

Funding Opportunity

State, Territorial, Local and Tribal Based Neonatal Abstinence Syndrome (NAS) Standardized Surveillance Case Definition Implementation Project

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PART I: OVERVIEW INFORMATION

Issuing Organization: Council of State and Territorial Epidemiologists (CSTE) at www.cste.org

Participating Organizations: CSTE, Centers for Disease Control and Prevention, Cooperative Agreement Number **1 NU38OT000297-02-00**.

PART II: FULL TEXT OF ANNOUNCEMENT

Section I. Funding Opportunity Description***Background***

The current opioid crisis has led to substantial increases in overdose deaths, hospitalizations, and opioid use disorder among the U.S. population. Of particular concern is opioid use disorder among women of reproductive age, particularly during pregnancy. (1) Chronic opioid use during pregnancy, including medication-assisted therapy with opioid agonists, and the use of benzodiazepines and barbiturates can result in withdrawal signs in newborns, known as Neonatal Abstinence Syndrome (NAS). NAS involves a constellation of central and autonomic nervous system, respiratory, and gastrointestinal dysregulation signs in the newborn. (2)

Opioid use among women of reproductive age and NAS are important emerging public health problems (3). However, efforts to examine trends in NAS at state and national levels and to compare incidence across jurisdictions have been hampered by the lack of a standardized surveillance case definition (3). It is important to document the existing status of NAS surveillance and develop promising practices for surveillance and reporting that can be adapted by other jurisdictions to increase timely surveillance of NAS and other emerging threats to pregnant women and infants. In collaboration with CDC, states, and local jurisdictions, CSTE developed the Neonatal Abstinence Syndrome Standardized Surveillance Case Definition Position Statement, which was ratified by the CSTE Council at the CSTE Annual Business meeting in June 2019. The development of the NAS Position Statement was informed by the CSTE Neonatal Environmental Scan Analysis Report, which was developed and conducted in the fall of 2018 to understand the ways that states defined and operationalized NAS surveillance and the data sources that were being used. This position statement describes two tiers for NAS surveillance: (1) real time case reporting based on public health legal authority, and (2) case reporting based on claims-based administrative data.

This funding opportunity will provide a mechanism for state, local, tribal, and territorial public health organizations or agencies with public health authority to conduct population health surveillance using the CSTE NAS Standardized Surveillance Case Definition (Tier 1) while leveraging existing surveillance infrastructure (example: collaborating with state local, territorial birth defects surveillance system where one exists, zika surveillance system, NEDSS, notifiable disease systems). This funding opportunity will provide up to \$150,000 per selected agency to conduct NAS surveillance using existing surveillance systems.

Objectives

By July 31, 2020, the awardees will conduct NAS Surveillance by implementing the CSTE NAS Standardized Surveillance Case Definition (Tier 1) while leveraging existing surveillance infrastructure (example: birth defects surveillance system, zika surveillance system, NEDSS, or other notifiable disease system). CSTE and our partners seek to identify more timely and consistent data on NAS, inform optimal care, and improve associated health outcomes. Through this project, CSTE seeks to learn:

1. Any gaps or needs for revision to the CSTE NAS Standardized Surveillance Case Definition (Tier 1)
2. Any challenges for STLT implementation of the CSTE NAS Standardized Surveillance Case Definition (Tier 1)
3. Estimate the associated level of capacity or resources required for effective health department implementation of the CSTE NAS Standardized Surveillance Case Definition (Tier 1)
4. Identify advantages or challenges across existing surveillance infrastructure and the use of various systems for NAS
5. Deidentified jurisdictional data collected by awardees will further CSTE and our partner's NAS surveillance goals as outlined in the CSTE Neonatal Abstinence Syndrome Standardized Surveillance Case Definition Position Statement that include:
 - Estimating the incidence of NAS using standard surveillance case definitions
 - Tracking trends in NAS and making meaningful comparisons between geographic regions in order to plan prevention and treatment efforts for women and infants.
 - Evaluating the effectiveness of treatment and intervention strategies
 - Monitoring for long term health and developmental effects of in utero exposure to opioids
 - Identifying women with chronic opioid use and linking them to treatment
 - Allocating public health and clinical resources to provide services to affected families
 - Connecting families with health and social services to promote optimal child development and family well-being

Deliverables**Phase 1 (February 11, 2020-July 31, 2020)**

- Obtain any state level approvals or data use agreements required, including state IRB approval (if needed) for this public health surveillance
- Provide data sharing and publication agreements to CSTE
- Participate in conference calls with CSTE staff, members, and partners as needed
- Participate in project check in call and provide invoices to CSTE
- Report individual-level data on the defined list of variables to CDC using current existing surveillance infrastructure on a quarterly basis (see appendix A) for the purposes of multi-state analysis of descriptive epidemiologic data to describe NAS prevalence and trends.

Phase 2 (August 1, 2020- September 31, 2020)

- Report individual-level data on the defined list of variables to CDC using current existing surveillance infrastructure on a quarterly basis (see appendix A) for the purposes of multi-state analysis of descriptive epidemiologic data to describe NAS prevalence and trends.
- Participate in conference calls with CSTE staff, members, and partners as needed
- Participate in project check in calls and submit invoices to CSTE
- Prepare and submit final narrative report to include the following:
 - CSTE NAS Standardized Case Definition for Surveillance Implementation Report
 - Describe case ascertainment timeframe
 - Describe resources utilized for project. How many people worked directly on implementing the CSTE NAS Standardized Surveillance Case Definition (Tier 1), what were their tasks, approximately how much time was spent on the project?
 - Describe data sources used for classification of cases
 - Describe steps taken for review and completion of case investigation for each identified case
 - Describe the process of auditing, abstracting, or identifying records meeting the NAS case definition
 - Describe the process for deduplication
 - Classify each case found as Confirmed, Probable, Suspect or Not a Case, and provide the number of cases in each classification
 - Describe differences in NAS surveillance data when comparing to previously used NAS case definition (if applicable), and the CSTE NAS Standardized Surveillance Case Definition (Tier 1) (CSTE will provide fillable tool that will calculate % and incidence per 1000 live births)
 - Describe referential dates
 - Enumerate the number of days since withdrawal signs noticed (14 days vs. 28 days).
 - Define numerator and denominator for both old and new case definitions (CSTE will provide fillable tool that will calculate % and incidence per 1000 live births)
 - Describe the transition plan to reconcile the previously used NAS surveillance definitions and the CSTE NAS Standardized Surveillance Case Definition (Tier 1) to leadership and other stakeholders
 - Explain how the data are being disseminated to stakeholders, best practices, and how the CSTE NAS Standardized Surveillance Case Definition (Tier 1) is being utilized
 - Describe the process for linking services for children and provide the evaluation metrics
 - Please list any problems, issues or concerns with classifying cases using the proposed case definition
 - Does your jurisdiction have any additional feedback or concerns to share?
 - Provide recommendations for revising the case definition, if any

- Coordinate with CSTE to disseminate project results via webinar, conference call, or meeting presentations.

Timeline

Phase 1

November 21, 2019	Funding opportunity release
January 21, 2020	Applications due date
February 4, 2020	Notification of award
February 11, 2020	Project implementation start date
May 1-31, 2020	Project conference calls and quarterly data submission
TBD, as requested	Technical Assistance calls
July 31, 2020	Progress report for Phase I

Phase 2

August 1- 31, 2020	Project conference calls and quarterly data submission
September 31, 2020	Project completion: final invoice and final project summary report due to CSTE

*Please note that the timeline is subject to change

Section II. Award Mechanism

Mechanism(s) of Support

CSTE will manage matters related to financial support for this project.

Funds Available

Funding for this project will be firm-fixed. CSTE intends to commit up to \$150,000 per funded project. The final award amount is contingent on submission of a detailed and reasonable budget proposal, to be approved by CSTE.

Funds awarded to contractors under this announcement are subject to the laws, regulations and policies governing the U.S. Public Health Service grant awards. All estimated funding amounts are subject to the availability of funds.

Section III. Eligibility Information

Eligible Applicants

Eligible applicants are any state, local, tribal, and territorial public health organizations or agencies with a population with a range of 30,000 to 100,000 births under surveillance (based on no more than 2 birth years of data) and public health authority to conduct population health surveillance with expertise in the field of substance use, maternal and child health.

Preference will be given to applicants who have justified a substantial burden of NAS or opioid misuse/ overdose by providing data from the state and jurisdiction, and capacity to implement the CSTE NAS Standardized Surveillance Case Definition (Tier 1) will be measured by providing an explanation of the ability to conduct population health surveillance and the existing surveillance system that will be used. CSTE is seeking to fund jurisdictions who have a range of racial/ethnic, socioeconomic and geographic populations to ensure that NAS surveillance is distributed across the U.S. and not clustered to one region.

Section IV. Application and Submission Information

Content and Form of Application Submission

The application should be no longer than 10 pages, and should be written using a 12-point, double-spaced, unreduced, Times New Roman font, on 8.5x11 inch paged paper with one-inch margins. Additional pages or appendices may not be reviewed. Please include the headings below in the order listed and address all the issues included under each heading.

1. Contact Information

- Provide applicant contact information

2. Background

- Describe prior experience in applied epidemiology with an emphasis on substance use, maternal and child health, and NAS surveillance
- If available, please include the current method of identifying NAS cases
- Include size of population that jurisdiction covers and the burden of NAS, provide the rates of births diagnosed with NAS in the state and jurisdiction, racial/ethnic, socioeconomic status information
- Describe how implementing the CSTE NAS Standardized Surveillance Case Definition (Tier 1) will impact public health surveillance in your jurisdiction
- Describe the existing infrastructure (reporting mechanism) for public health surveillance and the capacity to capacity to implement the CSTE NAS Standardized Surveillance Case Definition
- Describe ability to link services for children and provide evaluation metrics

3. Plan/Methods

- Case Identification: Provide a strategy to identify all NAS cases
- Partnerships: Describe applicants' partnerships with local and state public health departments, laboratories (e.g., state, public health and private laboratories), hospitals. Indicate how the partnerships will contribute to the identification of NAS cases
- Personnel: Indicate the personnel that will be involved with the project to ensure timely case identification, chart abstraction, data entry and reporting
- Other Resources: Describe any other resources required for project completion
- Project Deliverables: Describe in detail all the anticipated deliverables for the implementation of the CSTE NAS Standardized Surveillance Case Definition (Tier 1)
- IRB: Indicate if human subject review process for the state is necessary and if so, estimate the length of the process
- Data Sharing Agreements: Indicate if data sharing agreements will be needed and the jurisdiction's anticipated plan for acquiring them
- Describe in detail all the anticipated deliverables for the implementation of the CSTE NAS Standardized Surveillance Case Definition (Tier 1)
- IRB: Indicate if human subject review process for the state is necessary and if so, estimate the length of the process
- Indicate if data sharing agreements will be needed
- Describe in detail all the anticipated deliverables for the implementation of the CSTE NAS Standardized Surveillance Case Definition (Tier 1)
- IRB: Indicate if human subject review process for the state is necessary and if so, estimate the length of the process
- Indicate if data sharing agreements will be needed

4. Budget and Justification

- Provide detailed budget breakdown of costs and budget justification

For further assistance, technical questions, or inquiries about the application, contact Nikka Sorrells at CSTE (770-458-3811 or nsorrells@cste.org). Representatives from CSTE will be available to speak to potential applicants to discuss technical or administrative questions. All questions and answers will be made available to all potential applicants upon request.

Submission Dates and Times

Submission, Review, and Anticipated Start Dates:

- Award Notification Date: within 30 days of submission
- Anticipated Start Date: within 30 days of notification

Submitting an Application:

Application materials should be sent to Nikka Sorrells at nsorrells@cste.org by 11:59 pm ET on January 21, 2020. Notification of successful receipt of the application will be sent to the applicant upon request. Electronic applications are encouraged, however, CSTE will accept applications mailed to CSTE National Office at the following address:

Nikka Sorrells
Council of State and Territorial Epidemiologists
2635 Century Parkway NE, Suite 700
Atlanta, GA 30345

Mailed applications must still arrive by Friday, January 21, 2020 at 11:59 pm ET.

Section V. Application Review Information

Criteria

The following criteria will be used to review all submitted applications:

1. **Background/Project Team (40 points)**
 - a. Applicant demographics and jurisdictional capacity (20 points)
 - i. Burden of NAS or opioid misuse/overdose in state and jurisdiction (5)
 - ii. Size and diversity of birth population (5)
 - iii. Existing infrastructure/ reporting mechanism for public health surveillance (10)
 - b. Demonstrated expertise (20 points)
 - i. Prior experience applied epidemiology with an emphasis on substance use, maternal and child health, and NAS surveillance (20)
2. **Project Plan/Methods (40 points)**
 - a. Detailed deliverables specific to the proposed project (10 points)
 - i. Describe ability and provide a plan to identify all NAS cases using the NAS Standardized Surveillance Case Definition (10)
 - b. Detailed work plan, method, and timeline for completing work (15 points)
 - c. Feasibility of proposed work plan (15 points)
3. **Detailed Budget Breakdown and Justification (20 points)**

Applications will be funded in order by score and rank, as determined by the review panel. The following factors may affect funding decisions.

- Annual live birth population of with a range of 30,000 to 100,000 births (based on no more than 2 birth years of data) socioeconomic status, and racial/ethnic diversity
- Geographic location to ensure capacity for birth defects and NAS surveillance is distributed across the U.S. and not clustered in one region
- Prevalence of opioid misuse/overdose and anticipated case burden of neonatal abstinence syndrome to ensure adequate sample size for analysis

- Authority to ascertain all pregnancy outcomes (i.e., live births, stillbirths, and pregnancy terminations)
- Availability of funds and program priorities

Review and Selection Process

Completed eligible applications submitted by the deadline will be evaluated for scientific and technical merit by CSTE in accordance with the review criteria stated above. A review panel of the CSTE National Office staff and subject matter experts will score each application. Funding awards will be made based upon the quality of the submitted proposal and the ability of the applicant to meet the criteria stated above.

Section VI. Award Admission Information***Award Notices***

All applicants will be notified via email within 30 days of application submission.

Award Recipient Responsibilities

The award recipient will have primary responsibility for the following:

- 1) Accomplish the objectives and deliverables listed in this announcement
- 2) Provide written progress reports and invoices to CSTE as required in the contract agreement
- 3) Be available through multiple avenues for feedback and discussion (conference calls, emails, etc.) on a regular basis
- 4) Actively engage partners and stakeholders

CSTE Responsibilities

CSTE will have the primary responsibility for the following:

1. Serve as the awardee's principal point of contact
2. Facilitate work and provide avenues for communication between awardee and stakeholders
3. Monitor the terms of the agreement
4. Fund according to the terms of the contract agreement

For More Information

For more information, contact:

Nikka Sorrells
Council of State and Territorial Epidemiologists
2635 Century Parkway NE, Suite 700
Atlanta, GA 30345
770-458-3811 (phone)
770-458-8516 (fax)
nsorrells@cste.org

References

1. Krans EE, Patrick SW. Opioid Use Disorder in Pregnancy: Health Policy and Practice in the Midst of an Epidemic. *Obstet Gynecol.* 2016;128(1):4-10.
2. Patrick SW, Schiff DM, Committee On Substance USE, Prevention. A Public Health Response to Opioid Use in Pregnancy. *Pediatrics.* 2017;139(3).
3. CSTE, Neonatal Abstinence Syndrome (NAS) Environmental Scan and Key Informant Interview Analysis Report,
[https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/NAS Environmental Scan Repor.pdf](https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/NAS_Environmental_Scan_Repor.pdf)

Appendix A: Variables of Interest

Category	Variable	Notes
Demographic/General	State or jurisdiction	
	Neonate date of birth or admission	Day/month/year or Month/year formats acceptable
	Neonate date of discharge	
	Vital status at discharge	
	GA at birth	
	Birth weight	
	Birth head circumference (cm)	
	Sex at birth	
	Maternal age	
	Maternal race	
	Maternal ethnicity	
	Maternal county of residence	Optional
	Payer for birth hospitalization	Optional
NAS	Categorization of case by CSTE Standardized Surveillance Case Definition (tier 1)	e.g., confirmed, Probable type 1, Probable type 2, Suspected type 1, Suspected type 2, Suspected type 3, Suspected type 4, or Suspected type 5
	Substances screened positive on maternal toxicology screen in 4 weeks prior to delivery	All substances (not just opioids, benzodiazepines, and barbituates)
	Substances screened positive on neonatal toxicology screen	All substances (not just opioids, benzodiazepines, and barbituates)
	Opioid, benzodiazepine, and/or barbituate substance use in 4 weeks prior to delivery by maternal history	
	Other drug use by maternal history in 4 weeks prior to delivery	All substances (include tobacco, alcohol, all prescription drugs, and illicit drugs)
	Complete list of discharge diagnosis codes for neonate	
	Whether pharmacologic therapy for NAS required for neonate	
	Start date of pharmacologic therapy for NAS	Optional

NAS	End date of pharmacologic therapy for NAS	Optional
	Number of days in step up care (e.g., NICU or level 2 nursery rather than well baby nursery or hospital floor unit)	
	Other birth defect diagnoses	
	Type of NAS scoring used in hospital record	
	Date of first NAS score	
	Date of highest NAS score	
	Date of last NAS score	
	Highest NAS score	
	Documented plan of safe care in discharge planning	
	Documented referral to early intervention services in discharge paperwork	
	Type of nutrition for majority of feeds (e.g., breastmilk, formula)	
	Delivery of nutrition for majority of feeds (e.g., breast, bottle, ng tube)	

***Note that the above is a preliminary list and subject to potential modification. Notice of any modifications will be provided to award recipients.**