timeliness and efficiency for cluster and outbreak response

i. Monitor for and detect foodborne, waterborne, and zoonotic enteric disease clusters

(a) Develop improved methods for the public to report suspected food- or water-related health concerns or outbreaks and for staff to follow-up these reports (e.g. illness hotlines or public complaint systems)

ii. Develop and/or implement standard investigation protocols and tools to facilitate expanded outbreak investigations that include epidemiologic, laboratory, environmental health, and health communication staff collaboration

(a) Develop and implement water related emergency response plans

iii. Increase the number of foodborne, waterborne, and zoonotic enteric disease outbreak investigations that include an environmental health component to identify contributing factors or root causes and preventive measures

☒Required ☐Optional

b) Conduct investigations prompted by detection of a cluster, or local, or multistate foodborne or waterborne disease outbreaks

i. Interview all foodborne, waterborne, enteric and environmentally transmitted disease cases (including zoonotic) identified as part of a cluster of infections and/or a multistate investigation. This includes conducting hypothesis-generating interviews and follow-up/focused interviews with outbreak-specific questionnaires when they are developed by CDC

ii. Participate fully in CDC-led multistate outbreak investigations, including participation in analytic epidemiologic investigations and obtaining product information from persons infected with a pathogen that matches by subtyping isolates from foods, water, animals, or the environment

iii. Work with other states on foodborne and waterborne disease outbreak investigations and reporting of other water-related issues

iv. Assist local jurisdictions in large, complex foodborne and waterborne disease outbreaks

(a) Provide technical assistance and training to local public health agencies and health departments on detection, investigation, control, and prevention

☒Required ☐Optional

c) Implement control measures as appropriate based on cluster and outbreak investigations

☒Required ☐Optional

IV. Strategy 1c: Improve Epidemiologic Surveillance and Reporting

a) Report cases of nationally notifiable (foodborne, waterborne, enteric, and environmentally transmitted) diseases to NNDSS, as appropriate. This includes real-time reporting or consultation for cases of botulism and free-living ameba infections

i. Manage electronic reporting of case data within state and to CDC (NNDSS)

ii. Respond 24/7 to cases of botulism and free-living ameba. Work with CDC clinical consultation service or Emergency Operations Center to ensure management and resolution of cases

☒Required ☐Optional

b) Collect and transmit national case surveillance data to CDC for all cases of nationally notifiable (foodborne, waterborne, enteric, and environmentally transmitted) diseases with a standard questionnaire or data elements that are specified in CSTE position statements (See Project F Appendix 1). This includes listeriosis, STEC and post-diarrheal HUS, vibriosis, cholera, typhoid fever, paratyphoid fever, salmonellosis, shigellosis, and campylobacteriosis, cryptosporidiosis, giardiasis, and cyclosporiasis

i. Work with the CDC programs to validate and to clean surveillance data for pathogens with standard questionnaires or data elements during annual data cleaning

ii. Improve reporting to CDC of data elements requested in standard questionnaires or specified by CSTE position statements

iii. Work with CDC national case surveillance programs to provide state laboratory identification numbers that allow linking routine national surveillance data with isolate or specimen data (PulseNet, CryptoNet, NARMS, reference laboratories)

☒Required ☐Optional

c) Conduct environmental health assessments or inspections as part of surveillance (e.g., food establishments, aquatic facilities, childcare centers) and report to CDC as appropriate

☒Required ☐Optional

d) Explore feasibility of making fungal and parasitic diseases reportable in your jurisdiction

☒Required ☐Optional

e) Report to NORS all foodborne outbreaks, waterborne outbreaks, and enteric disease outbreaks due to person-to-person, animal contact, environmental contamination, and indeterminate/unknown modes of transmission

i. Work with the CDC NORS team to validate and to clean outbreak data contained in NORS reports during annual data cleaning.

ii. Improve data completeness for NORS outbreak reports

iii. Report data for environmental health, contributing factors, and preventative measures in NORS reports

☒Required ☐Optional

f) Work with the CDC NARMS team to submit isolates from every outbreak caused by diarrheagenic *Escherichia coli*, *Salmonella*, and *Shigella* and report the state laboratory identification number for each submitted isolate in the corresponding NORS reports

☒Required ☐Optional

g) Review paper and electronic data systems for waterborne disease outbreaks (1971 through present) and enter unreported outbreaks in the NORS-Water module

☒Required ☐Optional

h) Explore feasibility of reporting HAB associated event and illness data (human and animal) to OHHABS

☒Required ☐Optional

V. Strategy 1d: Strengthen laboratory testing for response

a) Provide laboratory testing support and subject matter expertise in local and multi-jurisdictional outbreak investigations for foodborne, waterborne, enteric, and environmentally transmitted disease

☒Required ☐Optional

b) Participate in local and multi-jurisdictional outbreak investigations

i. Read bi-weekly PulseNet Quick Tips and engage in the use of the PulseNet/OutbreakNet SharePoint site to follow outbreak investigations

☒Required ☐Optional

c) Submit representative isolates from outbreaks for antimicrobial resistance characterization by NARMS, along with form 50.34 documents according to current Enteric Diseases Isolate Submission Table guidance (located here: https://www.cdc.gov/ncezid/dfwed/edlb/index.html) or according to additional requests from CDC

i. Outbreak isolates should be submitted as soon as possible and should not be batched, for example, with quarterly shipments of NARMS routine surveillance isolates.]

ii. If available, the CDC-assigned report identification number from NORS should be included in the "Previous Laboratory Results/Comments" section of the CDC 50.34 Form for each isolate submitted to CDC for AST]

iii. The state lab identification number for each outbreak isolate submitted to CDC for AST should be included in the "Isolates/Strains" section of the NORS Form (CDC 52.13 Form) for the reported outbreak

☒Required ☐Optional

VI. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Support the necessary infrastructure to conduct laboratory-based surveillance, diagnostics and subtyping

i. Procure or maintain appropriate laboratory and data analysis equipment (including software upgrades), supplies, service agreements, and personnel necessary to support PulseNet, CryptoNet, NARMS, CaliciNet, and general surveillance and outbreak investigation functions, including waterborne diseases]

ii. If necessary, maintain supplies, equipment and personnel necessary for obtaining and storing isolates from primary specimens positive for enteric pathogens by culture independent diagnostic tests

☒Required ☐Optional

b) Improve or maintain specimen delivery capacity

i. Work with local jurisdictions and clinical laboratories for submissions to the state public health laboratory for foodborne, waterborne, enteric, and environmentally transmitted diseases

ii. Work with CDC to submit specimens from the state public health lab, as appropriate, for foodborne, waterborne, enteric, and environmentally transmitted diseases

☒Required ☐Optional

c) Conduct real-time subtyping as part of PulseNet, the national molecular platform for food pathogens (enteric bacteria)

i. Upload subtyping results and associated metadata to the PulseNet national databases in real-time (within 4 working days from receipt in PulseNet lab for PFGE and within 7 working days from receipt for DNA extraction for WGS)

ii. Communicate data analysis findings (clusters/outbreaks) via the PulseNet/OutbreakNet SharePoint site in real-time

iii. Obtain cultures for subtyping in PulseNet by isolating organisms from patient specimens/broths tested positive by culture independent diagnostic testing methods (CIDT)

☒Required ☐Optional

d) Complete electronic logsheets and submit NARMS routine surveillance isolates within one month after the end of each quarter according to current NARMS sampling scheme

☒Required ☐Optional

e) Conduct testing for detection and/or typing for CaliciNet activities

i. Conduct norovirus testing and sequence-based typing using standardized laboratory protocols

ii. Document and store norovirus positive stool samples for 3 years

iii. Document and store stool samples of norovirus negative outbreaks for further testing at one of the Unexplained Viral Diarrhea Outbreak Support Centers (UVD-OSC). Contact calicinet1@cdc.gov for information on UVD OSC, if needed.

iv. Provide a minimum set of data elements in the CaliciNet outbreak reports

v. Include a unique outbreak identifier in CaliciNet reports enabling linkage of those records with the appropriate NORS outbreak report

☒Required ☐Optional

f) Send clinical, animal, and environmental (bacterial, viral, parasitic) specimens to CDC or state labs for testing

☒Required ☐Optional

g) Conduct testing and/or subtyping as part of CryptoNet, the national database for cryptosporidiosis

i. Collect, screen, and ship *Cryptosporidium* positive clinical (outbreak and/or sporadic) and zoonosis-associated animal specimens in compatible fixative to the CryptoNet Reference Laboratory at CDC for subtyping

ii. If certified, conduct near real-time subtyping of *Cryptosporidium* positive stools using CryptoNet protocols

iii. If certified upload subtyping results and associated metadata to CryptoNet using PulseNet infrastructure

☒Required ☐Optional

VII. Strategy 1f: Enhance coordination between lab-epi-HIS

a) Develop or maintain the ability to link laboratory data with epidemiologic data, environmental health data, and other sources as needed (e.g. geospatial and geographic data)

i. Enhance or maintain information and data sharing tools to communicate relevant findings between laboratory, epidemiology, and environmental health

ii. Share data interpretation reports and other relevant information between laboratory, epidemiology, and environmental health and with other appropriate public health staff in real-time

iii. Maintain continuity of epidemiology and laboratory points of contact to jointly achieve NARMS routine surveillance and outbreak representative testing goals

iv. Build and maintain relationships and with informatics and IT partners

☒Required ☐Optional

b) Regularly engage in coordination through routine meetings and information sharing between lab/epi/environmental health

☒Required ☐Optional

c) Facilitate coordination/exchange of data with other jurisdictions during multijurisdictional events and investigations

☒Required ☐Optional

VIII. Strategy 1g: Improve laboratory coordination and outreach to improve efficiency

a) Improve coordination/consolidation activities, workflows, and flow of information within laboratories

☒Required ☐Optional

b) Actively communicate with Area/Regional/Reference laboratories, within area/region laboratories, and CDC laboratories, as appropriate

i. Work with PulseNet Area Laboratories in your area/region and PulseNet Central at CDC to communicate information about subtyping data, troubleshooting issues, and any issues affecting network function

ii. Work with CryptoNet Regional Laboratories in your region and the CryptoNet Reference Laboratory at CDC to communicate information about specimen sampling and processing, subtyping data, and troubleshooting issues

iii. Work with area/regional laboratories and the CaliciNet reference laboratory at CDC about specimen sampling and processing, typing data, and troubleshooting issues

☒Required ☐Optional

IX. Strategy 1h: Advance electronic information exchange implementation

a) Incorporate all condition-specific data elements in the Foodborne and Diarrheal Diseases Message Mapping Guide (https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html) and listeriosis MMG, when available, into data management systems and test electronic data transmission processes for case surveillance with CDC partners to ensure accuracy and completeness of data transmitted

☒Required ☐Optional

b) Implement or continue HL7 transmission of national case surveillance data to CDC for all of nationally notifiable (foodborne, waterborne, and environmentally transmitted) diseases with a standard questionnaire or data elements that are specified in CSTE position statements. This includes listeriosis, STEC and post-diarrheal HUS, vibriosis, cholera, typhoid fever, paratyphoid fever, salmonellosis, shigellosis, and campylobacteriosis, cryptosporidiosis, and giardiasis

i. Transmit all core data elements in the Generic Version 2 Message Mapping Guide (https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html) via the HL7 electronic reporting standard)

ii. Transmit all condition-specific data elements in the Foodborne and Diarrheal Diseases Message Mapping Guide using the HL7 electronic reporting standard (https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html) and listeriosis MMG, when available.

iii. If HL7 transmission is not feasible, transmit or describe plans to transmit core and condition-specific data elements in an electronic tabular format (e.g., *.xls or *.csv) by email; if transmission of electronic tabular data is not feasible, describe plans to transmit data via traditional mechanisms (e.g., email/fax of individual case report forms).

iv. For cryptosporidiosis, if HL7 transmission is not feasible, assess feasibility of electronic transmission of data first for each case for which a *Cryptosporidium* specimen is submitted for subtyping to CryptoNet and for each outbreak-associated case and then sporadic cases for which a *Cryptosporidium* specimen has not been submitted for subtyping to CryptoNet.

☒Required ☐Optional

AREA B: PREVENTION AND INTERVENTION

X. Strategy 2c: Implement health promotion strategies

a) Develop and maintain public-facing foodborne and waterborne disease prevention websites

i. Recommended milestones:
   (a) Having launched a prevention website
   (b) Having updated an existing prevention website

☒Required ☐Optional

b) Develop and disseminate evidence-based health education and promotion materials/messages by a variety of modes to increase health literacy about disease prevention
   i. Review and update food-, water-, and hygiene-related health promotion materials annually, including web materials, social media, and fact sheets
   ii. Develop or maintain the capacity to carry out "Awareness Weeks" (e.g., Healthy Swimming, Healthy Contact Lens Week, Fungal Disease Awareness)
   iii. Websites/communications to explain to public how surveillance is done and what the benefit is to the public

☒Required ☐Optional

c) Work with CDC Waterborne Disease Prevention Branch staff in the first grant year to develop metrics for evaluating health promotion activities

☒Required ☐Optional

d) Use CDC's Model Aquatic Health Code (MAHC; http://www.cdc.gov/mahc), outbreak, and other surveillance data to inform efforts to reduce recreational water-associated illness, drowning, and injuries at public treated aquatic venues. Strategies could include:
   i. Inform the public
      (a) Expand recreational water health and illness, drowning, injury prevention information on state websites
      (b) Add links to all state/local pool codes to state recreational water health website
      (c) Add links, if feasible, to make pool inspection data publicly accessible
   ii. Work with partners
      (a) Build and maintain relationships between epidemiology, laboratory, health promotion, and environmental health staff and/or other staff involved in public pool regulation (e.g., building code, environment) related to healthy swimming and reducing the risk of illness, drowning, and injury in aquatic venues.
      (b) Conduct discussions between health department staff (e.g., epidemiology and environmental health) and aquatics sector representatives to discuss feasibility of adopting key MAHC elements
   iii. Understand, review, and improve the MAHC
      (a) Review the MAHC against existing pool code(s) to identify public health gaps in existing state/local pool code(s). See "Using the MAHC" for key comparison elements (www.cdc.gov/mahc/usingthemahc.html#comparing)

(b) Review the MAHC Annex to be aware of data supporting aquatic facility design and operational changes

(c) Participate in MAHC-related webinars and educational opportunities

(d) Participate in the Council for the Model Aquatic Health Code (CMAHC; www.cmahc.org) to inform or submit recommended improvements to the MAHC

1. Assign a state environmental health designee for CMAHC contact purposes

(e) Explore feasibility of adopting all or key portions of the MAHC identified in gap analysis. Core MAHC element(s) to consider are found at "Using the MAHC" (www.cdc.gov/mahc/usingthemahc.html#comparing) and include areas such as:

1. *Cryptosporidium* reduction and mitigation (Mini MAHCs at www.cdc.gov/mahc/editions/current.html)
2. Pool chemical-associated injury reduction
3. Lifeguarding improvements focused on zones of surveillance
4. Indoor aquatic venue air quality improvement
5. Bather hygiene and pool water contamination reduction
6. Required training and supervision

iv. Enhance pool inspections

(a) Adapt existing pool inspection forms to enhance risk based inspections and decision making

(b) Collaborate with IT/informatics partners to ensure data are entered electronically in a database designed for data analysis (see www.cdc.gov/healthywater/swimming/public-health-professionals/data-collection-database-construction.html)

(c) Use and analyze pool inspection data to inform and target resource use

☒Required ☐Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

XI. Strategy 3a: Coordinate and engage with partners

a) Provide technical assistance and training to local public health agencies and health departments on foodborne, waterborne, enteric, and environmentally transmitted disease prevention issues

☒Required ☐Optional

b) Build and maintain relationships and integration with food and water related partners (e.g., hospital infections, pathogen groups, antimicrobial resistance, environmental health, water utilities, aquatic facilities, beaches, animal health, regulatory partners)

☒Required ☐Optional

c) Work with other local, state, and federal partners to develop and use outbreak investigation materials and guidance for improving foodborne, waterborne, enteric, and environmentally transmitted diseases outbreak detection, investigation, response, reporting, and prevention

i. Collaborate with other jurisdictions and external partners to share lessons learned and improve coordination]

ii. Work with partners such as the Integrated Food Safety Centers of Excellence to identify and use tools and resources in your jurisdiction

iii. Work with partners such as the PulseNet Area Labs, CryptoNet Regional Laboratories, and CaliciNet Outbreak Support Centers (CN-OSCs) and Unexplained Viral Disease Outbreak Support Centers (UVD-OSCs) to identify and use tools and resources in your jurisdiction

iv. Collaborate with organizations such as APHL, FDA, USDA, EPA, USGS, CSTE, WHO INFOSAN, PulseNet International, and others required during investigations of national and international outbreaks and other public health activities

☒Required ☐Optional

XII. Strategy 3b: Information dissemination

a) Regularly analyze, prepare, and disseminate summaries of waterborne disease outbreak data (e.g., reports, manuscripts, and presentations)

☒Required ☐Optional

Tier 2: CryptoNet and CryptoNet Regional Labs

XIII. Strategy 1a: Enhance workforce capacity

a) Participate in monthly CryptoNet calls

☒Required ☐Optional

XIV. Strategy 1b: Enhance investigation and outbreak response

a) Enhanced epidemiologic interviews and investigations

i. Improve interviewing timeliness and completeness: this includes attempting to interview all cases of cryptosporidiosis

ii. Review exposure data for subtyping clusters in real-time

☒Required ☐Optional

XV. Strategy 1c: Improve surveillance and reporting

a) Assess feasibility of implementing electronic transmission of CryptoNet case report form

i. Collect all data elements in CryptoNet case report form for each case for which a *Cryptosporidium* specimen is submitted for subtyping to CryptoNet

ii. Routinely transmit/send data to CDC CryptoNet program

iii. Implement FDD MMG cryptosporidiosis tab

☒Required ☐Optional

XVI. Strategy 1d: Enhance laboratory testing for response

a) Enhanced case investigation response and reporting

i. Provide recommendations and guidance to laboratories within the appropriate region on issues related to laboratory testing or programmatic changes (i.e. WGS)

ii. Serve as a resource for surge capacity testing and reference capabilities in response to large outbreaks

☒Required ☐Optional

b) Sustain and enhance laboratory diagnostic/subtyping capacity

i. Actively participate in evaluation and/or validation of new methods, testing of new software modules and scripts, adopt improvements to laboratory, analysis, communications processes in a timely fashion]

ii. Conduct subtyping and/or WGS using CryptoNet protocols for *Cryptosporidium* clinical cases and zoonosis-related animal specimens, when available

☒Required ☐Optional

XVII. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Enhanced public health laboratory surveillance

i. If possible, conduct subtyping of specimens according to CryptoNet protocols

ii. If conducting subtyping in state public health is not feasible, ship specimens regularly to CDC or regional CryptoNet lab

iii. Provide subtyping and/or WGS capacity to CryptoNet participating laboratories within their designated area

☒Required ☐Optional

Tier 2: *Cyclospora* Genotyping

XVIII. Strategy 1d: Strengthen laboratory testing for response

a) Conduct genotyping of *Cyclospora* as part of case or outbreak investigations

☒Required ☐Optional

Tier 2: Environmental Microbiology

XIX. Strategy 1a: Enhance workforce capacity

a) Support a well-trained staff to conduct testing of environmental samples for waterborne disease investigations

i. Ensure staff are trained in required lab procedures to process and test environmental samples (e.g., water [small and/or large volume], soil, surface, and other samples) for fecal contamination, etiologic agents, and physicochemical water quality parameters

☒Required ☐Optional

XX. Strategy 1d: Enhance laboratory testing for response

a) Develop or maintain capacity to conduct testing of environmental samples for waterborne disease investigations

i. Process and test environmental samples (e.g., water [small and/or large volume], soil, surface, and other samples) for fecal contamination, etiologic agents, and physicochemical water quality parameters

☒Required ☐Optional

b) Collaborate with CDC to develop metrics for environmental assessments as part of waterborne disease investigations

☒Required ☐Optional

Tier 2: FoodCORE

XXI. Strategy 1a: Enhance workforce capacity

a) Participate in monthly program calls, annual vision meetings, and program site visits

☒Required ☐Optional

XXII. Strategy 1b: Enhance investigation and outbreak response

a) Enhanced epidemiologic interviews and investigations

i. Improve interviewing timeliness and completeness: this includes attempting to interview all cases of *Salmonella*, *Listeria* and STEC infection, all cases with WGS/NARMS testing results

ii. Review exposure data for subtyping clusters in real-time

iii. Obtain product information from patients infected with a strain of bacteria that matches a subtyped strain in a food product

iv. Participate in team trainings with state and local staff in outbreak investigation methods

☒Required ☐Optional

b) Enhanced environmental health-related investigation and response activities

i. Conduct assessments as part of cluster, outbreak, and complaint investigations]

ii. [Obtain samples (and associated product information) of implicated and suspect products for testing, as appropriate

☒Required ☐Optional

c) Report program-specific metrics to CDC

i. Working with CDC, develop/modify metrics and report via collaboratively determined mechanisms and timelines. Current metrics available at: https://www.cdc.gov/foodcore/metrics/index.html

☒Required ☐Optional

XXIII. Strategy 1c: Improve surveillance and reporting

a) Assess feasibility of implementing NORSDirect & NEARS

☒Required ☐Optional

XXIV. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Enhanced public health laboratory surveillance
   i. Ensure routine transport of clinical specimens and specimens from outbreak-associated cases to the public health laboratory
   ii. Conduct real-time subtyping of all *Salmonella*, STEC, and *Listeria*
   iii. Conduct real-time testing/diagnostics of parasitic identification and calicivirus characterization
   iv. Collect serologic samples from persons with Hepatitis A virus infection linked to foodborne disease outbreaks for molecular characterization

☒Required ☐Optional

Tier 2: FoodNet

XXV. Strategy 1a: Enhance workforce capacity

a) Support staff to collect and submit epidemiological data to CDC
   i. Ensures coordination with laboratory for prioritizing isolate sequencing of cases with exposure and antimicrobial use information
   ii. Works with laboratory point of contact to link laboratory and epidemiologic data
   iii. Ensures epidemiologic interviews and data is complete and submitted to CDC FoodNet

☒Required ☐Optional

XXVI. Strategy 1c: Improve surveillance and reporting

a) Enhance epidemiologic interviews and data collection
   i. Complete interviews of patients for standardized demographic, clinical, and travel data elements
   ii. Collect diagnostic method and test brand used for enteric testing
   iii. Collect standardized data elements associated with antimicrobial resistance infections and case exposure ascertainment
   iv. Complete transmission of data to CDC FoodNet on or before timeline requested by program

☒Required ☐Optional

b) Conduct surveillance for emerging enteric pathogens
   i. Collect standardized data associated with FoodNet designated pathogens (e.g. ETEC, EAEC)
   ii. Complete submission of data to CDC FoodNet on or before timeline requested by program]
   iii. Participate in project to evaluate polymicrobial detections

☒Required ☐Optional

c) Conduct surveillance for laboratory testing practices and volume data for laboratories reporting to FoodNet sites
   i. Collect standardized data elements associated with laboratory testing volume
   ii. Complete yearly submission of data to CDC FoodNet on or before timeline request by program

☒Required ☐Optional

d) Report FoodNet-specific measures to CDC
   i. Performance metrics for new activities will be developed in collaboration with sites in the first six months of the award
   ii. Sites will report data for laboratory practices and testing volume as determined with CDC
   iii. CDC will calculate other site-specific measures and provide an annual summary to sites

☒Required ☐Optional

XXVII. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Conduct laboratory testing and subtyping for FoodNet activities
   i. Develop laboratory capability for parallel testing by CIDT and culture
   ii. Develop laboratory capability for testing of emerging enteric pathogens
   iii. Enhance capacity to reflex culture

☒Required ☐Optional

b) Store/preserve isolates for future characterization
   i. Ensure all isolates with exposure and antimicrobial epidemiologic information are stored
   ii. Store a sample of isolates for all FoodNet pathogens

☒Required ☐Optional

XXVIII. Strategy 1f: Enhance coordination between lab-epi-

a) Develop and implement a plan for prioritizing isolate sequencing and epidemiologic interviews
   i. Laboratory and epidemiology staff must be involved in plan development and implementation

☒Required ☐Optional

XXIX. Strategy 1h: Advance electronic information exchange implementation

a) Update site surveillance systems to collect and transmit FoodNet active surveillance data through HL7
Recommended milestones:

- Have performed gap analysis using FDD MMG
- Have incorporated FoodNet data elements into state electronic surveillance system OR ensured elements are mapped into the HL7 message to be sent to CDC
- Have transmitted test messages with FoodNet-specific data elements to CDC
- Have validated HL7 FoodNet data with CDC staff
- Have completed full migration to HL7 data transmission

☒Required ☐Optional

XXX. Strategy 1i: Sustain and/or enhance information systems

a) Develop/maintain the ability to link laboratory data with FoodNet epidemiologic data

i. Maintain a current laboratory point of contact for FoodNet related activities

ii. Ensure laboratory specimen identifiers for PulseNet sequence information (e.g. PulseNet key, WGS ID) is transmitted to CDC

☒Required ☐Optional

Tier 2: NoroSTAT

XXXI. Strategy 1c: Improve surveillance and reporting

a) Report all suspected and confirmed norovirus outbreaks due to any mode of transmission through NORS within 7 business days of notification of the outbreak to the state health department

i. Provide a minimum set of data elements in the NORS outbreak reports (includes: state, date of outbreak, number ill, suspected or confirmed etiology, and setting)

☒Required ☐Optional

b) Report all laboratory-confirmed norovirus outbreaks due to any mode of transmission through CaliciNet within 7 business days of receipt of outbreak specimens

i. Include a unique outbreak identifier in CaliciNet reports enabling linkage of those records with the appropriate NORS outbreak report

☒Required ☐Optional

Tier 2: National Respiratory and Enteric Virus Surveillance System (NREVSS) Enhanced

XXXII. Strategy 1c: Improve surveillance and reporting

a) **E**stablish and/or increase participation in clinical laboratory reporting of aggregate norovirus diagnostic results via the National Respiratory and Enteric Virus Surveillance System (NREVSS), either directly or through local/state health departments

☒Required ☐Optional

b) Collect corresponding demographic and clinical data on patients tested for norovirus at clinical laboratories

☒Required ☐Optional

c) Request aliquots/residual stool specimens from patients that test positive for norovirus at clinical laboratories to be sent to public health laboratories for further confirmation and genotyping.

☒Required ☐Optional

Tier 2: HAB Surveillance, Response and Mitigation

Special funding is available for Tier 2: Harmful algal bloom (HAB) Activities. Priority will be given to geographic locations subject to a state of emergency designation related to toxic algae blooms within the past 12 months of the drafting of this funding opportunity.

- Estimated total availability of funds: $450,000 - $500,000
- Estimated number of awards given: 2-4

XXXIII. Strategy 1c: Improve surveillance and reporting

a) Address public health issues related to harmful algal blooms in one or more of the following areas: surveillance, mitigation, or event response.
   i. Report HAB associated event and illness data (human and animal) to OHHABS
   ii. Develop protocol and resources for public health response and mitigation to HAB events
   iii. Weekly/Ongoing surveillance, detection, investigation, and reporting of HAB-associated illnesses and events, as well as HAB-associated outbreaks, to CDC
   iv. Utilization of a **One Health** approach at state and local levels to build relationships supportive of HAB surveillance, mitigation, or event response in the state
   v. Participation in monthly state/ELC and HAB surveillance group calls coordinated by CDC

☒Required ☐Optional

b) Lead a peer-to-peer network of HAB planning and response
   i. Lead coordination across and between states (regardless of funding status) in sharing scientific evidence and programmatic best practices for HAB-associated outbreaks for both drinking and recreational waters

☐Required ☒Optional

Tier 2: OutbreakNet Enhanced

XXXIV. Strategy 1a: Enhance workforce capacity

a) Work with a CoE

i. Identify and implement projects or trainings that engage an Integrated Food Safety Center of Excellence (CoE); this could be a hands-on project or application of existing CoE-developed tools. A new/distinct project does not need to be developed for each grant year

☒Required ☐Optional

b) Participate in monthly program calls and site visits

☒Required ☐Optional

XXXV. Strategy 1b: Enhance investigation and outbreak response

a) Improve interviewing timeliness and completeness: this includes attempting to interview all cases of *Listeria* and STEC infection, all cases with WGS/NARMS testing results, and as many *Salmonella* cases as possible, in addition to those associated with multistate cluster investigations

☒Required ☐Optional

b) Report program-specific metrics to CDC

i. Working with CDC, develop/modify metrics and report via collaboratively determined mechanisms and timelines. Current metrics available at: https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html

☒Required ☐Optional

XXXVI. Strategy 1c: Improve surveillance and reporting

a) Assess feasibility of implementing NORSDirect and NEARS

i. In the first year, explore completion of the NEARS free e-Learning on Environmental Assessment of Foodborne Illness Outbreaks course (http://www.cdc.gov/nceh/ehs/elearn/ea_fio/index.htm).

ii. If feasible, develop a plan for participation in NEARS; if not feasible please describe primary barriers.

☒Required ☐Optional

Tier 2: PulseNet Area Laboratories

XXXVII. Strategy 1d: Enhance laboratory testing for response

a) Enhanced outbreak investigation response and reporting

i. Provide recommendations and guidance to laboratories within the appropriate region on issues related to laboratory testing or programmatic changes (i.e. WGS and non-culture based methods)

ii. Serve as a resource for surge capacity testing and reference capabilities in response to large foodborne outbreaks or potential threats of bioterrorism that might occur locally or nationally

☒Required ☐Optional

b) Sustain and enhance laboratory diagnostic/subtyping capacity

i. Actively participate in evaluation and/or validation of new methods, testing of new software modules and scripts, adopt improvements to laboratory, analysis, communications processes in a timely fashion

☒Required ☐Optional

XXXVIII. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Improve surveillance to drive public health action

i. Provide laboratory bench training, technical guidance and scientific expertise to PulseNet participating laboratories within their designated area

☒Required ☐Optional

XXXIX. Strategy 1f: Enhance coordination between lab-epi-HIS

a) Improve laboratory coordination and information flow between state public health laboratories

i. Coordinate and host PulseNet regional and training meetings

ii. Serve as representative of laboratories within their areas/region on the PulseNet Steering Committee and the PulseNet/OutbreakNet Regional Meeting and InFORM planning committees

☒Required ☐Optional

Tier 3: Integrated Food Safety Centers of Excellence

XL. Strategy 1a: Enhance workforce capacity

a) Develop and disseminate resources to improve surveillance and investigation of foodborne illness and outbreaks and to improve information systems (FSMA Legislative Activities 1 and 6)

i. Improve the ability of other health departments to conduct surveillance and investigation of foodborne illness and outbreaks; strengthen the knowledge base of the network of public health professionals that respond to foodborne illness, and provide a forum for peer-to-peer exchange of ideas

ii. Conduct in-person and/or remote site visits, trainings, consultations, etc. to other jurisdictions

iii. Host reverse site visits with public health staff visiting the CoE

iv. Develop materials and posted them to the CoEFoodSafetyTools.org

☐Required ☒Optional

b) Assist public health agencies perform analyses to evaluate the timeliness and effectiveness of surveillance and investigation of foodborne illness and outbreaks (FSMA Legislative Activity 2)

i. Provide assistance on the use of performance metrics and/or evaluation tools

ii. Create reports, manuscripts, and presentations completed using data from foodborne illnesses and outbreak surveillance systems

iii. Describe research and analysis projects funded by non-ELC sources

☐Required ☒Optional

c) Improve access to trainings and education for students and public health personnel in laboratory, epidemiological, and environmental investigation of foodborne illness (FSMA Legislative Activities 3, 4, & 5)

i. Deliver in-person and online courses (including live learning courses)

ii. Develop and deliver a food safety or foodborne illness certificate program

iii. Establish stipends/scholarships for food safety or foodborne illness programs

iv. Support students and projects through internships/field placements

☐Required ☒Optional

d) Enhance awareness and communication of available tools and resources surveillance and investigation of foodborne illness and outbreaks (FSMA Legislative Activity 7)

i. Maintain a CoE website

ii. Develop and distribute social posts about the CoEs and foodborne disease

iii. Attended meetings to present/promote the CoEs

☐Required ☒Optional

e) Participate in monthly program calls, workgroup calls, annual vision meetings, and program site visits

☐Required ☒Optional

f) Work with CDC CoE program staff to develop and report program-specific performance metrics

i. Working with CDC, develop/modify metrics and report via collaboratively determined mechanisms and timelines. Current metrics include tracking activities such as the number of other jurisdictions assisted, reports/manuscripts/presentations developed, training courses delivered, website usage data, and CoE promotion activities. Full details for these metrics are available via program staff: FoodSafetyCoE@cdc.gov

☐Required ☒Optional

Collaborations

a. With CDC funded programs

Integrated Food Safety Centers of Excellence (CoEs), CaliciNet, CryptoNet, EHS-Net, FoodCORE, FoodNet, NARMS, NCEH SAFE WATCH/Private Well Initiative, OHHABS, PulseNet.

b. With organizations external to CDC

Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, U.S. Environmental Protection Agency (EPA), U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), and the U.S. Food and Drug Administration (FDA)

Target Populations

N/A

Evaluation and Performance Measurement

Measures #1-2 (Tier 1)

1. Report completeness and timeliness data for interviews for cases of *Salmonella*, STEC, and *Listeria* infection associated with multistate outbreaks in which an outbreak-specific questionnaire was disseminated by CDC (Activity 1b.2)

2. Please report separately for *Salmonella*, STEC, and *Listeria*:

- Proportion of outbreak-specific questionnaires returned to CDC
- Median time (in days) from date of notification to completion using an outbreak-specific questionnaire disseminated by CDC

Measures #3-4 (Tier 1)

Report data for MMG use/implementation (Activity 1h.1)

3. Percent of generic version 2 data elements that have been incorporated into state electronic disease surveillance systems for transmission by HL7 message, by pathogen.

4. Percent of condition-specific data elements in the FDD MMG that have been incorporated into state electronic disease surveillance systems for transmission by HL7 message, by pathogen.

Measures #5-7 (Tier 1)

Report data for PulseNet activities (Activity 1e.1)

5. Total # of Isolates Received in the Public Health Lab

- *E. coli* O157, Non-O157 STEC, *Listeria*, *Salmonella*, Nontyphoidal *Salmonella* (including ser. Paratyphi B), *Salmonella* ser. Typhi, *Salmonella* ser. Paratyphi A, *Salmonella* ser. Paratyphi C, *Shigella*, *Campylobacter*, *Vibrio cholerae*, Non-cholerae *Vibrio*

6. WGS Measures for *E. coli* O157:H7, Non-O157 STEC, *Listeria*, *Salmonella*, *Campylobacter*, *Vibrio cholerae*, Non-cholerae *Vibrio*

- # of Human Isolates sent to another Lab for WGS
- Total # of Isolates Sequenced in-house
- # of Human Isolates Sequenced in-house
- % in-house WGS of Human Sequences Submitted within 7 Working Days
- Median Turn-Around-Time for in-house WGS of Human Isolates (in working days)

7. CIDT Measures for *E. coli*, STEC, *Salmonella*, and *Campylobacter*

- Specimens/Broths Received in PHL for *E. coli*, *Salmonella*, *Campylobacter*
- Specimens/ Broths sent to CDC for Isolation and/or Serotyping for *E. coli*, *Salmonella*, *Campylobacter*
- Number Identified for STEC O157, STEC Non-O157, STEC Negative/Repeat Tests, *Salmonella*, *Campylobacter*

Measure #8-11 (Tier 1)
Report data for CryptoNet activities (Activity 1e.3) 8. Number (percent) of outbreak-associated and sporadic *Cryptosporidium* specimens submitted to CDC for typing (required only if funded for CryptoNet) 9. Number (percent) of CDC or regional lab submitted specimens with completed CryptoNet forms submitted to CDC CryptoNet 10. Number (percent) of outbreak-associated and sporadic *Cryptosporidium* specimens subtyped (required only if funded for CryptoNet) 11. Number (percent) of in house typed specimens with completed CryptoNet case form submitted to CDC CryptoNet
Measures #12-14 (Tier 1)
Report data for CaliciNet activities (Activity 1e.4). Please note, there are additional CaliciNet measures that will be calculated by CDC staff; these are described later in the measures section. 12. Outbreaks (≥ 2 specimens) tested for norovirus: • total number • number with likely foodborne transmission • percentage with likely foodborne transmission 13. Outbreaks (≥ 2 specimens) sequenced for norovirus • total number • number with likely foodborne transmission • percentage with likely foodborne transmission 14. Frequency (e.g., weekly, monthly, quarterly) of meetings between epidemiology and laboratory staff on norovirus outbreaks
Tier 2 NREVSS Measures (#1-3)
1. Number of clinical laboratories reporting weekly aggregate counts of norovirus tests performed and the number of those testing positive into NREVSS. 2. Number (%) of patients testing positive for norovirus at clinical laboratories for whom demographic/clinical data are provided. 3. Number (%) of patients testing positive for norovirus at clinical laboratories for whom stool specimens were sent to the public health laboratory for confirmation and genotyping
Tier 2 HAB Measures (#4-5)
Report data for HAB activities. Please note, there are additional HAB measures that will be calculated by CDC staff; these are described later in the measures section. 4. Report of engagement with CDC or other federal agencies on waterborne or HAB disease and outbreak detection, investigation, and reporting, including with whom engagement occurred. 5. Report of coordination and technical assistance provided to participating jurisdictions by topic area Jurisdiction-reported metrics may be developed/modified via a collaborative process between CDC and participating jurisdictions. They will evaluate a list of measurable activities addressing HAB concerns and issues relevant to the jusisdictions awarded. These indicators will help state and local public health officials in the develop courses of action for surveillance, response and mitigation of HAB outbreaks.

Tier 2 PulseNet Area Laboratories Measures (#6-8)
6. Number of individuals your lab trained from other laboratories in your area (PFGE and/or WGS) 7. Number of isolates for which PFGE testing was done from other laboratories in your area 8. Number of isolates for which WGS testing was done from other laboratories in your area
Tier 2 FoodCORE Measures
The FoodCORE metrics data are reported biannually to the CDC FoodCORE Team; Applicants who are currently funded FoodCORE centers do not need to resubmit metrics data that were previously submitted in biannual reports. Otherwise, applicants should describe in general terms a plan for collecting FoodCORE metrics (e.g. if there are existing data sources or if systems or sources would need to be modified or developed). The metrics are developed/modified via a collaborative process between CDC and participating jurisdictions. They evaluate a list of measurable activities covering diverse aspects of outbreak response. These indicators will help state and local public health officials in the FoodCORE catchment areas evaluate and implement effective standardized surveillance and response for enteric disease outbreaks, document successful models, and hone response methodology. Additional information for the current metrics and relevant definitions can be accessed at: http://www.cdc.gov/foodcore/metrics.html.
Tier 2 OutbreakNet Enhanced Measures
The OutbreakNet Enhanced metrics data are reported annually to the CDC OutbreakNet Enhanced Team; Applicants who are currently funded OutbreakNet Enhanced sites do not need to resubmit metrics data that were previously submitted in annual reports. Otherwise, applicants should describe in general terms a plan for collecting OutbreakNet Enhanced metrics (e.g. if there are existing data sources or if systems or sources would need to be modified or developed). The metrics are developed/modified via a collaborative process between CDC and participating jurisdictions. They evaluate a list of measurable activities covering diverse aspects of outbreak response. These indicators will help state and local public health officials in the OutbreakNet Enhanced catchment areas evaluate and implement effective standardized surveillance and response for enteric disease outbreaks, document successful models, and hone response methodology. Additional information for the current metrics and relevant definitions can be accessed at: https://www.cdc.gov/foodsafety/outbreaknetenhanced/metrics.html.
Tier 2 FoodNet Measures
The FoodNet performance metrics will be developed via a collaborative process between CDC and FoodNet sites. Metrics and the reporting details will continue to be developed collaboratively during the project period. Additionally, CDC will calculate site-specific measures and provide an annual summary to sites.
Tier 3 Integrated Food Safety Centers of Excellence Measures
The Integrated Food Safety Centers of Excellence (CoEs) performance metrics are developed/modified via a collaborative process between CDC and CoE participating jurisdictions. Metrics and the reporting details will continue to be developed collaboratively during the project period. Full details for the current metrics are available via program staff: FoodSafetyCoE@cdc.gov
The following performance measures will all be reported to recipients by CDC program staff; recipients do not need to calculate or submit these data via ELC.

National Surveillance Team staff will calculate the following metrics using data from surveillance systems (See Project F Appendix 1). (Tier 1 Activities 1c.1 and 1.c2)

- The number of detected cases of *Salmonella*, *Shigella*, *Campylobacter*, and STEC infection reported to LEDS.
- Number of cases of listeriosis, cholera and vibriosis, typhoid and paratyphoid fever, and STEC reported through HL7 message transmission to CDC.
- Number of cases of listeriosis, cholera and vibriosis, and typhoid and paratyphoid fever reported through a standard questionnaire or data elements that are specified in CSTE position statements or electronic tabular format to CDC.
- The following metrics will be calculated separately for listeriosis, cholera and vibriosis, typhoid and paratyphoid fever, and STEC based on reporting of current standard questionnaires (or the corresponding data elements) to CDC:
    - The proportion of reports with minimally sufficient demographic data (age, sex, race, ethnicity and for listeriosis cases pregnancy status)
    - The proportion of reports with minimally sufficient epidemiologic data (travel history; for listeriosis nursing home history; for cholera and vibriosis outbreak status and water exposure history)
    - The proportion of reports with minimally sufficient clinical data (illness onset, hospitalization, clinical outcomes, signs and symptoms and medical history)
    - The proportion of reports with minimally sufficient laboratory data (specimen source, date of collection, state public health laboratory isolate identification number; for vibriosis species isolated or detected)
    - The proportion of reports with minimally sufficient food history data (not applicable to typhoid and paratyphoid fever cases)
    - The proportion of reports with submitted to CDC within 7 days of interview date for listeriosis, within 30 days of isolation or detection for cholera and vibriosis, typhoid and paratyphoid fever, and STEC
- The proportion of listeriosis cases with clinical isolates uploaded to PulseNet within 14 days of specimen collection date
- The proportion of culture-confirmed cases with an identifier that links epi data to PulseNet isolate data for STEC and listeriosis

NORS staff will calculate the following measures and will provide a summary to each reporting site that describes and assesses site-specific performance. The summary also will include performance data aggregated from all of the reporting sites in order to give sites a sense of their relative performance. For the data completion measures, entering unknown or undetermined when applicable will count as completion. The NORS reporting forms and guidance are available at www.cdc.gov/nors

- Number of finalized outbreaks reported to NORS per 1,000,000 persons per year. Target:
    - Animal contact: 0.5 outbreaks per million population per year
    - Foodborne: 2 outbreaks per million population per year
    - Person-to-person: 5 outbreaks per million population per year
    - Waterborne: 0.25 outbreaks per million population per year

- Percentage of outbreak reports with complete information on primary cases, based on the following fields. Target: 100%.
    - Age groups of cases, sex of cases, number of hospitalizations, number of cases with information on hospitalization status, number of deaths, and number of cases with information on death status.
- Percentage of outbreak reports with complete information on outbreak etiology, based on the following fields. Target: 100%.
    - For animal contact, environmental, foodborne, person-to-person, and unknown mode outbreaks, answer for "Is there at least one confirmed or suspected etiology?" Completion of etiology table when at least one etiology is confirmed or suspected, i.e., genus, species, serotype, confirmed/suspected status, and number of lab-confirmed cases.
    - For waterborne outbreaks, completion will be reviewed for genus/chemical/toxin, species, serotype/serogroup/serovar, genotype/subtype, total number of tested primary cases, and total number of primary cases tested positive.
    - Additionally, for confirmed etiologies of PulseNet/NARMS pathogens *Campylobacter*, *E. coli*, *Listeria*, *Salmonella*, *Shigella*, and *Vibrio*, completion of isolates table including CDC System, State Lab ID, and PulseNet cluster code.
- Percentage of animal contact, foodborne, and waterborne outbreak reports with complete vehicle or type of water exposure and venue/system information, based on the following fields. Target: 100%.
    - For animal contact outbreaks, animal vehicle, animal type, confirmed/suspected status, and reasons confirmed/suspected, or "animal vehicle undetermined" is selected with reason(s) animal contact with undetermined vehicle entered.
    - For foodborne outbreaks, food name, confirmed/suspected status, reason(s) confirmed/suspected, method(s) of processing and preparation, and import status, or "food vehicle undetermined" is selected with reason(s) foodborne with undetermined vehicle entered.
    - For waterborne outbreaks, completion will be reviewed for type of water exposure (including other type and unknown type), water venue (treated and untreated), drinking water system, and other type description ("water type" field).
- Percentage of outbreak reports with complete information on setting, based on the following fields. Target: 100%.
    - For animal contact outbreaks, settings of exposure are entered.
    - For environmental, person-to-person, and unknown mode outbreaks, major setting of exposure is entered.
    - For foodborne outbreaks, location where food was prepared and location of exposure fields are entered.
    - For waterborne outbreaks, recreational water setting of exposure (treated and untreated), drinking water setting of exposure, or other setting of exposure is entered (other/unknown type of water exposure).

NARMS staff will calculate the following measures using data on isolates and outbreaks from the previous calendar year. Guidelines for isolate shipping can be found at https://www.cdc.gov/ncezid/dfwed/edlb/index.html under "Laboratory protocols and resources" (in table,

under Service, see "NARMS" for routine surveillance and "Outbreak investigation" for outbreak isolate shipping)

- Number and percentage of isolates (collected from humans in previous calendar year) received by state laboratory that were shipped to NARMS as part of routine surveillance. These include isolates with specimen collection dates in 2018 that were shipped to NARMS during CY 2018 and early CY 2019. All isolates should be received at CDC before the routine surveillance isolate submission deadline. Target:

a) Nontyphoidal *Salmonella* (including serotype Paratyphi B): 5% - the first 2018 isolate received and every 20th thereafter
b) *Shigella*: 5% - the first 2018 isolate received and every 20th thereafter
c) *E. coli* O157: 5% - the first 2018 isolate received and every 20th thereafter
d) *Salmonella* typhi: 100% - all isolates, including duplicates
e) Paratyphi A and C: 100% - all isolates, including duplicates
f) *Vibrio* species other than *V. cholerae*: 100% - all isolates, including duplicates
g) *Campylobacter* (FoodNet sites only): varies by site

- Total number of routine surveillance shipments of 2018 isolates (those collected from humans in calendar year 2018) made to NARMS; target: at least 4 quarterly shipments within a month after each quarter
- Number of suspected single-state outbreaks of *Salmonella*, *Shigella*, and diarrheagenic *E. coli* having three representative isolates submitted to the appropriate contact person/laboratory unit within the Enteric Diseases Laboratory Branch at CDC for antimicrobial susceptibly testing (AST). These include outbreaks where the first primary case became ill in CY 2018. Target: Three representative isolates from 100% of suspected single-state outbreaks for *Salmonella*, *Shigella*, and diarrheagenic *E. coli* (If <3 isolates are available, sites should send as many isolates as are available)

CDC CaliciNet staff will calculate the following measures from data submitted to CaliciNet:

- Norovirus sequences submitted/uploaded to CaliciNet within 2 weeks after receiving samples in the laboratory
  - total number
  - percentage
- Mandatory attendance of at least one laboratorian per CaliciNet-certified laboratory to the annual CaliciNet User meeting

Tier 2 NoroSTAT Measures

CDC NoroSTAT staff will calculate the following measures surveillance and outbreak data

- Of all suspected and confirmed norovirus outbreaks due to any mode of transmission reported to NORS, number (percent) reported within 7 business days of initial report to state health department.
- Of all confirmed norovirus outbreaks (typically 2 specimens required by the state for confirmation) due to any mode of transmission reported to CaliciNet, number (percent) reported within 7 business days of receipt at the state laboratory.
- Of all suspected and confirmed norovirus outbreaks reported to NORS, number (percent) reported with the minimum data elements completed (state, date of outbreak, number ill, suspected or confirmed etiology, and setting).

- Of all confirmed norovirus outbreaks reported to CaliciNet, number (percent) containing an outbreak identifier that can be linked with a corresponding NORS Report

Tier 2 HAB Measures

CDC NoroSTAT staff will calculate the following measures surveillance and outbreak data

- Number of reports and human and animal case forms entered in OHHABS
- Percent of OHHABS reports that have been finalized
- Percent of NORS foodborne or waterborne HAB outbreak reports that have corresponding OHHABS reports.

Project F Appendix 1: National Case Surveillance Appendix

Disease	Message Mapping Guides (MMG)[1]	Surveillance case definition and Standard questionnaire or Data elements defined in CSTE position statement	Surveillance system
Listeriosis	GenV2 & Listeriosis MMG	https://www.cdc.gov/listeria/surveillance.html	*Listeria* Initiative, NNDSS
STEC	GenV2 & FDD MMG	https://wwwn.cdc.gov/nndss/conditions/shiga-toxin-producing-escherichia-coli/case-definition/2018/ https://www.cdc.gov/nationalsurveillance/ecoli-surveillance.html	STEC Initiative,[2] LEDS[4], NNDSS
Post-diarrheal HUS	GenV2	N/A	NNDSS
Cholera and Vibriosis	GenV2 & FDD MMG	https://www.cdc.gov/vibrio/surveillance.html	Cholera and Other *Vibrio* Illness Surveillance (COVIS) System, NNDSS
Typhoid and Paratyphoid Fever	GenV2 & FDD MMG	https://www.cdc.gov/typhoid-fever/surveillance.html	National Typhoid and Paratyphoid Fever Surveillance (NTPFS), NNDSS
Botulism	GenV2	https://www.cdc.gov/botulism/surveillance.html	National Botulism Consultatio

			n Service, NNDSS
Salmonellosis	GenV2& FDD MMG	https://www.cdc.gov/nationalsurveillance/salmonella-surveillance.html	LEDS[4], NNDSS
Shigellosis	GenV2 & FDD MMG	https://www.cdc.gov/nationalsurveillance/shigella-surveillance.html	LEDS[4], NNDSS
Campylobacteriosis	GenV2 & FDD MMG	https://wwwn.cdc.gov/nndss/conditions/campylobacteriosis/case-definition/2015/	NNDSS
Cryptosporidiosis	GenV2 & FDD MMG	https://wwwn.cdc.gov/nndss/conditions/cryptosporidiosis/ CryptoNet case report form: https://www.cdc.gov/parasites/crypto/cryptonet.html	NNDSS CryptoNet for enhanced molecular surveillance
Giardiasis	GenV2	No nationally defined disease specific elements https://wwwn.cdc.gov/nndss/conditions/giardiasis/	NNDSS
Free living amebae infections	Gen V2	Not nationally notifiable but under standardized surveillance: Naegleria fowleri causing primary amebic meningoencephalitis (PAM): https://wwwn.cdc.gov/nndss/conditions/naegleria-fowleri-causing-primary-amebic-meningoencephalitis-pam/ Balamuthia mandrillaris disease https://wwwn.cdc.gov/nndss/conditions/balamuthia-mandrillaris-disease/ Acanthamoeba Disease (Excluding Keratitis) https://wwwn.cdc.gov/nndss/conditions/acanthamoeba-disease-excluding-keratitis/	NNDSS

Abbreviations: Generic Version 2 (GenV2), Message Mapping Guide (MMG), Foodborne and Diarrheal Diseases (FDD), Shiga toxin-producing *E. coli* (STEC), Message Mapping Guide (MMG), Laboratory-based Enteric Disease Surveillance (LEDS), Cholera and Other Vibrio Illness Surveillance (COVIS), National Typhoid and Paratyphoid Fever Surveillance (NTPFS)

[1]Finalized MMGs can be accessed here: https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html

[2]STEC Initiative collects data only through electronic data transmission (HL7 or tabular electronic data).

[3]States will be asked to provide a PulseNet identifier for cases of post-diarrheal HUS cases reported to NNDSS, where applicable.

[4]LEDS data is collected directly from FoodNet for participating sites.

Abbreviations: Generic Version 2 (GenV2), Message Mapping Guide (MMG), Foodborne and Diarrheal Diseases (FDD), Shiga toxin-producing *E. coli* (STEC), Message Mapping Guide (MMG), Laboratory-based Enteric Disease

Surveillance (LEDS), Cholera and Other Vibrio Illness Surveillance (COVIS), National Typhoid and Paratyphoid Fever Surveillance (NTPFS)

[1]Finalized MMGs can be accessed here: https://wwwn.cdc.gov/nndss/case-notification/message-mapping-guides.html

[2]STEC Initiative collects data only through electronic data transmission (HL7 or tabular electronic data).

[3]States will be asked to provide a PulseNet identifier for cases of post-diarrheal HUS cases reported to NNDSS, where applicable.

[4]LEDS data is collected directly from FoodNet for participating sites.

G: Healthcare-associated Infections and Antibiotic Resistance Program

The Epidemiology and Laboratory Capacity for Infectious Diseases Guidance for the 2019–2023 cycle includes a program that addresses healthcare-associated infections (HAIs) and antibiotic resistance (AR). The HAI/AR Program includes two interrelated components —***G1: Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship*** and ***G2: Antibiotic Resistance Laboratory Network (AR Lab Network)***. During the last two years of the 2015–2019 cycle, the minimum required epidemiology activities for the health department HAI/AR program and related state-based laboratory activities were consolidated into a single project (K1A), while the regional laboratory activities were included in a separate project (K3). Notable changes in the 2019–2023 cycle are (a) the inclusion of all epidemiology activities in a single component (G1) rather than several discrete projects, and (b) the deconsolidation of epidemiology and laboratory activities into separate guidance such that state-based laboratory activities are included with regional laboratory activities in a single laboratory component (G2), reflecting that both the state and regional labs comprise the AR Lab Network. Applicants should note activities in their G1 and G2 applications aimed at improving epidemiology-laboratory (epi-lab) collaboration across the HAI/AR Program.

Key points about each component:

G1: Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship

- Epidemiology activities have been organized in two Tiers.
    - Tier 1 activities are required of all Recipients.
    - All Tier 2 activities are optional. Recipients may apply for funding of none, any, or all activities. We anticipate awarding funding to up to 10 Applicants per optional project.
- The activities described in this portion of the guidance are focused on epidemiology; there are no laboratory activities. However, the guidance includes several activities aimed at improving coordination between epidemiologists in the health department HAI/AR program and laboratories in the AR Lab Network. In general, epidemiologists should use data provided by the AR Lab Network (and other appropriate sources) to define local epidemiology, identify priorities for response and prevention, and facilitate coordinated containment and other response efforts, including sharing of laboratory results for timely action and providing recommendations for testing.
    - For containment, see Core Area A, Strategy I
    - For responses other than containment, see Core Area A, Strategy II
    - For other epi-lab collaboration, see Core Area A, Strategy IV
- The HAI coordinator should assure epi-lab coordination. This could be accomplished by the HAI coordinator directly or through assignment of this task.
- The health department HAI/AR program should work with public health laboratory partners to develop coordinated work plans (see Core Area A, Strategy IV).

G2: Antibiotic Resistance Laboratory Network (AR Lab Network)

- Laboratory activities have been organized in three Tiers, all in ELC Core Area A.
    - Tier 1 activities are required of all local or state laboratory Applicants. We anticipate funding up to 56 Applicants.

- Tier 2 activities are optional for local or state laboratory Applicants. We anticipate funding up to 56 Applicants. Applicants who apply for Tier 2 are required to apply for Activity I.a, but remaining activities are optional.
- Tier 3 activities are directed toward regional laboratories and the National TB Molecular Surveillance Center. We anticipate funding up to seven Applicants for regional laboratory activities and one Applicant as the National TB Molecular Surveillance Center.

- The activities described in this guidance are directed toward the laboratory. In general, laboratories should perform testing of isolates and other specimens, provide results back to submitting laboratories, and coordinate with and provide technical support to clinical and other public health laboratories. However, as in the epidemiology guidance, the laboratory guidance includes several activities aimed at improving coordination between laboratories in the AR Lab Network and epidemiologists in the HAI/AR program.
  - See Tier 1, Strategy III
  - See Tier 3, Strategy II (Activity a) and Strategy IV
- The AR lab expert should assure lab-epi coordination with regard to HAI/AR activities, including AR Lab Network activities. This could be accomplished by the AR expert directly or through the assignment of this task.
- The public health laboratory should work with the HAI/AR program to develop coordinated work plans (see Tier 1, Strategy III).

G1: Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship
Program Activity Contact Information
HAIAR@cdc.gov
Funding Opportunity Description
Background
a. Overview
The goals of the Healthcare-associated Infection (HAI)/Antibiotic Resistance (AR) Program are to prevent HAIs to protect patients and healthcare personnel; to advance the detection, response, and containment of AR; and promote antibiotic stewardship (AS), to ensure safety, quality, and value in healthcare delivery systems. Related activities in epidemiology are described here in G1: Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship), while laboratory activities are described in G2: Antibiotic Resistance Laboratory Network (AR Lab Network).
b. Healthy People 2020
The HAI objectives for Healthy People 2020 reflect the commitment of the U.S. Department of Health and Human Services to reduce HAIs and prevent spread of AR. The 2020 targets include reduction in central line-associated bloodstream infections (CLABSIs) by 50%, catheter-associated urinary tract infections (CAUTIs) by 25%, invasive methicillin-resistant *Staphylococcus aureus* (MRSA) infections by 50%, and *Clostridioides difficile* infection (CDI) by 30%.
c. Other National Public Health Priorities and Strategies
Detecting and preventing HAIs and AR is a cross-cutting federal priority. The National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination (HAI Action Plan) sets goals and priorities for reduction of HAIs across healthcare settings, while the National Strategy for Combating Antibiotic-Resistant Bacteria and companion National Action Plan articulate national goals, priorities, objectives, milestones, and reduction targets to provide an overarching framework for federal investments aimed at combating antibiotic-resistant bacteria. Key strategies include containing emerging threats from antibiotic-resistant organisms, detecting and responding to outbreaks within healthcare facilities, promoting surveillance through the National Healthcare Safety Network (NHSN), and expanding prevention efforts through collaborations and innovative approaches. Recipient activities should reflect these strategies as well as recommendations (as available) from the CDC/CSTE Antibiotic Resistance Surveillance Task Force (CSTE Position Statement 13-SI-01) and the Council for Outbreak Response for HAIs and Antimicrobial Resistance (CORHA).
CD Project Description
a. Problem Statement:
HAIs and AR have been a recognized public health threat for many years. HAIs are associated with morbidity, mortality, and increased healthcare costs, yet many are preventable. The threats posed by HAIs caused by antibiotic-resistant pathogens vary nationwide, but AR has been identified in every state. Inappropriate prescribing and consumption of antibiotics contributes to this growing problem of AR. Local, territorial, and state health departments have an important role in coordinating, implementing, and leveraging regional HAI/AR prevention and response efforts, including the promotion of antibiotic stewardship.
b. Purpose:

The purpose of this funding announcement is to support and enhance the capacity of local and state health departments to improve patient safety by preventing HAIs, containing emerging AR, and improving use of antibiotics.

c. Outcomes:

By the end of the project period, Recipients are expected to show measurable progress toward the following outcomes:

- Novel or high-concern resistance rapidly identified and contained
- Timely and effective response to HAI/AR outbreaks
- Reduction in HAIs in all healthcare settings
- Improved infection control capacity and practices in all healthcare settings
- AS core elements implemented in healthcare settings
- Improved information sharing
- Improved data-driven prevention
- Enhanced coordination of prevention efforts in all healthcare settings

Funding Strategy

As a condition of funding under this project, Recipients must attach a letter of commitment from state leadership (e.g., state epidemiologist, state health official) to support the HAI/AR prevention program goals. Recipients should utilize funds for personnel, travel, supplies, equipment, or contractual support for proposed activities. Mechanisms to acquire personnel could include direct hires by Recipient, CDC staff working in the state (e.g., CDC-sponsored fellows, trainees, or other field assignees), or contracts to local experts.

In general, in-state travel for containment, other response activities, onsite assessment of infection control and prevention practices, and other onsite technical assistance will be prioritized over other travel. With the exception of required travel to the annual HAI/AR Recipients' meeting in Atlanta, Georgia, in-state travel will be prioritized over out-of-state travel.

All Recipients are all eligible to apply for **optional** activities (i.e., Tier 2), after first addressing all of the required activities in Tier 1. Priority for funding optional activities in this year will be given to Recipients who showed progress during the prior ELC funding cycle as presented in the application (background and current capacity); propose feasible plans that reflect the Recipient's capacity, include the rationale for why the Recipient considers a problem high priority, and explain how performance measures will be captured and reported; and present credible justification of an unaddressed AR public health threat. Optional activities in Tier 2 might be included in only the first two or three years of the ELC cycle, so work plans should reflect the potential for time-limited funding. We anticipate awarding up to 10 Recipients for each optional activity.

Regardless of Tier, Recipients should make clear in their budget requests which strategies and activities (whether required or optional) will be supported by the requested funding, as well as the justification for why activities are needed; failure to do so may result in failure to receive funding. Recipients should be aware that future funding decisions will be based on measurable progress, as indicated by progress toward desired outcomes and financial spending and reporting, as reported in performance measures and as reported at least quarterly in updates to CDC.

Funding will be prioritized first to support an HAI coordinator and an AR/AS expert, and next for infrastructure (including other personnel) to carry out infection control and prevention work for **required** activities (i.e., Tier 1). Desired personnel should have knowledge and expertise in infection control (e.g., investigating outbreaks in healthcare facilities, use of the tiered containment strategy, decolonization strategies to interrupt transmission), AS, and analysis of surveillance data.

- Estimated total availability of funds: $28,000,000
- Estimated number of awards given: 57
- Estimated average per award: $400,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1b: I. Support containment of novel or high-concern antibiotic-resistant organisms. This includes prompt detection of and response to certain targeted resistant organisms (e.g., pan-resistant organisms) or mechanisms (e.g., mcr-1-producing Enterobacteriaceae) and implementation of regional control strategies for certain resistance mechanisms in geographic areas where these mechanisms are more commonly encountered (e.g., New Delhi metallo-β-lactamase (NDM)-producing Enterobacteriaceae in areas where this mechanism is endemic). Organisms included in each containment tier or targeted for regional intervention may vary by region depending on the local epidemiology.

a) In collaboration with public health laboratories, provide technical expertise and support to clinical laboratories, infection prevention networks, and healthcare facilities.
   i. Using guidance and elements provided by CDC, collaborate with the public health laboratories to develop and regularly update written plans that ensure timely detection and response to targeted resistant threats. The plan should include the list of antibiotic-resistant organisms or mechanisms by response tiers, based on epidemiology of the jurisdiction.
   ii. The plan should be available for review by CDC by the end of the funding year.
   iii. Implement timely detection and response to targeted organisms or mechanisms and track response actions and times. Initiate action within 1 business day of receiving an alert value from the AR Lab Network.
   iv. Provide technical and epidemiologic consultation to public health laboratories in the AR Lab Network to guide recruitment of clinical (i.e., not in the AR Lab Network) laboratories in their jurisdiction that serve facilities identified as high risk for multidrug-resistant organisms (MDROs), as defined by local epidemiology, infection control assessments, and/or CDC guidance for AR Lab Network isolate testing.
   v. Provide outreach and technical assistance to clinical microbiology laboratories and infection prevention networks to improve the detection of targeted organisms, case reporting, and response.
   vi. Advise health care facilities on which specimens to send for testing, promote local, state, and regional laboratory support, and facilitate isolate submission for testing.
   vii. Facilitate coordinated response among interconnected facilities. This includes but is not limited to sharing data, such as laboratory testing results, for situational awareness and action.

☒Required ☐Optional

b) Conduct colonization screenings and continue until spread is controlled. Refer to CDC guidance to determine when colonization screening is recommended. Facilitate timely sharing of colonization screening results and incorporate findings in recommendations to affected healthcare facilities and providers.

☒Required ☐Optional

II. Strategy 1b: Support rapid response. *Response* refers to efforts to control newly identified HAIs and AR risks not described in section I and includes but is not limited to investigation of possible outbreaks or serious infection control breaches.

a) Provide technical expertise to healthcare facilities.
   i. Implement timely detection and response and track response actions and times.
   ii. Use tracking of response requests and actions to inform future response and prevention efforts.
   iii. Facilitate coordinated response among interconnected facilities. This includes but is not limited to sharing data, such as laboratory testing results, for situational awareness and action.
   iv. Implement response-driven prevention through implementation of jurisdiction-wide interventions based on lessons learned during responses. Examples of activities include disseminating jurisdiction-wide health advisory or other communication to providers regarding outbreak investigations and recommendations, creating new tools or resources tailored to the setting or provider-type experiencing an outbreak, engaging with specialty organizations at a local or national level to share outbreak lessons and promote prevention (e.g., at an annual conference or webinar), or engaging with relevant licensing or specialty boards (e.g., to discuss including infection control in continuing education requirements for providers or licensing/accreditation requirements for facilities).

☒Required ☐Optional

b) Facilitate timely sharing of laboratory results and incorporate findings in recommendations to affected healthcare facilities and providers.

☒Required ☐Optional

III. Strategy 1b: Conduct response-driven onsite infection control assessments and evaluations and provide recommendations for containment and other responses.

a) Conduct onsite infection control assessments at facilities where targeted organisms or resistance mechanisms have been identified (i.e., as part of the containment described in Strategy I). Assessments may require direct observation and ongoing monitoring of infection prevention practices in affected areas/units.

☒Required ☐Optional

b) Conduct onsite infection control assessments at facilities where outbreaks have occurred (i.e., as part of response efforts described in Strategy II). Assessments may require direct observation and ongoing monitoring of infection prevention practices in affected areas/units.

☒Required ☐Optional

c) Provide continued assistance until infection control gaps have been addressed.

☒Required ☐Optional

IV. Strategy 1b, 1d, 1g: Enhance other aspects of epi-lab coordination not already covered in Strategies I and II. (For complementary strategies and activities directed toward public health laboratories, see the separate guidance for the AR Lab Network.)

a) Using elements and guidance provided by CDC, collaborate with public health labs (local, state, and regional) to develop coordinated work plans to improve coordination and information flow.

☒Required ☐Optional

b) Facilitate connections between facilities or clinical laboratories and public health labs to ensure appropriate isolates are forwarded to the regional AR laboratory for targeted surveillance activities

☒Required ☐Optional

V. Strategy 1a, 1b, 1c, 1d, 1g: Use data for action (e.g., NHSN, Emerging Infections Program [EIP], AR Lab Network, Targeted Assessment for Prevention [TAP], triangulation of multiple data sources).

a) Identify and use data sources to inform prevention and response activities.

i. Demonstrate access to NHSN (or equivalent data) and state/local data. Strong applications will reflect access to HAI data sufficient to define regional epidemiology.

ii. Use NHSN data in conjunction with state/local data to identify healthcare facilities and networks (e.g., acute care facilities, long- term acute care hospitals [LTACHs], nursing homes) with high incidence of selected HAIs (e.g., CDI) to facilitate prevention.

☒Required ☐Optional

b) Identify and implement mechanisms to detect emerging MDROs within the jurisdiction (e.g., sentinel lab/facility surveillance) and to define local and regional epidemiology.

☒Required ☐Optional

c) Use data to inform the HAI advisory committee structure, membership, and priorities. (See Area C for additional guidance for the HAI advisory committee. This activity in Area A refers to how data are used to determine structure, membership, and priorities of the committee. Area C, Strategy IV refers to minimum expectations of the committee.)

i. Ensure that membership includes stakeholders with expertise in areas identified by data as high priority. Strong applications will explain the rationale for how committee members

were selected based on an identified priority need. For example, if data indicate that dialysis bloodstream infections (BSIs) are high priority, then the committee should include someone with dialysis expertise.

ii. HAI advisory committee should use data to help define jurisdiction priorities for HAI prevention and response to AR. Strong applications will specify these priorities.

☒Required ☐Optional

d) [Tier 2] Implement, continue, or enhance an MDRO patient registry to facilitate inter-facility communication, target interventions, and improve surveillance. The registry should tie to public health actions, enable tracking of the regional spread of MDROs, and fit into the overall surveillance and response strategy. MDRO registries will only be considered for funding if the work plan addresses these requirements and articulates how the registry is related to other surveillance, laboratory, and response activities, including state HAI and AR surveillance, NHSN, and the AR Lab Network. Guidance for MDRO registries is forthcoming from CDC; CDC will share this guidance with applicants when it is available.

☐Required ☒Optional

e) [Tier 2] Conduct data validation to inform prevention. Preference for funding will be given to Recipients that will conduct their own validation rather than contracting for services. Recipients are expected to conduct some prior analysis of their state NHSN data to identify HAIs at priority need for external validation. Recipients are required to identify 2 HAIs that will be validated during a funding year. In addition to the inpatient facility-based HAI validation, recipients are strongly encouraged to conduct Dialysis Event validation and Long Term Care Facility HAI validation at least once during the current cooperative agreement cycle.

i. Conduct health department validator training to enhance workforce capacity for HAI.

ii. Assure competency in data validation and NHSN methods and definitions via certificates of completion of in-person or online training

iii. Prior to data validation, conduct an analysis of jurisdiction's data to target the HAIs, facilities, and records to be validated.

iv. During validation, assess local surveillance data quality, HAI surveillance data completeness, timeliness, sensitivity and specificity and identify reporter training needs.

v. After validating, produce a HAI validation report and an assessment of each guidance component, and provide feedback to facilities to have them correct their data in NHSN and provide user trainings to prevent future case misclassification.

vi. After validating, produce a HAI validation report, an assessment of each guidance component, quantitative information, and recommended modifications.

vii. Identify ongoing barriers among healthcare facilities to produce required line-listing information linking laboratory and admissions data. Provide recommendations for reducing barriers.

viii. Identify ways to ensure secure transmission of spreadsheet data from healthcare systems to health department.

ix. Build and foster data validation collaborations for improving upon tools and guidance. Strengthen partnerships with healthcare facilities by demonstrating transparency of validation processes.

☐Required ☒Optional

AREA B: PREVENTION AND INTERVENTION

VI. Strategy 2a: Implement data-driven prevention strategies.

a) Conduct ongoing onsite assessments and gap mitigation in long length-of-stay, high-acuity facilities (e.g., skilled nursing facilities that provide ventilator care [vSNF], LTACHs) or others (e.g., dialysis facilities, outpatient facilities), based on identified needs (e.g., poor infection control practices), with the goal to improve infection control practices to reduce transmission of selected MDROs or reduce HAIs. Assessments will require direct observation. Note that this activity is complementary to but distinct from Area A, Strategy III. (Area A, Strategy III focuses on facilities where targeted AR threats or outbreaks have been identified. Area B, Strategy I focuses on facilities at high risk for AR threats or outbreaks). Strong applications will include clear rationale (including data when available) for selection of settings.

☒Required ☐Optional

b) [Tier 2] Implement a targeted prevention project addressing MRSA BSIs or CDI, which involve transmission across facilities, based on data-identified need. The goal of this project is to reduce the burden of selected HAIs in facilities with high rates. Selected HAIs may include MRSA BSIs, CDI, or both. Recipients may select one or both of the following sub-activities.

i. Implement TAP Strategy (https://www.cdc.gov/hai/prevent/tap.html), including but not limited to 1) running TAP reports to target facilities, 2) assessing gaps in infection control, and 3) implementing prevention measures. Recipients should target facilities based on need (e.g., higher standardized infection ratio [SIR] or cumulative attributable difference [CAD]) with goal of reducing overall regional incidence of selected HAI. Outcome measure must be completed pre- and post-intervention. For most jurisdictions the minimum expectation is 10 facilities, but the target number should reflect jurisdiction size and funding (e.g., larger jurisdictions with higher funding should include more facilities). CDC is available for consultation to determine an appropriate number of minimum facilities. Strong applications will include all three TAP components; specify the selected HAI(s) and number of facilities needed to reach a jurisdiction-wide standardized infection ratio (SIR) goal for a given HAI; and describe data or other rationale to select an HAI for TAP implementation.

ii. Lead or actively support implementation of prevention Collaborative(s). Strong applications will include clear explanation of participants and roles/responsibilities, reduction goals, interventions to be implemented, and methods for baseline, process, progress, and outcome measurements. Facility participants should be targeted based on need (e.g., higher SIR or CAD) with the goal of reducing overall regional incidence of selected HAI. Outcome measure must be completed pre- and post-intervention. For most jurisdictions the minimum expectation is 10 facilities, but target number should reflect jurisdiction size and

funding (e.g., larger jurisdictions with higher funding should include more facilities). CDC is available for consultation to determine an appropriate number of minimum facilities.

☐Required ☒Optional

c) [Tier 2] Continue work with partners across settings for prevention of device- and procedure-associated infections (CAUTI, CLABSI, dialysis BSI, surgical site infection). Recipients may select one or both of the following sub-activities.

i. Implement the TAP Strategy (https://www.cdc.gov/hai/prevent/tap.html), including but not limited to 1) running TAP reports to target facilities, 2) assessing gaps in infection control, and 3) implementing prevention measures. Recipients should target facilities based on need (e.g., higher standardized infection ratio [SIR] or cumulative attributable difference [CAD]) with goal of reducing overall regional incidence of selected HAI. Outcome measure must be completed pre- and post-intervention. For most jurisdictions the minimum expectation is 10 facilities, but target number should reflect jurisdiction size and funding (e.g., larger jurisdictions with higher funding should include more facilities). CDC is available for consultation to determine an appropriate number of minimum facilities. This strategy may involve deployment of TAP for multiple HAIs based on data-identified need. Strong applications will include all three TAP components; specify the selected HAI(s) and number of facilities needed to reach a jurisdiction-wide standardized infection ratio (SIR) goal for a given HAI; and describe data or other rationale to select the HAI(s) for TAP implementation. Note: for dialysis facilities, use the NHSN Excess Infections report (i.e., CAD) to help target facilities for prevention and utilize CDC recommended interventions and tools to facilitate BSI prevention.

ii. Recipients may propose other prevention projects not addressed elsewhere. Proposed activities should be compatible with program goals and public health needs but may not include research. Strong applications will specify the selected HAI(s) and setting(s), reduction goals, interventions to be implemented, and methods for baseline, process, progress, and outcome measurements.

☐Required ☒Optional

VII. Strategy 2a: Implement antibiotic stewardship efforts

a) Facilitate core element implementation in designated settings. Core elements should be applied in the setting for which they were designed

i. Participate each year in CDC's U.S. Antibiotic Awareness Week observance.

ii. Distribute CDC's Core Elements and materials from Be Antibiotics Aware: Smart Use, Best Care to local partners, providers, healthcare systems, and the general public (year round).

iii. Provide access to education and expertise on antibiotic stewardship across the spectrum of health care.

iv. Coordinate activities with quality improvement programs (e.g., Quality Innovation Networks-Quality Improvement Organizations [QIN-QIOs], Hospital Improvement

Innovation Networks [HIINs]), hospital associations, state professional societies, and other key partners.

v. Monitor state-level outpatient antibiotic use and use of selected antibiotic classes (e.g., fluoroquinolones) in order to inform dissemination strategies and collaborative activities. Data can be obtained from CDC's Antibiotic Resistance Patient Safety Atlas at https://gis.cdc.gov/grasp/PSA/indexAU.html

☒Required ☐Optional

b) [Tier 2] Implement targeted project to improve antibiotic use. Recipients may select any of the following sub-activities.

i. Analyze state-specific or local antibiotic prescribing data (e.g., Medicaid data, all payers all claims data or other claims data, proprietary data, electronic health record data from local healthcare systems, other) to inform targeted stewardship interventions, such as providing feedback to providers on antibiotic prescribing practices or identifying facilities with significant opportunities to improve antibiotic use.

ii. Implement and evaluate evidence-based, local-level interventions, such as those from CDC's Core Elements, to improve antibiotic prescribing in human healthcare settings. For settings for which there are no core elements, Recipients should work with CDC SMEs on appropriate strategies for that setting. Strong applications should be scaled in regards to the number of facilities reached based on the type of facility included in interventions, size of the jurisdiction, and intensity of the interventions. Additionally, strong applications should target facilities or providers with the most opportunities and need to improve antibiotic use.

iii. Engage policymakers and support development of new state or local policies that encourage antibiotic stewardship implementation and/or tracking of human antibiotic use data. Examples of such policies could include (1) requirements for antibiotic stewardship programs in hospitals and/or nursing homes, (2) requirements for hospital antibiotic use reporting into the NHSN AU module, and (3) requirements for making antibiotic prescriptions reportable to health departments through prescription drug monitoring programs (PDMPs) or through other reporting mechanisms.

☐Required ☒Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

VIII. Strategy 3a: Sustain HAI/AR capacity to implement program (HAI coordinator, AR/AS expert).

a) The HAI coordinator should assure HAI prevention through coordination throughout the jurisdiction (including for containment and response); epi-lab collaboration, including but not limited to coordination with the AR Lab Network regional lab, and use of the Targeted Assessment for Prevention; serve on the ELC governance team to monitor HAI program performance and spending; and serve as the primary point of contact for HAI communications with and reporting to CDC.

☒Required ☐Optional

b) The AR/AS expert should provide senior-level expertise (e.g., doctoral level or equivalent experience) in epidemiology and infection prevention with proficiency in AR/AS and data for action. The expert should lead program and policy development to reduce AR infections and implement AS; provide expertise in infectious diseases, HAIs, and AR; lead and oversee in the development and implementation of locally relevant public health interventions and prevention guidelines that include AS and control of CDI, CRE, or MDROs; and lead the development and implementation of containment strategies for the jurisdiction.

☒Required ☐Optional

IX. Strategy 3a: Engage public health and healthcare providers

a) Building upon work previously funded through the Ebola supplement, maintain and update as needed an inventory of all healthcare settings in the jurisdiction. Use this inventory to guide outreach for containment, response, and prevention activities.

☒Required ☐Optional

b) Provide education/training on infection control for healthcare facilities on prevention of HAIs and control of targeted MDROs.

☒Required ☐Optional

c) Providing training and support for local health departments in investigations in healthcare settings, control of targeted MDROs, and prevention of HAIs.

☒Required ☐Optional

d) Improve onsite assessment capacity by developing expertise in facility assessment designed to improve infection prevention and control in outpatient or high-acuity, post-acute care settings. Examples of activities include training staff in conducting assessments or hiring, contracting with, or collaborating with infection prevention experts.

☒Required ☐Optional

X. Strategy 3a: Coordinate prevention activities with partners (e.g., health systems, hospital associations, quality improvement programs such as QIN-QIOs and HIINs, Epicenters, EIP, local health departments, regulatory/licensing entities, ESRD networks)

a) Identify and engage with partners for prevention activities. Strong applications will define specific roles and responsibilities of the Recipient and those of the partners.

☒Required ☐Optional

b) *Jurisdictions with EIP catchment areas:* Establish plans to share data and findings related to surveillance activities and projects and outbreaks. Funding requests should be of sufficient detail to demonstrate

there is no overlap with EIP-funded activities and that ELC funds will not be used for research purposes.

☒Required ☐Optional

XI. Strategy 3a: Convene HAI advisory committee. The committee should include local stakeholders, and representatives from the state and/or regional public health laboratories, state survey agency, hospital/emergency preparedness, and patient representatives. As stipulated in Core Area A, Strategy IV.c, data should inform advisory committee structure, membership, and priorities.

a) Assign strategies, roles, and responsibilities of members.

☒Required ☐Optional

b) Update the HAI plan regularly.

☒Required ☐Optional

Collaborations

a. With CDC-funded Programs:

Recipients are expected to coordinate planning, execution, and management of activities with laboratories funded under the ELC program (i.e., both state and regional laboratories in the AR Lab Network (as stipulated in core area A, strategies I, II, and IV) and relevant other ELC-funded programs (e.g., with Project I. Mycotics, for containment of *Candida auris*). Recipients are also expected to collaborate and ensure alignment with the CDC-funded Emerging Infections Program sites, Prevention Epicenters, and partnering collaborations.

b. With organizations external to CDC:

Recipients should collaborate with other health agencies, clinical or other partnering laboratories, hospitals and other facilities, public health (state, city, county, local) health partners, Centers for Medicare & Medicaid Services-funded networks (e.g., QIN-QIOs, HIINs), Hospital Preparedness Program, hospital associations, academic partners, and others to maximize detection and prevention efforts, make progress toward national targets, and reduce duplication of efforts.

Target Populations:

N/A

Evaluation and Performance Measurement:

Recipients are expected to report the performance measures in January 2020 and September 2020, and at the time of continuation applications when the emphasis will be on the narrative reporting. Recipients will also be expected to share progress of implementation of work plans (including but not limited to hiring of personnel or execution of contracts) as well as status of spending during regularly scheduled (i.e., at least quarterly) updates to CDC program personnel. Performance measure details including rationale, data elements, and additional guidance will be communicated to recipients in a separate document.

Performance measure details will be communicated to recipients in a separate document. An abbreviated list is included below.

1. Number of clinical laboratories engaged to improve testing
2. Proportion of index patients or clusters with targeted novel or high-concern antibiotic-resistant organisms or mechanisms for which the Recipient or a designee implemented the containment strategy
3. Number of responses in the jurisdiction conducted by the Recipient or a designee, by pathogen or issue and facility type
4. Number of proactive onsite infection control assessments conducted by the Recipient or designee in long length-of-stay, high-acuity facilities (e.g., vSNF, LTACHs) or others (e.g., dialysis facilities, outpatient facilities) in the jurisdiction, by facility type
    a. *Of the facilities where proactive onsite infection control assessments were conducted*: Average number and range of visits made per facility to mitigate identified infection control gaps, and description of gaps and steps taken to address them, by facility type
5. Number of facilities the Recipient or a designee engaged to facilitate core element implementation, by facility type
    a. *Of the facilities engaged by the Recipient or a designee to facilitate core element implementation*: Proportion of facilities with stewardship programs meeting all CDC core elements, by facility type
6. Status of state's HAI plan
7. Confirmation of update to inventory of all healthcare settings in the jurisdiction

Tier 2 (Measures #8-10)

8. Number of facilities implementing TAP Strategy, by facility type
9. Implementation of HAI prevention Collaboratives
10. Implementation of targeted project to improve antibiotic use

G2: Antibiotic Resistance Laboratory Network (AR Lab Network)
Program Activity Contact Information
ARLN@cdc.gov
Funding Opportunity Description
Background
a. Overview
The goals of the Healthcare-associated Infection (HAI)/Antibiotic Resistance (AR) Program are to prevent HAIs to protect patients and healthcare personnel; to advance the detection, response, and containment of AR; and to promote antibiotic stewardship (AS), to ensure safety, quality, and value in healthcare delivery systems. Related epidemiology activities are described in G1, Healthcare-associated Infections, Antibiotic Resistance, and Antibiotic Stewardship, while laboratory activities are described here in G2, Antibiotic Resistance Laboratory Network (AR Lab Network). The AR Lab Network builds laboratory capacity for early detection of drug-resistant pathogens and public health infrastructure for rapid response to stop transmission, which are critical components of effective strategies for preventing the spread of AR.
b. Healthy People 2020
Healthcare-associated Infections (HAIs)/AR objectives have been established for Healthy People 2020 that reflect the commitment of the U.S. Department of Health and Human Services (HHS) to prevent and reduce HAIs/AR.
c. Other National Public Health Priorities and Strategies
Detecting and preventing HAIs and AR is a cross-cutting federal priority. The National Strategy for Combating Antibiotic-Resistant Bacteria and companion National Action Plan articulate national goals, priorities, objectives, milestones, and reduction targets that provide an overarching framework for federal investments aimed at combating antibiotic-resistant bacteria and *Clostridioides difficile* infections. Key strategies include detecting and responding to emerging threats from antibiotic-resistant organisms, and containing outbreaks within healthcare facilities.
CDC Project Description
a. Problem Statement:
AR causes more than 2 million illnesses and 23,000 deaths in the United States annually. Combating AR requires early detection of new resistance and robust prevention efforts, including early outbreak detection and response. Creating state and regional laboratory capacity to detect antibiotic-resistant bacteria and fungi will improve the ability to implement timely local prevention efforts and to develop national strategies that limit transmission of resistant pathogens and prevent infections. Some AR threats like carbapenem-resistant Enterobacteriaceae (CRE) are resistant to nearly all available therapeutic agents and require enhanced detection and infection control measures to prevent the spread of infections. For other pathogens, like resistant *Neisseria gonorrhoeae*, and *Candida* species, detection of resistance is challenging because antibiotic susceptibility testing is not routinely performed in hospital or other laboratories. In these cases, resistance data are needed to identify outbreaks, prevention measures, and to develop treatment guidelines. *Streptococcus pneumoniae* infections are decreasing because of an effective

vaccine, but new resistant strains may emerge that are not protected by the vaccine. Early detection of these serotypes will help to keep the vaccine up-to-date. Detecting resistance in slow-growing bacteria, like *Mycobacterium tuberculosis* (Mtb), requires implementing new rapid methods, like whole genome sequencing (WGS), to identify critical resistance and to provide molecular typing data for tracking transmissions during outbreaks and for ongoing surveillance.

b. Purpose:

The AR Lab Network builds lab capacity to rapidly detect AR in healthcare and the community, and inform local responses to prevent spread and protect people. The AR Lab Network includes public health labs in all 50 states and Puerto Rico, including seven regional labs and the National Tuberculosis Molecular Surveillance Center (National TB Center). State and local laboratories will build or sustain capacity to detect and support response to concerning resistance. As a whole, the network tracks changes in resistance and helps identify and respond to outbreaks faster.

c. Outcomes:

Implementation of AR Lab Network activities will result in:

- Increased state, local, and regional public health laboratory capacity to detect and confirm antibiotic resistance using CDC recommended methods
- Rapid identification and containment of AR threats including novel resistance
- Timely and effective response to HAI/AR outbreaks
- Improved coordination and information sharing with epidemiology, laboratory and prevention partners to support outbreak response and prevention efforts
- Improved test results and data reporting to partners including public health epidemiologists, laboratorians, healthcare partners, and CDC to inform surveillance efforts and outbreak response
- Enhanced molecular surveillance of antibiotic resistance of Mtb
- Enhanced capacity for detection of outbreaks and transmission of Mtb

Funding Strategy:

Recipients should utilize funds for personnel, supplies, equipment, contractual support, or travel for proposed activities. Shipping costs for AR Lab Network activities are funded by CDC separately. If funding is requested for shipping supplies or the use of a courier service, please provide details and/or justification.

Applicants should make clear in their budget requests which strategies and activities will be supported by the requested funding as well as provide justification for why these activities are needed; failure to do so may result in failure to receive funding. Recipients should be aware that future funding decisions will be based on measurable progress, as reported by progress made toward desired outcomes, performance measures, and semi-annual updates to CDC.

All applicants are eligible to apply for Tier 2 activities. Priority for funding Tier 2 required and optional activities will be given to applicants who demonstrated progress during the prior ELC funding cycle; propose feasible plans that reflect the program's capacity, and explain how performance measures will be addressed and reported.

Tier 1: Basic funding for minimum required activities as described in guidance. All activities under Tier 1 are required for all applicants. (Activities I. – IV.)

- Estimated total availability of funds: $2,500,000
- Estimated number of awards given: 56
- Estimated average per award: $44,000

Tier 2: Enhanced laboratory capacity. CDC will fund up to 56 recipients to perform enhanced lab activities in addition to core activities under Tier 1, as described in the guidance. Applying for Tier 2 is optional, but encouraged. Tier 2 applicants must apply for Activity V.a., all other activities are optional. Note that average award may vary depending on number of awards given.

Activities V.a.-V.c.:

- Estimated total availability of funds: $2,250,000
- Estimated number of awards given: up to 56
- Estimated average per award: $40,000

Activity V.d.: Whole genome sequencing of CRE, CRPA, or other healthcare associated organisms

- Estimated total availability of funds: $250,000
- Estimated number of awards given: up to 5
- Estimated average per award: $50,000

Tier 3: (Activities VI. – XII.)
AR Lab Network regional labs-CDC will fund up to 7 regional labs to support AR Lab Network regions (https://www.cdc.gov/drugresistance/solutions-initiative/ar-lab-networks.html#about) and activities. Candidates for regional lab funding are not limited to laboratories that previously received funding for regional lab activities.

- Estimated total availability of funds: $14,000,000
- Estimated number of awards given: 7
- Estimated average per award: $2,000,000

National TB Molecular Surveillance Center. CDC will fund one public health laboratory to provide WGS and 24-locus MIRU-VNTR for all Mtb isolates from culture-confirmed cases of TB in the United States for surveillance of resistance determinants and transmission. Applying to be the National TB Molecular Surveillance Center is optional, but all related activities are required.

- Estimated total availability of funds: $1,800,000
- Estimated number of awards given: 1
- Estimated average per award: $1,800,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

Tier 1: Core AR lab activities for all jurisdictions applying for AR Lab Network funding

I. Strategy 1e: Enhance and sustain laboratory testing for surveillance and reporting

a) Increase or sustain laboratory capacity to perform CLIA-compliant organism identification and carbapenemase production testing on Carbapenem-resistant Enterobacteriaceae (CRE), including at

least E. coli, *Enterobacter*, and *Klebsiella*, and a proportion of Carbapenem-resistant *Pseudomonas aeruginosa* (CRPA) isolates, as recommended by CDC.

☒Required ☐Optional

b) Increase or sustain laboratory capacity to perform CLIA-compliant carbapenem-resistance mechanism testing on CRE (at least *E. coli*, *Enterobacter*, *Klebsiella,* and *Citrobacter*) and a proportion of CRPA isolates for the most common and important resistance mechanisms (e.g., PCR detection of KPC, NDM, VIM, OXA-48-like OR Cepheid CARBA-R panel) as recommended and updated annually by CDC.

☒Required ☐Optional

c) Report testing results to submitting clinical laboratory within two working days of testing completion.

☒Required ☐Optional

d) Store bacterial isolates for a minimum of two years. Transport isolates of interest (as defined or specifically requested by CDC) to AR Lab Network regional lab and/or to CDC for further characterization or to CDC for deposit in a CDC repository.

☒Required ☐Optional

e) Submit data, at least monthly, to CDC via APHL Informatics Messaging Services platform (AIMS) or CDC-provided templates. Participate in data reconciliation confirmation of counts and data quality. Communicate any test results defined as an "alert" by CDC (e.g., novel or high-concern resistance), within one business day to CDC and the state/local HAI/AR epidemiologist(s).

☒Required ☐Optional

II. Strategy 1a: Sustain AR capacity to implement program AR Lab Network Activities

a) An AR lab expert should clearly demonstrate expertise in AR testing (particularly focused on AR Lab Network guidance) and data reporting for the jurisdiction. Additionally, the AR lab expert should:

i. have knowledge of resources available at the AR Lab Network regional lab and how and when to access that testing,

ii. assure coordination between state and local HAI/AR programs and the AR Lab Network regional lab,

iii. facilitate submission of isolates and other specimens to the local, state, and/or regional lab,

iv. facilitate submission of testing data to CDC, and

v. serve as primary point of contact for AR Lab Network communications with CDC.

☒Required ☐Optional

b) Train and educate laboratorians and maintain adequate workforce to perform CRE and CRPA testing.

☒Required ☐Optional

III. Strategy 1g: Improve laboratory and epidemiology coordination and outreach

a) Coordinate epidemiology and laboratory functions at state, city, county, and local levels, as well as with the AR Lab Network regional lab.

☒Required ☐Optional

b) Using elements and guidance provided by CDC, collaborate with ELC-funded HAI/AR programs to develop and regularly update coordinated work plans to improve communication and information flow that ensure timely detection and response to targeted resistance threats. The plan should include the list of prioritized antibiotic resistant organisms and mechanisms, based on the epidemiology of the jurisdiction. States that participate in the Emerging Infections Program Healthcare-Associated Infections-Community Interface Activity (EIP HAIC) should demonstrate efforts to enhance relationships and collaboration with EIP HAI/AR staff.

☒Required ☐Optional

c) Coordinate connections with clinical laboratories serving the state or jurisdiction to solicit CRE and CRPA isolates from healthcare facilities (including short- and long-term acute care facilities) with specific focus on laboratories that serve high risk settings as defined by or in coordination with CDC. Provide outreach and technical assistance to clinical microbiology laboratories to improve the detection of targeted organisms, including timely submission and reporting of results.

☒Required ☐Optional

d) Facilitate coordinated connections with clinical laboratories in the state or jurisdiction to solicit isolates requested from the AR Lab Network regional lab for targeted surveillance activities (Tier 3, Strategy 1, Activity b) and for *Candida* activities (Tier 3, Strategy 1, Activity d).

☒Required ☐Optional

IV. Strategy 1h: Advance electronic information exchange implementation

a) Develop testing and communication protocols, reporting processes, and IT infrastructure to ensure timely testing and reporting of results to submitting laboratories, state prevention epidemiologists, jurisdictional public health laboratories, and CDC.

☒Required ☐Optional

b) Work with APHL to implement or sustain reporting using APHL Informatics Messaging Services (AIMS) platform.

☒Required ☐Optional

Tier II: Enhanced activities. Applicants may apply for funding to address the enhanced laboratory activities described below in addition to required Tier 1 core activities.

V. Strategy 1e: Expand and sustain AR Lab testing and reporting

a) Increase or sustain laboratory capacity to perform CLIA-compliant routine confirmatory antibiotic susceptibility testing on CRE and a proportion of CRPA isolates, in accordance with CDC guidance. This testing would be in addition to the organism identification, carbapenemase production testing and carbapenem-resistance mechanism testing described under Tier 1.

☒Required ☐Optional

b) Increase or sustain scope of CRE testing to include at least *Citrobacter, Providencia, Proteus,* and *Serratia*, in addition to target genera described under Tier 1.

☐Required ☒Optional

c) Increase or sustain laboratory capacity to conduct reference identification of *Candida* spp. using MALDI-TOF or DNA-based methods.

☐Required ☒Optional

d) Up to five non-regional public health laboratories may be funded to perform coordinated by CDC to support epidemiologic investigations in their state. These labs must be able to demonstrate sequencing capacity and follow guidance and training recommendations put forth by CDC. Sequencing priorities would be set by CDC, in accordance with emerging threats and current WGS capacities. CDC will provide resources and bioinformatics support for analysis of WGS data.

☐Required ☒Optional

Tier III: Antibiotic Resistance Lab Network Regional Laboratories: Applying to be an AR Lab Network regional lab is optional, but for those that apply, note that all activities except those under Strategy VI below are required.

VI. Strategy 1e: Expand and sustain AR lab testing and reporting for surveillance

a) In collaboration with CDC, provide CLIA-compliant organism identification, antibiotic susceptibility testing, carbapenemase production testing, and molecular detection of resistance mechanisms for new, unusual or emerging AR threats, including isolates suspected of carrying novel resistance mechanisms sent from state and local laboratories within the region. Guidance for required mechanism testing directory will be set by CDC.

☒Required ☐Optional

b) Perform targeted surveillance for emerging or changing AR threats (e.g. mobile colistin resistance or carbapenemase genes), as directed by CDC, using lab testing to fill gaps in detection and containment.

i. Lab will perform coordinated public health surveillance for CDC-targeted AR pathogens. This surveillance will involve CDC-directed collection of isolates, swabs or waste clinical specimens from a network of collaborating clinical laboratories throughout the jurisdiction, with results shared with submitting laboratories and CDC. Some specified isolates will be

shared with CDC for additional characterization. Techniques may include isolation of bacterial isolates from swabs or other clinical specimens, bacterial identification, antibiotic susceptibility testing, and molecular characterization (e.g., PCR or whole genome sequencing).

☒Required ☐Optional

c) Conduct reference identification and susceptibility testing of *Candida* spp. Funded labs will use MALDI-TOF or DNA-based methods for identification and CDC-recommended antifungal susceptibility testing methods to characterize 1,000 to 2,000 *Candida* spp. isolates annually. Regional laboratories will collect isolates from a diverse range of hospitals and other healthcare settings in their region to ensure wide surveillance coverage.

☒Required ☐Optional

d) Sustain/implement specimen storage and isolate transport per CDC guidance or upon request (e.g., isolates which harbor new or unusual resistance, a subset of isolates including representative isolates from outbreaks) for additional characterization and potential inclusion in CDC specimen repositories.

☒Required ☐Optional

e) Submit testing data at least monthly to CDC via APHL Informatics Messaging Services (AIMS) platform. Participate in data reconciliation confirmation of counts and data quality. For any results defined as an "alert" by CDC (e.g., novel or high-concern resistance), communicate results within one business day to CDC and the state/local HAI/AR program.

☒Required ☐Optional

VII. Strategy 1d: Expand and sustain AR lab testing for response

a) Provide regional laboratory support for state-led epidemiologic investigations and HAI/AR prevention efforts focused on carbapenemase-producing organisms (CPOs) by performing molecular tests, including CDC-recommended commercial assay(s), to detect colonization for CPOs. Regional labs will work with state/local epidemiologists or HAI/AR prevention programs to facilitate collection and transportation of specimens for colonization testing to ensure timely testing of specimens (e.g., ≤ two working days' time to reporting molecular results). AR Lab Network regional labs will:

i. work with state HAI/AR programs to transport collection kits to healthcare facilities where swabbing for colonization testing will take place,

ii. provide advice to healthcare facilities and personnel on the collection and transportation of specimens,

iii. have specimens collected at healthcare facilities sent directly from healthcare facilities to the regional lab,

iv. test and report results to the jurisdictional public health department and laboratory and submitting healthcare facility within two working days of specimen receipt, and

v. submit colonization testing data to CDC, via AIMS, at least monthly

☒Required ☐Optional

b) At the direction of CDC, laboratories will perform *C. auris* colonization screening testing to support surveillance activities and outbreak investigations occurring within the region. AR regional labs will:

i. Work with state HAI/AR program to transport collection swabs to healthcare facilities where swabbing for colonization testing will take place,

ii. provide advice to healthcare facility laboratories on the collection and transportation of specimens,

iii. have specimens collected at healthcare facilities sent directly from healthcare facilities to the regional lab,

iv. test and report results to the jurisdictional public health department and laboratory and submitting healthcare facility in timeframe consistent with CDC guidance, and

v. submit colonization testing data to CDC at least monthly.

☒Required ☐Optional

c) Implement or sustain CDC-directed reference antibiotic susceptibility testing to new antibiotic agents by broth microdilution (BMD) of pan-resistant or nearly pan-resistant bacteria. CDC will purchase and provide equipment to the labs for creating on-demand BMD panels and work with CDC to obtain drug powders for antibiotic susceptibility testing. Labs will validate testing and establish capacity to test up to 150 isolates per year. Testing and reporting results to submitters and CDC will be timely.

☒Required ☐Optional

d) Perform whole genome sequencing for HAI/AR pathogens to support epidemiologic investigations in the region. Labs must be able to demonstrate sequencing capacity and follow CDC guidance and training recommendations. Sequencing priorities will be determined by CDC, in accordance with emerging threats and current WGS capacities. CDC will provide resources and bioinformatics support for analysis of WGS data.

☒Required ☐Optional

e) Demonstrate surge capacity. Accept specimens for testing from outside of the region when CDC determines that a public health need exists and alternative testing capacity is limited or unavailable. The testing volume and turn-around time will be determined in collaboration with CDC.

☒Required ☐Optional

f) Report all colonization screening results to submitters within one day of testing completion. Report all targeted surveillance testing results at least monthly to submitting laboratories and the jurisdictional HAI programs. Submit colonization screening and targeted surveillance data at least monthly to CDC via APHL Informatics Messaging Services platform (AIMS). Participate in data reconciliation confirmation of counts and data quality. For any results defined as an “alert” by CDC (e.g., novel or

high-concern resistance), communicate results within one business day of the result to CDC and to local/state HAI/AR epidemiologist(s) of the originating jurisdiction.

☒Required ☐Optional

VIII. Strategy 1a: Sustain workforce capacity to implement AR Lab Network regional lab activities

a) Train laboratory personnel to demonstrate competency and proficiency for performing all AR tests (e.g., antibiotic susceptibility testing, detection of resistance mechanisms, and advanced molecular diagnostics, such as whole genome sequencing, to detect resistance and addressing the genetic relatedness of bacterial isolates) available in their test directory.

☒Required ☐Optional

IX. Strategy 1g: Improve laboratory and epidemiology coordination and outreach

a) A regional epidemiologist should work closely with regional laboratory staff and state HAI/AR epidemiologists throughout the region to recruit and coordinate sample submissions and testing, and use of data for containment and prevention activities, using elements and guidance provided by CDC.

☒Required ☐Optional

b) In collaboration with CDC programs, establish a project plan and protocol for collection of specimens and/or isolates from healthcare facility, other clinical microbiology laboratories, or other settings like sexually-transmitted disease clinics, for:

i. Clinical isolates requiring specialized testing [e.g., CRE, and CRPA, *Candida* spp., and MDR-*Streptococcus pneumoniae* (for AR regional labs conducting this testing), and

ii. Outbreak detection requested through state or local health authorities (CPO, *C. auris*, and other pathogens as needed and resources permit)

☒Required ☐Optional

c) Implement AR-related consultations and results interpretation for facilities, designated outbreak and prevention program staff, and partners, and other network clinical or public health laboratories.

☒Required ☐Optional

d) Offer troubleshooting expertise or training for laboratory personnel conducting AR testing in regional state or local AR lab network funded public health laboratories, as needed/requested.

☒Required ☐Optional

e) Host a regional partnership meeting for state HAI/AR prevention programs and public health laboratories within the region.

☒Required ☐Optional

f) Participate in regularly scheduled conference calls with CDC to discuss AR concerns, emerging issues, protocol plans, etc.

☒Required ☐Optional

X. Strategy 1h: Advance electronic information exchange implementation

a) Develop or sustain processes and IT infrastructure for timely reporting to submitting facilities, state or local public health laboratories, epidemiologists, regional AR prevention partners, and CDC for the following:

i. Clinical isolates requiring specialized testing (e.g., pan-resistant organisms, CPOs, and *Candida* spp.)

ii. Outbreak detection requested through state or local health authorities (CPOs, *C. auris*, and other pathogens as needed and resources permit)

iii. Representative sets of isolates to describe estimates of scope and magnitude of specific AR threats and mechanisms for resistance (*Neisseria gonorrhoeae*, *Candida* spp., and MDR-*Streptococcus pneumoniae* for regional labs conducting this testing)

☒Required ☐Optional

b) Work with APHL to implement or sustain reporting using APHL Informatics Messaging Services (AIMS) platform and Lab Web Portal for applicable testing. Lab Web Portal should be implemented using sync services and not HL7.

☒Required ☐Optional

XI. Strategy 1e: Implement or maintain additional laboratory capacity (some regional labs)

a) Establish or sustain laboratory capacity for *N. gonorrhoeae* resistance surveillance by performing AST on up to 5,000 isolates and WGS for up to 1,250 isolates per funded laboratory annually.

i. Preference will be given to laboratories that have demonstrated proficiency in antibiotic susceptibility testing of *N. gonorrhoeae* using agar dilution and β-lactamase testing in accordance with methods recommended by CDC's Division of STD Prevention (http://www.cdc.gov/std/gisp/gisp-protocol-feb-2015_v3.pdf), and those with capacity to manage data and report results as required by project protocols.

ii. Funded labs must comply with CDC's GC AR surveillance data reporting, data quality management, and specimen submission protocols (See hyperlink above).

iii. Work plan must address/describe processes for ensuring timely AST and maintaining data integrity (data QC-check) at all stages. CDC recommends importing manifests from submitters into LIMS Labs that hand-enter data from submitter manifests must implement processes to ensure data entry accuracy.

iv. Testing will be done on isolates sent from STD surveillance clinic sites (GISP and eGISP) and from state public health laboratories funded for the rapid detection and response program (SURRG).

v. Funded regional laboratories must complete AST and communicate non-alert antibiotic susceptibility testing results to submitters or designates within 3 weeks of submission or as otherwise directed by CDC.

vi. For any results identified as a defined "alert" by CDC (i.e. resistant or emerging resistance) funded laboratories must communicate results within one business day to both CDC and submitters.

vii. Funded laboratories will also submit data routinely (at least monthly) to CDC via APHL Informatics Messaging Services platform (AIMS).

viii. AR Lab Network laboratory staff will participate in semi-annual agar dilution proficiency assessments administered by CDC.

ix. Sequencing priorities would be set by CDC. WGS data will be transmitted to CDC within one month of AST testing; CDC will provide resources and bioinformatics support for analysis of WGS data. These sequence data will be used to detect and characterize isolates with unique antibiotic susceptibility patterns and to strengthen epidemiologic investigations through sexual network analysis.

x. Funded laboratories must store gonorrhea isolates for at least 2 years, and transport all isolates at least two times per year to CDC for further characterization or to deposit in a CDC Biorepository.

☐Required ☒Optional

b) Antibiotic susceptibility testing and serotyping of MDR-*Streptococcus pneumoniae* (up to 500 isolates per year). Funded laboratories will perform whole genome sequencing (WGS) for up to 500 isolates per funded laboratory annually. These WGS data will be used to detect and characterize *S. pneumoniae* isolates with unique antibiotic susceptibility patterns.

☐Required ☒Optional

c) Perform CDC-directed and coordinated public health assessments of emerging or changing epidemiology of *Clostridium difficile* by implementing culture capacity for clinical specimens and environmental specimens. As directed by CDC, apply advanced molecular detection testing to type isolated bacteria and to assess *C*. *difficile* transmission.

☐Required ☒Optional

XII. Strategy 1e: Serve as the National TB Molecular Surveillance Center to enhance or sustain molecular testing of *M. tuberculosis* (Mtb) isolates for surveillance and reporting.

a) Establish or sustain laboratory capacity for Mtb 24 locus MIRU-VNTR typing by testing approximately 9,000 isolates in total annually (from all 50 states and U.S. territories). Preference will be given to laboratories that have demonstrated proficiency in 24 locus MIRU-VNTR testing in accordance with methods recommended by CDC's Division of TB Elimination. Testing will be done on isolates submitted from public health laboratories. The funded laboratory is expected upload the 24 locus MIRU-VNTR

result into the web based TB Genotyping Information Management System within two weeks of submission.

☒Required ☐Optional

b) Establish or sustain whole genome sequencing (WGS) of Mtb by sequencing approximately 9,000 isolates in total annually (from all 50 states and U.S. territories). The NextSeq sequencer is the preferred platform for this work. These sequence data will be used to conduct molecular surveillance of antibiotic susceptibility patterns and to strengthen epidemiologic investigations through transmission network analysis. Preference will be given to laboratories that have demonstrated proficiency In WGS testing of *M. tuberculosis* in accordance with methods recommended by CDC's Division of TB Elimination. WGS testing will be done in parallel with 24 locus MIRU-VNTR testing on isolates submitted from public health laboratories. The laboratory should transmit the WGS FASTQ file and run report to CDC within three weeks of submission.

☒Required ☐Optional

c) Implement Mtb sample inventory storage system; prepare subcultures of all submitted isolates and provide transport to CDC within three months of submission for long term storage.

☒Required ☐Optional

Collaborations

a. With CDC-funded programs:

Collaboration with CDC programs is expected to ensure implementation of approved or recommended methods and protocols that support national data needs. To ensure that efforts and activities are complimentary and minimize the burden on clinical laboratories, sites should coordinate their activities with:

- Other ELC-funded Antibiotic Resistance Lab Network programs and initiatives,
- ELC-funded HAI/AR Programs,
- Emerging Infections Program (EIP) sites and initiatives, if present in their state or jurisdiction
- APHL AIMS program implementation team collaborations
- Prevention Epicenters and partnering collaborations

b. With organizations external to CDC:

Recipients should collaborate with other state or public health laboratories, clinical laboratories, and medical and/or public health academic centers to assure that efforts are being maximized while avoiding duplication of efforts.

Target Populations:

N/A

Evaluation and Performance Measurement:

Recipients are expected to report the performance measures in January 2020 and September 2020, and at the time of continuation applications when the emphasis will be on the narrative reporting. Recipients will also be expected to share progress of implementation of work plans (including but not limited to hiring of personnel or execution of contracts) as well as status of spending during regularly scheduled (i.e., at least quarterly)

updates to CDC program personnel. Performance measure details including rationale, data elements, and additional guidance will be communicated to recipients in a separate document.

Tier 1 (Measures #1-7)

Performance measure details will be communicated to recipients in a separate document. An abbreviated list is included below.

1. Characterization of the clinical laboratory network in jurisdiction
2. Median and range (in days) from receipt of CRE/CRPA and *Candida* (if applicable) isolates to communication of final mechanism testing and antibiotic susceptibility testing (AST) results to submitting laboratory
3. For results identified as a defined "alert" by CDC (e.g., novel or high-concern resistance): Median and range (in days) to communicate test results with alert values to CDC and the HAI/AR program of originating jurisdiction
4. Number of laboratory personnel trained to proficiency in performing all tests in their AR Lab Network test directory
5. Proportion of isolates tested, and number of isolates tested by genera
6. Number of isolates transported upon request to CDC
7. Frequency and content of laboratory testing report or summaries shared with the HAI/AR program

Tier 2 (Measures #8)

8. For laboratories performing whole genome sequencing (WGS) **(optional for Tier 2)**: Proportion of healthcare associated organism isolates tested by WGS that passed quality control in accordance with CDC testing protocols

Tier 3 (Measures #10-15)

9. Proportion of colonization swabs (for CPOs and *C. auris*) tested with results returned to submitter, in accordance with timeline per CDC guidance
10. Proportion of isolates tested for expanded drug susceptibility with results returned to submitter, in accordance with timeline per CDC guidance
11. For laboratories conducting *C. difficile* testing: Proportion of specimens cultured and the proportion of isolates sequenced
12. For laboratories conducting *N. gonorrhoeae* testing: The number and percent of GC samples received including non-viable and contaminated specimens from i) each submitting SURRG laboratory and ii) from all assigned sentinel sites
13. For laboratories conducting *N. gonorrhoeae* testing: Number and percent of AST results reported to submitters within 3 weeks of submission.
14. For laboratories conducting *N. gonorrhoeae* testing: Whole genome sequencing (WGS) testing, number and percentage of isolates selected for sequencing and number of isolates sequenced successfully.
15. For laboratories conducting molecular Mtb testing: Number of isolates successfully tested by 24-loci MIRU-VNTR or whole genome sequencing within the appropriate timeframe

H: Vector-borne Diseases:
Building Comprehensive Programs to Identify, Diagnose, Report, Prevent, and Respond

Program Activity Contact Information

General program inquiries and questions on this guidance: VBDELC@cdc.gov; Jeff Borchert, gqx1@cdc.gov; (970) 221-6494
Arbovirus diseases: Stacey Martin, zmt0@cdc.gov; (970) 494-6703
Lyme disease, plague, tularemia: Kiersten Kugeler, bio1@cdc.gov; (970) 225-4245
Rickettsial diseases: Kristen Nichols-Heitman, wwd7@cdc.gov; (404) 718-4670
Parasitic vector-borne diseases (non-malaria): Elizabeth Gray, djn8@cdc.gov; (404) 718-4725

Funding Opportunity Description

Background

a. Overview

Vector-borne diseases, including those transmitted to humans by mosquitoes, ticks, fleas, and lice, are a large and growing public health problem in the United States. Mosquito-borne viruses such as West Nile virus (WNV) are often characterized by unpredictable and episodic epidemics that vary in place and time. Tick-borne diseases, including but not limited to Lyme disease, have more than doubled in number and increased in geographic range over the last few decades. Timely surveillance and reporting, accurate diagnostics, and vector control are needed. This program supports sustainable, locally relevant vector-borne disease prevention programs to respond to the increasing threat of vector-borne diseases.

b. Healthy People 2020

N/A

c. Other National Public Health Priorities and Strategies

N/A

CDC Project Description

a. Problem Statement:

Vector-borne diseases, caused by a diverse array of pathogens, are transmitted to humans by various types of vectors. These recognized threats, as well as novel and emerging conditions, have increasingly challenged the public health programs tasked with preventing, detecting, reporting, and controlling them.

b. Purpose:

The purpose of this program is to support state and local health departments to implement and maintain accurate and relevant surveillance for human disease and their vectors, improve diagnostics, and to implement and evaluate prevention strategies. This program comprises all vector-borne surveillance and control activities related to pathogens transmitted by mosquitoes, ticks, fleas, and lice, thus replacing arboviral (M1), Lyme (N1), and non-Lyme tick-borne (N2) projects in past iterations of this cooperative agreement.
Applicants should focus their proposed activities on the most important vectors and vector-borne diseases in their jurisdiction.

c. Outcomes:

1. Improved laboratory capacity to support vector-borne disease surveillance.
2. Improved completeness and timeliness of reporting of vector-borne disease surveillance data to monitor the epidemiology, incidence, and geographic spread of vector-borne diseases.

3. Improved ecologic surveillance to detect and monitor vector species distribution, abundance, infection, and insecticide resistance to inform vector control and public health response.
4. Increased availability of timely and accurate information on vector-borne disease risk and prevention to public health partners, healthcare providers, vector control agencies, decision makers, and the public.
5. More rapid and complete identification of vector-borne disease outbreaks to facilitate timely and effective control measures.
6. Better prepared workforce to identify, diagnose, report, prevent, and respond to vector-borne disease cases and outbreaks.

Funding Strategy:

Funds are intended to support building a comprehensive vector-borne disease program based on a three-tiered approach that focuses on the most relevant vector-borne diseases in the jurisdiction. Jurisdictions should document that they have existing capacity at lower tiers, if applying for high tier activities. Activities may include:

- Tier 1 activities: Required core capacity for locally-relevant vector-borne disease surveillance, laboratory and response across all jurisdictions receiving funds;
- Tier 2 activities: Enhanced capacities for vector-borne disease laboratory testing, surveillance, or response across a sub-set of jurisdictions;
- Tier 3 activities: Comprehensive capacity to serve as reference centers for vector-borne disease laboratory testing, and surveillance, response, and coordination with multiple external partners.

A summary of the capacities associated with each tier appears in Project H Appendix 1. Recipients should utilize funds for any combination of personnel, travel, supplies, equipment, or contractual support needed to execute proposed activities in line with jurisdictional need and proposed capacity tier(s). Two separate budgets should be included; one budget for Tier 1 activities and one budget for Tier 2 and Tier 3 activities.

- Estimated total availability of funds: $16,000,000
- Estimated number of awards given: 60
- Estimated average award amount: Approximately $266,000. The average award will depend upon the project activities (tiers) in which a jurisdiction participates. In year 1, CDC intends to support several (<8) jurisdictions to develop and maintain Tier 2 and Tier 3 activities with award levels up to $1,000,000, depending on proposed activities. These jurisdictions must document capacity at lower tiers to be granted higher tier funding.

Successful applications should include the following information:

- Discussion of overall vector-borne disease burden and population at risk
- Discussion on completeness of vector-borne disease reporting and demonstrated success with past CDC funding
- Description of existing surveillance, laboratory and vector-control capabilities
- Description and relevance of proposed activities
- Description of current or planned collaborations with external partners and local health departments

Additionally, jurisdictions should provide a point of contact for each of the programmatic areas where relevant:

- Arbovirus diseases

- Lyme disease, plague, tularemia
- Rickettsial diseases
- Parasitic vector-borne diseases (non-malaria)

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1c: Improve human surveillance, outbreak response and reporting for vector-borne diseases

a) Identify and report nationally notifiable vector-borne disease cases to CDC using standard CSTE case definitions with complete reporting of key variables (using NNDSS, supplemental case report forms or enhanced surveillance platforms, e.g. ArboNET).

☒Required ☐Optional

b) Identify and report blood donations with evidence of vector-borne pathogens (including West Nile virus, Zika virus, *Ehrlichia* and *Anaplasma* spp. and *Babesia* spp.) to CDC

☒Required ☐Optional

c) Identify and report possible transfusion and transplant transmitted infections.

☒Required ☐Optional

d) Analyze and interpret vector-borne disease surveillance data.

☒Required ☐Optional

e) Identify and report non-nationally notifiable vector-borne disease cases to CDC.

☐Required ☒Optional

f) Perform expanded analysis and interpretation of vector-borne disease surveillance data to inform public health action.

☐Required ☒Optional

g) Investigate and report vector-borne disease cases with new or unusual modes of transmission or clinical manifestations.

☐Required ☒Optional

h) In coordination with CDC and other ELC-funded jurisdictions, conduct enhanced case investigations and surveillance for vector-borne diseases to: 1) improve estimates of disease incidence and burden; 2) describe clinical features and outcomes; and 3) identify groups at increased risk for infection or disease to target prevention.

☐Required ☒Optional

i) Develop and maintain capacity to lead and coordinate complex investigations involving multiple jurisdictions or agencies (e.g., transfusion- or transplant-associated transmission, and complex outbreaks).

☐Required ☒Optional

j) Evaluate novel ways to conduct improved public health surveillance and collaborate with CDC to evaluate next generation public health surveillance (including informatics modernization initiatives).

☐Required ☒Optional

II. Strategy 1c: Improved ecological and vector surveillance, response and reporting

a) Report *passively* collected ecologic surveillance data already being collected (e.g. veterinary cases, sentinel animal infections, vector abundance and infection prevalence) for vector-borne disease to the appropriate CDC systems (e.g. ArboNET, MosquitoNET) and local vector control programs.

☒Required ☐Optional

b) Advise local agencies (e.g. mosquito abatement districts, health departments) on surveillance and control of vectors to reduce human disease where appropriate.

☒Required ☐Optional

c) *Actively* conduct or coordinate ecologic/vector surveillance and pathogen testing, and report to the appropriate CDC systems (e.g. ArboNET, MosquitoNET).

☐Required ☒Optional

d) Perform or obtain insecticide resistance testing results for mosquitos and submit, coordinate or verify submission of results to national systems (e.g. MosquitoNET). Use data to inform emergency mosquito control activities.

☐Required ☒Optional

e) Implement advanced vector control activities
   i. Implement emergency vector control, as appropriate
   ii. Conduct insecticide field-testing and evaluate insecticide resistance management plans
   iii. Provide regional capacity for pathogen testing in vectors

☐Required ☒Optional

III. Strategy 1e: Strengthen laboratory testing for vector-borne disease of relevance

a) Maintain core capacity to perform testing for vector-borne diseases of public health importance to the jurisdiction, including but not limited to:
   i. PCR and IgM antibody testing for at least one arbovirus

ii. Where relevant, PCR *Rickettsia* 510(k) assay and IFA for spotted fever group *Rickettsia*, *Ehrlichia* and *Anaplasma* spp. and typhus group *Rickettsia*

☒Required ☐Optional

b) Participate in annual proficiency testing for vector-borne disease diagnostic testing.

☒Required ☐Optional

c) Maintain enhanced capacity to perform testing or confirmation for an expanded number of vector-borne diseases of public health importance to the jurisdiction such as for a panel of arboviral infections and PCR testing for *Ehrlichia* and *Anaplasma* spp.

☐Required ☒Optional

d) Develop and maintain capacity to serve as a regional reference laboratory for other states and jurisdictions for advanced and confirmatory vector-borne disease diagnostic testing, including but not limited to plaque reduction neutralization testing.

☐Required ☒Optional

IV. Strategy 1a: Enhanced workforce capacity for vector-borne disease surveillance and response

a) Participate in CDC coordinated national and/or regional vector-borne disease meeting (e.g. ELC annual meeting and/or vector-borne disease focused meeting).

☒Required ☐Optional

b) Participate in relevant meetings and trainings to improve capacity for vector-borne diseases detection, reporting and response.

☐Required ☒Optional

AREA B: PREVENTION AND INTERVENTION

V. Strategy 2a: Implement vector-borne disease interventions and tools

a) In coordination with CDC and other partners, investigate and respond to vector-borne disease outbreaks, implement timely control measures, and disseminate findings.

☒Required ☐Optional

b) Develop and maintain surveillance and response plans for vector-borne diseases (e.g. emerging infections, outbreaks) as appropriate for the jurisdiction.

☐Required ☒Optional

c) Develop and implement a comprehensive integrated vector surveillance and control plan.

☐Required ☒Optional

VI. Strategy 2c: Implement health promotion and education strategies to improve vector-borne disease recognition, diagnosis and prevention activities

a) Conduct outreach and educational activities to increase awareness of healthcare providers, public health personnel and the public regarding the risks, clinical manifestations, diagnosis and prevention of vector-borne diseases.

☒Required ☐Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

VII. Strategy 3a: Enhance coordination and collaboration with external stakeholders

a) Collaborate with CDC and other CDC-supported extramural programs to evaluate the effectiveness and feasibility of integrated strategies to prevent, control or reduce the burden of vector-borne diseases (e.g. vaccines, therapeutics, clinical management, vector control or public education).

i. Possible collaborations include the Regional Centers of Excellence for Vector-Borne Diseases (CoE) or Emerging Infections Program (EIP)

☐Required ☒Optional

b) Establish and manage regional collaborations with other state and local health departments to improve resource sharing, staffing and capacity for vector-borne disease surveillance and control measures

☐Required ☒Optional

VIII. Strategy 3b: Disseminate relevant vector-borne disease information to stakeholders

a) Post jurisdiction specific vector-borne disease surveillance data to health department website

☒Required ☐Optional

b) Prepare up-to-date summaries of vector-borne disease data, and distribute to healthcare providers, public health partners, policy makers and the public.

☐Required ☒Optional

c) Evaluate and modify prevention and control messages as appropriate.

☐Required ☒Optional

d) Develop comprehensive vector-borne disease communication plans.

☐Required ☒Optional

e) Develop and evaluate innovative communication approaches to improve information reach and retention.

☐Required ☒Optional

f) Perform workforce training, intensive public outreach and/or clinician education.

☐Required ☒Optional

Collaborations

a. With CDC-funded programs:

Jurisdictions are expected to collaborate with subject matter experts in the Division of Vector-Borne Diseases (DVBD) including the Arboviral Diseases Branch, Bacterial Diseases Branch, Dengue Branch and Rickettsial Zoonoses Branch and with the Parasitic Disease Branch in the Division of Parasitic and Malarial Diseases as well as DVBD and ELC programmatic staff.

b. With organizations external to CDC:

Jurisdictions are encouraged to increase collaborations with vector-borne disease stakeholders as they advance their programs. Collaborations could include the business community; universities (including the Centers of Excellence and EIP partners); emergency management groups; hospitals and physician offices; media; non-government and non-profit organizations; other federal, state, local government or tribal agencies. Applicants should describe plans for how they will interact with local jurisdictions including description of activities at local level, methods to assess local needs and description of funding mechanisms to support local vector control and vector-borne disease related activities.

Target Populations:

This guidance targets the entire U.S. population and the public health system within the U.S. and its territories. Funding awarded for vector-borne disease programs is intended to support the needs of jurisdictions impacted by vector-borne diseases and to ensure that the public health system is ready and capable to mitigate the impacts of endemic and new introductions or discoveries of vector-borne diseases.

Evaluation and Performance Measurement:

Measure 1: Diagnostic Capacity

1. Reported jurisdiction vector-borne disease diagnostic capability (Tables 1 and 2)
2. Participation in 2019-2020 CDC proficiency evaluation for vector-borne diseases

Table 1: Jurisdiction Arboviral Diagnostic Capability (check all that apply)

Pathogen	ELISA		MIA		IFA		PRNT	PCR
	IgM	IgG	IgM	IgG	IgM	IgG		
California serogroup†								
Chikungunya								
Colorado tick fever								
Dengue								
Eastern equine encephalitis								

Japanese encephalitis								
Powassan								
St. Louis encephalitis								
Western equine encephalitis								
West Nile								
Zika								
Yellow fever								

†Such as La Crosse or Jamestown Canyon viruses

Table 2: Jurisdiction Non-Arboviral Vector-Borne Diseases Diagnostic Capability (check all that apply)

Pathogen	**ELISA**		**IFA**		**Culture**	**PCR**
	IgG	**IgM**	**IgG**	**IgM**		
Spotted fever group *Rickettsia*						
Typhus group *Rickettsia*						
Ehrlichia spp.						
Anaplasma spp.						
Yersinia pestis						
Francisella tularensis						
Relapsing fever *Borrelia* spp.						

Measure #2 – Surveillance Capacity and Completeness of Reporting

1. Estimated number of Lyme disease cases if using estimation or alternative approaches to surveillance procedures. Please also provide methodologic details.
2. Number and proportion of counties that included in annual human surveillance for tick-borne diseases (please specify which tick borne diseases)
3. Number and proportion of non-Lyme tick-borne diseases cases receiving confirmatory laboratory testing instead of only supportive laboratory evidence
4. Completeness of reporting to ArboNET including:
    a. Number of probable or confirmed locally-transmitted arboviral disease cases reported to ArboNET
    b. Incidence of probable or confirmed locally-transmitted neuroinvasive arboviral disease cases reported to ArboNET
    c. Number of probable or confirmed imported arboviral disease cases reported to ArboNET
    d. Proportion of reported human disease cases reported to ArboNET with complete data for the following categories: age, sex, clinical syndrome, hospitalization, and death for 2014-2018
    e. Number of West Nile and Zika virus viremic blood donors reported to ArboNET for 2014-2018

f. Proportion of total jurisdiction population that live in an area with environmental surveillance data (bird, mosquito, and sentinel animal; numerator and/or denominator) reported to ArboNET in 2018
g. Number of veterinary disease cases reported to ArboNET from 2014-2018

Measure #3 – Vector Surveillance and Control Capacity

5. Number and proportion of counties that report data related to entomologic or ecologic investigations for vector-borne diseases
6. Submission of monthly mosquito vector monitoring data reported to MosquitoNET
7. Submission of monthly mosquito insecticide resistance data reported to MosquitoNET
8. Number of counties from which ticks were collected and reported to ArboNET
9. Percentage of vector-borne disease or vector control staff that are trained in tick identification and collection
10. Vector control capacities and enhancements reported to CDC in ELC annual report
11. Vector control activities undertaken in response to identified arboviral disease outbreaks

Measure #4 – Cross Cutting Coordination and Collaborations

12. Estimated number of stakeholders reached through presentations/outreach activities, including healthcare professionals (physicians, nurses, nurse practitioners, physician assistants), local jurisdictions, and public
13. Reported established collaborations between state or territorial health departments, CDC-supported extramural programs (e.g., regional Vector-Borne Diseases Centers of Excellence, EIP sites), other academic institutions, and mosquito control jurisdictions to improve arboviral disease prevention and response strategies in annual report.

Project H Appendix 1: ELC Vector-Borne Disease Program Capacity Tiers

<u>Tier 1: Required core capacity for locally-relevant vector-borne disease surveillance, laboratory and response across all jurisdictions receiving funds</u>

- Identify and report nationally notifiable vector-borne disease cases to CDC using standard CSTE case definitions with complete reporting of key variables (using NNDSS, supplemental case report forms or enhanced surveillance platforms, e.g. ArboNET)
- Identify and report blood donations with evidence of vector-borne pathogens (including West Nile virus, Zika virus, *Ehrlichia* and *Anaplasma* spp. and *Babesia* spp.) to CDC
- Identify and report possible transfusion and transplant transmitted infections
- Analyze and interpret vector-borne disease surveillance data
- Report <u>*passively*</u> collected ecologic surveillance data already being collected (e.g. veterinary cases, sentinel animal infections, vector abundance and infection prevalence) for vector-borne disease to the appropriate CDC systems (e.g. ArboNET, MosquitoNET) and local vector control programs.
- Advise local agencies (e.g. mosquito abatement districts, health departments) on surveillance and control of vectors to reduce human disease where appropriate
- Maintain core capacity to perform testing for vector-borne diseases of public health importance to the jurisdiction, including but not limited to:

    - PCR and IgM antibody testing for at least one arbovirus
    - Where relevant, PCR *Rickettsia* 510(k) assay and IFA for spotted fever group *Rickettsia*, *Ehrlichia* and *Anaplasma* spp. and typhus group *Rickettsia*
- Participate in annual proficiency testing for vector-borne disease diagnostic testing
- Participate in CDC coordinated national and/or regional vector-borne disease meeting (e.g. ELC annual meeting and/or vector-borne disease focused meeting)
- Participate in relevant meetings and trainings to improve capacity for vector-borne diseases detection, reporting and response
- In coordination with CDC and other partners, investigate and respond to vector-borne disease outbreaks, implement timely control measures, and disseminate findings
- Conduct outreach and educational activities to increase awareness of healthcare providers, public health personnel and the public regarding the risks, clinical manifestations, diagnosis and prevention of vector-borne diseases
- Post jurisdiction specific vector-borne disease surveillance data to health department website

<u>Tier 2: Enhanced capacities for vector-borne disease laboratory testing, surveillance, or response across a sub-set of jurisdictions</u>

- Identify and report non-nationally notifiable vector-borne disease cases to CDC
- Perform expanded analysis and interpretation of vector-borne disease surveillance data to inform public health action
- Investigate and report vector-borne disease cases with new or unusual modes of transmission or clinical manifestations
- <u>*Actively*</u> conduct or coordinate ecologic/vector surveillance and pathogen testing, and report to the appropriate CDC systems (e.g. ArboNET, MosquitoNET)
- Perform or obtain insecticide resistance testing results for mosquitos and submit, coordinate or verify submission of results to national systems (e.g. MosquitoNET). Use data to inform emergency mosquito control activities
- Maintain enhanced capacity to perform testing or confirmation for an expanded number of vector-borne diseases of public health importance to the jurisdiction such as for a panel of arboviral infections and PCR testing for *Ehrlichia* and *Anaplasma* spp.
- Develop and maintain surveillance and response plans for vector-borne diseases (e.g. emerging infections, outbreaks) as appropriate for the jurisdiction
- Prepare up-to-date summaries of vector-borne disease data, and distribute to healthcare providers, public health partners, policy makers and the public

<u>Tier 3: Comprehensive capacity to serve as reference centers for vector-borne disease laboratory testing, surveillance, response, and coordination with multiple external partners</u>

- In coordination with CDC and other ELC-funded jurisdictions, conduct enhanced case investigations and surveillance for vector-borne diseases to: 1) improve estimates of disease incidence and burden; 2) describe clinical features and outcomes; and 3) identify groups at increased risk for infection or disease to target prevention
- Develop and maintain capacity to lead and coordinate complex investigations involving multiple jurisdictions or agencies (e.g., transfusion or transplant-associated transmission, and complex outbreaks)

- Evaluate novel ways to conduct improved public health surveillance and collaborate with CDC to evaluate next generation public health surveillance (including informatics modernization initiatives).
- Implement advanced vector control activities
    - Implement emergency vector control, as appropriate
    - Conduct insecticide field-testing and evaluate insecticide resistance management plans
    - Provide regional capacity for pathogen testing in vectors
- Develop and maintain capacity to serve as a regional reference laboratory for other states and jurisdictions for advanced and confirmatory vector-borne disease diagnostic testing, including but not limited to plaque reduction neutralization testing
- Develop and implement a comprehensive integrated vector surveillance and control plan
- Collaborate with CDC and other CDC-supported extramural programs to evaluate the effectiveness and feasibility of integrated strategies to prevent, control or reduce the burden of vector-borne diseases (e.g. vaccines, therapeutics, clinical management, vector control or public education).
    - Possible collaborations include the Regional Centers of Excellence for Vector-Borne Diseases (CoE) or Emerging Infections Program (EIP)
- Establish and manage regional collaborations with other state and local health departments to improve resource sharing, staffing and capacity for vector-borne disease surveillance and control measures
- Evaluate and modify prevention and control messages as appropriate
- Develop comprehensive vector-borne disease communication plans
- Develop and evaluate innovative communication approaches to improve information reach and retention
- Perform workforce training, intensive public outreach and/or clinician education

Section III: Disease-Specfic Projects

I: Mycotics: Detecting and Preventing Fungal Infections

Program Activity Contact Information

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Funding Opportunity Description

Background

a. Overview

The Mycotics activities are intended to help prevent disability and death as a result of fungal infections by improving state and local health departments' capacity to:

1. Conduct surveillance for key endemic mycoses (coccidioidomycosis, histoplasmosis, blastomycosis, *Cryptococcus gattii* infection)

2. Detect and respond to emerging antifungal-resistant pathogens, like *Candida auris* and certain *Aspergillus fumigatus*

3. Improve outbreak response to fungal diseases

4. Engage with clinicians and the public to improve awareness of often neglected diseases to save lives by early detection

b. Healthy People 2020

- **EH-22 – Environmental health objective.** Increase the number of States, Territories, Tribes, and the District of Columbia that monitor diseases or conditions that can be caused by exposure to environmental hazards
- **HAI-1 – Healthcare-associated infection objective.** Reduce central line-associated bloodstream infections (CLABSIs)

c. Other National Public Health Priorities and Strategies

N/A

CDC Project Description

a. Problem Statement:

Fungi are environmental pathogens that cause a broad spectrum of illness, including community-acquired respiratory diseases, hospital-associated infections, and opportunistic infections among immunocompromised hosts. They are important causes of disease but are often overlooked and misdiagnosed. Improved surveillance can guide efforts to prevent exposures and improve early diagnosis. Several fungal diseases of particular concern include:

- Certain endemic mycoses, specifically coccidioidomycosis (Valley fever), histoplasmosis, and blastomycosis, which are common causes of respiratory infections in some U.S. regions. These

infections, usually acquired from soil and other environmental exposures, are widely misdiagnosed. Many patients with these diseases presumed to have bacterial pneumonia and receive multiple rounds of antibacterial drugs, which are ineffective against these fungal pathogens and pose risks to patients. All three of these endemic mycoses can lead to severe and invasive disease, and all have caused large outbreaks.

- *Candida auris*, an emerging drug-resistant yeast that spreads in healthcare facilities. Intensive public health response and use of infection control measures can help contain its spread.
- Resistant fungal infections in healthcare environments, especially those caused by certain *Candida* and *Aspergillus* species. These fungi are increasingly important issues for public health. Strains of *Aspergillus fumigatus* have recently been detected in the United States that are resistant to all triazole antifungals, a major concern for this deadly opportunistic pathogen. Such resistant strains have already emerged as an important cause of illness in Europe and have been linked to agricultural and environmental fungicide use

Fungal disease outbreaks, like the fungal meningitis outbreak caused by contaminated steroids and numerous mucormycosis outbreaks in hospitals, represent an urgent need to build capacity to detect, respond, and control fungal infections.

b. Purpose:

The purpose of this project is to strengthen state health department epidemiologic and laboratory capacity to detect and prevent fungal diseases. Specifically, this project aims to:

- Strengthen epidemiologic data on endemic mycosis in order to guide prevention efforts, including targeted outreach to improve early diagnosis and treatment.
- Build jurisdictions' capacity to detect and respond to antifungal resistant fungal pathogens, including *C. auris* and *A. fumigatus*.
- Improve epidemiologic capacity to investigate outbreaks, monitor trends, and track the emergence of fungal disease.
- Enhance laboratory capacity to identify fungi from clinical and environmental samples and aid in diagnosis fungal diseases from clinical specimens.

c. Outcomes:

1. Improved epidemiologic data con coccidioidomycosis, histoplasmosis, and blastomycosis, including ability to assess geographic spread, temporal trends, and emerging risk factors, to guide prevention measures.

2. Tracking of emerging antifungal resistant fungal pathogens, including *C. auris* and *A. fumigatus.*

3. Increased public health, healthcare provider, and public awareness of fungal infections, their diagnosis and treatment (e.g., via local outreach, reports and participation in Fungal Disease Awareness Week activities).

4. Better laboratory detection of fungi from clinical and environmental sources, particularly those due to *Coccidioides*, *Histoplasma*, *Blastomyces*, and *Cryptococcus* from other clinical specimens and environmental samples.

Funding Strategy:

Funds should be utilized for personnel, travel, supplies, equipment, or contractual support for proposed activities

- Estimated total availability of funds: ~ $600,000
- Estimated number of awards given: ~ 20
- Estimated average per award: ~ $10,000 - $30,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1a: Enhance workforce capacity

a) Improve laboratory detection of fungal infections

i. CDC Mycotic Diseases Branch - Mold Identification Course

☐Required ☒Optional

II. Strategy 1b: Enhance investigation and outbreak response

a) Respond to fungal disease outbreaks and report findings to CDC

☐Required ☒Optional

b) Contain or prevent the spread of antifungal-resistant fungal pathogens

☐Required ☒Optional

III. Strategy 1c: Improve surveillance and reporting

a) Use CSTE case definitions to conduct surveillance for fungal diseases

☐Required ☒Optional

b) Help improve standardized data collection for fungal disease surveillance, including revised case definitions and optional data elements harmonized across states

☐Required ☒Optional

c) Conduct enhanced surveillance for one or more endemic mycoses to better characterize patient characteristics, diagnostics used, clinical illness, and possible exposures

☐Required ☒Optional

d) Conduct active, population-based surveillance for invasive mold infections, including collection of clinical isolates and pathology specimens; states may consider using a case investigation form used by the Emerging Infections Program.

☐Required ☒Optional

IV. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Establish or enhance fungal testing capacity by acquiring laboratory equipment or supplies (*note that testing should not be duplicative with Candida AR Lab Network testing*)

☐Required ☒Optional

b) Implement or improve testing protocols for fungal infectious diseases

☐Required ☒Optional

AREA B: PREVENTION AND INTERVENTION

V. Strategy 2a: Implement public health interventions and tools

a) Develop health promotion materials for healthcare providers and the public to increase health literacy about fungal disease prevention (e.g., participate in national Fungal Disease Awareness Week activities)

☐Required ☒Optional

Collaborations

a. With CDC-funded programs:

Applicants should describe participation in the Antibiotic Resistance Lab Network (ARLN) for *Candida*, including involvement in coordinating isolate transfer to a regional laboratory or participation as a regional laboratory. Efforts to control *C. auris* also fall under ELC activities on healthcare-associated infections.

b. With organizations external to CDC:

- Applicants may wish to collaborate with other state health departments that have already developed educational materials to raise awareness of fungal infections (e.g., a Valley fever video produced by the New Mexico state health department or collaborations with the Valley Fever Center for Excellence in Arizona).
- Local healthcare providers may be helpful in facilitating surveillance and providing clinical training.

Target Populations:

Systemic fungal diseases can affect a wide range of people. Endemic mycoses can cause disease in nearly anyone exposed and pose an even higher risk for outdoor workers in endemic areas. African-Americans appear to be at elevated risk for severe disease, including meningitis, from coccidioidomycosis. Immunocompromised people are at greater risk than the general population for nearly all systemic fungal infections, particularly those caused by *Candida*, *Aspergillus*, and mucormycetes.

Evaluation and Performance Measurement:

Measure #1) Number of fungal disease cases reported in your jurisdiction during 2018, grouped by pathogen.
Measure #2) Participation during 2019 in efforts to improve standardized case definitions and data elements for fungal diseases.
Measure #3) Number and types of fungal disease educational materials developed and outreach events held (please describe and report number of unique materials rather than number of copies distributed).

Measure #4) *For jurisdictions that received laboratory-related Mycotics funding*: Describe implementation of fungal-related laboratory equipment, method, technique, or protocol to improve diagnostic capacity.

J: Binational Border Infectious Disease Surveillance (BIDS) Program

Program Activity Contact Information

DGMQ Coordinator: Pamela Nonnenmacher, fsb6@cdc.gov ; 404 639 7112
Technical POC: Alba Phippard, ign7@cdc.gov , 619-692-8479

Funding Opportunity Description

Background

a. Overview

The Binational Border Infectious Disease Surveillance (BIDS) Program was established to foster local, state, and federal collaboration to improve surveillance for infectious diseases of binational importance.

b. Healthy People 2020

The BIDS Program supports the following Healthy People 2020 goals:

- To strengthen and sustain communities' abilities to prevent, protect against, mitigate the effects of, respond to, and recover from incidents with negative health effects
- Improve public health and strengthen U.S. national security through global disease detection, response, prevention, and control strategies.

c. Other National Public Health Priorities and Strategies

By enhancing surveillance among binational populations and strengthening binational systems for communication, reporting, and collaborative response, BIDS activities support the following objectives of the Global Health Security Agenda:

- Prevent the emergence and spread of antimicrobial drug resistant organisms and emerging zoonotic diseases
- Reduce the number and magnitude of infectious disease outbreaks
- Strengthen the global norm of rapid, and transparent reporting

BIDS binational surveillance also supports the National Strategy to Combat Antibiotic Resistance Bacteria by improving international collaboration to detect antibiotic resistance in the border region.

CDC Project Description

a. Problem Statement:

Numerous binational infectious disease outbreaks, including vector-borne, vaccine-preventable, foodborne, waterborne, mycotic, and mycobacterial diseases, have been documented over the last two decades. Many of these diseases have emerged with higher incidence in the U.S.-Mexico border region compared to other areas of the United States. Optimal investigation and control of binational disease cases and outbreaks requires better surveillance, quantification of disease burden, and epidemiological and laboratory collaboration with both U.S. and Mexico public health (PH) agencies at all levels.

b. Purpose:

The purpose of this funding is to improve disease detection, reporting and prevention of infectious diseases of binational concern in the U.S.-Mexico border region. Infectious diseases of binational concern are those affecting humans that can be introduced or amplified in the other country by virtue of the movement of people, products, or animals between countries; these often require binational coordination to identify, monitor and control.

c. Outcomes:

- Implementation of the U.S.-Mexico Guidelines for infectious disease prevention and control via the Operational Protocol for Binational Communication and Coordination for
  - Improved coordination and exchange of PH information in the border region and binationally; and
  - Rapid investigation and control of binational outbreaks
- Improved surveillance through:
  - Improved detection of binational cases and completeness of binational case data
  - Improved timeliness of reporting binational cases
- Improved understanding of the epidemiology and incidence of infectious diseases of binational importance
- Electronic mechanisms for binational data exchange are in place

Funding Strategy:

U.S. states that share a border with Mexico are eligible to apply for BIDS funding. Funding may be used for personnel, travel, supplies, equipment, or contractual support for proposed activities. Awards will preferentially support integration of Binational Reporting Criteria and related variables into jurisdictions' investigations and electronic disease surveillance systems, operationalization of the US-Mexico Guidelines, and implementation of the recommendations made for BIDS by the 2018 US-Mexico Border Disease Prioritization Work Group. For projects related to a specific infectious disease or technical area, program planning and funding decisions may be administered by the most appropriate state program or office to manage and implement activities, in consultation with the state ELC principal investigator, ELC, and CDC. Funding recipients will be required to attend an out-of-state BIDS grantee meeting.

- Estimated total availability of funds: $750,000
- Estimated number of awards given: 1 - 4
- Estimated average per award: $50,000 - $750,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1i: Sustain and/or enhance information systems through integration of binational variables

a) Assess the completeness, and data quality of Binational Variables (i.e., Binational Reporting Criteria, Country of Exposure, Country of Usual Residence and Country of Birth) in state and local systems by county

   i. This activity may be done during 1 or 2 discrete periods of time during years 2 and 4 on a sample of cases

☒Required ☐Optional

b) Train state and local staff on the use of the Binational Reporting Criteria and related variables

☒Required ☐Optional

c) Binational Case Reporting

i. Facilitate the timely reporting of binational cases and outbreaks, with border jurisdictions, states, and federal partners, consistent with local protocols, International Health Regulations, and Binational Case Reporting Standards for BIDS.

☒Required ☐Optional

d) Integrate the Binational Variables into local and state electronic disease surveillance systems

i. The Binational variables are Binational Reporting Criteria, Country of Exposure, Country of Usual Residence and Country of Birth (endorsed by Council of State and Territorial Epidemiologists' position statement 13-SI-02)

ii. States should be working towards integration in 100% of border counties.

iii. Once state has integrated these variables into the border county information systems, states may expand efforts to non-border counties.

☐Required ☒Optional

e) Incorporate the Binational Variables into routine case notifications to the National Notifiable Disease Surveillance System

i. per the Generic V2 HL7 message mapping guide, or through the existing state processes

☐Required ☒Optional

II. Strategy 1b: Enhance investigation and outbreak response

a) Implement or enhance human surveillance

i. The state should prioritize surveillance activities as recommended by the 2018 Disease Prioritization for US Southern Land Border work group.

ii. Surveillance must include laboratory testing for infectious diseases of binational concern among BIDS target populations

iii. For sites proposing ILI or SARI surveillance, surveillance methods should be consistent with BIDS border-wide protocol for ILI/SARI surveillance

iv. Enhanced surveillance activities includes activities beyond those routinely conducted, e.g. conducting lab testing on a greater number or broader scope of patients, performing laboratory testing not usually performed, or collecting additional exposure information during a case interview, not typically collected

☐Required ☒Optional

b) Develop, test, and refine binational information sharing and collaboration protocols

i. In conjunction with U.S. and Mexican state and local partners in the U.S.-Mexico border region, consistent with International Health Regulations (IHR), U.S.-Mexico Guidelines, and the Operational Protocol for Binational Communication and Coordination; or document the operationalization of the protocol at the local and state levels. Funding recipient will be

required to report on the date protocols were exercised and the date the final After Action Report was approved by the state (and sister jurisdiction if applicable).

☐Required ☒Optional

III. Strategy 1c: Improve surveillance and reporting

a) Assess, enhance, or systematize data collection

i. Data elements may relate to: 1) the population in the border states (such as detailed Hispanic/Latino origin categories, country of birth, years in the US, primary language spoken at home); 2) cross-border mobility, including frequency/reason for crossing, destination, and activities (such as visiting family, work, study); and 3) access to medical care and sources of health information.

ii. This could be done on an ongoing basis by enhancing disease surveillance questionnaires, or through discrete projects

☐Required ☒Optional

b) Share best practices through Peer to Peer training or consultation

i. The requesting grantee must describe specific objectives of the training to be considered for the funds.

ii. The grantee receiving the training is required to complete and submit a progress report detailing the training objectives, lessons learned, and anticipated outcomes within 30 days after completing the training.

iii. Trainee may request a specific match, or to be matched through the program POC.

☐Required ☒Optional

c) Assist local health jurisdictions with binational outbreak investigations

☐Required ☒Optional

d) Train border region epidemiologists/disease investigators, or physicians to improve surveillance and response

☐Required ☒Optional

Collaborations

a. With CDC-funded programs:

Sites should collaborate with NNDSS Program, Emerging Infections Program, ILI-Net, BioSense, PulseNet, and other states participating in the BIDS program, as applicable, and provide description of these collaborations in the application. Sites will collaborate closely with the CDC BIDS program within the Division of Global Migration and Quarantine's US-Mexico Unit. CDC BIDS program staff will provide technical oversight and assistance; liaise with other CDC subject matter experts; and review products resulting from activities.

b. With organizations external to CDC:

Collaboration with infectious disease offices of local/regional/state health departments is required and must be described in the proposal, along with how the proposed activities fit into the state's broader disease surveillance plans. Collaborations with universities and non-governmental institutions are encouraged, with associated letters of support. States proposing binational collaborations with Mexico should provide documentation of binational agreement to collaborate, such as a letter of support from a collaborating Mexican institution.

Target Populations:

Projects should target U.S.-Mexico border-crossing populations and their networks, and residents of the U.S.-Mexico border region at risk for diseases of binational concern, with an emphasis on foreign-born Latino populations and those with limited English proficiency. Applicants should clearly identify which population(s) will be targeted by each proposed project.

Evaluation and Performance Measurement:

Measure #1

1.1 State's electronic disease surveillance system's electronic case reports include all Binational Reporting Criteria as defined in NNDSS
1.2 Number and percent of border counties in the state that include the Binational Reporting Criteria in case reports
1.3 Number and percent of all counties in the state that include the Binational Reporting Criteria in case reports
1.4 State electronic disease surveillance system case report includes:

- Country of Exposure
- Country of Usual Residence
- Country of Birth

1.5 List of diseases reported through the system(s) referenced in indicators 1.1-1.4

Additional Guidance:
All reportable infectious diseases should be included in the indicator reporting.

Binational Reporting Criteria, as defined in NNDSS, are:

- Potentially exposed while in Mexico or Canada
- Potentially exposed by a resident of Mexico or Canada
- Resident of Mexico or Canada
- Has case contacts in or from Mexico or Canada
- Exposure to suspected product from Mexico or Canada
- Other situations that may require binational notification or coordination of response)

Border counties are defined as the 44 border counties with the majority of their area within the 100 km line, as established by the 1983 La Paz agreement. They are:
Arizona: Cochise, Pima, Santa Cruz, Yuma; **California:** Imperial, San Diego; **New Mexico:** Doña Ana, Grant, Hidalgo, Luna, Otero, Sierra; **Texas:** Brewster, Brooks, Cameron, Crockett, Culberson, Dimmit, Duval, Edwards, El Paso, Frio, Hidalgo, Hudspeth, Jeff Davis, Jim Hogg, Kenedy, Kinney, La Salle, Maverick, McMullen, Pecos,

Presidio, Real, Reeves, Starr, Sutton, Terrell, Uvalde, Val Verde, Webb, Willacy, Zapata, Zavala.

Performance Targets:
By the end of the 2nd year of the cooperative agreement all states receiving BIDS funding will include the following variables, in the state's electronic disease surveillance system: Binational Reporting Criteria, Country of Exposure, Country of Usual Residence and Country of Birth.

Additionally, 100% of the states' border counties will have integrated the Binational Reporting Criteria variable into the primary investigative and reporting systems.

Measure #2

2.1 Establish and report on a measure of the Binational Reporting Criteria variable in border counties.

2.2 Establish and report on a measure of the negative predictive value of the Binational Reporting Criteria variable in border counties.

2.3 Provide the number and percent of all border-county confirmed cases which have the following variables populated:
Country of Exposure
Country of Usual Residence
Country of Birth

Additional Guidance:
CDC will provide specific guidance about how to conduct PPV and NPV studies after consultation with grantees. This will be issued within 6 months of the start of the performance period. Additionally, diseases of interest will be specified in year 1 and will be consistent throughout the project period.

Performance Targets:
For measure 2.1: at least 80%
For measure 2.2: at least 90%
In years 2-5, also report on the percent change from previous year.

For measure 2.3:
Country of Exposure variable completed: at least 80%
Country of Usual Residence variable completed: at least 80%
Country of Birth variable completed: at least 80%

Measure #3

3.1 Report number and percent of all confirmed cases that are binational in border counties.

3.2 Report, by disease, number and percent of confirmed cases that met each of the criteria of the Binational Reporting Criteria variable in border counties.

3.3* Report, outcomes of binational case reports. Outcomes are (mutually exclusive): known public health follow-up in Mexico; binational collaboration on investigation or cluster/outbreak; and unknown public health follow-up in Mexico.

3.4 Report a list of all binational outbreaks and clusters detected. The list should describe each of the following elements or each outbreak or cluster: disease or syndrome investigated; month and year of notification; direction of notification; which authorities notified; collaborative response with Mexico; and the final outcome.

3.5 Report the number and percent of all confirmed cases reported to public health counterparts in Mexican sister jurisdictions within the timeframe specified by the Binational Case Reporting Standards for BIDS.

Additional Guidance:
*Measure 3.3: Binational collaboration is defined as responding to requests for further information after initial report, receiving information from other country regarding the event after the initial report, or communication to discuss the event or response activities. Any of these activities are considered binational collaboration.

Performance Targets:
Measure 3.5: 90%

Measure #4

4.1 Provide number and percent of cases for which BIDS supported or facilitated laboratory testing, by surveillance project and by local jurisdiction. If the BIDS program limits the number of specimens to be tested (either number or %), describe the sampling frame for testing.

4.2 Provide percent of states' border county specimens tested for the pathogen that were facilitated or supported by BIDS. Provide additional description/justification of the target population if needed. For example, if the BIDS program contributes a very small % of specimens to the border county's surveillance system, but targets a population for which there are existing surveillance gaps, please describe how the BIDS testing fills those gaps.

4.3 Provide number of specimens tested for antimicrobial resistance, by BIDS surveillance project.

4.4 Provide number and percent positive for antimicrobial resistance, by BIDS surveillance project.

4.5 For sites conducting influenza-like illness (ILI) surveillance, report the number and % of ILI cases tested for influenza.

4.6 For sites conducting ILI surveillance, report the number and percent of ILI cases tested that were positive for influenza (by type).

4.7 For sites conducting severe acute respiratory infection (SARI) surveillance, report the number and percent of cases tested that were positive for influenza, and other major respiratory pathogens (by type).

4.8 For sites conducting BIDS enteric disease surveillance, report the number and percent of confirmed enteric cases for which genetic typing was performed.

4.9 For sites conducting BIDS enteric disease surveillance, report the number and percent of confirmed enteric cases that were part of a local, state or national cluster.

Additional Guidance:
If grantee does not conduct the specified type of surveillance through this Cooperative Agreement, the indicator is Not Applicable.

Enhanced Surveillance project are defined as surveillance activities conducted that are beyond those routinely conducted, e.g. conducting lab testing on a greater number or broader scope of patients, performing laboratory testing not usually performed, or collecting additional exposure information during a case interview, not typically collected.

For these indicators, “supported or facilitated” is defined as paid for, transported by or coordinated by BIDS staff.

A cluster is defined as refers to an aggregation of cases grouped in place and time that are suspected to be greater than the number expected, even though the expected number may not be known.

Performance Target:
No performance target is provided due to the fact that numbers may vary for multiple reasons from year to year.

K: Global Migration, Border Interventions and Migrant Health

Program Activity Contact Information

Pamela Nonnenmacher, DGMQ Coordinator, (404) 639-7112
Gayathri Kumar– Refugee/Immigrant Health
Reena Gulati – Points of Entry

Funding Opportunity Description

Background

a. Overview

The mission of the Division of Global Migration and Quarantine is to reduce morbidity and mortality among globally mobile populations and to prevent the introduction, transmission, and spread of communicable diseases through regulation, science, research, preparedness, and response.

b. Healthy People 2020

Topic Area: Global Health--Improve public health and strengthen U.S. national security through global disease detection, response, prevention, and control strategies

c. Other National Public Health Priorities and Strategies

N/A

CDC Project Description

a. Problem Statement:

Every day close to one million travelers arrive in the United States by air, sea, or land. Some arrive from countries with infectious disease epidemics and limited healthcare access. Due to tight seating space on conveyances and prolonged contact en route, communicable diseases can spread quickly and may result in cases or outbreaks in communities. Additionally, about 70,000 refugees and 400,000 immigrants settle in the United States every year. Refugees are particularly vulnerable because of limited access to healthcare in their country of origin and countries providing temporary asylum. They may have complex health-care issues, such as low baseline vaccination rates and high rates of infectious diseases.

b. Purpose:

The purpose of this funding is to mitigate the public health risks of travel-associated importation of pathogens into the U.S. and to improve public health surveillance, case management, and response of communicable diseases of public health concern among globally mobile populations.

c. Outcomes:

- Improved surveillance of diseases of public health concern associated with or identified by travel or border crossings
- Improved completeness of travel associated case reports
- Improved timeliness of travel-associated case reports
- Improved coordination and exchange of data (e.g. linkage of overseas vaccination information for refugees from DGMQ's Electronic Disease Notification (EDN) system available for download in HL7.2.5.1 national standard into state immunization registries, linking between various databases to allow for long-term follow up of refugees and/or immigrants, etc.)
- More efficient efforts in:
    - Detecting cases and outbreaks of diseases of public health concern

- Responding to cases and outbreaks of diseases of public health concern (e.g., providing recommendations to health care providers)
- Investigating cases and outbreaks of diseases of public health concern (e.g., determining risk factors)
- Implementing disease control measures

- Inform public health treatment approaches for, refugees and/or immigrants with a special emphasis given to approaches to address LTBI, hepatitis B, vaccine preventable diseases, and/or mental health (refugees only)
- Inform program and policy development
- Minimized transmission of infectious diseases in globally mobile populations
- Improved health outcomes, quality, and equity

Funding Strategy:

Funding should be used for personnel, travel, supplies, equipment, or contractual support for proposed activities

- Approximate total availability of funds: $250,000
- Approximate number of awards given: 3 - 5
- Approximate average per award: $50,000
- Approximate range of awards: $15,000 - $100,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1b: Enhance investigation response and reporting

a) Develop new investigation materials, processes, procedures, or technology that would more quickly and completely detect cases of immediate public health interest among globally mobile populations

☒Required ☐Optional

II. Strategy 1c: Improve surveillance to drive public health action

a) Analyze, report, and share surveillance, epidemiological, or clinical data for globally mobile populations

☒Required ☐Optional

AREA B: PREVENTION AND INTERVENTION

III. Strategy 2a: Implement and evaluate standard, routine, accepted or evidence-based public health practice activities or interventions

a) Implement interventions addressing the health needs of refugee and /or immigrant populations at conveyances or at border crossings
b) Evaluate the effectiveness of interventions addressing the health needs of refugee and/or immigrant populations

☒Required ☐Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

IV. Strategy 3a: Coordinate and collaborate

a) Enhance staff training and education on port of entry International Health Regulations core capacities (http://www.who.int/ihr/procedures/en)

☒Required ☐Optional

V. Strategy 3a: Maintain and enhance integrated surveillance information

a) Facilitate coordination/exchange of surveillance, epidemiological, or clinical data for globally mobile populations

☒Required ☐Optional

Collaborations

a. With CDC-funded programs:

Collaboration with other CDC funded programs is optional. However, if applicant proposes to collaborate with other CDC funded programs to conduct activities, applicant should provide evidence of prior collaborations with these groups and should describe: 1) the work of the collaborating CDC-funded programs in their jurisdiction or community, 2) the programs' success in achieving Cooperative Agreement outcomes; and 3) the way the applicant will work with the program. Prior evidence may be provided as a MOU, MOA, or letters of support.

b. With organizations external to CDC:

Collaboration with organizations external to the CDC is optional. However, if applicant proposes to collaborate with organizations external to CDC, applicant must provide evidence of prior collaborations with such groups, describe the organization's success in achieving the Cooperative Agreement outcomes, and indicate how the applicant will interact with the organization in specific terms. Prior achievements and evidence may be provided as an MOU, MOA, or letters of support.

Target Populations:

Projects should target globally mobile populations such as refugees, immigrants, travelers, expatriates, migrants, asylees, those adjusting to LPR status in the United States (status adjusters), or communities with significant migrants or refugees. Applicants should clearly identify which population(s) will be targeted by the proposed project.

Evaluation and Performance Measurement:

Performance measures and evaluation activities used to monitor and track progress will be specific for each approved and funded project. This is necessary as the number and scope of projects may vary in the area of emphasis, strategy, and activity. As projects are approved and funded, CDC will work with awardees to develop the specific performance measurements that best meet the purpose and objective of that project. The performance measures will be closely tied to the pertinent strategies, activities, and outcomes. There may be both qualitative and quantitative data collected for evaluation purposes. Performance measures, other evaluation data and summaries of progress will be provided in the final report at the completion of the budget period. Any interim evaluation data and summaries of progress will also be collected via quarterly calls through verbal communication, although awardees are not required to provide a written summary of data during these times. However, a discussion guide for collection of interim evaluation data and progress will be

provided to the awardee beforehand to guide discussions during these calls. Optional activities that awardees may be given an opportunity to share or present their work include Division-wide seminars and peer-to-peer networking calls (i.e., networking calls where awardees will be given an opportunity to present their work to one another). Overall, reports will be submitted at a minimum once in a budget period (i.e., final progress report), not including the ELC application.

For instance, for improved completeness and timeliness of reporting the following performance measures may include:

- Time from detection of case to initial response to public health departments
- Number of reports with 90% of required information completed
- Retrospective review of cases to identify public health risks, areas for improving detection of and/or response to cases
- Measurable outcomes in public health surveillance, including increased numbers of complete screening records reported and increased number of reported records having high data quality
- Number of meetings and/or trainings conducted for planning exercises
- Number of reports, recommendations, and evidence-based policy change documentation

L: Prion Surveillance
Program Activity Contact Information
Teresa Hammett, Tah5@cdc.gov 404-639-4389; Ryan Maddox, Zzp7@cdc.gov , 404.639.1170
Funding Opportunity Description
Background
a. Overview
This project contributes to national surveillance of human prion diseases with goals of monitoring their incidence in the United States and assisting clinicians with accurate diagnoses. This family of diseases, which are progressive, transmissible, neurodegenerative disorders that are always fatal, includes variant Creutzfeldt-Jakob disease (vCJD), the human form of bovine spongiform encephalopathy (BSE, or "mad cow" disease). Other human prion diseases include sporadic Creutzfeldt-Jakob disease (sCJD, iatrogenic (iCJD), genetic CJD (gCJD), fatal familial insomnia (FFI), and Gerstmann-Sträussler-Scheinker (GSS) syndrome.
b. Healthy People 2020
N/A
c. Other National Public Health Priorities and Strategies
N/A
CDC Project Description
a. Problem Statement:
Prion diseases, or transmissible spongiform encephalopathies (TSEs), are a family of rare progressive neurodegenerative disorders that affect both humans and animals. These diseases are characterized by unusually long incubation periods often measured in years. They are 100% fatal and are caused by unconventional transmissible agents that are highly resistant to usual inactivation methods. Human prion diseases include the classic forms of Creutzfeldt-Jakob disease (sporadic, iatrogenic, genetic), the types most commonly occurring throughout the world, including the United States, and variant Creutzfeldt-Jakob Disease (vCJD), a type of human prion disease that emerged in the United Kingdom in the mid-1990s associated with eating meat products contaminated with the agent of BSE. Prion disease surveillance in the United Kingdom enabled recognition of the emergence of vCJD. Similarly, prion disease surveillance in the United States is monitoring for the emergence of vCJD and other potentially preventable new prion diseases (iatrogenic CJD and possible human chronic wasting disease (CWD)). In 2018, results of a study by researchers in Canada and Germany supported concerns that CWD may pose a risk to human health. The researchers reported that CWD was transmitted to cynomolgus macaques that were fed infected brain or muscle tissue from infected elk or deer. CWD has been identified in free-ranging cervids in increasing numbers of states (23 states as of 2018) and is regularly found in new areas. Once CWD is present in an area, it is difficult or impossible to eradicate. Prion disease surveillance data is also used in the assessment of the efficacy of ongoing U.S. prevention measures. Many clinicians and public health personnel have little experience dealing with prion diseases; funding of surveillance personnel at state health departments helps these departments to work more closely with CDC in developing and disseminating knowledge about prion diseases and enhancing prion disease surveillance.
b. Purpose:
Human prion disease surveillance serves to provide a better understanding of this illness and the prions that appear to cause it. The purpose of this project is to maintain and enhance surveillance for Creutzfeldt-Jakob

disease (including sporadic, iatrogenic and genetic) as well as to detect the possible emergence of new forms of human prion disease such as variant CJD (vCJD) and possibly human CWD. Human prion disease surveillance is critical for the early detection of any new prion disease as well as monitoring for the occurrence of previously described rare classic forms of prion disease attributable to medical procedures. A sensitive human prion disease surveillance system can also help determine whether efforts and expenditures made to reduce and minimize exposures are adequate. For prion diseases, particularly for recognition of new human prion diseases, brain autopsies constitute the "gold standard" for confirmation of diagnoses. Hence, CDC currently pays the National Prion Disease Pathology Surveillance Center (NPDPSC) to provide to US clinicians and US public health surveillance personnel access to, free-of-charge, state-of-the-art prion disease diagnostic autopsy services.

c. Outcomes:

- Outcome 1: Follow-up investigations of all suspected CJD or clinically diagnosed cases reported to the state department of health especially for high priority cases: cases in persons less than 55 years of age; cases in hunters of cervids or consumers of venison from free ranging deer; reported case clusters of concern to the public; suspected iatrogenic cases.
- Outcome 2: Effective coordination and exchange of information and data between state health departments, the National Prion Disease Pathology Surveillance Center, the CJD Foundation and CDC.
- Outcome 3: Develop an effective collaborative network between pathologists, neurologists, funeral and mortuary directors, and other appropriate professionals within the state dealing with persons diagnosed with human prion disease and distribute educational materials about CJD surveillance and the role of state health departments, CDC and the National Prion Disease Pathology Surveillance Center.
- Outcome 4: Effective coordination and exchange of information and data between the state departments of health and wildlife/natural resources
- Outcome 5: Complete reporting of all suspected CJD cases to CDC through a biannual linelist of cases.

Funding Strategy:

- Estimated total availability of funds: $500,000
- Estimated number of awards given: 7
- Estimated average per award: $70,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1b: Enhance investigation response and reporting

a) Actively investigate all cases of suspected prion disease reported in state residents; refer out-of-state cases to the health department of patient's residence.

i. Track the number of suspected cases of prion diseases for which autopsy or biopsy was conducted.

ii. Submit linelist of persons reported with suspected prion disease to CDC at least twice a year.

☒Required ☐Optional

b) Within two weeks of a report, actively investigate all cases of suspected prion disease in higher priority cases of suspected prion disease (e.g., suspected cases in persons < 55 years of age, suspected cases of variant CJD or possible human CWD, suspected iatrogenic cases, and suspected case clusters.

i. Submit to CDC the pertinent portions of the medical record for the highest priority cases of suspected prion disease in persons less than 45 years of age, or whenever variant CJD or possible human CWD is suspected, or whenever an unusual mode of transmission is suspected. (Medical records for persons 45 – 55 years of age are not required to be submitted unless an exogenous source of infection is suspected.) Pertinent sections of the medical record includes the admission summary, discharge summary, EEG reports, MRI reports, neurology consultation notes, psychiatry consultation notes, pathology reports from a biopsy, and pathology reports from autopsy.

ii. Attempt to ascertain whether the case hunted (deer, elk, or moose) or consumed venison. If so, attempt to determine when and where the hunting occurred or from where the venison was harvested.

☒Required ☐Optional

c) Cross check various data sources to ensure that all cases are identified in the project area. Specifically, access State Vital Statistics' death certificate data looking for specific codes or terms appearing anywhere on the death certificate. (ICD-9 046.1 for deaths before 1999; ICD-10 A81.0 for deaths from 1999 to the present, 'jakob', 'jacob ', 'creutz', 'crutz', 'critzfield', 'cjd', 'spongiform', 'spongioform', 'spongeform', 'sponaiform', 'tse', 'prion, 'gss', 'gerstman', 'gertsman', 'straussler', 'strausler', 'scheinker', 'ffi', 'familial insomnia', 'familial fatal insomnia', 'sfi', 'sporadic fatal insomnia')

☒Required ☐Optional

AREA B: PREVENTION AND INTERVENTION

II. Strategy 2b: Advance policies to improve public health capabilities

a) Utilize human prion disease surveillance to better inform and lessen undue concerns among health professionals and the public.

☒Required ☐Optional

b) Obtain scientific data to support development of evidence based and cost-effective policies

☒Required ☐Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

III. Strategy 3a: Coordinate and engage with partners

a) Work collaboratively with the state wildlife/natural resources department to ascertain the degree of CWD surveillance within the state, conduct chronic wasting disease related education and consider other activities aimed at persons who hunt within the state and those who consume venison provided by hunters.

i. In areas where chronic wasting disease is endemic, inform/educate hunters about this disease in cervids and how to protect themselves from possible exposure to the disease agent.

☒Required ☐Optional

b) Work collaboratively with CDC and other sites funded for enhanced surveillance of CJD and other prion diseases.

☒Required ☐Optional

c) Work collaboratively with the National Prion Disease Pathology Surveillance Center at Case Western Reserve University by maintaining regular contact including at least twice-yearly phone or email contact.

☒Required ☐Optional

d) Identify facilities within the state that are able to perform brain autopsy on persons suspected of or clinically diagnosed with a prion disease.

☒Required ☐Optional

e) Develop relationships with the CJD Foundation or comparable patient groups to enhance collaborative work and to educate and provide assistance to family members of persons affected by prion diseases. Conduct outreach with hospitals and facilities that care for persons with prion disease to educate caregivers, including family members and medical personnel, about prion disease-related infection control issues and about the importance of prion disease surveillance and confirming clinically suspected cases.

☒Required ☐Optional

f) Work collaboratively with pathologists, neurologists, funeral and mortuary directors, and other appropriate professionals within the state to ensure these professionals are aware of the state's prion disease surveillance system as well as the prion disease-related resources available to support them, including at CDC, the National Prion Disease Pathology Surveillance Center, the state health department and the CJD Foundation.

☒Required ☐Optional

g) Disseminate data and information on human prion disease within the state (e.g., reports, workshops, grand rounds, etc.)

☒Required ☐Optional

h) Education of infection control practitioners and other relevant staff at hospitals and other facilities about the importance of appropriate infection control regarding human prion diseases.

☒Required ☐Optional

Collaborations

a. With CDC-funded programs:

1. States funded through ELC for enhanced prion surveillance will be actively collaborating with the National Prion Disease Pathology Surveillance Center located at Case Western Reserve University. CDC (NCEZID/DHCPP/PPHO) funds this Center.
2. Referrals to the CJD Foundation to educate and assist family members of persons affected by prion diseases. CDC (NCEZID/DHCPP/PPHO) funds in part this Foundation.

b. With organizations external to CDC:

1. There will be collaborations with health care facilities within the state that are able to perform brain autopsy on persons suspected of or clinically diagnosed with a prion disease.
2. When applicable, state health departments funded for enhanced prion surveillance through ELC are asked to work collaboratively with state wildlife/natural resources to conduct chronic wasting disease related education and other activities aimed at persons who hunt within the state and those who consume venison provided by hunters.

Target Populations:

Clinicians who see suspected and diagnosed cases of human prion disease, infection control personnel in hospitals, others in the community who work with patients suspected of having or been diagnosed with a human prion disease and their families. When applicable, hunters and consumers of venison.

Evaluation and Performance Measurement:

#1) Number of cases of suspected prion disease received via surveillance (by reporting source) and the number of investigations conducted.

#2) Number of suspected and clinically diagnosed cases of prion disease for which a brain biopsy or brain autopsy was conducted. (If possible human CWD is suspected, tissues other than brain may be requested.)

#3) Submission of semi-annual (July and January) linelist report of all persons with a suspected or confirmed diagnosis of CJD, indicating which reports your project area accepts as a case (i.e., definitive, probable, possible, neurologist diagnosed). For each case submitted, the following information should be included: a) Year of death, b) State of residence, c) Sex, d) Age, e) Date of birth, f) CJD Status, g) Was the case diagnosed by a neurologist?, h) Is the case still under investigation and if yes, please explain, i) Was CJD noted on the death certificate?, j) Was an Autopsy performed?, k) Was a Biopsy performed?, l) Were specimens sent to NPDPSC?, m) Were specimens sent to another laboratory?, n) Were clinical data for cases < 45 years of age sent to CDC?, o) Was the CJD Surveillance Report Form completed for cases < 55 years of age?
#4) Number of suspected or confirmed case of CJD in a person less than 55 years of age, suspected cases of variant CJD or possible human CWD, suspected iatrogenic cases, and suspected case clusters reported to CDC within two weeks of the report to the state department of health.

For those less than 45 years of age and for each of the other above investigations: the number of persons for whom the pertinent portions of the medical record were submitted to CDC.

#5) Number of suspected cases of CJD identified through at least annual review of death certificate- data or other data sources; the number of newly identified cases found by this review; the number of cases identified

through surveillance that did not indicate CJD on the death certificate; and where possible, for those cases where CJD was not indicated on the death certificate, what was listed as the cause and underlying cause of death.

#6) Description of collaborative work conducted with the National Prion Disease Pathology Surveillance Center, the CJD Foundation, health care facilities within the state, relevant health care professionals (pathologists, neurologists, funeral and mortuary directors, infection control professionals, hospice staff, etc.), state wildlife/natural resources department, other state departments of health (when appropriate) and CDC. This may include mention of how these parties confront issues such as barriers to reporting and obtaining consent for autopsy.

#7) Number and types of educational interactions (presentations, dissemination of printed materials, poster presentation, workshops, Grand Rounds, etc.) provided to pathologists, neurologists, funeral and mortuary directors, infection control professionals, hospice staff, etc. to maximize knowledge about human prion diseases and reporting of suspected and diagnosed cases of CJD and ensure they are knowledgeable about the appropriate infection control recommendations related to prion disease.

#8) Description of how surveillance data is used to 1) describe human prion disease within the state, 2) redirect surveillance activities and strategies within the state and 3) inform evidence-based state/national policy recommendations, guidelines, etc.

#9) For awardees where CWD has been identified: Number of meetings with wildlife/natural resources department to conduct CWD-related education and other activities aimed at persons who hunt within the state and those who consume venison provided by these hunters.

M: Rabies Surveillance
Program Activity Contact Information
Jesse D. Blanton, Rabies Surveillance and Epidemiology Unit Lead, asi5@cdc.gov, 404-639-2289
Funding Opportunity Description
Background
a. Overview
Improved communication between laboratories conducting rabies diagnosis and those supporting clinical decisions of exposed individuals is critical for improving adherence to national recommendations for postexposure prophylaxis. In addition, more timely transfer of standards based laboratory information for national notification improves the ability to respond to regional and national changes in the epidemiology of rabies. This is particularly critical in relation to the national oral rabies vaccination programs conducted by USDA.
b. Healthy People 2020
Goal Immunization and Infectious Diseases-21: Increase the number of States that use electronic data from rabies animal surveillance to inform public health prevention programs.
c. Other National Public Health Priorities and Strategies
N/A
CDC Project Description
a. Problem Statement:
An estimated 35,000 to 55,000 persons receive rabies post-exposure prophylaxis (PEP) each year due to potential rabies exposures. Another 180,000 persons each year have a potential rabies exposure that is ruled out by diagnostic testing of the suspect animal; and hundreds of thousands more by public health observation of suspect animals. Managing a person who has a suspect rabies exposure involves information sharing between public health, personal health care, laboratory, animal control, and veterinary providers to provide timely and appropriate care. Delays or inability to share information while managing a suspect exposure case can result in unnecessary administration of rabies biologics or, more worrisome, failure to provide timely treatment. Electronic management systems can help increase access and accountability of all persons involved in managing rabies exposures, but are not widely available across state health departments.
b. Purpose:
Funding will support public health partners in developing electronic laboratory reporting mechanisms or improving existing systems for the electronic management of suspect rabies exposures. Such systems should provide a web accessible application combining demographic and exposure information, laboratory data, and animal observation data to aid local officials in the management and follow-up of potential rabies exposure cases. The system should reflect recommendations contained within the Advisory Committee on Immunization Practices – human rabies prevention guidance- to help ensure that national guidance is followed and will ideally capture case management data for evaluation purposes. Preference will be given to applications that can show adaptation of currently available platform, particularly those that might be extensible or adaptable for use in other state or jurisdiction platforms.
c. Outcomes:

- Improved timeliness of the exchange of state laboratory and animal observation data within reporting jurisdictions, for the management of potential rabies exposure cases
- Improved data accuracy and timeliness for reporting and national notification of laboratory diagnosis of rabies in animals
- Improved completeness of data reported to CDC for the national notification of animal rabies cases

Funding Strategy:

Funds should be utilized for workshop travel, supplies, equipment, or contractual support for proposed activities.
Estimated total availability of funds: $100,000 - $150,000
Estimated number of awards given: 2
Estimated average per award: $50,000-$75,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1f: Improve laboratory coordination and outreach/information flow

a) a) Develop or improve electronic systems that facilitate real-time flow of results between local and state agencies responsible for managing suspect rabies exposure cases

☒Required ☐Optional

II. Strategy 1h: Advance electronic information exchange implementation

a) Develop or improve electronic systems that facilitate electronic laboratory reporting based on standard message mapping guides for national notification of animal rabies

☒Required ☐Optional

b) Improve sharing of laboratory data to help facilities confirmatory testing of samples between state and federal laboratories

☐Required ☒Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

III. Strategy 3a: Coordinate and collaborate

a) a) Improve real-time laboratory data sharing to facilitate coordination of rabies response activities between local, state, and federal agencies

☒Required ☐Optional

Collaborations

a. With CDC-funded programs:

NCEZID/DHCPP/Poxvirus and Rabies Branch

b. With organizations external to CDC:

Association of Public Health Laboratories (APHL)

Target Populations:

Human rabies exposures are generally higher among children and in rural populations; declines in rabies diagnosis quality or case management would affect these populations disproportionately.

Evaluation and Performance Measurement:

Required performance measures for the project period are listed below. Data will be reported on an annual basis (calendar year), and are used to indicate progress made toward program outcomes.

Measure #1) Number of state and local staff trained on new case management system
Measure #2) Proportion of suspected rabies exposures in jurisdiction managed using an electronic case management system (Number of suspected rabies exposures in jurisdiction/ number managed using an electronic case management system)
Measure #3) Average time from rabies suspected exposure reported to end of follow-up (e.g. received final guidance on PEP)

N: Parasitic Diseases Surveillance

Program Activity Contact Information

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Funding Opportunity Description

Background

a. Overview

This project aims at strengthening the capacity and capability of public health departments to control and prevent parasitic infections.

b. Healthy People 2020

N/A

c. Other National Public Health Priorities and Strategies

N/A

CDC Project Description

a. Problem Statement:

Several parasitic infections that are transmitted in the United States can cause serious health problems, including Babesiosis, Chagas disease, eosinophilic meningitis due to *Angiostrongylus cantonensis* infection, neurocysticercosis, toxocariasis, toxoplasmosis, and trichomoniasis. The burden of disease in the United States for these parasitic infections, and others that were historically endemic, such as soil transmitted helminth infections, is poorly defined. Health care providers often have limited familiarity with diagnosis and management of these diseases. Many parasitic infections are treatable but may not be detected or diagnosed in a timely manner. Activities in this project will increase capacity in public health departments to diagnose parasitic infections, identify parasitic diseases that represent a burden in their population and implement control measures.

b. Purpose:

CDC will support state led efforts to increase or maintain laboratory capacity to monitor and track parasitic diseases of public health importance in their jurisdiction.

c. Outcomes:

- More efficient and accurate diagnosis of parasitic infections
- More effective public health workforce better prepared to detect parasitic disease threats in the United States
- Improved identification of parasites to the species level, which will help to manage cases of infections more efficiently.
- More rapid detection of cases and outbreaks
- More timely, complete and effective investigation efforts including more complete ascertainment of cases and detection of cases through laboratory confirmation.
- Improved detection of soil-transmitted helminth infections in areas of the United States where soil transmitted helminth transmission may persist.

Funding Strategy:

Funding for implementation and training in use of diagnostic parasitology tools, including hands-on workshops, telediagnosis, and molecular diagnostic detection of parasitic diseases.

- Estimated total availability of funds: $100,000
- Estimated number of awards given: 10
- Estimated average per award: $10,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1a: Enhance workforce capacity for use of diagnostic parasitology tools

a) Training in use of diagnostic parasitology tools

i. Participate in CDC-sponsored diagnostic parasitology workshops or other equivalent training events

☐Required ☒Optional

II. Strategy 1c: Improved Surveillance and reporting

a) Expand surveillance for soil transmitted helminth infections

i. Expand surveillance activities for STH infections in areas of the United States where STH infections formerly were known to be endemic and that remain at risk for ongoing transmission (AL, GA, KY, LA, MS, NC, SC, TN) and implement control strategies if ongoing transmission is identified

☐Required ☒Optional

III. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Maintain or improve the use of appropriate diagnostic parasitology tools for case detection, surveillance and outbreak investigations

i. Implement or maintain internet-based telediagnosis, which involves the generation and exchange of images captured from diagnostic specimens in which confirmation of parasitic disease is needed

ii. Implement or maintain molecular diagnosis of the following parasitic diseases that represent a public health burden in the grantee's jurisdiction

- Babesiosis in states where this disease is considered endemic: Connecticut, Massachusetts, Minnesota, New Jersey, New York, Rhode Island, and Wisconsin. Other states with evidence of well-established tick-borne transmission may also qualify.
- Angiostrongyliasis in states with high disease burden.

☐Required ☒Optional

Collaborations:

a. With CDC funded programs:

N/A

b. With organizations external to CDC:

N/A

Target Populations:

N/A

Evaluation and Performance Measurement:

Measure #1) Number of clinical specimens from cases of suspected parasitic diseases that the grantee processed for diagnostic testing.

Measure #2) Description of activities/tests that were introduced or changed as the result of ELC-supported trainings.

Measure #3)

- Number of adequately trained public health laboratorians required for the diagnostic parasitology workload in jurisdiction (Denominator)
- Number of public health laboratorians currently proficient in performing diagnostic parasitology tests (Numerator).

Measure #4)

- Number of patients, divided into age groups and region of residence, at risk for STH infections in a defined area (denominator)
- Number of patients, divided into age groups and region of residence, diagnosed with STH infections in a defined area (numerator).

O: Enhanced Vaccine-Preventable Disease (VPD)

Program Activity Contact Information

Sandra W. Roush (Overall NNDSS VPD Surveillance Coordination), swr1@cdc.gov, 404-639-8741; Amy Blain (meningococcal disease), wgi9@cdc.gov, 404-639-2563; Adriana Lopez (varicella and AFM), ail7@cdc.gov, 404-639-8369

Funding Opportunity Description

Background

a. Overview

The overall goal of the ELC Cooperative Agreement for Enhanced VPD Surveillance (O Project, previously R1) is to strengthen and coordinate VPD case-based and outbreak surveillance, building upon established surveillance systems to provide more complete and representative data. Four required activity areas for this cooperative agreement include overall VPD surveillance coordination and enhanced surveillance specifically for meningococcal disease, varicella, and acute flaccid myelitis (AFM). Current guidelines for VPD surveillance can be found in the *Manual for the Surveillance of Vaccine-Preventable Diseases* (https://www.cdc.gov/vaccines/pubs/surv-manual/index.html). Additional guidance/guidelines referenced throughout this document can be found on CDC disease-specific websites.

b. Healthy People 2020

The Public Health Infrastructure Objectives 11 and 13 include: increase the proportion of tribal, state, and local public health agencies that provide or assure comprehensive laboratory and surveillance/epidemiology services, respectively, to support essential public health services. https://www.healthypeople.gov/2020/topics-objectives/topic/public-health-infrastructure/objectives

The Immunization and Infectious Diseases 2020 Objectives include: IID-1 Reduce, eliminate, or maintain elimination of cases of vaccine-preventable diseases, IID-3 Reduce meningococcal disease, and IID-4 Reduce invasive pneumococcal infections. https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives

The Immunization and Infectious Diseases 2020 Objectives specifically call for reducing the number of varicella cases among children <17 years of age (IID-1.10), helping maintain 2-dose varicella vaccination coverage levels above 95% among kindergarteners (IID-10.5), and helping increase 2-dose varicella vaccination levels among adolescents aged 13-15 years (IID-11.2). https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives

The Immunization and Infectious Diseases 2020 Objectives call for reducing the number of meningococcal disease cases by 10% (IID-3). The Objectives also call for increasing the vaccination coverage level of 1 dose meningococcal conjugate vaccine for adolescents by age 13 to 15 years (IID-11.3). https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives

c. Other National Public Health Priorities and Strategies

The CDC Surveillance Strategy calls for improving the timeliness, quality, and completeness of surveillance data available to CDC programs; state, tribal, local, and territorial (STLT) agencies; and other stakeholders. https://www.cdc.gov/surveillance/Improving-Surveillance-Background.html

CSTE determines the list of nationally notifiable diseases/conditions and indicates the timeframes for case notification within NNDSS. https://www.cste.org/page/About_CST

CDC Project Description

a. Problem Statement:

Surveillance activities are critical for detecting VPDs and obtaining critical information to help control disease and address public health problems. However, both case reporting and notification are dependent on many factors, including reporting source, timeliness of investigation, completeness of data, and ability of surveillance systems to collect and transmit data representing historically recognized and newly identified variables of public health importance. In addition, various surveillance methods are used to collect information, depending on disease incidence, specificity of clinical presentation, available laboratory testing, control strategies, public health goals, and stage of vaccination program. Support for overall NNDSS VPD surveillance coordination, in addition to support specifically for enhanced meningococcal disease, varicella, and AFM surveillance, will help address the problems in case reporting and notification. Specific challenges within each of the four required activity areas are described below:

Overall NNDSS VPD Surveillance Coordination: NNDSS supports assessment of epidemiologic trends and programmatic impact. However, NNDSS data has known limitations (e.g., missing data for key variables) and those surveillance data have not been sufficient to fully assess the impact of vaccine programs. NNDSS data are collected by states/jurisdictions and are electronically transmitted to CDC. Variations in VPD reporting within jurisdictions and case notification to CDC may be due to disease/condition characteristics (e.g., symptoms, incidence, severity); availability of laboratory diagnostics; patient and provider awareness; jurisdiction attributes (e.g., laws, regulations); disease transmission setting; ability to coordinate across epidemiology, laboratory, immunization, and informatics; and/or capacity for electronic data exchange. However, interpretation of incomplete and untimely data for any of these reasons poses challenges for measuring disease burden and vaccine program impact. These challenges negatively impact decision making and public health action.

Meningococcal disease is a serious bacterial infection that can lead to death or severe long-term sequelae. Serogroups B, C, and Y are the major causes of meningococcal disease in the United States. Meningococcal conjugate vaccines protect against serogroups C and Y and are routinely recommended for adolescents. Serogroup B meningococcal vaccines have also recently been licensed in the United States. With the incidence of disease at historic lows, surveillance and vaccine program evaluations through established systems are challenging. High quality surveillance data and collection of circulating isolates from a broad and representative population are key for following disease trends, making vaccine program policy recommendations, and monitoring vaccine program impact. Recent outbreaks among special populations (e.g., college students, homeless, MSM) reinforce the need for particular emphasis on high quality and complete surveillance data.

Varicella was added to the list of nationally notifiable conditions in 2003 and is reportable in 40 states as of 2017. In 2007, routine two-dose varicella vaccination was recommended for children, primarily in response to outbreaks of varicella in populations with high 1-dose coverage. Data from the first 5 years of the two-dose varicella vaccination program demonstrated reductions in the number and size of outbreaks. Varicella outbreak surveillance supports assessment of vaccine program impact and informs public health

interventions. Case-based surveillance is the only data source currently available to monitor trends in varicella incidence. Improving varicella surveillance by increasing reporting completeness for varicella-specific clinical and epidemiologic variables of reported cases, including severe cases (e.g., hospitalizations), will allow monitoring for the impact of the 2-dose varicella vaccine program and enhance understanding of changing varicella epidemiology.

Acute Flaccid Myelitis (AFM) is characterized by flaccid limb weakness and abnormalities of the spinal cord gray matter on magnetic resonance imaging (MRI) scan. Acute Flaccid Paralysis (AFP) has numerous etiologies including viruses, genetic conditions, and environmental toxins and can prove diagnostically challenging. Anterior horn cell disease, or AFM, is a subset of AFP, and is caused by poliovirus, West Nile virus, and other viruses including non-polio enteroviruses. Since the widespread implementation of polio vaccination worldwide, AFM due to poliovirus has decreased substantially and had been eliminated in the United States, but not yet eradicated globally. AFM is not a nationally notifiable syndrome, but may be reportable within specific jurisdictions. Ensuring that imported and indigenously acquired poliomyelitis cases are detected in the U.S. and interpreting any apparent increase in reports of AFM has been challenging in the absence of baseline incidence of AFP due to AFM (https://www.ncbi.nlm.nih.gov/pubmed/27318332). Additional information about investigations of AFM and guidance for clinicians and health departments can be found on the CDCs AFM webpage (https://www.cdc.gov/acute-flaccid-myelitis/index.html).

b. Purpose:

The purpose for providing resources for NNDSS VPD Surveillance Coordination is to enhance and strengthen case-based and outbreak surveillance for VPDs and related conditions, allowing public health agencies to effectively collect and provide timely and complete surveillance data. This CoAg will build on established immunization programs and surveillance systems (e.g., NNDSS) to provide broader and more representative data for nationally notifiable diseases. Along with surveillance coordination, this CoAg will also focus specifically on enhancing surveillance for meningococcal disease and varicella, and supporting/establishing surveillance for AFM. In addition, jurisdictions may choose to participate in optional activities to further enhance VPD surveillance.

c. Outcomes:

Outcomes for Required Tier 1 Activities (VPD Surveillance Coordination, Meningococcal Disease, Varicella, and AFM):

- Improved coordination and exchange of surveillance data and information across jurisdictions' programs and partners
- Improved surveillance data quality and completeness (e.g., completeness of vaccine history, importation)
- Improved timeliness of case notifications to NNDSS and associated surveillance systems
- Improved timeliness of detection, investigation, and response to cases, outbreaks, and deaths
- Increased support for and utilization of surveillance data assessments to inform public health practice
- Improved linkages between epidemiology, immunization, laboratory, and health information partners to support surveillance-related activities and resources
- Improved educational awareness to health care providers and other public health partners
- Enhanced support for laboratory testing as appropriate for investigation and control

- Enhanced standardization, interoperability, and use of surveillance information systems by jurisdiction and CDC

Outcomes for Optional Tier 2 Activities:

Enhance surveillance for severe cases of varicella:

- Improved completeness of data collected for severe (e.g., hospitalized) cases of varicella (e.g., vaccination history, clinical presentation, reason for hospitalization) to monitor severe varicella disease during the mature varicella vaccination era

Enhance pertussis surveillance:

- Enhanced monitoring for molecular changes in pertussis through submission of isolates to CDC
- More complete and timely surveillance data (e.g., vaccination history, clinical presentation, laboratory results) to monitor the incidence and epidemiology of pertussis
- Increased notification of suspected pertussis-related deaths

Enhance *Haemophilus influenzae* surveillance:

- More complete and timely surveillance data to monitor the incidence and epidemiology of *H. influenzae*, with particular focus on children < 5 years of age
- Availability of isolates sent to CDC for *H. influenzae* serotyping

Enhance Invasive Pneumococcal Disease (IPD) surveillance:

- More complete and timely surveillance data to monitor the incidence and epidemiology of IPD
- Enhanced serotype monitoring of changes in IPD through testing of appropriate sterile site isolates

Enhance measles surveillance:

- Surveillance data used to identify subpopulations at risk for measles
- Identification of appropriate interventions or tailoring of standard/evidence-based interventions to the specific needs of a particular outbreak in order to prevent measles in subpopulations at increased risk

Enhance mumps surveillance:

- Surveillance data used to identify risk factors responsible for increased number of mumps cases and outbreaks
- Enhanced characterization of mumps cases (e.g., in high 2-dose vaccination coverage settings, in outbreak settings) through improved completeness of clinical, laboratory, and epidemiologic data
- Improved molecular surveillance for mumps

Enhance AFM surveillance and long-term follow-up for AFM cases:

- Increased jurisdiction capacity to increase awareness for AFM among healthcare providers
- Increased number of jurisdictions reporting AFM patients under investigation (PUIs) to CDC (NOTE: A suspected AFM case is considered a PUI when the patient summary form is received by CDC)
- Increased completeness and timeliness of surveillance data submitted and used to monitor AFM PUIs and cases
- Increased timeliness of laboratory specimens sent to CDC laboratories for etiologic testing
- Increased understanding of AFM outcomes through long-term follow-up of confirmed and probable cases

Enhance surveillance for other VPDs and related conditions:

- If optional activities for other VPDs and related conditions are proposed, outcomes should be defined in collaboration with CDC programs to improve surveillance and public health response

Funding Strategy:

Tier 1 funds should be used for personnel (e.g. VPD Surveillance Coordinator, varicella epidemiologist) and shipping of specimens and isolates. Funds to support shipping costs to CDC are not to exceed ~$5,000 per site. Jurisdiction participation on CoAg-related phone calls and communications is a requisite of funding. The total funded amount for Tier 1 activities per site is expected to fund approximately one full-time person, with the understanding that if there is already a specified VPD Surveillance Coordinator in the jurisdiction, this funding does not need to be used to support that specific person.

- Estimated total availability of funds: $6.4 million
- Estimated number of awards given: 64
- Estimated average per award: $100,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1b: Enhance investigation and outbreak response

a) VPD surveillance coordinator will serve as the point of contact for VPDs and related conditions for which surveillance is conducted through NNDSS or the ELC O Project (previously R1)

i. Support surveillance for VPDs and related conditions, including, but not limited to measles, mumps, rubella, congenital rubella syndrome, varicella, pertussis, *H. influenzae*, meningococcal disease, tetanus, diphtheria, IPD, paralytic poliomyelitis, non-paralytic poliovirus infection, and AFM (understanding that the individual surveillance activities may or may not be duties specifically assigned to the VPD Surveillance Coordinator)

ii. Ensure the use and implementation of standard investigative questionnaires, data collection/sharing tools, and methods

iii. Lead/assist in the timely investigations of and data submissions for cases, clusters, and outbreaks

iv. Engage in and evaluate ELC O Project activities (e.g., participate on quarterly All-Jurisdiction VPD Surveillance calls, submit Quarterly Surveillance Coordination Activity Summaries)

☒Required ☐Optional

b) Collect case data on key and enhanced variables, as described in CDC guidance

☒Required ☐Optional

c) Provide surveillance data to support evaluations of public health response to meningococcal disease, as appropriate (e.g., risk factors for meningococcal disease, serogroup B meningococcal vaccine effectiveness, retrospective record review to identify cases among the same household)

☒Required ☐Optional

d) Ensure reporting sources follow jurisdiction requirements to inform state/local health departments of varicella outbreaks; for jurisdictions where varicella is not a reportable condition but outbreaks of all

etiologies are reportable, processes should be put into place to facilitate reporting of varicella outbreaks

☒Required ☐Optional

II. Strategy 1c: Improve surveillance and reporting

a) Develop, implement, and maintain surveillance systems

☒Required ☐Optional

b) Evaluate and enhance surveillance systems based on CDC guidelines

☒Required ☐Optional

c) Conduct regular assessment of surveillance data and implement processes to improve completeness, timeliness, and quality of case data

i. Review surveillance indicator reports at least annually (e.g., provisional, final) to identify areas for improvement (e.g. electronic, programmatic)

ii. Review surveillance data regularly (e.g. quarterly) to identify areas for improvement (e.g. electronic, programmatic)

iii. For meningococcal disease: check immunization information system (IIS) for vaccination information for cases; check HIV registry for HIV status for cases (if feasible in accordance with jurisdiction policies and procedures), check previous sexually transmitted infections (STI) investigations for MSM status, follow-up with providers and/or parents regarding clinical presentation

iv. For varicella cases in jurisdictions where varicella is a reportable condition: check IIS for vaccination information for cases, check databases for varicella-related hospitalizations, follow-up with providers and/or parents regarding clinical presentation

☒Required ☐Optional

d) Facilitate coordination/exchange of surveillance data with CDC

i. Provide case notifications and other surveillance data reports to CDC with complete information on key and enhanced variables for confirmed and probable meningococcal disease cases

ii. Provide outbreak-related case data to CDC quarterly, including the number and characteristics of varicella outbreaks reported to the jurisdiction

iii. In jurisdictions where varicella is a reportable condition and varicella case-based surveillance is in progress, enhance established case notification processes for submitting case-based varicella data to CDC

iv. In jurisdictions where varicella is a reportable condition and varicella case-based surveillance is in progress, provide annual summaries to CDC listing the varicella-related variables collected and the data completeness for those variables in the previous year

v. In jurisdictions where AFM cases are reported to the local/state health department and specimens are submitted, notify/report to CDC the suspect cases of AFM (https://www.cdc.gov/acute-flaccid-myelitis/index.html)

☒Required ☐Optional

III. Strategy 1d: Enhance laboratory testing for surveillance and reporting

a) For each disease/condition, support maintenance of the availability of appropriate surveillance testing capacity (e.g., culture, serotyping/serogrouping, molecular sequencing) within jurisdiction public health laboratories, VPD Reference Centers (RCs), and/or CDC laboratories

☒Required ☐Optional

b) Implement a flexible plan for se and acquisition of laboratory supplies and testing that addresses changing needs/purposes for each disease/condition

☒Required ☐Optional

c) Collect isolates from confirmed and probable cases of meningococcal disease and test for serogroup and additional molecular characterization

☒Required ☐Optional

IV. Strategy 1f: Improve laboratory coordination and outreach to improve efficiency

a) Support linkage of laboratory specimens, isolates, and results with epidemiologic and clinical case-patient data

☒Required ☐Optional

b) Coordinate activities to increase access to specimens and isolates so that laboratory data are available to inform surveillance activities

i. Ensure routine transportation of clinical isolates to jurisdiction public health or other lab

ii. Ship isolates from confirmed and probable cases of meningococcal disease to CDC for molecular characterization

☒Required ☐Optional

V. Strategy 1g: Enhance coordination between partners between epi-lab-HIT

a) Support and integrate epidemiology, laboratory, immunization, and health information activities

i. Foster collaboration between VPD program and other public health programs (e.g., STD) to facilitate collection of key and enhanced variables for confirmed and probable meningococcal disease cases

ii. Ensure coordination between partners (e.g., immunization, epidemiology, health information) to facilitate access to IIS data for assessing meningococcal vaccination status for confirmed and probable meningococcal disease cases

iii. Ensure coordination between partners (e.g., immunization, epidemiology, health information) to facilitate access to IIS data for assessing varicella vaccination status of varicella cases, including cases associated with outbreaks

☒Required ☐Optional

VI. Strategy 1i: Sustain and/or enhance information systems

a) Support VPD surveillance through coordination between epidemiology, laboratory, immunization, and health information systems (e.g., NNDSS, IIS, electronic lab reports (ELR), electronic case reports (eCR), Health Level 7 (HL7) messages) to enhance use and exchange of electronic data files

☒Required ☐Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

VII. Strategy 3a: Enhance coordination between partners

a) Foster collaboration among city, county, state, federal, and other internal and external partners to improve outbreak and case-based reporting for VPDs and related conditions (e.g., AFM)

☒Required ☐Optional

b) Engage and collaborate with stakeholders by providing surveillance data to inform and support policies and public health evaluations for VPDs and related conditions (e.g., AFM)

☒Required ☐Optional

c) Communicate and coordinate with public health partners to ensure appropriate investigation, testing, and case-based reporting for VPDs and related conditions (e.g., AFM)

i. Ensure public health partners receive ongoing training and education so they are informed of the importance of collecting the key variables for meningococcal disease surveillance

ii. Ensure public health partners receive ongoing training and education so they are informed of the importance of collecting the key variables for varicella case-based surveillance

iii. Disseminate information to reporting sources (e.g., schools, physicians' offices) to raise awareness of varicella reporting requirements (e.g., what variables to report, how to report, when and how to report cases/outbreaks)

iv. Educate and increase awareness for AFM by ensuring that public health partners (e.g., infectious disease specialists, intensive care physicians, pediatricians, neurologists, radiologists/neuroradiologists, infection preventionists, primary care providers, emergency departments, microbiology laboratories) are provided AFM-related clinical, epidemiologic, and laboratory information (e.g., importance of early collection of 2 stool specimens at least 24 hours apart to rule out poliovirus infection)

v. In jurisdictions where AFM cases are reported to the local/state health department and specimens are submitted, ensure awareness of access to laboratory testing of appropriate specimens (e.g., stool, respiratory, serum, and cerebrospinal fluid specimens for poliovirus, non-polio enteroviruses, West Nile virus, and other known infectious etiologies) to support surveillance

vi. In jurisdictions where AFM is a reportable condition, communicate reporting requirements to clinicians (e.g., report suspect cases of AFM to local/state health department, collect specimens from cases as early in the course of illness as possible, collect 2 stool specimens at least 24 hours apart and as early

☒Required ☐Optional

OPTIONAL TIER 2 ACTIVITIES TO EXPAND/ENHANCE SURVEILLANCE

In addition to the required Tier 1 outcomes and strategies/activities listed above, applicants may select one or more additional pathogen-specific activities from those listed below. Applicants may select optional Tier 2 activities that a) expand and enhance current surveillance infrastructure based on the priorities and public health needs of their jurisdiction, and b) will make progress toward the outcomes defined in the "Outcomes" section of this ELC Project O (previously R1) guidance. Jurisdictions must address all of the Tier 1 activities in order to also be eligible to apply for any of the Tier 2 enhanced activities.

VIII. Strategy: Activities to Expand/Enhance Surveillance

a) Enhance surveillance for severe cases of varicella

i. Improve completeness of data collected for severe (e.g., hospitalized) cases of varicella, including reason for hospitalization and clinical presentation, in sites where varicella is reportable and case-based surveillance is conducted (1b)

ii. Submit hospitalization data to CDC (1c)

☐Required ☒Optional

b) Enhance pertussis surveillance

i. Collect complete data on key and enhanced variables (e.g., clinical course of infection, vaccination history, maternal Tdap history for infant cases aged <1 year, laboratory testing) for cases of pertussis (1b)

ii. Notify CDC of suspected pertussis-related deaths via e-mail for non-reportable cases or via NNDSS for cases meeting the public health case definition for nationally notifiable conditions (1c)

iii. Collect isolates of *Bordatella pertussis*, when available, and routinely ship to CDC for further laboratory characterization (1e) NOTE: if the optional pertussis activity is proposed, the plan must include collection and shipment of isolates to CDC

iv. Utilize IIS to obtain/verify pertussis vaccination history (1i)

☐Required ☒Optional

c) Enhance *H. influenzae* surveillance

i. Collect complete data on key and enhanced variables (e.g. serotype, outcome) for cases of *H. influenzae* (1b)

ii. Enhance existing surveillance systems and submit *H. influenzae* case data to CDC (1c)

iii. Collect isolates from cases of *H. influenzae* for serotype confirmation (1e)

☐Required ☒Optional

d) Enhance IPD surveillance

i. Establish/support surveillance for IPD (e.g., all ages, among children <5 years of age) and submit case data to CDC (1c)

ii. Collect complete data on key and enhanced variables (e.g., age, race, ethnicity, vaccination status, dates of administration, and vaccine type) for cases of IPD (e.g., all ages, among children <5 years of ages) (1b)

iii. Evaluate completeness of case ascertainment (1b)

iv. Identify laboratories capable of isolating *Streptococcus pneumoniae* within the jurisdiction (1g)

v. Collect sterile-site isolates of *S. pneumoniae* from children <5 years old and submit those isolates for serotyping at VPD RCs (e.g., Minnesota Department of Health, Wisconsin Department of Health) (1e)

vi. Implement surveillance among targeted at-risk populations; however, if this tier 2 IPD activity is proposed, planning should be done in collaboration with CDC (1b)

☐Required ☒Optional

e) Enhance measles surveillance

i. Use local/jurisdiction vaccine data (e.g., IIS) to identify and describe populations/communities/cohorts that are potentially at risk for measles outbreaks (1i)

ii. Describe specific community data (e.g., groups by ethnicity, religion, objector/hesitancy status, geography) that would place individuals and populations at risk for measles (1b)

iii. Use epidemiologic and surveillance data to 1) describe potential impact of a measles outbreak, 2) plan for appropriate interventions, and 3) describe impact of those interventions (1b)

☐Required ☒Optional

f) Enhance mumps surveillance

i. Collect complete data on key and enhanced variables (e.g., symptoms, complications, incubation period) for cases of mumps, ensure lab testing, and support inclusion of lab results in case notifications to CDC (1b)

ii. Review mumps data (e.g., vaccination history, symptoms and complications, laboratory information, transmission and source data), characterize high risk groups, and further identify risk factors for infection and modes of transmission (1b)

iii. Submit data for outbreak-associated cases to CDC routinely and establish mumps outbreak resources (1c)

iv. Collect specimens for molecular surveillance and submit for testing in accordance with CDC guidelines (1e)

☐Required ☒Optional

g) Enhance AFM surveillance

i. Ensure timely and appropriate collaborations with pediatric hospitals and tertiary referral centers to increase awareness and understanding of AFM, reporting mechanisms, and appropriate laboratory testing (3a)

ii. Report all patients under investigation for AFM to CDC, including submission of AFM patient summary form (1c)

iii. Collect complete information on key variables (e.g., medical history, radiologic reports, vaccine history) and submit to CDC in a timely manner (1b)

iv. Establish and maintain processes to reduce the interval between symptom onset and clinical specimen collection (1b)

v. Establish and maintain processes to improve the timeliness between symptom onset, submission of AFM case report form to the CDC, and completion of the medical chart abstraction (1c)

NOTE: Only jurisdictions that have reported at least one PUI to CDC in the previous 4 years are eligible to apply for funding through this Tier 2 activity. This funding should be used to support surveillance personnel.

☐Required ☒Optional

h) Enhance long-term follow-up for AFM cases

i. Establish and maintain processes to collect information about clinical outcomes for confirmed and probable AFM cases for the first year after onset of limb weakness (1b)

ii. Ensure coordination with pediatric hospitals, tertiary referral centers, rehabilitation centers, and physicians to collect complete information about the long-term disposition of AFM cases and submit data to CDC in a timely manner (1c)

NOTE: Only jurisdictions that have, in the previous year, reported a PUI to CDC that was subsequently classified as a confirmed or probable case are eligible to apply for funding through this Tier 2 activity. This funding should be used to support surveillance personnel.

☐Required ☒Optional

i) Enhance surveillance for other vaccine preventable diseases

i. If tier 2 activities for other VPDs and related conditions are proposed, activities should be defined in collaboration with CDC programs to improve surveillance and public health response

☐Required ☒Optional

Collaborations:

a. With CDC funded programs:

Collaboration with ELC, epidemiology, laboratory, health information and immunization programs (including Immunization Program Manager) is required.

b. With organizations external to CDC:

APHL, VPD Reference Centers, CSTE

Target Populations:

For Overall NNDSS VPD Surveillance Coordination: VPD surveillance should be coordinated across epidemiology, laboratory, immunization and health information partners within the jurisdiction. See additional guidance in the *Manual for Surveillance of Vaccine-Preventable Diseases* http://www.cdc.gov/vaccines/pubs/surv-manual/index.html.

For Meningococcal Disease: Monitoring individual cases of meningococcal disease in all ages is important to track progress of the vaccination program. See additional guidance in the *Manual for Surveillance of Vaccine-Preventable Diseases* http://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.html.

For Varicella: Monitoring individual cases of varicella in all ages is important to track progress of the vaccination program. See additional guidance in the *Manual for Surveillance of Vaccine-Preventable Diseases* http://www.cdc.gov/vaccines/pubs/surv-manual/chpt17-varicella.html.

For AFM: Focus should be on patients with acute onset of flaccid limb weakness. Although AFM has been more commonly reported in children, monitoring reports of cases in all ages will be important for understanding the full spectrum of illness. See additional guidance on the CDC AFM website https://www.cdc.gov/acute-flaccid-myelitis/hcp/case-definition.html.

Evaluation and Performance Measurement:

Required performance measures are listed below and will be used to indicate progress toward the specific CoAg outcomes. Surveillance data will be submitted electronically to CDC through NNDSS or through regular disease-specific reports. Data for the performance measures will be provided to jurisdictions by CDC, will be submitted by jurisdictions during the annual ELC application process, or will be submitted by jurisdictions throughout the project year via required reports. See footnotes regarding sources of data for the performance measures.

1) For Overall NNDSS VPD Surveillance Coordination:

- Identification of a VPD Surveillance Coordinator[1]
- Participation in VPD Surveillance calls (e.g., Quarterly All-Jurisdiction calls, meningococcal disease-specific calls, AFM-specific calls)[1]
- Proportion of cases with complete and timely information for key surveillance indicator variables[2]
- Percentage of reports of selected reportable diseases (e.g., measles, meningococcal disease, pertussis) for which initial public health control measure(s) were initiated within appropriate timeframe[3]

- Review of Surveillance Indicator Reports at least annually (e.g., provisional, final) and documentation of regular (e.g. quarterly) utilization of surveillance data and Surveillance Indicator Reports to improve and/or make changes to current processes in order to improve the quality of surveillance data[4]
- Utilization of HL7 messaging to enhance standardization, interoperability, and use of surveillance information systems by jurisdiction and CDC[1]

2) For Meningococcal Disease:

- Proportion of meningococcal disease cases with isolates and enhanced surveillance data submitted to CDC[1]
- Proportion of cases with complete information for key surveillance indicator variables (e.g., serogroup, vaccination status, outcome)[2]
- Proportion of cases with complete information for enhanced surveillance variables (e.g., clinical presentation, college attendance, MSM, HIV status5, homelessness)[6]

3) For Varicella:

- Number of varicella outbreak-associated cases with enhanced surveillance data submitted to CDC[1]
- For sites where varicella is a reportable condition and case-based varicella surveillance is conducted, proportion of cases with complete information for key surveillance indicator variables (e.g., age, number of lesions, hospitalization status, confirmation status, laboratory testing, relation to outbreak, vaccination status)[1,2]

4) For AFM:

- Documentation that AFM education is in place in jurisdiction and description of educational tools developed/outreach conducted[4]
- Number of AFM cases investigated, confirmed, and ruled out[4]

[1]These data will be maintained by CDC and will be informed by jurisdiction activity participation and submission of required reports throughout the project year (e.g. Quarterly Surveillance Coordination Activity Summary, Biannual Meningococcal Data/Isolate Submission, Quarterly Varicella Outbreak Report).
[2]These data will be provided to jurisdictions via the VPD Surveillance Indicator Reports. VPD Surveillance Indicator Reports are created by NCIRD for the 50 states, New York City, and Washington DC, as those are the jurisdiction codes specified in NNDSS. Jurisdictions that do not receive jurisdiction-specific surveillance indicator reports from NCIRD are still required to conduct internal surveillance data reviews and must document how their reviews are used to make improvements to the quality of surveillance data.
[3]These data will be collected via the Public Health Emergency Preparedness Cooperative Agreement (13.2); awardees may be expected to verify these data for measures through ELC but will not be expected to report on these data.
[4]These data will be submitted by jurisdictions in the 'Performance Measures' section of the annual ELC application.
[5]Completeness of HIV status will only be assessed when the CDC meningococcal program is able to receive this data in a manner that complies with jurisdiction and federal policies and procedures.
[6]These data will be provided to jurisdictions via CDC meningococcal program feedback reports.

Performance measures for the optional tier 2 activities selected by the awardee should be defined in collaboration with CDC.

P: Legionnaires' Disease Prevention
Program Activity Contact Information
Candis M. Hunter, MSPH, REHS, hlb8@cdc.gov, 770-488-1347 Laura Cooley, MD, MPHTM, whz3@cdc.gov, 404-639-2096
Funding Opportunity Description
Background
a. Overview
The goals of this program are to build epidemiologic, environmental, and laboratory capacity for Legionnaires' disease (LD) response and prevention through: 1) enhanced case surveillance and reporting 2) improved environmental assessments and outbreak response 3) increased utilization of water management programs (WMPs) compliant with industry standards
b. Healthy People 2020
N/A
c. Other National Public Health Priorities and Strategies
N/A
CDC Project Description
a. Problem Statement:
From 2000 to 2016, there has been a 350% increase in the incidence of LD in the United States. The burden of LD is substantial, with case fatality rates of 10% (25% among healthcare-associated cases) and hospitalization cost estimates of $433 million per year. LD outbreaks comprise over half of all reported potable water outbreaks. In the United States, LD case surveillance is currently conducted through the National Notifiable Diseases Surveillance System (NNDSS) and the Supplemental Legionnaires' Disease Surveillance System (SLDSS). SLDSS collects exposure information such as travel history and exposure to healthcare facilities. CDC's *Legionella* program is in the process of transitioning to an HL7-based reporting mechanism using the Respiratory and Invasive Bacterial Diseases (RIBD) Message Mapping Guide (MMG). LD outbreak surveillance is conducted through the National Outbreak Reporting System (NORS). Transmission of *Legionella* depends on environmental transmission through inhalation of aerosolized water rather than person-to-person spread. LD outbreak investigations require an environmental assessment to identify potential sources of exposure. Environmental health capacity varies widely across jurisdictions. Lapses in routine maintenance of large, complicated building water systems can almost always be identified during outbreak investigations. An industry standard for the primary prevention of LD in building water systems was published in 2015, although awareness, implementation, evaluation, and regulation of these preventive maintenance strategies remains limited. In 2016, CDC published a toolkit entitled Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings to translate the industry standard into plain language for wider audiences, including health department staff, building owners and managers, and healthcare facility staff. The document serves as a step-by-step overview to creating and

implementing WMPs to reduce Legionella growth and spread. State and local health departments need environmental, laboratory, epidemiological, and communication resources to reduce the risk of Legionella growth and spread in their jurisdictions.

b. Purpose:

Cases of LD must be identified in a timely manner for clusters and outbreaks to be recognized. Once clusters and outbreaks are identified, an environmental assessment must be performed to identify possible sources of exposure. Implementation of maintenance strategies for the primary prevention of LD in building water systems can interrupt the amplification, aerosolization, and transmission of *Legionella*, thereby reducing incidence of disease as well as outbreaks. As such, CDC wishes to build capacity at the state and local levels among epidemiologists, environmental health specialists, and public health laboratorians regarding 1) enhanced surveillance and reporting, 2) improved environmental assessment and outbreak response, and 3) understanding, implementation, evaluation, and regulation of industry standards for primary prevention.

c. Outcomes:

- Improved timeliness, completeness, and number of LD cases reported with exposure information
- More timely, efficient, and coordinated outbreak detection, investigation, and response and implementation of control measures (i.e. best practices for outbreak response)
- Increased awareness of WMPs compliant with industry standards among target audiences (e.g., state/local health departments, building owners and managers)

Funding Strategy:

Funding may support personnel, laboratory or office supplies, training and communications materials, code/licensing/regulatory expenses, specimen storage and shipping costs, and other supplies needed for capacity building and/or an effective response to a situation involving LD or the implementation of preventive maintenance strategies. Future year funding is not guaranteed.

- Estimated total availability of funds: $3,000,000
- Estimated number of awards given: 25
- Estimated average per award: $50,000 - $150,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1a: Enhance workforce capacity

a) Develop an LD investigative team consisting of epidemiology, environmental health, and laboratory staff

☐Required ☒Optional

II. Strategy 1b: Enhance investigation and outbreak response

a) Develop and implement a comprehensive, multi-disciplinary LD outbreak response protocol. The protocol should include the following:

i. Epidemiology, laboratory, and environmental health response activities (e.g., staff roles and responsibilities in an outbreak setting, identification of surge capacity)

ii. For environmental health activities, steps specific to performance of environmental assessments and coordination of Legionella environmental sampling, which can be used to

identify contributing factors, root causes, immediate control measures, and long-term prevention strategies

iii. Plans for other outbreak preparedness activities (to be conducted prior to the identification of an outbreak, e.g., cooling tower identification/development of a registry, lab workflow outline)

iv. Plans for coordination between state and local jurisdictions

Please see the following resources for additional guidance on outbreak response protocols:

- CDC Outbreak Response Considerations
- CDC Environmental Investigation Resources
- CDC Laboratory Response Toolkit

☒Required ☐Optional

b) Evaluate interventions resulting from outbreak investigations. For each investigation, identify and report:

i. Deficiencies identified from the environmental assessment (e.g., process failures [status of WMPs], human errors, equipment failures, unmanaged external changes)

ii. Recommended facility actions (e.g, provide training, increase hot water temperatures, adjust residual disinfectant, implement flushing protocol)

iii. Follow-up activities with facility to confirm which interventions were implemented

Please see the following for more information on deficiency reporting:

- Vital Signs: Deficiencies in Environmental Control Identified in Outbreaks of Legionnaires' Disease — North America, 2000–2014

☐Required ☒Optional

III. Strategy 1c: Improve Surveillance and Reporting

a) Attempt to interview all suspect and confirmed legionellosis cases to obtain exposure information (e.g., using a form similar to the SLDSS Case Report Form or the RIBD MMG)

☒Required ☐Optional

b) Report all cases including exposure information to CDC via SLDSS (using a data extract, if possible) or an HL7-based reporting mechanism using the RIBD MMG

☒Required ☐Optional

c) Participate in RIBD MMG transition

☐Required ☒Optional

d) Perform enhanced surveillance to improve capture of possible sources of exposure. Activities could include:

i. Routine use of an extended hypothesis-generating questionnaire in addition to a standard legionellosis case report form

ii. Environmental testing of possible sources for single cases

☐Required ☒Optional

Please see the following example of an adaptable hypothesis-generating questionnaire:
CDC Template Hypothesis-Generating Questionnaire

e) Utilize software packages such as SaTScan for geospatial detection of LD clusters and outbreaks

☐Required ☒Optional

IV. Strategy 1d: Strengthen laboratory testing for response

a) Operationalize clinical Polymerase Chain reaction (PCR) capacity at the state laboratory

☐Required ☒Optional

b) Become CDC Environmental Legionella Isolation Techniques Evaluation (ELITE) member laboratory

☐Required ☒Optional

c) Build internal capacity for analysis of Legionella whole genome sequencing

☐Required ☒Optional

d) Collaborate with hospital and clinical laboratory systems to increase number of respiratory specimens cultured for Legionella

☐Required ☒Optional

AREA B: PREVENTION AND INTERVENTION

V. Strategy 2a: Implement public health interventions and tools

a) Develop and implement an LD Primary Prevention Strategy

i. Designate and/or collaborate with environmental health personnel to improve environmental health expertise in LD response and prevention within the health department

ii. Proactively conduct WMP outreach to building and facility staff in healthcare and non-healthcare settings

iii. Engage building and facility staff during outbreak investigations to develop or revise WMPs

☒Required ☐Optional

b) (OPTIONAL) Develop and implement an LD Primary Prevention Strategy

i. Plans for collaborating with industry partners

ii. Plans for collaborating with state and local regulatory bodies

iii. Plans for evaluating WMP implementation in buildings at increased risk

☐Required ☒Optional

Please see the following resources for additional guidance on implementing WMPs:
Developing a Water Management Program to Reduce *Legionella* Growth and Spread in Buildings
CDC WMP Considerations

c) Evaluate uptake of WMPs in buildings at increased risk

☐Required ☒Optional

d) Evaluate effectiveness of policies and public health approaches to the implementation of industry standards for primary prevention of LD

☐Required ☒Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

VI. Strategy 3d: Information dissemination

a) Prepare and distribute communication materials regarding programmatic activities to relevant audiences. Activities may include:

i. Newsletters, trade journal articles, manuscripts (please send courtesy copy of publications to CDC; publications should acknowledge CDC ELC support if applicable)

ii. Fliers, fact sheets, infographics, checklists, toolkits, templates, and other printed materials

iii. Surveillance reports

iv. Press releases

v. Lessons learned

☐Required ☒Optional

Collaborations:

a. With CDC funded programs:

N/A

b. With organizations external to CDC:

Per applicant's LD Primary Prevention Strategy, collaborations and outreach could include health departments, building managers, healthcare facilities, industry organizations, and other groups involved in WMPs

Target Populations:

Populations at increased risk for developing LD include people who are 50 years or older, current or former smokers, have chronic lung disease, and have weakened immune systems. Investigations of building-associated outbreaks show the most common places for getting the disease are hotels, long-term care facilities, and hospitals. Health departments, building managers, and healthcare facilities can facilitate implementation of maintenance strategies for the primary prevention of LD in building water systems

Evaluation and Performance Measurement:

Awardees are required to demonstrate that measurable progress is being made throughout the project period and share this progress in workgroup and partner conference calls. To indicate progress made toward program outcomes, data will be reported through:

- Bimonthly (every two months) conference calls
- Bimonthly (every two months) written updates to submitted via email prior to conference calls
- Performance Measures for Tier 1 activities

Measure #1 Development of LD Outbreak Response Protocol

- Comprehensive outbreak response protocol was developed, approved, and shared with CDC and relevant partners (yes/no) and is inclusive of the following:
    - Designates epidemiology, laboratory, and environmental health activities (yes/no)
    - Specifies a Point of Contact for epidemiology, laboratory, and environmental health activities (yes/no)
    - Addresses outbreak preparedness and coordination with state and local jurisdictions (yes/no)

Measure #2 Implementation of LD Outbreak Response Protocol

- Number and % of LD outbreak investigations utilizing outbreak response protocol
- Number and % of LD outbreak investigations for which environmental assessments were performed
- Number and % of LD outbreak investigations for which Legionella sampling was performed
- Number and % of LD outbreak investigations for which a clinical isolate was obtained

Measure #3 Completeness of Legionellosis Surveillance and Reporting

- Number and % of total suspect and confirmed legionellosis cases that were interviewed
- Number and % of total cases reported to CDC that were reported with exposure information (to SLDSS or RIBD)

Measure #4 Development of LD Primary Prevention Strategy

- LD Primary Prevention Strategy was developed, approved, and shared with CDC and relevant partners (yes/no) and is inclusive of the following:
    - Strengthening WMP expertise within the health department (yes/no)
    - Proactively conducting WMP outreach to building and facility staff in healthcare and non-healthcare settings (yes/no)
    - Engaging building and facility staff during outbreak investigations to develop or revise WMPs (yes/no)

Measure #5 Implementation of LD Primary Prevention Strategy

- Number and type (e.g., hospital, long-term care facility, hotel) of buildings/facilities engaged in WMP outreach activities proactively (i.e., not as part of an outbreak investigation)
    - Number and % of buildings/facilities engaged for which an WMP compliant with industry standards was in place

- Number and % of total local health departments for which WMP outreach activities were performed
- Number and type of WMP outreach activities (e.g., webinars, trainings, workgroups, presentations, table top exercises, consultations, written guidance)

Q: Influenza Surveillance and Diagnostic Testing
Program Activity Contact Information
Lenee Blanton, MPH, acy9@cdc.gov, 404-639-1400 or Lynnette Brammer, MPH, lsb1@cdc.gov, 404-639-1303 or Alicia Budd, MPH, acp4@cdc.gov, 404-718-5380 (for Tier II Enhancement Activities)
Funding Opportunity Description
Background
a. Overview
The U.S. influenza surveillance system is a collaborative effort between CDC and its many partners in state, local, and territorial health departments, public health and clinical laboratories, vital statistics offices, healthcare providers, clinics, and emergency departments. Information in five categories is collected from eight different data sources that allows CDC to find out when and where influenza activity is occurring, track influenza-related illness, determine what influenza viruses are circulating, detect changes in influenza viruses, and measure the impact influenza is having on hospitalizations and deaths.
b. Healthy People 2020
N/A
c. Other National Public Health Priorities and Strategies
N/A
CDC Project Description
a. Problem Statement:
Influenza is an acute respiratory disease caused by infection with influenza viruses. Influenza types A and B viruses are responsible for epidemics of respiratory illness that occur almost every winter in temperate climates and are often associated with increased rates of hospitalization and death. Although the highest rates of illness occur among school-aged children, the highest rates of hospitalizations from influenza-related causes occur among infants and pre-school children, persons of any age with certain chronic medical conditions and among those ≥ 65 years of age. The estimated rates of influenza-associated illnesses, hospitalizations and deaths vary substantially from one influenza season to the next, depending, in part, on the characteristics of the circulating influenza virus strains. Therefore, there is a need for CDC and public health partners to implement and maintain a comprehensive plan for detecting, measuring, and reducing the impact of influenza. The CDC/Influenza Division continuously works to make improvements to each of the components of the U.S. Influenza Surveillance System and expand surveillance capacity to fill gaps. In collaboration with the Council of State and Territorial Epidemiologists (CSTE), CDC supports the enhancement of influenza surveillance at state and local health departments to leverage available resources and maximize the utilization of existing influenza surveillance systems. Three priority influenza surveillance gaps have been identified at the national level: 1) inability to determine the proportion of outpatient visits for influenza-like illness (ILI) that is due to influenza virus infection; (2) lack of information about the severity of illness associated with influenza viruses tested at public health laboratories (PHL); (3) inability to calculate rates of outpatient ILI. Therefore, there is a need for CDC and public health partners to implement modifications to existing surveillance components to address these gaps.

b. Purpose:

The required activities will fund influenza surveillance and diagnostic testing strategies. CDC wishes to build capacity for the detection, investigation, and reporting of influenza to enable future prevention initiatives. This requires building and strengthening epidemiologic and laboratory health capacity at the state and local level, which the proposed sub-activities should address. These efforts lead to more timely and efficient efforts to improve turnaround time, detection of outbreaks, response to outbreaks, investigation of outbreaks, and implementation of control measures.

The enhancements (optional activities) will fund any one or more of the activities described below that address the following gaps in routine surveillance at the national level:

- Influenza-attributable proportion of ILI: Through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), providers report the number of patients meeting the case definition for ILI; no laboratory confirmation of influenza is required. While the ILI case definition is used for surveillance due to the high positive predictive value during periods of influenza virus circulation, influenza illness is often clinically indistinguishable from other respiratory pathogens. The influenza attributable proportion of ILI, not biased by clinician-directed testing, is needed to better inform influenza disease burden estimates and improve interpretation of data from ILINet and other influenza surveillance components.
- Level of care associated with specimens tested for influenza: PHLs throughout the United States conduct testing for influenza, and report specimen level results electronically to CDC through the Public Health Laboratory Interoperability Project (PHLIP). A subset of specimens are sent to CDC for antigenic and genetic characterization, and antiviral resistance testing. The clinical level of care (inpatient, outpatient) is not uniformly reported to CDC along with the specimen-level virologic surveillance data, but could be used as an indicator of illness severity. Identification of care level associated with specimens tested at the PHL would allow for evaluation of differences by virus characteristics.
- Outpatient ILI rates: Population-based rates of influenza allow for disease burden comparisons across seasons, geographic regions, and influenza viruses. Population based rates can be calculated from the current national influenza hospitalization (FluSurvNet) and mortality (NCHS and pediatric death) surveillance components but not from the outpatient ILI component (ILINet). An estimate of the population served by ILINet providers would allow outpatient ILI rates to be calculated and used to inform disease burden estimates.

c. Outcomes:

Required activities will result in:

- Comprehensive national influenza surveillance
- Better coordination and exchange of influenza surveillance data among eight components of influenza surveillance (http://www.cdc.gov/flu/weekly/overview.htm) across jurisdictions and to CDC
- Improved completeness and timeliness of reporting of influenza surveillance data
- Trained laboratory staff proficient in PCR methods for influenza virus detection, typing, and subtyping.

The compilation of data from each enhancement activity across awardees will contribute to improved influenza disease burden estimation and a greater understanding of influenza viruses across illness severity

levels by providing information about the proportion of ILI due to influenza, severity of illness associated with influenza viruses and rates of outpatient ILI. More specifically, the surveillance system enhancements funded by this project will facilitate collection of data that will allow CDC to:

- Determine weekly the proportion of ILI that is due to influenza through systematically collecting respiratory samples from patients presenting meeting the ILI case definition and presenting to a subset of ILINet providers.
- Assess the effect of virus characteristics on influenza disease severity by identifying the level of care (inpatient/outpatient) at the time of specimen collection for patients with specimens tested at the PHL.
- Estimate population-based rates of outpatient ILI by enumerating the patient population size for a subset of ILINet providers.

Funding Strategy:

For the required activities, funds will support a minimum of 0.5 FTE personnel to conduct influenza surveillance and a minimum of 0.5 FTE personnel to conduct influenza diagnostic testing. Both of these positions serve as the CDC point of contact for influenza surveillance and laboratory diagnostics, respectively. If available, awards will support the purchase of laboratory supplies and reagents not provided through the Influenza Reagent Resource (IRR). Since 2016, IRR will not offer the plastics previously available. Activities related to determining and achieving the optimal volume of laboratory testing for surveillance purposes, such as shipping supplies and transport costs, as outlined in the CDC-Association of Public Health Laboratories (APHL) Influenza Virologic Surveillance Right Size Road Map document distributed in June 2013 may be supported if funds are available.

- Estimated total availability of funds: $8.1 million
- Estimated number of awards given: 57
- Estimated total availability of funds: $138,596

For the optional activities, recipients are responsible for allocating appropriate amounts to support activities influenza compensation for providers and to supplement the PHL for the duration of the project. Funding will not be automatically renewed yearly. Award amounts will be determined commensurate with activities outlined in the proposal and may vary based on the optional activities included and the complexity of the methods for each activity. 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.

- Estimated total availability of funds: $770,000
- Estimated number of awards given: 15
- Estimated average per award: $51,333

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1b: Enhance investigation and outbreak response

a) Use standard investigative tools (i.e. influenza-associated pediatric death and novel influenza A case report forms), data sharing tools, and methods

☒Required ☐Optional

b) Participate in influenza outbreak investigations and assist local jurisdictions in large, complex outbreaks

☒Required ☐Optional

II. Strategy 1c: Improve surveillance and reporting

a) Identify and maintain an influenza surveillance coordinator

☒Required ☐Optional

b) Recruit, retain, and encourage timely reporting from ILINet providers

☒Required ☐Optional

c) Develop, implement and maintain the components of the U.S. Influenza Surveillance System

☒Required ☐Optional

d) Collect, analyze, and disseminate influenza surveillance data

☒Required ☐Optional

e) Advance meaningful public health use of electronic health records, including exploring the availability and utility of existing sources of electronic influenza morbidity (including influenza hospitalization data) and mortality data

☒Required ☐Optional

f) Facilitate the improvement of influenza surveillance as recommended by the Council of State and Territorial Epidemiologists (CSTE)

☒Required ☐Optional

III. Strategy 1e: Enhance laboratory testing for surveillance and reporting

a) Utilize modern techniques for diagnosis (i.e. real-time RT-PCR) for typing and subtyping of influenza viruses, including detection of novel influenza viruses, year-round

☒Required ☐Optional

b) Identify and maintain a laboratorian who is proficient in influenza diagnostic testing (i.e. PCR methods for influenza virus detection, typing, and subtyping

☒Required ☐Optional

IV. Strategy 1f: Improve laboratory coordination and outreach to improve efficiency

a) Continue to assess your capacity for achieving the guidance and goals within the Right Size Road Map by evaluating and updating your implementation plans for achieving the Right Size objectives.

☒Required ☐Optional

V. Strategy 1g: Enhance coordination between epi-lab

a) Maintain weekly reporting of influenza test results from the U.S. World Health Organization (WHO) collaborating laboratories in your jurisdiction

☒Required ☐Optional

b) Coordinate connections between epidemiology and laboratory functions, at state and local levels

☒Required ☐Optional

c) Implement and maintain electronic mechanisms for exchange of public health information, including the Public Health Laboratory Interoperability Project (PHLIP) system to transmit specimen-level data to CDC each week

☒Required ☐Optional

VI. Strategy 1c: Improve surveillance and reporting. Optional Enhancement Activities. Applicants may apply for one or more of the following 3 activities:

a) Systematic surveillance sampling of patients meeting the ILI case definition and presenting to ILINet providers.

i. Identify a subset of ILINet providers (can be existing providers or recruited new for the 2019-2020 season) who are willing to

(a) Collect respiratory specimens from patients meeting the ILI case definition AND

(b) Report weekly ILI visits by age group and total patient visits to ILINet.

ii. Determine a sampling scheme based on the number of providers participating that will yield at least 100 - 150 specimens per ILINet age group per season. ILINet age groups are 0-4 yrs, 5-24 yrs, 24-49 yrs, 50-64 yrs and ?65 yrs.

iii. For each specimen collected, report to CDC the following information: date of birth (age is acceptable), specimen collection date, and a means to identify that the specimen was collected as part of this project.

iv. Specimens should be tested at the PHL using the CDC IVD kit including influenza A subtype and influenza B lineage.

v. Test results and additional information (iii above) must be reported to CDC.

(a) Ideally this would occur as part of the PHL routine transmission of influenza test result data via PHLIP by including a project flag and the ILINet provider ID for each specimen.

(b) If this is not feasible, an alternative mechanism such as an Excel spreadsheet can be utilized as long as there is a method for linking the PHL test results transmitted via PHLIP with the information indicating that the specimen was collected as part of this activity.

vi. Prioritize specimens from this activity for routine submission to the National Influenza Reference Centers while maintaining adherence to the stated specimen submission guidance.

☐Required ☒Optional

b) Report level of care (inpatient or outpatient) for patients with specimens tested at the PHL.

i. Determine level of care (inpatient or outpatient) at the time of specimen collection for patients with specimens tested for influenza at the PHL. Supplying this information for a subset of specimens is acceptable.

ii. Report test results and level of care information to CDC.

(a) Ideally this would occur as part of the PHL routine transmission of influenza test result data via PHLIP by populating the optional data element "patient location" with "inpatient" or "outpatient."

(b) If this is not feasible, an alternative mechanism such as utilization of an alternative PHLIP field or an Excel spreadsheet is acceptable provided there is a method for linking the PHL test results transmitted via PHLIP with the level of care information collected as part of this activity.

iii. Prioritize specimens from this activity for routine submission to the National Influenza Reference Centers while maintaining adherence to the stated specimen submission guidance.

☐Required ☒Optional

c) Estimate population served by ILINet providers.

i. Identify a subset of ILINet providers (can be existing providers or recruited new for the 2019-2020 season) who

(a) Estimate their total population served for each of the ILINet age groups (0-4 years, 5-24 years, 24-49 years, 50-64 years and ?65 years) AND

(b) Report weekly ILI visits by age group and total patient visits by age group to ILINet.

ii. This can be achieved using one of the following methods or a different method if clearly described in the application.

(a) Total number of patients registered with the provider.

(b) Average over at least 3 years of the number of unique persons that were seen by the provider in a given year.

iii. This activity needs to occur once a season.

☐Required ☒Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS
VII. Strategy 3a: Enhance coordination between partners
a) Foster general collaboration and relationship building among city, county, state, and federal partners and other external partners (e.g. CSTE, APHL) ☒Required ☐Optional b) Coordinate epidemiologic services throughout the state, including developing a collaborating relationship between ELC and FluSurv-NET staff (if applicable) ☒Required ☐Optional
Collaborations
a. With CDC-funded programs:
N/A
b. With organizations external to CDC:
APHL/Influenza Virologic Surveillance Right Size Project Council of State and Territorial Epidemiologists (CSTE)
Target Populations:
N/A
Evaluation and Performance Measurement:
Required performance measures for the project period are listed below. Data will be reported to CDC/Influenza Division in a timely manner, as described below, and are used to indicate progress made toward program outcomes. Measure #1) ILINet recruitment target: One regularly reporting ILINet provider (a provider who reports ≥17 of the 33 weeks from beginning of October to the end of May or ≥26 weeks per year for year-round surveillance) for every 250,000 residents, or for states with smaller populations, a minimum of 10 regularly reporting ILINet providers. Measure #2) Per specimen submission guidelines, influenza viruses (if available) will be submitted to the designated National Influenza Surveillance Reference Center every two weeks, year-round. Target: A minimum of 40 specimens over 10 shipments shipped at two week intervals Measure #3) Jurisdictions will identify the appropriate number of influenza positive specimens calculated for each jurisdiction to achieve the Right Size virologic surveillance novel event detection goals. Target: meet the 1/700 goal for at least one week during the peak of influenza season Measure #4) Percentage of influenza A viruses tested by the public health laboratory that are subtyped. Target: >95% Measure #5) For Strategy II, activity a (systematic surveillance sampling of patients meeting the ILI case

definition and presenting to ILINet Providers).

Establish methods for and demonstrate implementation of systematic sampling of patients meeting the ILI case definition through (1) identifying a subset of ILINet providers who report to ILINet at least half of the 33 weeks AND submit samples for influenza testing each week that ≥10 ILI cases are reported and (2) identifying for CDC which specimens received through routine laboratory surveillance transmissions were collected as part of this activity.

Measure #6) For Strategy II, activity b (report level of care for patients with specimens tested at the PHL).

Establish methods for and demonstrate implementation of reporting to CDC level of care data for patient with specimens tested at the PHL through routine weekly laboratory surveillance transmissions or linking of independently reported level of care data with data included in laboratory surveillance transmissions.

Measure #7) For Strategy II, activity c (estimate population served by a subset of ILINet providers).

Establish methods for and demonstrate implementation of a process for providing data needed to calculate rates of outpatient ILI through identifying a subset of ILINet providers who (1) report to ILINet at least half of the 33 weeks AND (2) provide an estimate of the population served.

R: Non-Influenza Respiratory Diseases: Diagnostics, Reporting, and Surveillance
Program Activity Contact Information
Mila Prill, mprill@cdc.gov, (404) 639-8292
Funding Opportunity Description
Background
a. Overview
The primary objective is to strengthen the capacity of state and local health departments to conduct surveillance, outbreak support, and laboratory testing for non-influenza respiratory viruses and transmit the data to CDC.
b. Healthy People 2020
N/A
c. Other National Public Health Priorities and Strategies
N/A
CDC Project Description
a. Problem Statement:
Non-influenza respiratory viruses cause a large burden of illness each year, including severe lower respiratory tract infections. Viruses of particular public health importance include respiratory syncytial virus (RSV), human metapneumovirus, parainfluenza viruses, rhinoviruses, enteroviruses, coronaviruses, and adenoviruses, as well as re-emergent and novel viruses such as adenovirus type 14, SARS-coronavirus, Enterovirus-D68, and Middle East Respiratory Syndrome coronavirus (MERS-CoV). Identification of these viruses and appropriate public health response measures have been critical in mitigating their spread. For instance, surveillance for MERS-CoV and other viruses requires ruling out common viral etiologies of severe pneumonia, and not all states currently have the capacity to detect non-influenza respiratory viruses using the most sensitive molecular techniques. To track the epidemiology of these viruses on a national level, CDC developed several surveillance systems including: the National Respiratory and Enteric Virus Surveillance System (NREVSS), the Public Health Laboratory Interoperability Project (PHLIP)/NREVSS collaboration, the National Adenovirus Type Reporting System (NATRS), and the National Enterovirus Surveillance System (NESS). These systems track the seasonality and circulating subtypes of these viruses and may help identify outbreaks across jurisdictions. CDC relies on health departments with the capacity to test for these viruses to report results to these systems and to help CDC collect data from clinical, academic, and reference laboratories within their jurisdiction. In addition, there are several vaccines under development to prevent RSV infections, so it is increasingly important to have current baseline measures of severe morbidity and mortality associated with RSV to understand populations at risk and to monitor the success of future public health treatments and interventions.
b. Purpose:
This project will strengthen laboratory capacity at the state and local level to identify non-influenza respiratory virus cases including novel viruses. Additionally, the purpose is to streamline data collection of test results and epidemiologic data via national surveillance systems. Working closely with public health partners to identify and characterize seasonal trends of respiratory viruses will help identify outbreaks and implement prevention measures. RSV infection data will help determine the timing and impact of current and future interventions.
c. Outcomes:

- Trained laboratory and public health workforce better prepared to detect and respond to respiratory illness associated with non-influenza respiratory viruses
- Improved surveillance capacity resulting in more rapid detection of emerging respiratory infectious diseases
- Improved completeness and timeliness of reporting laboratory and epidemiologic data to the CDC via national surveillance systems.
- Better coordination and exchange of laboratory and epidemiologic data related to non-influenza respiratory virus infections between private, local, state, and federal stakeholders
- More timely detection, response, and investigation of outbreaks of non-influenza respiratory viral illness

Funding Strategy:

Funding may support personnel, laboratory or office supplies, specimen storage and shipping costs, and other supplies needed for capacity building and/or an effective response to a situation involving respiratory viruses. Given the year-to-year nature of funding for this component, requests for new full-time personnel may not be funded.

- Estimated total availability of funds: $750,000
- Estimated number of awards given: 10-15
- Estimated average per award: $55,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1d and 1e: Strengthen and enhance laboratory testing for surveillance, reporting, and response

a) Perform diagnostic testing for non-influenza respiratory viruses in eligible ELC public health state and local laboratories

i. Include a brief description of current laboratory capacity, including the testing methods and platforms being used or undergoing validation, and your primary criteria for testing respiratory specimens for non-influenza respiratory viruses. Specifically, were all specimens tested, a subset of all surveillance specimens, a subset or all of the influenza negatives, all fatal cases, all outbreak specimens, only upon request, on a case-by-case basis, some combination of the above, or using some other criteria?

☐Required ☒Optional

II. Strategy 1c: Improve surveillance and reporting

a) Increase or maintain the number of clinical laboratories that report respiratory virus laboratory results to CDC via the National Respiratory and Enteric Virus Surveillance System (NREVSS), either directly or by pass-through from local and state public health departments.

i. Target enrollment for each jurisdiction to be determined in consultation with CDC.

☒Required ☐Optional

b) Establish or improve non-influenza respiratory virus surveillance

☐Required ☒Optional

c) Assist CDC in investigations of deaths associated with RSV among children less than five years of age

☐Required ☒Optional

d) Work with CDC to determine rates of RSV-associated ICU admissions for some or all ages in specific catchment areas

☐Required ☒Optional

e) Report appropriate type-specific respiratory virus results from public health laboratories to CDC via the National Enterovirus Surveillance System (NESS) and/or the National Adenovirus Type Reporting System (NATRS)

i. This activity is only applicable to laboratories that perform typing for enterovirus or adenovirus positive specimens.

☐Required ☒Optional

III. Strategy 1b: Enhance investigation and outbreak response

a) Participate in respiratory illness outbreak investigations and assist local jurisdictions in outbreaks as needed.

☐Required ☒Optional

IV. Strategy 1h: Advance electronic information exchange implementation

a) Transmit information regarding non-influenza respiratory virus testing from public health laboratories to CDC via the Public Health Laboratory Interoperability Project (PHLIP) system, including clinical variables when feasible.

i. If reporting via PHLIP is not possible, then these data should be reported directly to the NREVSS system on a weekly basis by manual data entry or data upload.

☐Required ☒Optional

b) Collaborate with CDC to implement electronic data transfers from clinical or health department laboratories to CDC of respiratory virus laboratory results, including epidemiologic and clinical data when feasible such as age, specimen collection date, illness onset date, location, severity/outcome measures (e.g., hospitalization, ICU admission, death).

i. This strategy is primarily applicable to clinical laboratories as well as local health department jurisdictions that are not currently eligible for reporting via PHLIP.

☐Required ☒Optional

Collaborations:
a. With CDC-funded programs:
Depending upon the capacity of applicants, collaborations with CDC programs, including NREVSS, NATRS, NESS, and PHLIP, may be expected.
b. With organizations external to CDC:
Applicants are expected to work with organizations such as local health departments; academic, clinical, and commercial medical facilities and laboratories; and the public health community, as needed to achieve the NOFO outcomes.
Target Populations:
Not applicable.
Evaluation and Performance Measurement:
Measure #1
Ability to test for non-influenza respiratory viruses, including respiratory syncytial virus (RSV), human metapneumovirus, parainfluenza viruses, and respiratory adenoviruses. Some states may have also developed or are working to build the capacity to test for coronaviruses, rhinoviruses, and enteroviruses, including EV-D68. Baseline/target: No progress / some progress / great progress / completed.
Measure #2
Number of specimens associated with respiratory virus surveillance and outbreaks that were *received* from clinics, hospitals, coroners, local health departments, or other sources. Target goal- as circumstances warrant and considering criteria such as severity of outbreaks and capacity for testing.
Measure #3
Number of specimens associated with respiratory virus surveillance and outbreaks that were *tested* for non-influenza respiratory viruses. Target goal- as circumstances warrant and considering criteria such as frequency of testing, capacity for testing, severity of outbreaks, and representativeness of specimens.
Measure #4
Number of aliquots shipped to CDC for additional or confirmatory non-influenza respiratory virus testing (as needed).
Measure #5
Reporting has been implemented from health department laboratories to CDC via HL7 messages in PHLIP for respiratory specimens tested for a non-influenza respiratory virus (including clinical variables such as hospitalization/ICU/death when feasible) and have been validated for inclusion in NREVSS. Baseline/target: No progress / undergoing validation / post-validation updates in progress / completed
Measure #6
The number of weeks a health department submits at least one non-influenza health department laboratory test result to CDC for inclusion in the National Respiratory and Enteric Virus Surveillance System (NREVSS).
Measure #7
Periodic reporting from health department labs to CDC for the National Enterovirus Surveillance Systems (NESS) (if applicable, based on current testing capacity).
Measure #8

Periodic reporting from health department labs to CDC for the National Adenovirus Type Reporting Systems (NATRS) (if applicable, based on current testing capacity).
Measure #9
Number of *clinical* labs whose aggregate test results were transmitted to CDC for inclusion in NREVSS on a weekly basis, either directly or on their behalf with pass-through reporting by a health department. (Target enrollment for each jurisdiction to be determined in consultation with CDC.)
Measure #10
Identification and reporting of RSV-associated deaths among children <5 years of age in which key clinical and other data are obtained and transmitted to CDC. Target goal >50% of all RSV-associated deaths from 2014 to the present, ideally within 2 months of death.
Measure #11
If applicable, briefly describe any progress made toward calculating a rate of RSV-associated ICU admissions for one or more hospitals or for a catchment area within your jurisdiction. Indicate steps accomplished, including: initiating work with hospitals, developing a standardized approach for data collection, collecting denominator data, collecting numerator data, data cleaning. (Indicate "N/A" if the jurisdiction did not propose working on this activity.)
Measure #12
Number of investigations conducted for respiratory outbreaks.
Measure #13
If applicable, briefly describe any progress made toward facilitating reports of laboratory and epidemiologic data from clinical or health department laboratories to CDC for individual respiratory specimens with accompanying key data, including age, relevant dates (e.g., onset date, specimen collection date, testing date), location, and severity/outcome measures (e.g., hospitalization, ICU admission, death). Indicate steps accomplished: No progress / initiating work with clinical laboratories / developing a standardized approach for data collection and messaging / implementing the mapping and coding for messaging / testing the messaging / validating the messaging / completed. (Indicate "N/A" if the jurisdiction did not propose working on this activity.) Target goal of initiating reporting for at least one new institution.

S: Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity

Program Activity Contact Information

Karen Schlanger, Lead Epidemiologist, khs4@cdc.gov, 404-718-5660

Funding Opportunity Description

Background

a. Overview

The "Threat of Antibiotic-Resistant Gonorrhea (ARGC): Rapid Detection and Response Capacity" program, also called "Strengthening United States Response to Resistant Gonorrhea (SURRG)", employs four strategies to achieve outcomes of interest. The first strategy is to **strengthen local resistant gonorrhea (GC) threat coordination and epidemiological capacity through workforce development**. Activities under this strategy include: (1) maintaining and training key staff to fill the following roles: project director (SURRG principal investigator or PI), epidemiologist coordinator, laboratorian(s), disease investigator(s) (DIS), epidemiologist/analyst, consulting STD clinician, and data manager; (2) continuing to develop, implement, and improve project protocols and IT systems to facilitate ARGC rapid detection and response clinic, laboratory, surveillance, investigations, and data management-related activities; and (3) (optional) develop/implement additional ARGC rapid detection and response messaging, outbreak response exercises, and surge capacity planning.

The second strategy is to continue and improve local processes to **enhance timely detection of resistant GC threats**. For this strategy, activities include: (1) robust collection of genital and extragenital specimens for GC culture in STD clinics and in at least two other health care settings with high GC morbidity; (2) the use of GC specimen collection and transport techniques, GC culture, Etest antimicrobial susceptibility testing, other diagnostic tools, and laboratory information management systems (LIMS) to increase laboratory capacity and the speed and success at which resistant GC infections are identified and reported to the local health department for action; and (3) collection, processing and submission of required laboratory isolates and associated data to assigned regional Antibiotic Resistance Laboratory (ARLN), and CDC per CDC protocols.

The third strategy is to **conduct robust field investigations** with the following goals: enhance GC case investigations to confirm infection resolution; identify and engage sexual and social contacts of partners in GC testing (including culture) and treatment; document the impact of GC partner services on case identification and transmission disruption; identify and describe the network structure and epidemiological characteristics of cases and those in the network of cases; and assess transmission dynamics of GC and emerging resistant GC threats. Activities related to this strategy include: epidemiologic investigation of selected cases, elicitation of and outreach to recent sexual partners (and their sexual partners' other recent sex partners); elicitation and outreach to others in the social network of the cases, and testing (including culture) and treatment (if indicated).

The fourth strategy is to **collect and analyze data for ongoing process and outcome evaluations and quality improvement activities, and enhanced epidemiological characterization of GC and resistant GC** (including network analysis), to inform effective and efficient prevention and control interventions to mitigate the spread of GC and antimicrobial-resistant GC threats locally, and through the dissemination of findings and lessons learned, nationally as well as locally. Activities related to this strategy include: (1) conducting routine

process and outcome evaluations on core clinic and laboratory activities; (2) conducting two SURRG-specific quality improvement projects; (3) conducting analyses on SURRG field investigation activities to document impact and value; and (4) compiling and disseminating ARGC rapid detection and response activities and lessons learned locally and nationally

b. Healthy People 2020

This project supports Healthy People 2020 objectives to: reduce gonorrhea rates among men and women ages 15-44 (Objectives STD-6.1 and STD-6.2), as well as to strengthen public health laboratory services to support diagnosing and investigating health hazards in the community; support emergency response; support disease control and surveillance, and; support specialized testing (Objectives PHI-11.1–PHI-11.3; PHI-12.2–PHI-12.4; and PHI-12.6–PHI-12.7). This work will also support objectives to assure comprehensive epidemiology services (Objective PHI-13.4).

c. Other National Public Health Priorities and Strategies

This project supports two goals of the National Strategy for Combating Antibiotic-Resistant Bacteria (CARB): (1) Slow the emergence of resistant bacteria and prevent the spread of resistant infections (Objective 1.1); and (2) Advance use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria (Objective 3.2).

CDC Project Description

a. Problem Statement:

GC is the second most commonly reported communicable disease in the United States with over 500,000 cases reported in 2017. Untreated GC can lead to pelvic inflammatory disease, ectopic pregnancy and infertility in women, epididymitis in men, serious disseminated infection in men and women, and can facilitate HIV acquisition and transmission. Timely and effective treatment for GC can prevent these severe adverse health outcomes and onward transmission in the community. However, *N. gonorrhoeae* has progressively acquired resistance to each of the antimicrobial agents that have been recommended for treatment over the past 70 years. In the past several years, *N. gonorrhoeae* has rapidly become less susceptible to the third-generation cephalosporins and macrolides, the components of currently recommended combination therapy. Particularly as the antibiotic pipeline has dwindled, the threat of untreatable GC is increasing. Development and spread of strains with cephalosporin and macrolide resistance will severely complicate control and prevention of GC. Because GC is primarily diagnosed through nucleic acid amplification testing (NAAT) technologies, rather than culture, few clinicians readily have access to gonococcal susceptibility testing. While the Gonococcal Isolate Surveillance Project (GISP) is critically important for monitoring long-term trends in gonococcal susceptibility to inform treatment guidelines, the susceptibility results are not available quickly enough to allow for rapid local responses to resistant strains. Developing local and state public health capacity for timely detection of and rapid response to emerging resistant GC threats is urgently needed to mitigate the spread of resistant GC.

b. Purpose:

Activities funded as a part of this project will strengthen state and local GC public health infrastructure and build capacity in high-risk local jurisdictions to support rapid detection of and response to threats of antibiotic-resistant GC. High-risk jurisdictions include: (1) geographic areas at elevated risk of experiencing emergence of resistant GC based on the historical epidemiologic factors associated with the development of penicillin and fluoroquinolone resistance in the U.S (e.g. areas in the western part of the U.S.(2) areas with local GC

epidemics that include large percentages of gay, bisexual, or other men who have sex with men (MSM); or (3) geographic areas with high GC rates.

c. Outcomes:

By the end of the project period, awardees are expected to show measurable progress toward the following outcomes:

- Maintenance of a trained state and local public health workforce better prepared to respond to GC and antimicrobial-resistant GC threats.
- Improved capacity (e.g. informatics infrastructure, laboratory infrastructure, etc.), coordination, and implementation of clinical, laboratory and rapid response activities designed to quickly identify, fully investigate, treat, and interrupt transmission of reduced susceptible/resistant GC threats.
- Expanded data sharing between clinicians, laboratorians, field epidemiologists, and programmatic staff to facilitate rapid detection and response activities.
- Increased specimen collection for GC culture at selected STD clinics and community partner locations with high GC morbidity for antibiotic susceptibility testing across gender and anatomic sites.
- Improved surveillance of GC antibiotic susceptibility patterns in local jurisdictions and robust epidemiological analyses (including network analyses) that supports: 1) improved characterization of GC and resistant GC epidemiology and social and sexual networks in local jurisdictions, and informs targeting of prevention and control interventions.
- Ongoing and increased collection and use of process and impact evaluations and quality improvement efforts to document and improve implementation of core GC rapid detection and response-related clinic, laboratory, and field investigation activities, and to inform effective and efficient prevention and control interventions to mitigate the spread of GC and antimicrobial-resistant GC threats.
- Compilation and dissemination of programmatic lessons learned and findings via grantee calls, grantee meetings, presentation at national conferences and publication.
- Long term outcomes include: modernization of approaches for GC and resistant GC detection and rapid response; improved treatment and prevention of GC and resistant GC threats; development of data-driven control strategies for GC and resistant GC informed by network and epidemiologic analyses, and potentially data from genomic analyses; minimized transmission of GC and resistant GC; and overall improvement in the population's health.

Funding Strategy:

It is anticipated that $5,164,038 of funding will be available to support up to eight (8) sites to provide capacity for the rapid detection and response of antibiotic resistant GC. The selection of sites will be determined through demonstrated background and capacity in the application.

Funding can be used to support costs for personnel, staff travel and training, laboratory supplies, local specimen transport, IT equipment, contractual support for surveillance or public health information system enhancements, and approved innovative GC prevention activities. Direct assistance is available if needed. CDC may not be able to fund grantees at prior levels including for positions that may have been necessary while building up project infrastructure (e.g. IT staff needed to build or modify existing databases; data entry clerks needed prior to improved automated or electronic data processing). Requests must include funding to support attendance and travel of the project Epidemiologist Coordinator, and at least two additional key project staff (typically the local SURRG Director/Principle Investigator, the laboratory lead for the project,

and/or the lead project data analyst or manager) to an annual resistant GC rapid detection and response capacity (SURRG) meeting (to be held in Atlanta in late 2019 or early 2020). All budget justifications should be clear and detailed enough to guide funding decisions (e.g. clearly defined project role of each funded position; itemized list of the type of supplies, with per unit item costs and number of items requested; contract deliverables, etc.).
Funded state health department applicants are expected to collaborate with local health department partners to implement activities at the local (city or county) level. Activities will focus on local health department STD clinics and collaboration with at least two community-based sites (i.e. non-STD clinic healthcare settings) with high GC morbidity and capacity to collect genital and extragenital specimens from clinic attendees for gonococcal culture and antimicrobial susceptibility testing (AST) by Etest. All project activities should directly relate to improvements in ARGC rapid detection and response-related laboratory, surveillance, epidemiology, and clinical capacity, as well as informing innovative GC control efforts in the designated local jurisdiction.

An appropriate local health department should have, at a minimum, the below features, and ideally, a proven track record of the following:

1. a) Health department leadership committed to implementing program strategies outlined in this NOFO; b) STD and community partner clinic staff with the capacity and commitment to follow project protocols related to effectively collecting, handling, and transporting GC culture specimens; c) proximity of a laboratory (state or local) with demonstrable experience and proven quality performance in culturing GC specimens and conducting timely Etest AST; d) capacity to conduct high quality field investigations consistent with the SURRG protocol, e) functional data systems capable of absorbing and storing project data in a usable fashion, and staff capacity to input, manage, store, extract, and clean project data; f) staff capacity to clean and electronically submit required data to CDC at scheduled intervals and in specified formats; and g) staff capacity and commitment to analyze locally-collected programmatic, clinical, laboratory, epidemiological, and network data for local programmatic efforts, quality improvement efforts, and dissemination, including through local and national presentations.
2. A high GC case-count in the local health department jurisdiction, and the presence of a categorical STD clinic that diagnoses at least 200 cases of GC per year;
3. Agreements in place with at least two community partner sites that serve groups known to experience high rates of GC (e.g. MSM, adolescent females), that have capacity to collect genital and extragenital specimens from clinic attendees for gonococcal culture and antimicrobial susceptibility testing (AST). Each community partner site must submit on average 6 specimens for GC culture per month.
4. The capacity and ideally proven track-record to conduct AST testing (by Etest) on at least 15% of total reported GC cases in the jurisdiction per year, or 1,000 cases, whichever is less. This includes isolates collected at STD clinics and community partner sites. Grantees will also be required to collect on average at least 10 specimens for GC culture from women per month (any anatomic site), and at least 40 extragenital specimens for GC culture from men (rectal or pharyngeal specimens)
5. Commitment of state and local STD Directors, STD clinic medical director, epidemiology and laboratory staff to work actively and collaboratively to implement this project, and lead on-going improvement efforts.

Strong applicants for funding consideration can demonstrate current capacity in the background section.

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1a: Strengthen local resistant GC threat coordination and epidemiological capacity

a) Identify and maintain appropriate staffing.

i. Maintain appropriate staffing in place, including staff members who can fill the role(s) of: a Project Director (i.e. SURRG PI), an epidemiologist coordinator (responsible for coordinating and managing local project and resistant GC activities); an epidemiologist (with capacity to conduct programmatic, epidemiologic and network data analyses); data manager (with capacity to manage, clean, extract, and submit to CDC required data in specified formats), laboratorians capable of performing *N. gonorrhoeae* culture and susceptibility testing by Etest, case investigators, a clinician with expertise in STDs (especially gonorrhea), and others to support local

ii. The STD clinician should ideally be medical director of the STD clinic or otherwise serve in a leadership role with influence on STD clinic operations. The STD clinician can, but does not necessarily have to serve as the Project Director, but must be readily accessible to the project team to guide protocol development, and to clinical staff from both the STD and community partner clinics for training and case consultation (such as providing sound management, treatment, and follow-up guidance on patients with infections with reduced antibiotic susceptibility).

iii. Individuals can serve in more than one role if their skillsets are clearly conducive to effective completion of required responsibilities for the roles.

☒Required ☐Optional

b) Maintain and update (as needed) local SURRG project protocols and IT systems to address clinic, laboratory, surveillance, investigation, and data management GC rapid detection and response activities.

i. SURRG project protocol should be sufficiently detailed and include at minimum: project staff roles and responsibilities; data and specimen flow charts; specimen collection and transport; laboratory processes for GC culturing, AST, and reporting of results; SURRG epidemiologic investigation processes and patient messaging; clinic, epi investigation and laboratory data management, including processes for completion of CDC-required monthly and annual metrics reports, and extraction, cleaning and submission to required line listed data to CDC; processes for submission of isolates and associated data to regional laboratories; and local process and outcome evaluation and analysis processes and plans

ii. SURRG clinic protocols must be developed for both STD and community partner sites, and include at minimum: project purpose; criteria for culturing; culture specimen collection, labeling, requisitioning and transport procedures; required data collection; results interpretation; key messages for providers to provide to patients found to have GC with reduced antibiotic susceptibility; processes for DIS contacting patients infected with gonorrhea with reduced susceptibility; processes for clinic handling of contacts of index cases with infections found to have reduced susceptibility (including collecting specimens for culture from such contacts); any test of cure procedures; and contact information of key

project staff including SURRG Epi Coordinator and Lab POC, and a lead clinician who clinic staff can contact to address relevant clinical questions, and provide case consultation, as needed.

☒Required ☐Optional

c) Community messaging, workforce development, and training related to rapid response to resistant GC

i. Grantees are encouraged to implement at least one of the following types of activities during the project year: 1) conduct a resistant GC outbreak tabletop or other planning exercise; 2) develop resistant GC media messages; 3) identify and train additional local clinical sites that could conduct GC testing (including culture) and treatment in the event of a large-scale resistant GC outbreak; 4) identify and establish partnerships with additional local laboratories that could receive specimens for and perform *N. gonorrhoeae* culture in the event of a large-scale resistant GC outbreak; 5) implement webinars, public health detailing, HANs, or other educational activities for local providers about resistant GC and how to access susceptibility testing for patients with suspected treatment failure or resistant GC.

☐Required ☒Optional

II. Strategy 1d: Perform robust and timely detection of resistant GC threats

a) Robust collection of specimens for gonococcal culture and performance of AST

i. Specimens must be collected from at least one STD clinic and two community-based sites. Each partnering community site must collect on average at least 6 specimens for GC culture per month.

ii. During the project period, AST via Etest must be conducted on isolates from at least 15% of total GC cases reported in the jurisdiction per year, or a total of 1,000 unique isolates, whichever is less. Grantees must also collect on average at least 10 specimens for GC culture each month from women (any anatomic site), and on average at least 40 extragenital specimens for GC culture each month from men. These requirements can include isolates from both STD clinics and partnering community-based sites.

☒Required ☐Optional

b) Conduct timely GC culture and AST via Etest, and maintain associated data

i. Conduct timely GC culture and AST via Etest on collected specimens following CDC's SURRG Etest SOP

ii. Rapidly communicate Etest results to ordering clinicians (using accurate and easy to understand interpretive language), and local SURRG Epidemiology Coordinator with a goal of reporting Etest results, on average, within 5 business days from specimen collection.

iii. Rapidly report Etest results indicating reduced antibiotic susceptibility to local SURRG Epidemiology Coordinator, jurisdiction surveillance staff, and CDC SURRG program and lab contacts within 1 business day.

iv. Collect required lab data in LIMS system

v. Extract and clean data (as needed) for timely submission of required monthly and annual metric reports, and line listed data to CDC, following CDC guidance.

☒Required ☐Optional

c) Ship GC isolates and transmit manifests to the appropriate Antibiotic Resistance Laboratory (ARLN) for confirmatory agar dilution AST and whole genome sequencing.

i. Following CDC protocols, ship all GC isolates and electronically transmit associated completed manifests to the appropriate Antibiotic Resistance Laboratory (ARLN) for confirmatory agar dilution AST and whole genome sequencing (weekly for isolates with reduced cefixime, ceftriaxone, or azithromycin susceptibility; monthly for batched isolates).

☒Required ☐Optional

III. Strategy 1b: Conduct enhanced SURRG GC case investigations

a) Rapidly initiate SURRG case investigations on all patients with elevated ASTs

i. Rapidly (within 48 hours of AST results) disease investigators/disease intervention specialists (DIS) initiate SURRG case investigation (i.e. treatment confirmation, symptom resolution, partner services, epi investigations), ideally in-person, of all patients found through laboratory diagnostics or clinical presentation (e.g. unsuccessful treatment) to be infected with a gonococcal strain with reduced susceptibility to cefixime, ceftriaxone, or azithromycin.

ii. DIS should attempt to collect all SURRG epi investigation case data elements, including eliciting named sexual partners and up to 5 social contacts on all index cases. Following CDC-developed SURRG guidance documents, DIS will attempt to contact, bring in for testing, culturing (and treatment if indicated) and collection of epi data on any named contacts, and sex partners of any named sex partners (i.e. 2nd generation sex partners). Any new case of GC identified through these investigations (whether susceptible GC or not) should be classified as a new index case, and subsequently DIS are required to attempt to conduct these investigate two generations out from these newly identified cases.

iii. All epi investigation and partner services data should be entered into a data system that allows for routine data extraction and tracking of partnerships between cases and sexual and social contacts.

☒Required ☐Optional

b) Initiate SURRG investigations/partner services/epi investigations on at least an additional **12 seed index cases** (with susceptible GC) in the jurisdiction (and their social contacts, sex partners, and sex partners of sex partners as per the SURRG Epi Investigation protocol).

i. Applicants should propose a local population of interest focus and sampling strategy for these supplemental investigations.

ii. DIS should attempt to collect all SURRG epi investigation case data elements, including eliciting named sexual partners and up to 5 social contacts on all index cases. Following CDC-developed SURRG guidance documents, DIS will attempt to contact, bring in for testing, culturing (and treatment if indicated) and collection of epi data on any named contacts, and sex partners of any named sex partners (i.e. 2nd generation sex partners). Any new case of GC identified through these investigations (whether susceptible GC or not) should be classified as a new index case, and subsequently DIS are required to attempt to conduct these investigate two generations out from these newly identified cases.

iii. All epi investigation and partner services data should be entered into a data system that allows for routine data extraction and tracking of partnerships between cases and sexual and social contacts

☒Required ☐Optional

AREA B: PREVENTION AND INTERVENTION

IV. Strategy 2a: Collect and analyze data for ongoing process and outcome evaluations, quality improvement activities, and enhanced epidemiological characterization of GC and resistant GC, with the goal of informing implementation of effective and efficient prevention and control interventions to mitigate the spread of GC and antimicrobial-resistant GC threats both locally, and through the dissemination of findings and lessons learned, nationally.

a) Conduct routine process and outcome evaluations on core clinic and laboratory activities (e.g. monitor implementation and success of specimen collection criteria for gonococcal culture and AST, transport time, or culture yield by anatomic site).

i. Propose 5-10 salient process or outcome metrics related to core clinic and laboratory activities that team will review on a monthly or quarterly basis

ii. Develop monitoring plan, including measure definitions, benchmarks, frequency of data review, roles and responsibilities for extracting, analyzing, and reviewing data, and for sharing findings.

☒Required ☐Optional

b) Analyze program data for programmatic quality improvement efforts.

i. Awardees must conduct two local quality improvement (QI) projects; one should be focused on an important SURRG laboratory activity and the other on either a programmatic ARGC outbreak response activity or SURRG clinical activity. For each QI project, a quality improvement change should be made and the impact measured through collecting and analyzing prospectively collected data. Local data should be analyzed to establish a baseline. Additional guidance and details will be provided by the Division of STD Prevention at CDC.

ii. Develop quality improvement plan including QI project description, measures, proposed modifications, roles and responsibilities, timeline, and analysis plan

☒Required ☐Optional

c) Develop and implement a plan to conduct analyses on GC rapid detection and response epi investigation and partner services activities. These analyses should attempt to 1) document of the impact and value of conducting local partner services and outbreak response activities, and 2) improve local understanding of GC and resistant GC epidemiology and transmission dynamics. These analyses may include partner services metrics, network information, epi, clinical, AST and/or genomic data.

i. Develop analysis plan, including analytic questions, data definitions, analysis timelines, roles and responsibilities, etc.

☒Required ☐Optional

d) Evaluate routinely collected programmatic data related to test-of-cure among persons tested and treated for GC who return for a test-of-cure visits.

☐Required ☒Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

V. Strategy 3b: Information Dissemination

a) To inform and improve GC and ARGC prevention and control efforts more broadly, awardees are required to disseminate (through documentation and/or presentation) lessons learned, best practices, local protocols, or results of programmatic analyses.

i. Awardees are required to participate in a SURRG lessons learned and best practices report or SURRG journal supplement. In consultation with CDC, awardees will select a topic(s) to contribute to the report or supplement (e.g. culturing criteria and yield; media selection, specimen viability and contamination; successes and challenges with conducting field investigations; ARGC communication strategies with patients and/or providers; use of epidemiological or network data for programmatic action, etc.). Additional guidance and details will be provided by the Division of STD Prevention at CDC.

ii. In addition to any SURRG best practices report or supplement, awardees are also required to disseminate clinical, laboratory, and epidemiological analyses and programmatic best practices with community partners, on grantee calls, at the annual SURRG grantee meeting, and ideally also at local and national conferences and through publication.

☒Required ☐Optional

Collaborations

a. With CDC-funded programs:

Awardees are required to work with the Antibiotic Resistant Lab Network (ARLN) laboratories, which serve as reference labs, performing confirmatory resistance testing and advanced molecular characterization of locally tested specimens. Programs will also be expected to work with state and local STD prevention programs funded through Strengthening STD Prevention and Control for Health Departments (STD PCHD), and with state and local HIV prevention programs that receive CDC funding.

b. With organizations external to CDC:

N/A

Target Populations:

All persons diagnosed with or at risk for GC will represent the target population.

Evaluation and Performance Measurement:

Evaluation and performance measures are collected both in the ELC Application as well as submitted directly to the CDC DSTDP SURRG Team, as outlined below.

Every other month, awardees must submit to CDC (via SAMS portal following CDC project guidance documents) required variables for: 1) all GC cases identified in the STD clinics via GC NAAT; 2) all patients for whom a specimen was collected for GC culture; 3) culturing and antibiotic susceptibility test results, and 4) any GC case investigations (including data on 1st and 2nd generation sexual and social contacts) initiated.

Strategy I: Strengthen local resistant GC treat coordination and epidemiological capacity

1. List of qualified personnel hired or retained to support activities and other in-kind key-project staff and their role on SURRG. (report in ELC renewal application)
2. Indicate the number of trained personnel who can perform GC culture using Etest. (report in ELC renewal application)
3. Local SURRG project protocols (and protocol updates), including participating clinic protocols, will be submitted annually (submit annually via email directly to DSTDP SURRG Team)

Strategy II: Perform robust and timely detection of resistant GC threats

The following performance measures under *Strategy II* are required to be reported monthly and annually to CDC via email using PDF fillable forms created by the DSTDP SURRG Team, "SURRG Clinic and Laboratory Monthly Performance Metrics", and "SURRG Annual Clinic and Laboratory Performance Metrics":

1. Number of specimens collected for GC culture and number cultures determined to be positive for GC at each participating clinic (by specimen source, patient sex/gender identity, and sex of sex partner).
2. Number of GC NAATS performed and proportion positive from each participating clinic, by anatomic site.
3. Minimum, maximum, and average number of days from specimen collection (at participating clinics) to Etest completion and reporting of results, and number and percent of GC isolates processed within 5 and 7 business days.
4. Number and proportion of GC isolates found to have reduced susceptibility or resistance to antibiotics tested; and number and proportion with reduced susceptibility or resistance for which results were reported within 1 working day to the local health department, the ELC-funded health department, and CDC.
5. Number of GC cases reported in the jurisdiction; Number of in and out of jurisdiction GC cases diagnosed at participating STD clinics

Strategy III: Conduct enhanced SURRG GC case investigations:

The following performance measures under *Strategy III* are required to be reported annually to CDC via email using PDF fillable forms created by the DSTDP SURRG Team, "SURRG Annual Clinic and Laboratory Performance Metrics":

1. Number and percent of GC index patients' case investigations opened ("initiated"), reached, interviewed, named ≥ 1 sex partner, named ≥ 1 social contact.

2. Number and percent of index patients' sex partners and social contacts "initiated", reached, interviewed, GC NAAT-positive, GC culture-positive, identified with reduced susceptible GC
3. Number of SURRG investigation index patients identified through STD clinics, non-STD clinics, and SURRG investigations

Strategy IV: Collect and analyze data for ongoing process and outcome evaluations, quality improvement activities, and enhanced epidemiological characterization of GC and ARGC

The following performance measures and evaluation requirements under *Strategy IV* will be reported annually to CDC via email using templates created by the DSTDP SURRG Team

1. Brief summary of the 5-10 grantee defined routinely reviewed SURRG process and outcome measures and evaluation results from the previous 12 months
2. Brief summary of the two SURRG quality improvement initiatives implemented during the project year, including description of each QI project, measures, modifications attempted, and results over time.
3. Brief description of salient locally initiated epi investigation and partner services analyses conducted that year (including: analytic question, methods, and results)
4. List of titles, dates and venues for any SURRG-related talks, presentations, or publications of local SURRG staff during the previous 12 months.

T: Gonococcal Isolate Surveillance Project (GISP)

Program Activity Contact Information

Sancta St. Cyr, Medical Epidemiologist, oew3@cdc.gov, 404-718-5447

Funding Opportunity Description

Background

a. Overview

The Gonococcal Isolate Surveillance Project (GISP) was established in 1986 to monitor antimicrobial susceptibility trends in *Neisseria gonorrhoeae* in the United States and to establish a rational basis for the selection of gonococcal therapies. The project collected urethral gonococcal isolates and accompanying clinical/ demographic data from symptomatic men presenting to participating sentinel sites. In 2017, an enhanced project (eGISP) was introduced to evaluate gonococcal antimicrobial resistance at additional anatomic sites and in expanded populations. It also allowed for a more robust characterization of isolates by gathering epidemiology on *Neisseria meningitidis* isolates found within the surveillance population. GISP is now a combined project made up of both GISP and eGISP components. The project functions to phenotypically characterize isolates collected through this surveillance system and uses this data to assist in national gonococcal treatment recommendations.

b. Healthy People 2020

The Gonococcal Isolate Surveillance Project (GISP) supports Healthy People 2020 topic areas. The first supported topic area is Sexually Transmitted Diseases (STDs). One of the objectives in this area is to decrease the rates of gonorrhea in males and females ages 15 to 44 years (STD-6). This project assists in decreasing gonorrhea rates by analyzing antimicrobial susceptibility trends to help determine and encourage use of appropriate and effective antimicrobial therapies. By collecting data on sex of sex partners as a standard part of the surveillance system, GISP contributes to another STD objective to increase the number of population-based data systems that include in their core a standardized set of questions that identify lesbian, gay, bisexual, and transgender populations (LGBT-1). The eGISP component of this project evaluates the epidemiology of meningococcal infections in collected urethral, pharyngeal, rectal and cervical isolates. This project aims to better characterize *N. meningitidis* in the surveillance system and use that information to help reduce meningococcal disease, which is an objective (IID-3) of the Immunization and Infectious Diseases topic area.

c. Other National Public Health Priorities and Strategies

The National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) is also supported by this project. *Neisseria gonorrhoeae* is considered one of three urgent threat level pathogens. Goal one of the National Strategy is to slow the emergence of resistant bacteria and prevent the spread of resistant infections. By monitoring for antimicrobial resistance, especially in areas where resistance has previously been imported, this project is contributing to this goal. The CDC's strategic priorities of (1) excellence in surveillance, epidemiology, and laboratory services and (2) strengthening support for state, tribal, local, and territorial public health have been supported by GISP through its more than 30 years of gonococcal surveillance and partnerships with state and local health departments. This project also aligns with the priorities of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) to reduce the rate of non-HIV STDs. In addition, GISP addresses the goals of the Division of STD Prevention (DSTDP) strategic plan, which

includes addressing the threat of antibiotic-resistant *N. gonorrhoeae* and building capacity to respond to emerging STD threats.

CDC Project Description

a. Problem Statement:

N. gonorrhoeae is the second most common notifiable disease in the United States. Prevention and control of gonococcal infections relies on timely and effective antibiotic treatment. *N. gonorrhoeae*'s ability to mutate and develop antibiotic resistance has tested the ability to provide effective treatment. Due to the development of antimicrobial resistance to multiple classes of antibiotics, including current first line therapies, the organism has been designated as one of three urgent threat level pathogens in the United States. *N. gonorrhoeae* is, therefore, a priority of both the National Strategy for Combating Antibiotic-Resistant Bacteria and the CDC's Antibiotic Resistance Solutions Initiative.

Surveillance is a critical process for monitoring and defending against antimicrobial resistance. The National Strategy for Combating Antibiotic-Resistant Bacteria has made the strengthening of surveillance a fundamental component of its action plan. The Gonococcal Isolate Surveillance Project (GISP) is a collaborative project between local and state jurisdictions, regional laboratories and CDC that collects and analyzes gonococcal isolates across the United States. The core component of GISP involves the surveillance of male urethral isolates only and the enhanced component involves the surveillance of vaginal, endocervical, pharyngeal and rectal isolates. By having geographic, gender and anatomic diversity as part of the project, GISP may be able to better detect changes in susceptibility patterns sooner.

The enhanced component of GISP, which was added to the project in 2017, includes the collection of *N. meningitidis* in addition to *N. gonorrhoeae*. Although believed to be less commonly associated with urethritis, *N. meningitidis* has been identified with increasing frequency in some GISP jurisdictions. Therefore, evaluating the burden of urethritis associated with *N. meningitidis* better maximizes the specificity of the GISP surveillance. *N. meningitidis* also has different resistance profiles than *N. gonorrhoeae*, making it critical that jurisdictions identify what proportion of presumed *N. gonorrhoeae* infections are actually *N. meningitidis* infections. Therefore, it is not only the timely detection of gonococcal infections that allow for an effective local response to the threat of resistant *N. gonorrhoeae*, but also having the maximal specificity for the surveillance efforts performed.

b. Purpose:

The Gonococcal Isolate Surveillance Project (GISP) monitors trends in antimicrobial susceptibilities of strains of *N. gonorrhoeae* in the United States to establish a scientific basis for the selection of treatment options. It supports changes in gonococcal treatment recommendations and practices before widespread treatment failures due to resistance occur. The enhanced GISP (eGISP) increases state and local capacity to detect and monitor resistant gonorrhea among additional important populations, such as gay, bisexual, and other men who have sex with men (MSM) (in whom gonococcal resistance has often initially emerged) and women, a population from whom specimens have not been previously collected systematically for surveillance of resistance in the United States.

c. Outcomes:

By the end of the project period, the following outcomes are expected to be achieved:

- Improved surveillance of resistant *Neisseria gonorrhoeae* at the local and state level (GISP, eGISP)
- Maintenance or improvement of laboratory culture capacity for *Neisseria gonorrhoeae* at the local and state level (GISP, eGISP)
- Improved understanding of the epidemiology of *Neisseria meningitidis* in urethral, pharyngeal, rectal and cervical isolates at the local and state level (eGISP)
- Increased collaboration between local and state jurisdictions, regional Antibiotic Resistance Laboratory Network (ARLN) laboratories and CDC (GISP, eGISP)
- Increased awareness of antibiotic resistant gonorrhea risk factors, protective actions and appropriate public health actions (GISP, eGISP)

Funding Strategy:

GISP: Core GISP Component (GISP) Activities (required)

This funding is open to all jurisdictions who have identified at least one STD clinic in their jurisdiction with the capacity to collect cultures for *N. gonorrhoeae* from male urethral samples. Applicants who are currently funded to perform similar activities in selected STD clinic(s) in their jurisdiction through ELC J1: Threat of Antibiotic-Resistant Gonorrhea: Rapid Detection and Response Capacity are eligible to apply, but must identify at least one different STD clinic(s) in different geographic location(s) in their jurisdiction for activities funded through this project.

The jurisdiction must have the organizational and project management capacity to support and/ or operate a STD specialty clinic and public health laboratory over the course of the project period. The jurisdiction must also have the capacity to execute the program strategies and activities and demonstrate the ability to meet the project period outcomes. Jurisdictions must also identify in writing, as part of the funding application, the burden of gonococcal infection in their proposed STD specialty clinic(s) by providing the number of infections seen in the two years prior to the application year for each clinic.

The anticipated level of specific project management capacity needed to execute the GISP approach successfully includes the:

1) Ability to enroll men for the collection of urethral samples, culture isolation of *N. gonorrhoeae*, storage of duplicate isolates and shipment of viable and non-contaminated isolates,
2) Ability to collect and electronically transmit requested demographic and clinical data elements,
3) Organizational leadership and support to support the GISP approach, and
4) Human resource management and financial management to support the GISP approach.

Funding should be used to support costs for personnel, training, laboratory supplies, IT equipment, and contractual support for surveillance or public health information systems enhancements. Funds may also be used to support FTE who are trained in epidemiology/data management, since it is required that a jurisdiction must demonstrate data management and epidemiologic capacity to review local data to inform public health action and prepare data for transmission to CDC. All funding should support core GISP component activities. A detailed, itemized budget of each category is required for each funding year.

- Estimated total availability of funds: $300,000
- Estimated number of awards given: 25

- Estimated average per award: $12,000

GISP: Enhanced GISP Component (eGISP) Activities (optional)

While any Tier 2 section is optional for applicants, if a jurisdiction is applying for a Tier 2 project then all the activities within that project are required. This optional additional funding is only open to jurisdictions who apply for the Core GISP Component activities. Enhanced GISP Component funding is open to those jurisdictions that are eligible for the Core GISP Component and who have identified at least one STD clinic in their jurisdiction with the capacity to collect cultures for *N. gonorrhoeae* at multiple anatomic sites (i.e., vagina, cervix, rectum, and oropharynx). The jurisdiction must have the organizational and project management capacity to execute the program strategies and activities and demonstrate the ability to meet the project period outcomes.

The anticipated level of specific project management capacity needed to execute the eGISP approach successfully includes the:

1) Ability to enroll men and women for the collection of genital and extragenital samples, culture isolation and NAAT testing of *N. gonorrhoeae*, storage of duplicate isolates and shipment of viable and non-contaminated isolates,
2) Ability to collect and electronically transmit requested demographic and clinical data elements,
3) Organizational leadership and support to support the GISP approach, and
4) Human resource management and financial management to support the GISP approach.

Funding should be used to support costs for personnel, training, laboratory supplies, IT equipment, and contractual support for surveillance or public health information systems enhancements. Funds may also be used to support FTE who are trained in epidemiology/data management, since it is required that a jurisdiction must demonstrate data management and epidemiologic capacity to review local data to inform public health action and prepare data for transmission to CDC. All funding should support enhanced GISP component activities. A detailed, itemized budget of each category is required for each funding year. This itemized budget should be separate from the itemized budget for core GISP component activities.

- Estimated total availability of funds: $360,000
- Estimated number of awards given: 6
- Estimated average per award: $60,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1c: Improve surveillance and reporting of *Neisseria gonorrhoeae* isolates from men with symptomatic urethritis – GISP

a) Identify one or more categorical STD clinics and a local public health laboratory in a jurisdiction that will execute the program activities and meet the project period outcomes

i. Selected STD clinics must demonstrate a known significant burden of gonococcal disease by providing yearly number of gonococcal infections for each participating clinic for years 2017 and 201

☒Required ☐Optional

b) Collect urethral *N. gonorrhoeae* isolates from the first 25 men with symptomatic gonococcal urethritis seen in the STD clinic each month

☒Required ☐Optional

c) Inoculate specimens for culture onto selective media at the STD clinic(s). Subculture gonococcal isolates from the selective primary medium to a non-inhibitory medium in the local public health laboratory, as described in the GISP protocol

☒Required ☐Optional

d) Maintain adequate specimen handling quality control to maximize isolate viability and minimize contamination

☒Required ☐Optional

e) Assign isolates an identifying number, freeze the isolates and ship them monthly to the assigned GISP regional Antimicrobial-Resistance Laboratory Network (ARLN) reference laboratory for antibiotic susceptibility testing

☒Required ☐Optional

f) Maintain and store duplicates of submitted isolates in the local public health laboratory

☒Required ☐Optional

g) Review antibiotic susceptibility test results received from the ARLN laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform patient management and local public health response

☒Required ☐Optional

h) Collect line-listed, coded specified demographic and clinical data elements associated with each isolate and electronically submit to CDC following standardized protocols

☒Required ☐Optional

II. Strategy 1c: Improve surveillance and reporting of *Neisseria gonorrhoeae* isolates from female genital and male and female extragenital sites- eGISP

a) Identify one or more categorical STD clinics in the jurisdiction and a local public health laboratory that will execute the program strategies and meet the project period outcomes

☒Required ☐Optional

b) Collect urethral swabs for Gram stain, gonococcal culture and urethral/urine specimens for nucleic acid amplification testing (NAAT) from the first 25 men presenting to the participating STD clinic(s) each month with symptomatic urethritis

i. These isolates should be the exact same isolates submitted for the first 25 men with urethritis as part of core GISP component

☒Required ☐Optional

c) Collect pharyngeal and/or rectal swabs for culture and NAAT from patients (men or women) seen in the participating STD clinic(s) reporting pharyngeal and/or rectal exposure (e.g., men reporting oral sex or receptive anal sex) until 25 cases of gonococcal infection at extragenital sites are identified each month

i. The local public health lab will isolate and ship the gonococcal isolates to the assigned laboratory in the CDC-supported Antibiotic Resistance Laboratory Network (ARLN)

☒Required ☐Optional

d) Collect cervical swabs for gonococcal culture and NAAT from women undergoing pelvic examinations with concerns of cervicitis, women with known exposures to a GC case and women with a positive NAAT result in the participating STD clinic(s) until 25 cases of gonococcal genital infections in women are identified each month. A urine specimen for NAAT (rather than a swab) is acceptable

☒Required ☐Optional

e) Inoculate specimens for culture onto selective media at the STD clinic(s). Subculture gonococcal isolates from the selective primary media to a non-inhibitory medium in the local public health laboratory, as described in the eGISP protocol

☒Required ☐Optional

f) Maintain adequate specimen handling quality control to maximize isolate viability and minimize contamination

☒Required ☐Optional

g) Assign isolates a unique identifying number, freeze the isolates and ship them monthly to the assigned eGISP regional Antimicrobial-Resistance Laboratory Network (ARLN) reference laboratory for antibiotic susceptibility testing

☒Required ☐Optional

h) Ship isolates associated with positive gonorrhea NAAT results monthly to the assigned ARLN laboratory for antimicrobial susceptibility testing by agar dilution and possible molecular characterization (including whole genome sequencing)

i. CDC may request that selected specimens of interest be shipped from the ARLN to CDC for additional laboratory investigation and archival storage

ii. Isolates with negative gonorrhea NAATs will be shipped to the CDC Meningitis Branch laboratory (see Strategy III, Activities a and b)

☒Required ☐Optional

i) Review antibiotic susceptibility test results received from the ARLN laboratory, describe the epidemiology of resistant *N. gonorrhoeae* in submitting jurisdictions, and use results to help inform local public health response

☒Required ☐Optional

j) Collect line-listed, coded specified demographic and clinical data elements associated with each isolate and electronically submit to CDC following standardized protocols

i. Awardees will collect and transmit standardized data elements for domains such as anatomic site (from which the specimen was collected), gender of recent sex partners, recent sex with anonymous partners, HIV status (including results from HIV testing at the clinic visit when the specimen was collected), travel history, recent sexual practices (such as insertive oral sex or receptive anal sex), and NAAT results of the specimen

ii. The unique identifying number assigned to each isolate will enable identification of multiple isolates that were collected from the same patient. This identifier will be included with the line-listed transmitted data

☒Required ☐Optional

III. Strategy 1c: Improve the specificity of surveillance and reporting of *Neisseria gonorrhoeae* by monitoring *Neisseria meningitidis* isolates from male and female genital and extragenital sites- eGISP

a) Identify and maintain records of all urethral, pharyngeal, rectal, and cervical isolates that are suggestive of *N. meningitidis*

i. Isolates are suggestive of *N. meningitidis* when they have "discordant results" demonstrated by bacterial growth on culture consistent with *N. gonorrhoeae* (positive culture) and have a negative gonorrhea NAAT results, or in the case of urethral specimens, demonstrate Gram-negative intracellular diplococci (GNID) by microscopy, but have a negative gonorrhea NAAT results

☒Required ☐Optional

b) Ship the identified presumed *N. meningitidis* isolates monthly directly to the CDC Meningitis Branch Laboratory in Atlanta, Georgia for antibiotic susceptibility testing, confirmatory identification, and molecular characterization (including whole genome sequencing)

☒Required ☐Optional

c) Maintain adequate specimen handling quality control to maximize isolate viability and minimize contamination

☒Required ☐Optional

d) Review antibiotic susceptibility test results received from the CDC Meningitis Branch Laboratory, describe the epidemiology of *N. meningitidis* in urethral, pharyngeal, rectal and cervical isolates in their jurisdiction to help inform patient management and local public health response

i. Annual reports of isolate data for specific sentinel sites can be provided upon request

☒Required ☐Optional

e) Collect line-listed, coded specified demographic and clinical data elements associated with each isolate and electronically submit to CDC following standardized protocols

i. In addition to the epidemiological variables described in Strategy II, Activity j, data collection for these isolates will also include epidemiological data of meningococcal vaccination status

☒Required ☐Optional

Collaborations:

a. With CDC funded programs:

All awardees will be assigned to an Antibiotic Resistance Laboratory Network (ARLN) laboratory that will serve as the regional reference laboratory for their clinical sites. ARLN laboratories will receive all of their jurisdiction's isolates and perform the antimicrobial susceptibility testing on them. Assigned ARLN laboratories will also be responsible for providing each awardee with its specific antimicrobial testing results. Awardee programs will also be encouraged to work with state and local STD prevention programs, which may include programs funded through CDC's Improving Sexually Transmitted Disease Programs through Assessment, Assurance, Policy Development, and Prevention Strategies (STD AAPPS).

b. With organizations external to CDC:

Awardees are also expected to work with clinical providers in the participating STD clinic(s) in their jurisdictions

Target Populations:

The core GISP component targets men with symptomatic gonococcal urethritis only. The enhanced GISP component performs surveillance of gonococcal isolates from men and women at genital and extragenital sites. Awardees, therefore, are expected to identify persons with urethral, pharyngeal, rectal, or cervical

gonococcal infections, including racial, ethnic, and sexual minorities, for the purposes of surveillance of gonococcal antibiotic resistance.

Evaluation and Performance Measurement:

Measure #1

Improved surveillance of resistant *Neisseria gonorrhoeae* at the local and state level

- GISP
  - Ability to collect 25 male urethral isolates monthly from participating clinics
  - Ability to collect and transmit the following clinical and demographic data for each isolate
  - Patient gender
  - Ethnicity
  - Race
  - Date of clinic visit
  - Age
  - Sex of sex partner
  - Presence of symptoms
  - Previous history of gonorrhea
  - Number of previous confirmed episodes of gonorrhea in past year
  - HIV status at time of clinic visit for gonorrhea (including results of HIV testing at the time of the clinic visit)
  - Travel outside the United States during the 60 days prior to clinic visit
  - History of giving or receiving drugs / money for sex in the 12 months prior to clinic visit
  - Any antibiotic use during the 60 days prior to clinic visit
  - History of injection drug use in the 12 months prior to clinic visit
  - History of non-injection recreational drug use (excluding alcohol) in the 12 months prior to clinic visit
  - Primary treatment for gonorrhea (such as ceftriaxone, if recommended dual therapy administered)
  - Secondary treatment for gonorrhea (such as azithromycin 1 g, if recommended dual therapy administered; previously considered co-treatment for presumed chlamydia)
- eGISP
  - Ability to collect 25 female genital isolates monthly from participating clinics
  - Ability to collect 25 male or female extragenital isolates monthly from participating clinic
  - Ability to collect and transmit the following clinical and demographic data for each isolate
  - Anatomic site of isolate collection
  - Nucleic acid amplification test (NAAT) result
  - Patient gender
  - Ethnicity
  - Race
  - Date of clinic visit
  - Age
  - Sex of sex partner
  - Presence of symptoms
  - Previous history of gonorrhea

- Number of previous confirmed episodes of gonorrhea in past year
- HIV status at time of clinic visit for gonorrhea (including results of HIV testing at the time of the clinic visit)
- Travel outside the United States during the 60 days prior to clinic visit
- History of giving or receiving drugs / money for sex in the 12 months prior to clinic visit
- Any antibiotic use during the 60 days prior to clinic visit
- History of injection drug use in the 12 months prior to clinic visit
- History of non-injection recreational drug use (excluding alcohol) in the 12 months prior to clinic visit
- Primary treatment for gonorrhea (such as ceftriaxone, if recommended dual therapy administered)
- Secondary treatment for gonorrhea (such as azithromycin 1 g, if recommended dual therapy administered; previously considered co-treatment for presumed chlamydia)
- Meningococcal vaccination history

Measure #2

Maintenance or improvement of laboratory culture capacity for *Neisseria gonorrhoeae* at the local and state level

- GISP
  - Ability to culture and isolate *Neisseria gonorrhoeae* from clinical specimens
  - Ability to limit contamination and maintain viability of *Neisseria gonorrhoeae* isolates
  - Ability to ship isolates to the regional laboratory for standardized antibiotic susceptibility testing
  - Ability to transmit the following laboratory data to the regional laboratory
  - GISP identification number
  - Sentinel site code
- eGISP
  - Ability to culture and isolate *Neisseria gonorrhoeae* from clinical specimens
  - Ability to limit contamination and maintain viability of *Neisseria gonorrhoeae* isolates
  - Ability to ship isolates to the regional laboratory for standardized antibiotic susceptibility testing
  - Ability to transmit the following laboratory data to the regional laboratory
  - Patient identification number
  - eGISP identification number
  - Sentinel site code
  - Age
  - Possibility of *N. meningitides*
  - Gender
  - Specimen collection date
  - Specimen source

Table 1. Core GISP Component (GISP) Project Measures Table

GISP activities/objectives	**Aug 2018- December 2018**	**Jan 2019- July 2019**

	No./%	No./%
Number of cases of gonococcal urethritis diagnosed in men attending the participating clinic		
Number and percentage of urethral gonococcal isolates submitted to the assigned GISP regional laboratory		
Percentage of submitted isolates that were found by the GISP regional laboratory to be non-viable or contaminated		
Percentage of monthly isolate batches that were shipped to the GISP regional laboratory within one week after the end of monthly collection		
Percentage of monthly demographic/clinical data transmissions that were submitted to CDC within one month of the completion of specimen collection		
Percentage of collected isolates for which the following data elements were reported:		
• Age		
• Gender of sex partners/sexual orientation		
• HIV status		
• Antibiotic use		
• Treatment		

Table 2. Enhanced GISP Component (eGISP) *Neisseria gonorrhoeae* Project Measures Table

	Men			Women
eGISP Activities/ Objectives	**Urethral**	**Pharyngeal**	**Rectal**	**Cervical or Vaginal**
	# (%)	*# (%)*	*# (%)*	*# (%)*
Number of men who presented to the affiliated STD clinic(s) with urethritis				
Of the men who presented to the STD clinic(s) with urethritis, the number and percentage from whom urethral specimens for Gram stain, culture and urethral or urine specimens NAAT were collected				
Number and percentage of urethral specimens that demonstrated typical growth by culture (i.e., were positive cultures)				
Number of urethral gonococcal isolates submitted to the ARLN for susceptibility testing from the affiliated STD clinic(s)				
Number of men reporting oropharyngeal exposure				

Number/percentage of men reporting oropharyngeal exposure from whom pharyngeal specimens for culture and NAAT were collected				
Number and percentage of pharyngeal specimens from men that demonstrated typical growth by culture (i.e., were positive cultures)				
Number of pharyngeal gonococcal isolates from men submitted to the ARLN for susceptibility testing from the affiliated STD clinic(s)				
Number of men reporting rectal exposure				
Number/percentage of men reporting rectal exposure from whom pharyngeal specimens for culture and NAAT were collected				
Number/percentage of rectal specimens from men that demonstrated typical growth by culture (i.e. were positive cultures)				
Number of rectal gonococcal isolates from men submitted to the ARLN for susceptibility testing from the affiliated STD clinic(s)				
Number of women undergoing a pelvic examination at the affiliated STD clinic(s)				
Number/percentage of women undergoing a pelvic exam from whom cervical/vaginal specimens for culture and cervical/vaginal or urine specimens for NAAT were collected				
Number/percentage of cervical/vaginal specimens that demonstrated typical growth by culture (i.e., were positive cultures)				
Number of cervical/vaginal gonococcal isolates submitted to the ARLN for susceptibility testing from the affiliated STD clinic(s)				
Number/percentage of submitted isolates, stratified by anatomic site, that were found by the ARLN laboratory to be non-viable or contaminated				

Number/percentage of collected isolates, stratified by anatomic site, for which complete epidemiological data were reported to CDC				

Measure #3

Improved understanding of the epidemiology of *Neisseria meningitidis* in urethral, pharyngeal, rectal and cervical isolates at the local and state level

- eGISP
  - Ability of local or state laboratory to identify potential *Neisseria meningitidis* isolates based on culture and NAAT results
  - Ability to ship possible *Neisseria meningitidis* isolates to CDC for antimicrobial susceptibility testing
  - Ability of the clinic to collect and transmit the following clinical and demographic data for each isolate
- Anatomic site of isolate collection
- Nucleic acid amplification test (NAAT) result
- Patient gender
- Ethnicity
- Race
- Date of clinic visit
- Age
- Sex of sex partner
- Presence of symptoms
- Previous history of gonorrhea
- Number of previous confirmed episodes of gonorrhea in past year
- HIV status at time of clinic visit for gonorrhea (including results of HIV testing at the time of the clinic visit)
- Travel outside the United States during the 60 days prior to clinic visit
- History of giving or receiving drugs / money for sex in the 12 months prior to clinic visit
- Any antibiotic use during the 60 days prior to clinic visit
- History of injection drug use in the 12 months prior to clinic visit
- History of non-injection recreational drug use (excluding alcohol) in the 12 months prior to clinic visit
- Primary treatment for gonorrhea (such as ceftriaxone, if recommended dual therapy administered)
- Secondary treatment for gonorrhea (such as azithromycin 1 g, if recommended dual therapy administered; previously considered co-treatment for presumed chlamydia)
- Meningococcal vaccination history

Table 3. Enhanced GISP Component (eGISP) *Neisseria meningitidis* Project Measures Table

eGISP *Neisseria meningitidis* Measures	**All Nm Isolates**	**Urethral Nm Isolates**	**Cervical or Vaginal**	**Oropharyngeal Nm Isolates**	**Rectal Nm Isolates**

			Nm Isolates		
	# (%)	*# (%)*	*# (%)*	*# (%)*	*# (%)*
Total number of isolates, stratified by anatomic site (positive cultures for *Neisseria*)					
Number of isolates, stratified by anatomic site, identified that had discordant laboratory results (i.e. GNID by Gram stain/positive cultures and negative gonorrhea NAAT)					
Number of isolates, stratified by anatomic site, with discordant results that were shipped to CDC, stratified by anatomic site					
Number of isolates, stratified by anatomic site, with discordant results shipped to CDC that were non-viable or contaminated					
Number/percentage of isolates, stratified by anatomic site, for which requested epidemiological data were reported to CDC					

Measure #4

Increased collaboration between local and state jurisdictions, Regional Antibiotic Resistance Laboratory Network (ARLN) laboratories and CDC

- GISP
  - Ability of the local and state laboratory to provide viable, non-contaminated *Neisseria gonorrhoeae* male urethral isolates and associated documentation to the regional ARLN laboratories
  - Ability to retrieve completed antibiotic susceptibility test results performed by the regional ARLN laboratory
  - Ability to have bidirectional communication with the regional ARLN laboratory
- eGISP
  - Ability of the local and state laboratory to provide viable, non-contaminated *Neisseria gonorrhoeae* male and female genital and extragenital isolates and associated documentation to the regional ARLN laboratories in a timely manner
  - Ability to retrieve completed antibiotic susceptibility results performed by the regional ARLN laboratory
  - Ability to have bidirectional communication with the regional ARLN laboratory

- Ability of the local and state laboratory to provide viable, non-contaminated suspected *Neisseria meningitidis* isolates and associated documentation to the CDC laboratories

Measure #5

Increased awareness of antibiotic resistant gonorrhea risk factors, protective actions and appropriate public health actions

- GISP and eGISP
  - Regularly discuss and share the importance of gonorrhea surveillance and the role of GISP/ eGISP
  - Review antibiotic susceptibility test results provided by the regional ARLN laboratories
  - Review local and state GISP/ eGISP data including the annual GISP Profiles and Supplements
  - Review National STD Treatment Guidelines and encourage recommended treatment for gonococcal infections

U: Syphilis and HIV Prevention Through Social, Sexual and Phylogenetic Networks

Program Activity Contact Information

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Funding Opportunity Description

Background

a. Overview

The goal of the MATRIX project is to improve HIV and STD prevention and care for vulnerable MSM and Transgender women in local settings. Partners in New York City and North Carolina health departments will 1) uncover and follow networks of racial and ethnic minority gay, bisexual and other MSM and transgender women who are either HIV-infected or at risk of HIV and STDs; and 2) efficiently implement high-impact prevention interventions within those networks (i.e. HIV pre-exposure prophylaxis [PrEP], HIV antiretroviral treatment [ART], STD treatment, services referrals). Collected network data will be used to inform models of transmission dynamics. Sites will also collect cost data to evaluate overall cost effectiveness and inform resource allocation decisions.

b. Healthy People 2020

This project supports Healthy People 2020 objectives (which cohere closely with the National HIV/AIDS Strategy objectives) HIV-2, *Reduce the number of new HIV infections among adolescents and adults*, and HIV-3, *Reduce the rate of HIV transmission among adolescents and adults*. The project also supports HIV-13, *Increase the proportion of persons living with HIV who know their serostatus*, and HIV-14.2, *Increase the proportion of men who have sex with men who report having been tested for HIV in the past 12 months*. With respect to STD, this project supports HP 2020 objective STD 7.2, *Reduce domestic transmission of primary and secondary syphilis among males*.

c. Other National Public Health Priorities and Strategies

This project supports two of the goals of the National HIV/AIDS Strategy: (1) Reduce the number of people who become infected with HIV; and (2) Increase access to care and improve health outcomes for people living with HIV.

The Secretary's Minority AIDS Initiative Fund also derives goals from NHAS. The most clearly relevant high-priority goal is D(1): Innovative strategies to promote access to comprehensive PrEP services for high-risk racial/ethnic minorities for whom it is appropriate and desired, especially MSM and transgender persons.

CDC Project Description

a. Problem Statement:

The overarching problem is that men who have sex with men (MSM) and transgender women form two subpopulations with high STD/HIV prevalence. More specifically, the United States is currently experiencing steep rises in syphilis rates, and the majority of syphilis cases are among MSM, many of whom are MSM of color. Secondly, syphilis and HIV are intertwined epidemics among MSM and transgender women – essentially part of the same constellation of sexual health needs. Thirdly, STD incidence (especially syphilis) among HIV-uninfected MSM is a marker for extremely high vulnerability to HIV infection among this population. Remediation of infectious diseases requires treatment or care for current disease and prevention for vulnerable persons. Case detection enables both treatment and prevention: the former because case detection identifies morbidity, and the latter because those exposed to cases are by definition at high risk and

thus priority candidates for prevention. Network methods enable more productive and more efficient case detection. Because HIV and syphilis are intertwined and highly concentrated among MSM and transgender women, there is a good case for basing networks on members of these two groups.

b. Purpose:

Recipients will describe and use social, sexual and phylogenetic networks to improve management of STDs, particularly syphilis, and to identify MSM and transgender women who are either HIV-infected or at risk of HIV and STDs for high-impact prevention interventions. Discovery and use of networks allows for the connections among the target populations to be used to efficiently provide prevention and control interventions. The activities are based on expansion and extension of existing disease control activities enumerated in current guidance and program funding cooperative agreements.

c. Outcomes:

The three major outcomes expected from the approach are to:
(1) Demonstrate that networks identify candidates for treatment and prevention by showing that networks seeded from individuals with a recent syphilis/HIV history lead to finding new cases and at-risk people.

(2) Increase the number and proportion of members of networks linked to HIV care if infected with HIV and to high-quality prevention services – especially PrEP – if not infected with HIV and at risk, and

(3) Reduce duration of infection for syphilis in these networks in order to reduce transmission of both syphilis and HIV infection.

Funding Strategy:

- Estimated total availability of funds: $1.4 million
- Estimated number of awards given: 2
- Estimated average per award: $700,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1b: Enhance investigation and outbreak response

a) Engage in formative assessment of MSM populations and transgender women with particular attention to local epidemiology and behaviors, social context, service availability, and disease.
   i. Conduct focus groups of target population and service providers (e.g., Disease Intervention Specialists)

☒Required ☐Optional

b) Use network methodological techniques to describe networks seeded from STD clinic patients who are MSM or transgender women who have a recent history of HIV infection or syphilis, or who have a history of repeated syphilis infection.
   i. Network links should be based on sexual and social links (mandatory) and phylogenetic testing (optional)

☒Required ☐Optional

AREA B: PREVENTION AND INTERVENTION

II. Strategy 2a: Implement public health interventions and tools

a) Assure the provision of interventions to identify candidates for PrEP/ART and assure linkage to PrEP services, as well as interventions to assure treatment for syphilis.

i. Recipient may provide interventions directly or assure provision through arrangements with third parties

ii. Recipient should evaluate outcomes on an ongoing basis and adjust the intervention mix as needed with attention to maximizing synergies and efficiencies among interventions.

iii. Recipient should include behavioral and social services assessments and link candidates to care as needed.

☒Required ☐Optional

b) Measure all costs related to identification of networks and implementation of network-level interventions

i. Collect time-motion data

☒Required ☐Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

III. Strategy 3a: Coordinate and engage with partners

a) Participate in discussions about common protocols and common data elements across grantees

☒Required ☐Optional

b) Contribute data to inform models of transmission dynamics

☒Required ☐Optional

Collaborations:

a. With CDC funded programs:

Recipients will be expected to work with STD programs funded through the DSTDP Program NOFO (STD PCHD).

b. With organizations external to CDC:

Grantee STD programs will be expected to collaborate with external organizations as this facilitates provision of interventions to improve STD/HIV prevention and control for the target populations. These organizations might include:

- clinical providers, health care organizations,
- medical associations,
- other local government entities,
- social services organizations,
- and other community-based organizations in the selected jurisdiction.

Target Populations:

Network seeds must be racial or ethnic minority MSM or transgender women who have evidence of early syphilis, a recent history of an early syphilis diagnosis, or recent HIV. Specifically, they will be STD clinic patients who meet at least one of the following criteria:

- Current early syphilis diagnosis: this means P&S diagnosis or early latent diagnosis
- A history of recent early syphilis infection: i.e., within the past 12 months
- A history of more than one syphilis infection in the prior 24 months
- A history of recent HIV infection

Evaluation and Performance Measurement:

Measure #1: Develop adequate networks

- Awardee will enroll seeds from STD clinics
  - Number of seeds enrolled
  - Number of seeds interviewed and social/sexual contacts elicited
- Awardee will interview at least two waves of contacts based on seeds
  - Number of social and sexual contacts interviewed and social/sexual contacts elicited
  - Number of second generation social and sexual contacts interviewed

Measure #2: Identify candidates for treatment and prevention

- Number of seeds and first and second generation contacts who are tested for HIV and syphilis
  - Number found to be infected with HIV (new positives and prior positives)
    - Number of those infected with HIV sequence data in health department
    - Number of those infected who are linked to care
    - Number of those retained in care
    - Number of those virally suppressed at follow-up
- Number found not to be infected with HIV (HIV-negative)
  - Number evaluated and referred for PrEP
- Number found to be infected with syphilis
  - Number staged and infections by stage
  - Number treated with evidence of cure (non-reactive/significant titer decrease)

Measure #3: Provide services and linkage to services

- Awardee will evaluate seeds and first and second generation contacts for behavioral health and social service needs
  - Number evaluated for behavioral health or social services needs
    - Number eligible for behavioral health or social services
    - Number of those eligible who are directly provided or linked to behavioral health or social services
    - Number of those eligible who received behavioral health or social services

Measure #4: Reduce duration of syphilis

- Awardee will show evidence that duration of syphilis in networks is decreased
  - Number of people in network diagnosed with syphilis
  - Time to estimated date of infection (median of range) among infected seeds and first and second generation contacts
  - Number of seeds and first and second generation contacts diagnosed at each stage of syphilis (P&S, secondary, latent)

V: Human Papillomavirus Surveillance Among Men
Program Activity Contact Information
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Funding Opportunity Description
Background
a. Overview
Young men who have sex with men (MSM) are at high risk for developing HPV infection and associated diseases, including anal cancer, and would benefit from receiving HPV vaccine. Studies and monitoring data from the United States and other countries have demonstrated impact of HPV vaccination on outcomes in women (genital warts and cervical precancers) and data from some countries have shown indirect impact on heterosexual males from female vaccination programs. However, to date there are no impact data for HPV vaccine in MSM. Clinical trials of quadrivalent HPV vaccine in MSM showed high efficacy, but trials were limited to MSM with 5 or fewer lifetime sexual partners. Ongoing determinations of HPV prevalence in this population could monitor HPV vaccine impact among MSM as vaccine uptake continues to increase in the United States.
b. Healthy People 2020
This project supports Healthy People 2020 objectives to increase the vaccination coverage level of human papillomavirus (HPV) vaccine for males (IID-11.5), and to increase the proportion of Tribal, State, and local public health agencies that provide or assure comprehensive epidemiology services to support essential public health services (PHI-13). In addition, herd effects could help reduce the proportion of females with HPV infections (STD-9, developmental).
c. Other National Public Health Priorities and Strategies
Since 2011, the Advisory Committee on Immunization Practices (ACIP) has recommended routine HPV vaccination for all U.S. males at age 11 or 12 years, through age 21 years for men not previously adequately vaccinated, and through age 26 years for MSM. ACIP recommendations to provide HPV vaccine are specifically included in the National Prevention Strategy.
CDC Project Description
a. Problem Statement:
Infection with HPV in men can cause genital warts, and anal, penile, and oropharyngeal cancers. MSM are at particularly high risk for persistent HPV infection and related diseases. The majority of these diseases could be prevented by pre-exposure vaccination against the relevant HPV types. Surveillance activities for this vaccine-preventable infection among MSM are critical to gain information to monitor ongoing vaccination programs.
b. Purpose:
Ongoing assessment of HPV prevalence among MSM will identify HPV vaccine impact including anticipated reduced prevalence of vaccine-preventable HPV among MSM. Awardees will collect anal swab specimens from sexually active MSM (n>300 annually) and coordinate batch shipment of specimens to CDC laboratory for HPV testing.
c. Outcomes:
Intended outcomes include core area/strategy (1c): Improve surveillance and reporting • Short-term: conduct surveillance of HPV infections • Mid-term outcomes: Improve understanding of the epidemiology and incidence of infectious diseases

- Long-term outcomes: Improve use of data to inform program and policy development for HPV, and develop and implement public health best practices and/or guidelines for HPV vaccination

Funding Strategy:

Continuing funding is open to jurisdictions who have identified at least one sexually transmitted disease (STD) care clinic or community organization providing anal STD testing to MSM in their jurisdiction. Grantee must demonstrate ongoing data management and epidemiologic capacity to review local data to inform public health action and prepare data for transmission to CDC.

Funds should be used for personnel, travel, supplies, equipment (e.g., specimen collection and shipping supplies) or contractual support for the proposed activities.

- Estimated total availability of funds: $375K
- Estimated number of awards given: 3 (continuing)
- Estimated average per award: $125K

Applicants must have the statutory authority to conduct state- or project-area-wide communicable disease or infectious disease surveillance and the organizational structure and capacity to execute the program approach and strategies and meet the project period outcomes, including the organizational capacity to support and/or operate an STD care clinic or community organization serving >300 MSM annually.

The anticipated level of specific organizational capacity needed to execute the approach successfully includes capacity in:

- Surveillance, data management, and epidemiology to support the activities Organizational structure and management to support the activities
- Clinic staffing structure and expertise to support the activities
- Human resource management and financial management to support the activities

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1c: Improve surveillance and reporting of anal HPV prevalence among MSM

a) Identify participating health center/s (STD clinics or community organizations providing anal STD testing to MSM)

   i. Identify health center/s with sufficient numbers of visits from target population

☒Required ☐Optional

b) Obtain anal specimens from sexually active young adult MSM (N>300 annually) within the age range specified below (see "Target Population"). Anal specimen collection methodology should be consistent over time, and may be residual/remnant specimens collected for gonorrhea/chlamydia testing. Anal specimen collection should be in concordance with CDC HPV laboratory methodology.

   i. Identify specimen collection procedures used at participating site/s

☒Required ☐Optional

c) Methodology and procedures for storage and shipping of specimens to CDC for HPV testing should occur in accordance with CDC HPV laboratory recommendations.

☒Required ☐Optional

d) Obtain relevant surveillance information, including but not limited to: age, sex (e.g., current gender identity and sex assigned at birth), race/ethnicity, HPV vaccination status (e.g., number of doses administered, with dates and/or intervals), sexual orientation and/or sex of sex partners, number of lifetime sex partners, and HIV status.

☒Required ☐Optional

e) Line-listed de-identified demographic and clinical data elements associated with each specimen will be collected by the awardee and electronically submitted to CDC following standardized protocols.

☒Required ☐Optional

f) Coordinate submission of specimens and surveillance data to CDC for HPV testing and analysis.

☒Required ☐Optional

g) Collaborate with CDC to evaluate changes in HPV prevalence.

☒Required ☐Optional

h) OPTIONAL: Expand surveillance age range from 18-26 years (required) to 18-45 years.

☐Required ☒Optional

Collaborations:

a. With CDC funded programs:

Close collaboration is expected with subject matter experts and staff from CDC HPV epidemiology (HPV Team, Division of Viral Diseases, National Center for Immunization and Respiratory Diseases) and laboratory (HPV Laboratory, Division of High-Consequence Pathogens and Pathology, National Center for Emerging and Infectious Diseases) groups.

b. With organizations external to CDC:

Awardees are also expected to work with clinical providers in the participating health center(s) in their jurisdiction.

Target Populations:

Adult (i.e., ages 18-26 years, inclusive [required] with or without ages 27-45 years [optional]) men (i.e., born male, regardless of current gender identity or expression) who have sex with men (i.e., who identify as gay or

bisexual, or have ever had any type of sexual contact with a male partner) with remnant anal specimens originally collected for clinical purposes (e.g., anal STD screening).

Evaluation and Performance Measurement:

Awardees are required to demonstrate that measurable progress is being made throughout the project period and share this progress in workgroup and partner conference calls. To indicate progress made toward program outcomes, data will be reported through:

- Bimonthly (every two months) conference calls
- Bimonthly (every two months) written updates to submitted via email prior to conference calls
- Performance Measures for Tier 1 activities

Measure #1) Name and number of participating health centers (i.e., health center partners that submit anal swab specimens for HPV testing).

Measure #2) Number of anal swab specimens obtained and methodology, and percent of anal specimens available for HPV testing at CDC, from among all anal specimens submitted by target population of MSM within the target age range from each participating health center.

Measure #3) Number of anal swab specimens submitted to the CDC laboratory for HPV testing (following standardized protocols).

Measure #4) For each specimen submitted, line-list of associated surveillance data on age, sex (e.g., current gender identity and sex assigned at birth), race/ethnicity, HPV vaccination status (e.g., number of doses administered, with dates and/or intervals), sexual orientation and/or sex of sex partners, number of lifetime sex partners, and HIV status.

W: Infants with Congenital Exposure:
Surveillance and Monitoring to Emerging Infectious Diseases and Other Health Threats

Program Activity Contact Information

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Funding Opportunity Description

Background

a. Overview

The program's goals are to: 1) Support surveillance systems developed to address emerging threats to mothers and babies, including the US Zika Pregnancy and Infant Registry's REDCap databases to improve the understanding of virus infection, including Zika and influenza, and other emerging threats on pregnant women and their children; 2) Work collaboratively with state, local, and territorial health departments to extend the follow up of babies born to mothers with evidence of infection and other emerging threats; 3) Work with clinical experts and clinical professional organizations to develop recommendations for enhanced follow up and targeted screening and evaluation of infants with congenital virus exposure and other emerging threats; and 4) Develop and disseminate clinical guidance and health communications materials and tools for mothers and babies and their providers when new evidence emerges.

b. Healthy People 2020

This funding addresses the Healthy People 2020 goal of improving the health and well-being of women, infants, children, and families, including the following specific objectives:
MICH-1: Reduce the rate of fetal and infant deaths
MICH-1.6: Reduce the rate of infant deaths related to birth defects (all birth defects)
MICH-3: Reduce the rate of child deaths
MICH-6: Reduce maternal illness and complications due to pregnancy (complications during hospitalized labor and delivery)
MICH-10: Increase the proportion of pregnant women who receive early and adequate prenatal and pediatric care
MICH-16: Increase the proportion of women delivering a live birth who received preconception care services and practiced key recommended preconception health behaviors

c. Other National Public Health Priorities and Strategies

N/A

CDC Project Description

a. Problem Statement:

The Zika virus outbreak reminded the world how vulnerable mothers and babies are to emerging congenital infections. CDC developed an innovative system to monitor the impact of Zika virus on mothers and babies. Jurisdictions were able to detect threats faster and arm healthcare providers with the information to protect these vulnerable populations. With help from our partners, this system could be leveraged against future threats on mothers and babies, including infections and natural disasters.

This enhanced surveillance includes the collection of information about antenatal diagnostic testing, and clinical outcomes among pregnant women and their infants through the first two years of life. The critical

information obtained will inform CDC clinical recommendations and public health guidance and messages. This information collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

b. Purpose:

The purpose of this NOFO is to provide jurisdictions financial and technical support for collaborative participation in surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry for completion of follow up on pregnant women and the exposed fetuses, infants, and children to expand the surveillance approach to monitor for other emerging infections and threats to the healthy development of fetuses and infants. Infections during pregnancy that potentially pose a risk of congenital infection or other adverse outcomes in the fetus or infant would be considered under this NOFO. CDC encourages all US jurisdictions to participate in order to have full monitoring of pregnant women and their infants with Zika virus infection and other emerging threats. All collaborating jurisdictions who request funding should confirm that they plan to submit all variables requested, with redaction only of variables that cannot be submitted due to specific state laws or regulations. The data forms and electronic databases will be distributed to ELC awardees and will be available upon request. Funding will provide jurisdictions support to obtain a jurisdictional-level Coordinator to conduct these activities and to perform data management. The jurisdictional-level Coordinator will serve as the primary contact and is expected to collaborate with CDC points of contact. In partnership with state, local, and territorial health departments, the US Zika Pregnancy and Infant Registry will continue to collect critical data to update recommendations for clinical guidance for infants with congenital Zika virus infections and other congenital infections, and to plan for services for pregnant women, infants and their families affected by emerging infections and threats.

c. Outcomes

1. Improve epidemiological capacity to monitor pregnant women, infants, and children, who meet the required case definition.
    - This includes reporting to the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry, for the following:
        - Infants and children with laboratory evidence of possible congenital Zika virus infection or other congenital infections and their/mothers
        - As a surveillance activity, no additional tests or follow up visits are required for the sole purpose of the US Zika Pregnancy and Infant Registry.
    - This includes reporting emerging threats and infections for the monitoring of congenital infections through pregnancy and infant surveillance
        - Pregnant women and infants with laboratory evidence of infection
        - Description of case inclusion criteria, if novel infection is being monitored
2. Improve completeness and timeliness of reporting to surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry (including all data on the US Zika Pregnancy and Infant Registry surveillance forms where reporting is allowable by state laws/regulations) to state health departments and CDC in alignment with CDC established timelines. This includes the following:
    - Rapid and complete identification of women and infants who meet the stated case definition
    - Timely and accurate information on women and infants who meet the stated case definition
    - Improve follow up of pregnant women with laboratory evidence of possible Zika virus infection and their infants to assess fetal, birth, infant, and child outcomes
3. Improve monitoring of infants and children with laboratory evidence of possible congenital virus infection to assess long term health outcomes, with follow up to at least 24 months

4. Translation of public health data into clinical and public health recommendations, particularly in the realm of early detection of developmental delays in infants

Funding Strategy:

Funds should be utilized for personnel, travel, supplies and equipment, or contractual support for proposed activities, specifically to support a jurisdictional-level Coordinator for surveillance activities. Awardees need to provide justification for using a percentage of current staff for this activity, hiring new full time staff, or using contractual mechanisms. This funding is dependent upon continued appropriations for related efforts.

Funding decisions will be based on:

1) Quality of application
2) Number of births per year in the proposed area of surveillance
3) Estimates of exposure to emerging infections and other health threats among pregnant women in the jurisdiction
4) Public health importance of the emerging health threat proposed for monitoring by the applicant

Jurisdictions, which have a high cost of living or which may otherwise experience difficulties hiring a Coordinator, may request additional funds above the base amount for this activity.

We expect the funding for individual jurisdictions to range from $200,000 -- $425,000. Jurisdictions must provide strong justification for their requests to support the surveillance systems for emerging threats, such as US Zika Pregnancy and Infant Registry and the use of these funds.

- Estimated total availability of funds: $3,000,000
- Estimated number of awards given: 4-9
- Estimated average per award: $320,000

Strategies and Activities:

AREA A: SURVEILLANCE, DETECTION, AND RESPONSE

I. Strategy 1a: Enhance workforce capacity to address the impact of congenital Zika infection and other emerging infectious diseases that disproportionately impact pregnant women and their infants.

a) Identify personnel or contractual staff to function as a jurisdictional-level Coordinator who will track and report all follow-up information for infants born to women enrolled in the US Zika Pregnancy and Infant Registry or other surveillance systems for emerging threats.

☒Required ☐Optional

II. Strategy 1b: Enhance case investigation of reports of congenital infection during pregnancy and the impact on infants and children.

a) Coordinate with birth defects surveillance efforts, the investigation and reporting of possible congenital Zika virus infection and other congenital infection cases with severe clinical manifestations.

☒Required ☐Optional

b) Work with CDC to guide analytic direction and identify prenatal and pediatric care facilities for prioritized assessments/response

☒Required ☐Optional

III. Strategy 1c: Improve surveillance of emerging threats to pregnant women and their infants by building on the surveillance capacity established as part of the Zika emergency response.

a) Identify and report all eligible cases that meet required case definition within 30 days of case identification

☒Required ☐Optional

b) Participate in the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry by collecting follow-up clinical data at designated time points for Registry-eligible pregnant women and infants.

☒Required ☐Optional

c) Develop, maintain and/or enhance surveillance systems for emerging infections

☒Required ☐Optional

d) For emerging infections, describe case inclusion criteria and preliminary case definitions for public health awareness and collaboration

☒Required ☐Optional

e) Analyze data, prepare summaries of data (e.g., reports, maps, manuscripts, and presentations), and distribute to medical providers, public health partners, policy makers, and the public

☒Required ☐Optional

IV. Strategy 1g: Strengthen connections across the health department to establish strong coordination and collaboration between infectious disease experts, maternal/child health experts, and birth defects experts.

a) Coordinate connections between epidemiology and laboratory functions, at state and local levels

☒Required ☐Optional

b) Collaborate with the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry to leverage the existing infrastructure

☒Required ☐Optional

V. Strategy 1g: Strengthen connections across the health department to establish strong coordination and collaboration between infectious disease experts, maternal/child health experts, and birth defects experts.

a) Identify and connect with national/local partners to raise awareness and increase provider support and collaboration. Examples include, but are not limited to: professional societies, health care systems, health plans, schools/universities, and community interest groups

☒Required ☐Optional

b) Implement and maintain electronic mechanisms for exchange of public health information

☒Required ☐Optional

VI. Strategy 1h: Advance innovative IT strategies to monitoring linked mother-child health information while minimizing burden

a) Implement and maintain electronic mechanisms for exchange of public health information

☒Required ☐Optional

b) Ensure surveillance systems are modernized and integrated when possible, and linked mother-child health information is used to assess the impact of congenital infection

☒Required ☐Optional

AREA C: COMMUNICATIONS, COORDINATION AND PARTNERSHIPS

VII. Strategy 3a: Coordinate with key public health partners with expertise in protecting mothers and babies and promoting infant health

a) Actively participate in the Data Use Working Group to communicate the public health message to protect mothers and babies

☒Required ☐Optional

VIII. Strategy 3a: Coordinate and collaborate with key clinical partners that are committed to advancing the health of pregnant women, infants, and children

a) Participate in the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry by collecting follow-up clinical data at designated time points for Registry-eligible pregnant women and infants

☒Required ☐Optional

IX. Strategy 3b: Disseminate information on the importance of avoiding congenital virus infection, including Zika and influenza, and other emerging threats during pregnancy, and strategies to reduce risk

a) Participate collaboratively to development of best practices for preparing and responding to emerging threats to pregnant women and their infants

☒Required ☐Optional

X. Strategy 3b: Develop and disseminate information on protection of pregnant women and their infants from other emerging infectious diseases, and known health threats to pregnant women/infants such as CMV

a) Participate collaboratively to disseminate information on protection of pregnant women and their infants from other emerging infectious diseases, and known health threats to pregnant women/infants such as CMV

☒Required ☐Optional

XI. Strategy X: Work with cross-cutting health information systems team within your health department to develop core surveillance capacity within health departments to monitor and protect pregnant women, infants, and children

Collaborations:

a. With CDC funded programs:

Collaboration is strongly encouraged with birth defects surveillance efforts in state health departments including awardees supported by the National Center on Birth Defects and Developmental Disabilities (NCBDDD).

b. With organizations external to CDC:

Awardees are encouraged to collaborate with national and local professional organizations such as American Academy of Pediatrics, American College of Obstetricians and Gynecologists, American Board of Obstetrics and Gynecology, Society for Maternal Fetal Medicine, American Nurses Association, Association of Clinical Nurse Midwives, and other professional groups as appropriate to increase provider support and collaboration with the Registry.

Target Populations:

Infant and children

Evaluation and Performance Measurement:

The Programmatic Team at CDC will support recipients by ensuring that the strategies and activities are implemented as expected and that performance outcomes are achieved in a timely manner. The program will monitor activities according to the Work Plan through monthly jurisdictional calls, emails, and progress reports. The program will provide technical assistance to awardees to overcome any barriers and to improve the effectiveness of the program.

Outcome measures:

1. Proportion of cases among infants reported to the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry with follow-up data reported for all time points: 2, 6, 12, 18 & 24 months.

   a. The Registry will use quarterly Jurisdictional Data Completeness reports to assess what proportion of cases have reported data for the applicable time points. These reports will take into account cases that have been lost to follow-up as reported by the jurisdiction.

2. Completeness of reporting of variables requested by the surveillance systems for emerging threats, such as the US Zika Pregnancy and Infant Registry.

   a. The Registry will use the quarterly Jurisdictional Data Completeness reports to assess the completeness of data submitted USZPR for a limited number of key variables.

   b. The report is also utilized to identify challenges in reporting and communicate these to the Registry so that we may continue to collaborate to improve data quality and completeness.