STRENGTHENING HEALTH AGENCIES' NEONATAL ABSTINENCE SYNDROME SURVEILLANCE THROUGH CONSENSUS-DRIVEN DATA STANDARDS AND PRACTICES

SEPTEMBER 2021

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DISCLOSURES:

This internal report was prepared by the Association of State and Territorial Health Officials (ASTHO) for the Office of the National Coordinator (ONC) as part of a an awarded contract opportunity through Briljent under State Technical Assistance (TA) HHSP23320160000291 75P00120F37002 for Task 1: Neonatal Abstinence Syndrome (NAS) Project.

EXECUTIVE SUMMARY

The rise of the opioid epidemic also marked an increase in the incidence of Neonatal Abstinence Syndrome (NAS). This prompted a nationwide effort to uncover what data elements are currently being collected as part of NAS surveillance.

ASTHO conducted an environmental scan consisting of a literature, policy, and guidelines review and convened a series of multi-state focus groups with health agencies to identify and determine the consistency of key NAS data elements, case definitions, and standards in the field. Focus groups were convened from eight states: Florida, Ohio, and Virginia for one session, and Alabama, Arizona, Minnesota, Tennessee, and Texas for another. Most states diagnosed NAS based on existing ICD-9 (779.5) and ICD-10 (P96.1) codes, while others considered incorporating the Council of State and Territorial Epidemiologists NAS case definition.

There are variations in NAS data elements collected by states, which include patient demographics, race/ethnicity, age, education, insurance status, Medicaid status, opioid exposure/history of use, and length of hospitalization. ASTHO compiled a list of common data elements that some or all states are collecting around NAS. States also shared challenges in establishing data linkages but expressed interest in exploring partnerships with Health Information Exchanges (HIEs) and Patient Drug Monitoring Programs.

From these findings, ASTHO determined a need for standard data elements, noting inconsistencies in NAS case definitions across states, the extent to which stakeholders were using NAS data, and how NAS data was being used. To address these challenges, ASTHO and our partners at EMI Advisors LLC supported the launch of a NAS data element submission tool using consensus-based voting to create a master list of NAS data elements, a data dictionary, and a template request for proposals to support health agencies in building a NAS registry.

Across states, ASTHO also captured information on key stakeholders (listed below) involved with NAS data, including (but not limited to) Perinatal Quality Collaboratives, Medicaid, hospital associations, HIEs, birth defects registries, vital statistics, and health agencies at large. Health agencies should consider developing or strengthening relationships with these stakeholders in their continued work to build capacity for NAS data collection and surveillance. Additionally, health agencies should consider how their stakeholders may interact with a state NAS registry.

KEY STAKEHOLDERS
Perinatal Quality Collaboratives
Medicaid
Hospital Associations
Health Information Exchanges
Birth Defects Registries
Vital Statistics
Health Agencies

With our partners Briljent and EMI Advisors LLC, ASTHO compiled information and worked with health agencies over the past year to understand and develop approaches for strengthening NAS data collection and surveillance, which are captured in the following considerations:

1. Build a registry for NAS.
2. Achieve consensus through a data element submission tool process to inform standards around NAS data elements and case definitions.
3. Understand the landscape of NAS surveillance capacity.
4. Improve data sharing between public health and Medicaid.
5. Expand Medicaid's capacity to use NAS data.

This report reviews findings from the literature and current public health practices for NAS data collection and surveillance. We incorporate these findings into considerations for health agencies to include a preliminary list of data elements that state health agencies are collecting on which was derived from focus groups. We also include an overview of available NAS guidance and case definitions that have been developed in the field and can be used as a reference point for health agencies in building a registry. We outline the process for achieving consensus from health agencies on a master list of data elements, and include those resources in an appendix.

INTRODUCTION

ASTHO summarizes takeaways from the available literature and public health practices of health agencies in this introduction. These takeaways include the challenges inherent in diagnosing NAS, common definitions that have been crafted to assist with identifying a case, and an overview of information from our focus groups with health agencies on how they are capturing NAS cases. We also discuss this public health issue in the context of COVID-19.

Neonatal abstinence syndrome (NAS) is a disorder in infants resulting from withdrawal from opioids and other substances in utero. The incidence of NAS in the United States has increased, parallel to the opioid epidemic, over the past decade. According to 2017 Healthcare Cost and Utilization Project data, seven newborns were diagnosed with NAS for every 1,000 newborn hospital stays. While the definition varies between providers, most define the disorder as a constellation of signs and symptoms of withdrawal experienced by the newborn following in utero exposure to medications or illicit drugs, most commonly opioids, benzodiazepines, and barbiturates. Other substances—including nicotine, alcohol, and other prescription medications—can exacerbate NAS. Furthermore, a diagnosis of NAS may result in health conditions that require treatment in the neonatal intensive care unit and pharmacological and/or non-pharmacological interventions. Infants born with NAS are at increased risk of preterm birth, congenital anomalies, and impaired neurodevelopment. In 2019, the Council of State and Territorial Epidemiologists (CSTE) proposed a nationally standardized case definition to capture surveillance measures across jurisdictions to inform clinical and public health treatment and prevention efforts.

Similarly, several jurisdictions are implementing activities to enhance functionality and improve surveillance in their own states. While most of the participating jurisdictions in the environmental scan (43-of-52) used hospital discharge data as the primary data source, and of that, 13 used Medicaid claims data. Currently, NAS surveillance in the United States is largely based on diagnosis codes in hospital discharge data, without validation of codes or confirmation of cases. Most states reported collecting NAS data through passive surveillance processes.

During focus group sessions, held in March 2021, states reported the following primary methods for defining NAS and capturing cases:

- Defining NAS based on existing ICD-9 (779.5) and ICD-10 (P96.1) codes, and using birth certificate and hospital discharge data to support NAS surveillance.
- Exploring how to incorporate CSTE's case definition into their data collection efforts.
- Using Research Electronic Data Capture to collect NAS-related data.

Additionally, while there is no national surveillance system for NAS, at least 11 states have made the diagnosis of NAS as a notifiable condition. The notification process, in which a healthcare provider or facility must notify the state health department, can support monitoring the prevalence of NAS cases. ASTHO continues to monitor policy and programmatic activity related to surveillance of NAS across jurisdictions.

OVERDOSE RATES IN THE CONTEXT OF COVID-19

Across the country, states have universally reported an increase in overdose rates since the onset of the COVID-19 pandemic. Heightened stress and social isolation are likely contributing factors to the increase in opioid use over the past year. Individuals with opioid use disorder are at an increased risk of contracting COVID-19 and have higher prevalence of known risk factors.

This is especially true for pregnant individuals experiencing opioid use disorder (OUD) who face unique barriers to care and treatment, including stigma and implicit bias, lack of access to medication assisted treatment, involvement of child welfare, transportation, and cost. While these barriers existed pre-pandemic, restrictions put in place secondary to COVID-19 have worsened these unmet needs.

To prevent NAS, it is imperative that women have access to prenatal care services. With access to providers limited, and reported increases in opioid use, systems should prepare to care for and treat increased numbers of infants with NAS.

CONSIDERATIONS FOR HEALTH AGENCIES TO IMPROVE NAS SURVEILLANCE

ASTHO includes key considerations for health agencies that wish to improve NAS data collection and surveillance through the development of a registry. These considerations are further described with consideration for health agencies' current capacity to collect data elements, leverage activities in the field that strengthen NAS surveillance, and apply a common case definition.

1. Build a registry for NAS.
2. Understand the landscape of NAS surveillance capacity.
3. Achieve consensus through a data element submission tool process to inform standards around NAS data elements and case definitions.

Improve data sharing between public health and Medicaid agencies with a goal of expanding their capacity to use NAS data.

BUILD A REGISTRY FOR NAS

While there are immense variations in the scope, size, and resources required to build registries, this method of data collection and exchange between partners represents one avenue for collecting standard information across the country. Registries maintain flexibility in the amount of data collected, operation duration, resources required to maintain operation, and target populations, which can be expanded based on new information or research.[1]

Steps to build a registry include:

1. Identify a purpose.
2. Determine if a registry is an appropriate means to achieve the purpose.
3. Identify key stakeholders and how they have used or interacted with registries for other conditions.
4. Assess feasibility.
5. Build a registry team.
6. Establish a governance and oversight plan.
7. Consider the scope and rigor needed.
8. Define the core data set, patient outcomes, and target population (data element submission process).
9. Develop a study plan or protocol.
10. Develop a project plan.

UNDERSTAND THE LANDSCAPE OF NAS SURVEILLANCE CAPACITY

ASTHO conducted an environmental scan from fall 2020 to spring 2021 to better understand how state and territorial health agencies conduct NAS surveillance and what gaps remain related to capacity, feasibility, and data standards. Information was sourced from literature and guidance documents prepared by several national organizations and associations. ASTHO also conducted focus groups in March 2021 to understand what states were referencing for NAS case definitions and data elements.

While Table 1 does not capture the full range of data elements a state or territorial health agency collects, it does represent the data elements most commonly found in the literature and/or used by these agencies. The definitions referenced include both informally and formally published definition, where one was documented. This table provides a starting point for creating a core or minimum data set. Unique data elements not included in this table will make up a larger NAS compendium and be discussed for relevance

and utility during the consensus-driven approach that comprises the data element submission tool process.

TABLE 1. NAS DATA ELEMENTS USED BY HEALTH AGENCIES

DATA ELEMENTS	DEFINITION	SOURCE
Patient Demographics (Maternal/Infant)	Examples include race, sex, ethnicity, locality, primary spoken language, placement of child (residence vs. foster care). [5,6]	ASTHO Multi-State NAS Surveillance Focus Group (AL, AZ, FL, MN OH, TN, TX, VA)
Insurance Status	Insurance status included those enrolled in Medicaid or a Woman, Infants, Children program.[5,6] Infants with NAS covered by Medicaid had hospital stays that were significantly longer than infants without NAS who were covered by Medicaid or infants with NAS who were covered by private insurance.[14]	ASTHO Multi-State NAS Surveillance Focus Group (AL, AZ, FL, MN OH, TN, TX, VA) Kentucky NAS Reporting Registry - Annual Report 2019
Type of Drug Exposure	Most states favor a broader definition that is not limited to opioids, with the logic that there are other substances that cause neonatal dependence and withdrawal, and systems need to be made flexible as additional substances emerge. A minority of states also favored adding tobacco and alcohol to a surveillance system.[16]	Council of State and Territorial Epidemiologists
Maternal History of Substance Use	Maternal drug history and maternal use of other substances (e.g., cigarettes, benzodiazepines, gabapentin) that may influence the onset, severity, or duration of the withdrawal syndrome.[10]	Official Journal of the American Academy of Pediatrics
Opioid Exposure	Lab testing for infant and mothers for opioid exposure or history of opioid exposure.[6]	ASTHO Multi-State NAS Surveillance Focus Group (AL, AZ, MN, TN, TX)
Hospital Length of Stay by NAS Status	Infants with NAS have a much longer length of stay than non-NAS infants. (13.38 days vs. 3.76 days).[14]	Kentucky NAS Reporting Registry - Annual Report 2019
Number of NAS Cases	States defined NAS based on existing ICD-9 (779.5) and ICD-10 (P96.1) codes.[5]	ASTHO Multi-State NAS Surveillance Focus Group (FL, VA, OH)
Withdrawal Signs/ Symptoms	Examples include (but are not limited to) tremors, hyperactive reflexes, hyperirritability, excessive sucking, excessive crying, and inability to feed.[15]	Georgia NAS Annual Surveillance Report - 2017

DATA ELEMENTS	DEFINITION	SOURCE
Medication for Opioid Use Disorder	Having a valid prescription for opioid replacement therapy[14]	Kentucky NAS Reporting Registry - Annual Report 2019
Type of Medical Assistance to Treat NAS	Includes medical assistance treatment and/or legal/nonlegal prescription of opioids.[17]	Medication-Assisted Treatment

TABLE 2: OVERVIEW OF ACTIVITIES TO STRENGTHEN NAS SURVEILLANCE BY ORGANIZATION

DATA ELEMENTS	DEFINITION
American Academy of Pediatrics (AAP)	AAP has issued guidance and literature on care and treatment protocols for infants exposed to substances in utero.[18]
American College of Obstetricians and Gynecologists (ACOG)	In 2017, ACOG released a committee opinion on opioid use and opioid use disorder during pregnancy. The committee opinion outlines necessary care and treatment for pregnant individuals, including access to medication assisted treatment.[19]
American Academy of Family Physicians (AAFP)	AAFP released Medical Treatment Options for Opioid Use, including care and treatment options for pregnant individuals experiencing opioid use disorder and their infants.[20]
Association of Public Health Laboratories (APHL)	APHL is working with a group of stakeholders to define the role of public health laboratories in opioid bio-surveillance, including NAS surveillance.[21]

CSTE developed a national standardized case definition for NAS, which it recommends states use. The following states are considering or have already adopted the CSTE case definition:

TABLE 3: STATUS OF STATES ADOPTING THE CSTE NAS CASE DEFINITION

STATE	CSTE NAS CASE DEFINITION STATUS	SOURCE
Florida	In consideration.[5]	CSTE, ASTHO Multi-State NAS Surveillance Focus Group (FL, VA, OH)
Tennessee	Adopted.[6]	CSTE, ASTHO Multi-State NAS Surveillance Focus Group (AL, AZ, MN, TN, TX)
Minnesota	Adopted.[6]	CSTE, ASTHO Multi-State NAS Surveillance Focus Group (AL, AZ, MN, TN, TX)

ACHIEVE CONSENSUS THROUGH A DATA ELEMENT SUBMISSION TOOL PROCESS TO INFORM STANDARDS AROUND NAS DATA ELEMENTS AND CASE DEFINITIONS

ASTHO partnered with EMI Advisors to design and deploy a data element submission tool that all state and territorial health agencies can use to achieve consensus on Neonatal Abstinence Syndrome (NAS) surveillance. The NAS Data Element Tool (DET) visualizes the results of literature and guidance review along with focus group interviews with eight states. This tool informs considerations for building a NAS registry by standardizing what data elements need to be collected and how they are to be defined through a consensus-driven approach by state and territorial health agencies. The tool's strengths are its flexibility and scalability for future applications. The live version of the NAS DET Dashboards can be accessed by following this link: https://www.emiadvisors.net/nas-det-dashboard

The steps in this process discussed further in this section include:

1. Identification of data elements and case definitions through literature review, focus group feedback, and identification of existing NAS data collection tools.
2. Administration of the Case Definition and Data Element survey.
3. Subject matter expert review of the results of the survey.
4. Consensus voting from the state health agencies for the resulting case definition analysis and master data element list.

Table 4 on state health agency participation identifies 18 state health agencies who participated in various steps of the process in addition to the focus group states described earlier in this report.

TABLE 4. STATE HEALTH AGENCY PARTICIPATION

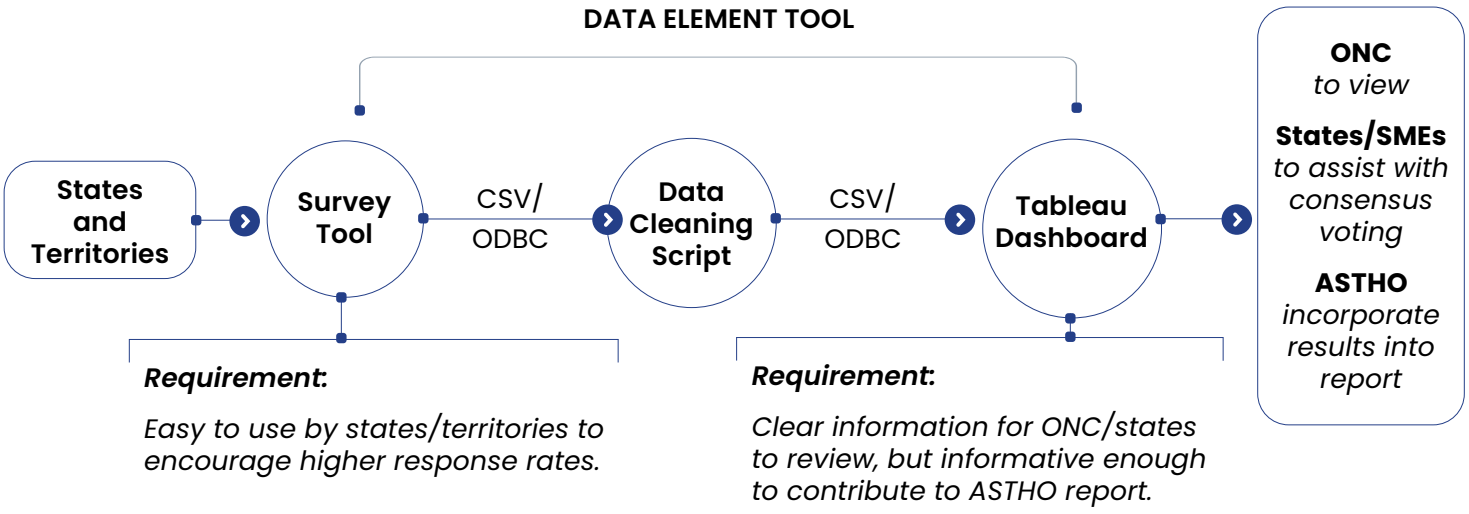
STATE	DATA ELEMENT TOOL SURVEY	CASE DEFINITION SURVEY	SUBJECT MATTER EXPERT REVIEW	CONSENSUS VOTING
Alabama	No	No	Yes ✓	No
Alaska	No	Yes ✓	No	No
Arizona	Yes ✓	Yes ✓	Yes ✓	Yes ✓
Florida	Yes ✓	Yes ✓	No	Yes ✓
Illinois	Yes ✓	Yes ✓	No	Yes ✓
Indiana	No	Yes ✓	No	No
Missouri	Yes ✓	Yes ✓	No	Yes ✓
Nevada	Yes ✓	Yes ✓	No	No
New Mexico	No	No	Yes ✓	Yes ✓
North Dakota	Yes ✓	Yes ✓		
Total:	**14**	**15**	**3**	**9**

STATE	DATA ELEMENT TOOL SURVEY	CASE DEFINITION SURVEY	SUBJECT MATTER EXPERT REVIEW	CONSENSUS VOTING
Ohio	Yes ✓	Yes ✓	No	Yes ✓
Pennsylvania	Yes ✓	Yes ✓	No	No
Rhode Island	Yes ✓	Yes ✓	No	Yes ✓
South Carolina	Yes ✓	Yes ✓	No	No
Tennessee	Yes ✓	Yes ✓	No	No
Texas	No	No	No	Yes ✓
Vermont	Yes ✓	Yes ✓	No	Yes ✓
West Virginia	Yes ✓	Yes ✓	No	No
Total:	**14**	**15**	**3**	**9**

DATA ELEMENT TOOL

The process to extract insight from survey data was simplified and automized by the DET (Figure 1):

FIGURE. 1 WORKFLOW OF THE DET DASHBOARD



NAS DATA AND SURVEILLANCE SURVEY

The NAS survey instrument is designed to gather information from states and territories regarding two aspects of a NAS data registry: case definition and data elements. Literature review and discussions with the states participating in focus groups over the last several months were used to identify an initial set of definitions and data elements to include in the survey. The responses to the survey serve to:

1. Obtain feedback on the status of development and implementation of a NAS case definition and report on the variation in definitions across the states.
2. Gather additional data elements for consideration from states that were not part of the focus groups.
3. Identify core and optional data elements to include in a NAS data registry, as well as the feasibility of implementation.

Aspects of case definitions that were surveyed were:

- Use of definitions identifying confirmed, probable, or suspected cases.
- Focus of the substance use included in the definition, ranging from only opioids to a broader list of substances.
- The specific guidelines used to determine the diagnosis of NAS.

The data element section of the survey was populated with data elements from focus group states that currently have a data registry. It is organized by type of data elements, such as maternal substance use, neonatal assessment, and demographics. Survey respondents were provided with the definition and reference for each data element and asked to identify what they would consider a core or optional element. The survey enabled respondents to add any missing data elements or upload a copy of their data collection tool.

NAS DET DEVELOPMENT

1. EMI Advisors and ASTHO first surveyed 15 people from participant states through a web-based survey application designed to be intuitive and easy-to-use for participants. The full list of survey questions are available for download. The DET can process several types of data inputs such as CSV/Excel files or a direct Open Database Connectivity connection to the survey tool. It can also be scaled up to crunch big data.
2. The survey data was exported as a CSV file and cleaned and curated by an R script. The DET can host a live database so data inputs can flow in, be cleaned automatically, and populate a dashboard without any host intervention.
3. A CSV file of the cleaned data is used to populate the NAS DET Dashboard created using Tableau. The DET can elicit meaning from data using any dashboard and visualization tools necessary such as Qlik, Excel, Tableau, and others to tell a story.

While designing this tool, there was a large emphasis on flexible architecture and ease of sharing. In the future, this tool can be used for other projects of a variety of purposes and project designs. This tool is scalable and is able to process other inputs and produce other visualizations. Time of submission and open-ended responses are also a function of this tool.

NAS DET DASHBOARDS

The dashboards created are flexible in the visualizations they can display. This allows the dashboards to answer specific questions based on the data the user needs to leverage. The dashboards also have built-in interactivity leveraged to improve the user experience. This interactivity has two main functions:

1. **Exploration:** The user can choose the level of detail they need by navigating through the dashboards. This allows the dashboards to contain more information without overwhelming the user. The user can drill down to more specific viewpoints as needed.
2. **Stories:** The user can be guided towards specific information or answers. This can be extremely useful in a scenario where the users aren't looking to answer the questions themselves but are being presented with the answers.

The live dashboards are embedded in the NAS DET website hosted by EMI to ensure easy viewing to a large audience, including the survey respondents, project stakeholders, and the public. The dashboards were also recreated with a set of colors that allows colorblind people to view it. The dashboards display the current usage and feasibility of Case Definitions and Data Elements as perceived by the states. The Case Definitions Dashboard allows users to glean how many states in the focus group use or would consider using this case definition and what is the feasibility of implementing this case definition. Users can read the full case definitions by clicking on their respective bars in the bar chart.

The second dashboard allows users to understand if a specific data element is essential to a NAS registry and what is the feasibility of tracking this data element. Data elements have been grouped by categories such as "Infant Demographics and Hospitalization" and "Maternal Substance Use." By selecting a single category, users can isolate related data elements. By selecting an individual data element, users can view any accompanying information.

NAS SURVEY SUMMARY ANALYSIS

On Aug. 23, 2021, ASTHO and EMI presented the NAS Data and Surveillance Survey and facilitated a formal Subject Matter Expert (SME) review process. The initial results of the survey were reviewed by a group of SMEs convened by ASTHO. The SME pool was composed of officials of other public health organizations, academic organizations, and state health agencies leading NAS data collection, registry development, or surveillance. The NAS DET dashboards were demoed, and the link was made available to all participants. This review process included analyzing responses, as well as evaluating additional NAS case definitions and data elements provided by the survey respondents.

Based on this review, a proposed list of NAS case definitions and master data elements was presented to the states and territories for a consensus vote. A total of six SMEs completed a comprehensive review process. Their input, along with NAS survey results, enabled the creation of the Consensus-Based Voting Survey for Neonatal Abstinence Syndrome Surveillance and Data that can be found here. Consensus voting allowed for a final review of the proposed master list and the incorporation of any additional feedback from states and territories.

ASTHO observed and documented the ways in which the process succeeded in achieving consensus toward a minimum core data set and common definition for NAS. Further discussions will seek to understand whether this process is feasible for other conditions in future projects.

NAS CASE DEFINITION ANALYSIS

The case definition section of the NAS Data and Surveillance Survey consisted of two parts. The first part consisted of an initial question identifying the state or territorial health agency's status of development or implementation of a NAS case definition. The second part of this section listed 18 definitions compiled from states currently collecting this data, focus groups, and the literature review. Respondents could select one or more definitions to answer two questions on definition feedback and implementation feasibility.

PART ONE: CASE DEFINITION STATUS

STATUS	# OF RESPONDENTS
Currently Use a Case Definition	10
Considering Adopting a Case Definition	3
Not Using a Case Definition	2

Fifteen respondents completed this section of the survey.

PART TWO: CASE DEFINITIONS

Respondents could select one or more definitions to answer two questions. One definition had 12 responses and three definitions had one response. The definitions that received at least four responses are listed as part of the analysis of the survey results.

1. Definition Feedback
    1. Currently use this definition.
    2. Currently use this definition but in the process of revising.
    3. Considering or would consider adopting this definition.
2. Implementation Feasibility
    1. Currently feasible.
    2. Not feasible at present but can be in the future.
    3. Not sure of feasibility.

DEFINITION	RESPONSE SUMMARY
Confirmed – Council of State and Territorial Epidemiologists (CSTE) Tier 1 Hospitalized neonate (<28 days) or neonate (<28 days) admitted to residential pediatric recovery center AND Diagnosis NAS with confirmatory neonatal laboratory evidence OR Chief complaint mentions NAS with confirmatory neonatal laboratory evidence OR Three or more signs of neonatal withdrawal and confirmatory neonatal laboratory evidence.	This definition received the most responses for "currently using" four with an additional eight respondents indicating they would "consider adopting." Pennsylvania's current definition is also consistent with the CSTE Tier 1 definition.

DEFINITION	RESPONSE SUMMARY
Confirmed - CSTE Tier 2 Neonate (birth hospitalization, or a hospitalization or similar clinic admission before 28 days of age) and any diagnosis of P96.1. Neonatal withdrawal symptoms from maternal use of drugs of addiction.	Eight respondents indicated that they use either the CSTE Tier 2 definition or a similar one using the ICD-10-CM code P96.1 to identify cases. An additional three respondents indicated they would consider adopting this definition. Another state uses P96.1 in addition to several additional ICD-10-CM codes based on maternal use of substances such as opiates, sedative-hypnotics, anxiolytics. These definitions are only based on ICD-10-CM codes to identify cases.
Confirmed - Virginia ICD-10-CM code 96.1 'Neonatal withdrawal symptoms from maternal use of drugs of addiction' during first 28 days of life.	Three respondents indicated that they are currently using this definition and one would consider adopting it.
Probable - CSTE Tier 1 Type 1 Maternal history of chronic opioid use (including MAT, illicit use, or pain medication), or benzodiazepine or barbiturate use in the four weeks prior to delivery AND Diagnosis of NAS OR Chief complaint of NAS OR Three or more signs of withdrawal and no or unknown laboratory evidence in the neonate.	Five respondents indicated that they would use this case definition with three additional respondents indicating they would consider using this definition. Note, the Pennsylvania definition is a combination of both CSTE Tier 1 Type 1 and 2.
Probable - CSTE Tier 1 Type 2 Confirmatory Maternal laboratory evidence in the four weeks prior to delivery AND Diagnosis of NAS OR Chief complaint of NAS OR Three or more signs of withdrawal and no or unknown laboratory results in the neonate.	Five respondents indicated that they would use this case definition and three additional respondents indicated they would consider using this definition. Note, the Pennsylvania definition is a combination of both CSTE Tier 1 Type 1 and 2.
Suspected - CSTE Tier 1 Type 2 Maternal history of chronic drug use of unknown type in the four weeks prior to delivery AND Diagnosis of NAS OR Chief complaint of NAS OR Clinically compatible presentation with three or more signs of withdrawal and no or unknown laboratory results and no or unknown maternal laboratory results.	One respondent is currently using this definition and three would consider adopting this definition.
Suspected - CSTE Tier 2 A neonate whose healthcare record does not contain any diagnosis of neonatal drug withdrawal AND contains any diagnosis noting maternal use of opiates, sedative-hypnotics, or anxiolytics within the birth hospitalization or a hospitalization or similar clinic admission before 28 days of age	Four respondents indicated that they would consider adopting this definition.

SUBJECT MATTER EXPERT REVIEW

Six subject matter experts representing different organizations provided input based on their preferred case definitions for health agencies to use. The following table summarizes their responses to the four questions listed. The preferred definitions listed in Question 1 are all in the list of case definitions with the highest response from the respondents of the survey with the exception of Arizona (see comment in Question 1 response summary).

QUESTION 1: DO YOU HAVE A PREFERRED DEFINITION FOR CONFIRMED, PROBABLE, AND SUSPECTED CASE DEFINITIONS FROM THE DEFINITIONS LISTED?

Response Summary

The Council of State and Territorial Epidemiologists (CSTE) definitions were preferred by all six reviewers.

- Confirmed Tier 1 selected by two reviewers.
- Confirmed Tier 2 selected by two reviewers.
- Probable Tier 1 Type 1 selected by one reviewer with the comment. It allows for maternal history in lieu of confirmed maternal positive drug screen which may be absent in some cases.
- Probable Tier 1 Type 1 and Type 2 (Pennsylvania definition) was selected by one reviewer.
- Suspected Tier 2 was selected by one reviewer.
- CSTE or other adopted definition instead of state-specific selected by two reviewers.

Arizona - Probably and Suspected definitions selected by one reviewer (note: Arizona indicated it was in the process of revising its definitions).

QUESTION 2: WHAT DO YOU THINK IS THE FEASIBILITY OF DEVELOPING OR PROPOSING AN EXISTING STANDARD DEFINITION THAT COULD BE USED ACROSS STATES AND TERRITORIES?

Response Summary

All reviewers felt that a standard definition across all states and territories is important and feasible.

Reviewer 1: Feasibility would be high and necessary. Disparate data from different states makes understanding the national scope of the affected population challenging. The implementation may be challenging, but many practitioners have acknowledged the need for a standard definition. This means the readiness and openness to it will prime any rollout.

Reviewer 2: From a practical standpoint, I think we need common definitions. Getting everyone to use them will be a different matter, but maybe because this is in the "infant" stages, we can start moving states toward standard definitions.

QUESTION 2: WHAT DO YOU THINK IS THE FEASIBILITY OF DEVELOPING OR PROPOSING AN EXISTING STANDARD DEFINITION THAT COULD BE USED ACROSS STATES AND TERRITORIES?

Reviewer 3: If the purpose is to standardize surveillance and epidemiologic tracking, then a standard definition should be used, and should be feasible. If the purpose is to allow states to provide family-specific interventions, services, and follow-up, then definitions will likely need to vary between states, depending on state resources and goals.For example, a state with robust Early Intervention (EI) services that seeks to engage as many opioid-exposed newborns in EI as possible might use a definition that is broader, perhaps only focusing on opioid exposure; a state with limited EI services that needs to be more selective in which infants are enrolled in EI might use a more specific definition that identifies higher risk infants, perhaps including both opioid exposure as well as neonatal symptoms as well as maternal factors.

Reviewer 4: I think it is feasible, as long as there are some exceptions/variabilities allowed.

Reviewer 5: I think it is very feasible. Like CSTE's, attention will have to be given to what is the purpose of a common criteria. The rationale behind CSTE's was to be able to better compare numbers, effectiveness of interventions, etc. CSTE also did not look to replace whatever each jurisdiction was doing but to offer a way to produce comparable data beyond the needs of each jurisdiction. The second item is to understand the obstacles that are encountered in order to be compliant with a definition. Again, in the CSTE, the two-tiered structure was based on what was available for different jurisdictions and/or their capabilities (i.e., time, personnel, etc.).

Reviewer 6: Testing the CSTE case definition and revising as appropriate. This will become increasingly important as laboratory testing becomes more available and specific.

Application of laboratory aspects of the case definition will likely require significant input from, and collaboration with, public health and/or clinical laboratories in individual states and territories. Jurisdictions will likely need to determine which entities will do the testing, which methods will be developed and validated, which specimen matrices will be analyzed, and how the laboratory data will be reported/to whom.

Furthermore, jurisdictions will need to ensure equitable and non-stigmatizing processes for selection of infants for testing, ensuring that a high level of privacy/confidentiality is upheld and that mothers are protected from punitive law enforcement actions.

QUESTION 3: IF FEASIBLE, WHAT WOULD BE INVOLVED IN MOVING A STANDARD DEFINITION FORWARD?

Response Summary

Three reviewers propose some form of initial consensus process with comments, such as:

Reviewer 1: Multiple stakeholders will need to be publicly part of the process to earn the trust of practitioners being asked to implement the new definitions.

QUESTION 3: IF FEASIBLE, WHAT WOULD BE INVOLVED IN MOVING A STANDARD DEFINITION FORWARD?

Reviewer 2: If one or two national groups endorse definitions, then other states are prompted to put together teams to look at them and consider adopting.

Reviewer 3: If a standard definition was desired for epidemiologic surveillance, probably most feasible would-be definitions based on ICD-10 codes (for example, CSTE confirmed Tier 2). Then what is needed to make this definition 'standardized' is more widespread agreement on how these ICD codes should be used, meaning what are the clinical criteria need for P96.1 and what are the clinical criteria need for the P04 codes. These criteria might be based on laboratory testing, maternal history, or neonatal course, but it seems like this should be doable.

Reviewer 4: Another reviewer included the need for 'Support for the definition in general, technical support for implementing and designing/guiding data collection, possible financial support to help states develop systems' as part of the implementation of a standard definition.

Reviewer 5: I believe I may have responded to this question as part of my previous response. I believe that one thing to add would be to make clear the distinction between substance-exposed neonate (which includes more substances than drugs) – drug-exposed neonates – and NAS. Also, NAS vs NOWS (which I see as a subset of NAS).

Another thing is that the surveillance definitions require that a diagnosis has been provided and or symptoms identified as due to the exposure to drugs of interest. Two issues are present here (if not more). One is/are the clinical criteria employed (which may itself be very diverse, introducing an artifact). Other, the instruments used (i.e., Eat-Sleep-Console, Finnegan) and how are they used and interpreted. If different ones, how to make them comparable. Finally, for those using ICD-10-CM codes, how text is translated into a code. That is, not mentioning whether subjective criteria may bias what is written (i.e., to avoid stigmatization or the contrary).

Reviewer 6: Adoption of a standardized case definition nationally, agreement that a national NAS registry is a good idea. There is considerable concern among clinicians and others as to how these data will be used. Understanding the different types of laboratory data, its uses, and limitations.

Incorporation of laboratory data in a NAS registry may not be feasible and is dependent on resources/expertise/laws within the state. Laboratory data alone should not be used to classify cases of NAS.

Understanding testing limitations and scopes is the only way to compare data from state to state.

QUESTION 4: DO YOU HAVE ANY OTHER COMMENTS REGARDING THE CASE DEFINITIONS?

Response Summary

Reviewer 1: I would suggest any probable and suspected cases of NAS not require a maternal positive drug test if neonate symptomatology is present. This reinforces stigmatizing practices and should only be employed for a confirmed test.

QUESTION 4: DO YOU HAVE ANY OTHER COMMENTS REGARDING THE CASE DEFINITIONS?

Reviewer 2: Why have three levels? Might be better to have confirmed and suspected/probable, two categories.

Reviewer 3: Both for surveillance and for directing services, I think the most important aspect of the definition is opioid-exposure, and NOT symptoms of withdrawal. If two infants are born to mothers using illicit opioids during pregnancy, but only one develops withdrawal symptoms for whatever quirk of biology, it seems both dyads should be included in both surveillance and allocation of resources. Definitions based on clinical symptoms could be useful when there is not a confirmed history of opioid exposure, but the clinical course is suggestive of neonatal opioid withdrawal without other possible causes. Thus, I might favor a definition along the lines of: "Newborn exposed to opioids during pregnancy, by maternal report, maternal record, or maternal or neonatal laboratory testing", OR "Newborn with clinical findings consistent with neonatal opioid withdrawal with all other potential causes of the symptoms ruled out, and no maternal history of opioid use is identified."

Review 4: No Comment

Reviewer 5: As I mentioned, I think having a common definition is important, as a big picture. If this will be moved into a reporting to CDC, then it needs to be accompanied by lots of assistance for implementation, both economically and politically.

I will list below some additional issues I find:

1. Prescription Drug Monitoring Programs have information on prescriptions filled. Not every jurisdiction has access to them or, if they do, is limited. That information should be available in a manner for it to be linked to other data sources.
2. Data on treatment (i.e., MAT) also needs/has to be available in a manner for it to be linked to other data sources. Although better outcomes have been reported for mothers in MAT, the risk of NAS is not zero.
3. Toxicology data is required to confirm a case. However, there is no consensus on who gets tested. I would consider universal testing to reduce bias.
4. Data stewardship in each jurisdiction should be allocated by expertise. If surveillance, to an epidemiology area or to a program that has data analysis capability. Some allocations are not based on that. In my state, NAS surveillance is not performed by the same outfits having the stewardship over the PDMP, or CARA/CAPTA Plan-of-Care data, and they themselves lack the capability to perform data analysis.
5. Diagnostic codes are very useful. However, does the placement (1st diagnostic variable, 2nd, 5th, 16th, 30th) mean anything? How about procedure codes that may have information on assessments or treatment? Do they exist as a reliable source?

QUESTION 4: DO YOU HAVE ANY OTHER COMMENTS REGARDING THE CASE DEFINITIONS?

Reviewer 6: Highlight different types of laboratory tests, the quality and limitations of each and interpretation of laboratory results within the context of the medical history.

Explain the differences between confirmatory testing and screening. Emphasize that laboratory detection may include parent drug compounds and/or drug metabolites. Highlight the potential for false positive laboratory results and cross-reactivity with other analytes.

In order to normalize the data from the labs, there will need to be some sort of representation of what testing has occurred.

NAS SURVEY AND SUBJECT MATTER EXPERT SUMMARY

The ability to either adopt or develop a standard case definition that can be used across state and territorial health agencies is viewed as both important and feasible. The information gathered during this project and the input of the subject matter experts selected have laid the foundation to further the consensus-driven processes toward the development of state health agency registries or national registries. Based on the survey responses and subject matter expert comments, the Council of State and Territorial Epidemiologists definitions are a good place to start.

CONSENSUS VOTING RESULTS

Twelve votes were received for the Case Definition Summary Analysis. The breakdown of organizations voting is:

- Nine state health agencies
- Two subject matter expert participants
- One birth defect registry

Voting Results

- Yes – 8
- Yes, with comments – 2

    1. *Selected Confirmed CSTE Tier 2 definition as preferred.*
    2. *On the definition, we do agree it is important to have a standardized definition, both for a comparison among states but also within the state. This state was part of a pilot study reviewing 2015 births and found that the ICD-9/10 codes were used inconsistently both between hospitals and within hospitals. A specific issue for any educational campaign for the use of a definition is that some hospital personnel are very reluctant to code an infant as NAS as they are concerned this would be stigmatizing. In regard to lab testing as part of the definition, this should only be implemented if there is universal testing – all infants.*

- Abstain – 1
- Formal Objection – 1

    1. *For both, my formal objection is the same: I believe our considerations of case definitions and master data elements, and any documents related to these, need to include a clear and explicit description of the use and purpose of the definition and data elements. While this was*

discussed informally on the last call, the materials being shared currently do not have this information. Perhaps more importantly, the information shared with participants in the earlier steps of the process also did not have that information; thus, to me, it becomes difficult if not impossible to interpret or evaluate the responses. I think the optimal definition and data elements list will vary substantially depending on the purpose identified.

The consensus voting results, in general, support the conclusions from the survey results and subject matter expert review that a standard case definition is desirable. Comments from both the subject matter experts and second consensus comment highlight some of the considerations that should be considered when developing the next steps to move toward a standard definition. The comments from the formal objection should be taken into consideration as part of these next steps, acknowledging the importance of setting a clear expectation of the purpose of the case definition. Input was solicited from as many stakeholders as possible, given the constraints of the project due to COVID-19, time, and funding.

The work that has been done should provide a solid foundation to advance the process to promote the selection and adoption of standard Neonatal Abstinence Syndrome case definitions.

IMPROVE NAS DATA SHARING BETWEEN PUBLIC HEALTH AND MEDICAID

Sharing data between public health and Medicaid is a key component of agency collaboration and is effective in monitoring health outcomes at the state-level.[2] Data sharing ranges from formal data-sharing agreements and/or data-use agreements that are bi-directional or multi-directional, to less formal ad hoc data requests intended for a specific purpose.[2]

Regarding use case, Medicaid uses public health registries in a variety of ways:

- Registry data may be matched against Medicaid administrative data to validate and ensure the quality of data or to meet federal reporting requirements. For example, to meet CMS reporting requirements to claim a 50% federal matching rate for tobacco quitline expenditures, Maryland, along with other states, executed a Memorandum of Understanding to share bi-directional data.[3] This involved matching the Maryland Tobacco Control Program quitline data against the Maryland Medicaid administrative claims data for claimed tobacco cessation services.
- Registry data may be used to inform Medicaid quality initiatives. A state Medicaid agency may seek to use immunization information systems to inform quality initiatives related to improving immunization rates for a specific population. For example, California's Medicaid agency partners with the California Department of Public Health Immunization Program to share relevant data to inform Medicaid performance improvement projects as part of their strategy to increase immunization rates.[4]

DATA COLLECTION AND DATA SHARING

Among the state health agencies that participated in focus groups, data collection generally includes data on demographic information such as race, gender, and ethnicity. Some states go beyond basic demographic data and collect information including type of insurance status, preferred language, and enrollment in benefit programs such as Women, Infants, and Children programs. Data sources include hospital discharge data, vital records, and mother's worksheet for child's birth certificate. Several state examples are outlined below.

STATE	DEMOGRAPHIC DATA	PARTNERSHIPS/DATA SOURCE
Virginia	Insurance status, specifically Medicaid status.[5]	Hospital discharge data.
Ohio	Race, ethnicity, preferred language, insurance status, and education level of the mother and father.[5]	Worksheet completed by mother.
Florida	Demographic data for individuals with NAS.[5]	Agency for Health Care Administration.
Arizona	Linking demographic data with vital records to include education.[6]	As part of its enhanced surveillance program goals, Arizona is connecting patients with the Health Start Program, which is using community health workers to provide health education and connect at-risk pregnant and postpartum women to community programs.[7] Arizona collects data, including education, employment status, type of insurance, and basic demographics. The goal is to link this data with the home-visiting database to gather more detailed information on families impacted by NAS.[8]
Tennessee	Linking demographic data with vital statistics.	Research Electronic Data Capture.[9]
Texas	Housing, employment, and other social determinants of health.[6] Percentage of births in each county covered by Medicaid for which there is a NAS diagnosis.	Medicaid data; survey. Receive legislative appropriations to support NAS grant funding for interventions and substance use disorder programs in counties with highest NAS rates.

DATA SHARING CHALLENGES

There remain significant challenges in sharing data between Medicaid and public health departments.

The Florida Department of Health (FDOH) is unable to access Medicaid claims data due to ongoing confidentiality issues. Hospitals in the state are not required to report claims to the Agency of Health Care Administration for six months. While FDOH has a team of researchers analyzing NAS statistics, there remain confidentiality issues in accessing the necessary data. FDOH indicated that this registry could catalyze open communication channels between state agencies.[5]

Of note, due to administrative burden and lack of interoperability, hospital discharge data sharing often occurs on an ad hoc basis or at various intervals, rather synchronously and bi-directionally. For example, The Minnesota Hospital Association (MHA), which houses the hospital discharge data, provides data quarterly with various data elements meeting the MDH program specific case definition.[6] There are several other programs within the Minnesota Department of Health that also receive hospital discharge data from MHA with data sharing timelines varying widely between each program. Tennessee shares aggregate NAS data stratified by county, regions, and hospitals, however there are often reporting lags into the vital statistics system.[6]

The strength of NAS surveillance also depends on the type of payer involved. In some states it is possible for Medicaid to cover newborns who have hospital stays longer than two days with suspected cases of NAS or Neonatal Opioid Withdrawal Syndrome (NOWS). However, beyond baseline demographic information, there are no standardized data elements to collect regarding coverage.[6]

CONCLUSION

LIMITATIONS

While this report reflects a robust understanding on NAS surveillance and data collection, there remain several limitations. First, ASTHO acknowledges that much of the information sourced represents just a handful of states conducting NAS surveillance. Second, time constraints of the project limited ASTHO's ability to engage in more robust discussions on data element submission and consensus-based voting results between health agencies and SMEs who were selected to provide input. As such, we suggest that this work serve as a foundation for additional discussions with public health agencies, Medicaid agencies, and SMEs to provide input on and review the master data element list and data dictionary developed from the information available during this project. We understand that many states are also defining their NAS surveillance practices, and those will continue to evolve. Finally, there are areas within NAS data collection, registry development and surveillance that can be expanded upon and which are detailed in future considerations.

FUTURE CONSIDERATIONS

In 2015, Congress passed The Protecting Our Infants Act of 2015 instructing HHS to study and develop recommendations to prevent, identify, and treat NAS. The law includes multiple recommendations for agencies to address data and surveillance changes for NAS and NOWS. Recommendations specifically for CMS, among other federal agencies, include:

- Collect substance- and diagnosis-specific data about prenatal substance abuse to develop adequate treatment capacity.
- Collect substance and diagnosis specific data about prenatal substance use to identify unmet service and care-coordination needs and any disparities in access.[10]

Further, there is potential for the development of a NAS registry, which would likely catalyze data-sharing agreements between Medicaid and public health agencies, thus requiring agencies to clearly define data sharing parameters. Examples of how Medicaid uses or could use NAS data are outlined below:

- **Ohio:** The Ohio Department of Health (ODH) and Ohio Medicaid partners with The Ohio State University for a Medicaid Technical Assistance and Policy Program project on NAS surveillance. The goal is to link Medicaid claims data with programs at ODH to improve screening practices, access to treatment, and health outcomes.[11] The project involves screening Medicaid recipients for depression, anxiety, and other mental health disorders by primary care physicians. ODH hopes that screening intervention and collaborative decision making will improve maternal health outcomes.[5]
- **Virginia:** The neonatal-perinatal collaborative has monthly meetings that include Medicaid and other social service agencies. Data is shared based on need across agencies.[12] The purpose of the

collaborative is to assist hospitals and obstetricians to improve pregnancy outcomes, decrease the preterm birth rate to Healthy People 2030 goals, and decrease maternal mortality by 50%.[5]

Other actions that health agencies and federal and national partners can consider as they relate to NAS surveillance include:

- Document current NAS registry or data collection mechanisms.
- Develop a standard NAS compendium of resources and data dictionary.
- Consider linking NAS registry data using electronic alerts, HIEs, or emergency department platforms.
- Detail and provide guidance around the technical aspects of registry development.
- Determine who has ownership of state or territorial registries or should have ownership to include the benefits and limitations of these governance models.

ACKNOWLEDGMENTS

We would like to recognize our partners at Briljent and EMI Advisors LLC, and the following ASTHO teams for their contributions on the project and this final report. rt:

- Family and Child Health – Sanaa Akbarali and Ellen Pliska
- Medicaid – Alexandra Kearly and Sameer Rao
- Data Analytics and Public Health Informatics – Priyanka Surio, Zeeshawn Chughtai, and Gabriel Smith

We also would like to recognize the following states that participated in our two focus groups:

- Florida, Ohio, and Virginia for participating in the ASTHO Multi-State NAS Surveillance Focus Group (March 15, 2021).[5]
- Alabama, Arizona, Minnesota, Tennessee, and Texas for participating in ASTHO's Multi-State NAS Surveillance Focus Group (March 29, 2021).[6]

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APPENDIX A: REQUEST FOR PROPOSALS (RFP) NEONATAL ABSTINENCE SYNDROME REGISTRY

Include the purpose of this document and how it is to be used as a guidance for developing your own RFP to solicit support for a Neonatal Abstinence Syndrome (NAS) registry or in developing a NAS registry. Each section includes considerations for items to include and sample language to reference.

I. SUMMARY INFORMATION

Purpose: Include 1-2 sentences on overall purpose of registry RFP (sample language below):

In the Summary section, consider including sample language below:

Proposal Due Date and Time: 09/30/2021, 5:00 pm EST

Selection Announcement Date: Input details

Monetary Assistance Available to Awardees: Not applicable

Maximum Funding Amount: Not applicable

Estimated Period of Performance and Final Report Date:

Bidder's Conference Call: Input details

Eligibility: All states and territories in good standing with ASTHO (Association of State and Territorial Health Officials) are eligible to apply.

ASTHO Point of Contact: The Data Analytics and Public Health Informatics Department: Informatics@astho.org

BACKGROUND

Neonatal abstinence syndrome (NAS) is a disorder in infants due to withdrawal from opioids and other substances in utero. The incidence of NAS in the United States has increased, in parallel with the opioid epidemic, over the past decade. According to 2016 HCUP (Healthcare Cost and Utilization Project) data, seven newborns were diagnosed with NAS for every 1,0000 newborn hospital stays. While the definition continues to vary among providers, most define the disorder as a constellation of signs and symptoms of withdrawal experienced by the newborn following in utero exposure to medications or illicit drugs, most used opioids including benzodiazepines, and barbiturates. Other substances, including nicotine, alcohol, and other prescription medications, can exacerbate NAS. Furthermore, a diagnosis of NAS may result in health conditions needing treatment in the neonatal intensive care unit and pharmacological and/or non-pharmacological interventions. Infants born with NAS are at increased risk of preterm birth, congenital anomalies, and impaired neurodevelopment.

CURRENT ENVIRONMENT:

- Challenges
- Stakeholders
- Technical components

PROJECT ACTIVITIES/DELIVERABLES:

- *Develop a fully functioning NAS Registry in a state/territory which includes minimum core elements*

from a master list of NAS data elements.

- *Strengthened relationship between public health and Medicaid to address NAS at the national and the state/territorial/local levels.*

REGISTRY REQUIREMENTS:

- *Include content from report + indicate users of registry i.e. public health).*

REQUESTED INFORMATION (THROUGH A PROPOSAL) – ADDRESS THE FOLLOWING QUESTIONS:

- *In what ways does your organization collect NAS data elements and use a consistent case definition?*
- *What is the current landscape your organization is facing regarding data sharing?*
- *Who will your organization work with?*
- *What would your organization want to see addressed in the RFP?*

II. DESCRIPTION OF RFP (REQUEST FOR PROPOSALS)

PROJECT ACTIVITIES

A. *Data assessment on what data sources are utilized for NAS.*
B. *Steps for building a registry (take from NAS external report).*
C. *Include collaborative or consensus-based meetings with other health agencies interested in building a registry.*
D. *Engaging in a relationship between public health and Medicaid to use the registry.*

EXPECTED OUTCOMES/EXPECTATIONS AND DELIVERABLES

E. *Outcome – Strengthened relationship between public health and Medicaid to address NAS at the national and the state/territorial/local levels.*
F. *Deliverable – NAS Registry (fully functioning in a state/territory); include minimum core elements from master list of NAS data elements.*

III. REQUIREMENTS FOR FINANCIAL AWARD

Allowable Expenses
Per HHS requirements, funds awarded under this RFP are prohibited from being used to pay the direct salary of an individual at a rate more than the federal Executive Schedule Level II (currently $187,000). All funds must be used towards the creation of a Neonatal Abstinence Syndrome Registry.

Required Grant Activities to be Covered by Award
Summary of project activities

Period of Performance
From [insert date and year] to [insert date and year]

Reporting Requirements
Sample language: The grantee will be required to provide with monthly conference calls, a mid-year report and final report.

IV. REQUIRED PROPOSAL CONTENT AND SELECTION CRITERIA

A. Cover Letter: *The cover letter should be specific to include public health and Medicaid partnership and include the name of the personnel receiving the award. All programmatic and fiscal points of contract details should be included. (Name, title, mailing address, e-mail, and phone number).*

B. Proposed Approach: *Provide a detailed outline of the approach and strategy to accomplish the project activities. Submit a detailed work plan which includes activities, timeline, goals, and milestones to achieve the deliverables and meet the expectations noted above.*

C. Prior Experience and Performance: *This section should include a detailed description of any experience and quality of performance on recent work completed like the creation of a registry or the study of Neonatal Abstinence Syndrome. Include information about familiarity with and understanding of the topic.*

D. Organization Capacity: *This section should include the resources and capacity to perform the services required within the timeframe. Please describe staff qualifications. Resumes/CVs should be provided for all key personnel.*

E. Budget & Budget Narrative: *Provide a detailed budget, including detailed projected costs for the completion of the project. Maximum award is $XX. Applicants may use an Excel spreadsheet as a template or simply as a guide to inform development of the project budget. A budget narrative must accompany the budget and indicate the costs associated with each proposed activity.*

- If you use either a fixed price budget or a cost reimbursement budget:
    - The fixed price budget should include a cost breakdown per task and a proposed payment schedule.
    - If you have a cost reimbursement budget, it should include salary, fringe benefits, other direct costs, and indirect costs, as appropriate. If indirect costs are included in your budget, please provide a copy of your approved Indirect Cost Rate Agreement.

F. Response to Contract Terms and Conditions: *Your organization and selected applicant(s) will enter a [Contract type] agreement.* ***Review the terms and conditions with your project officer or legal team and confirm that if selected, you will enter into this agreement; or identify and include any proposed changes to the terms with your proposal application.*** *[Insert state/territory] reserves the right to accept or decline any proposed changes to the terms and conditions. Significant proposed changes, which could affect the agreement's timely execution, may impact your selection as a successful applicant.*

G. Inclusion of Health Equity: *Throughout the proposal, incorporate the following: (1) describe the extent to which health disparities are evident within the health focus of the application, (2) identify specific group(s) which experience a disproportionate burden of the health condition, and (3) demonstrate how proposed activities address health inequities (this also includes identifying social and/or environmental conditions which are the root causes of health disparities). The root causes of health inequities are sometimes referred to as social determinants of health. All information regarding health inequities must be supported with data.*

H. Sustainability/Availability of Funds or Resources: *Provide a detailed outline of the approach and strategy to accomplish sustainability over the course of the project and the next 3-5 years once the workplan has ended. Submit a detailed sustainability plan which includes activities, goals, and milestones to meet the expectations noted above.*

I. Evaluation Plan: *Provide a detailed outline of the approach and strategy to how your project activities will be evaluated. Submit a detailed plan listing the personnel involved in the evaluation, timeline, and overall goals. Provide resumes/CV of every individual involved and how they will be involved in the evaluation plan.*

V. SUBMISSION INFORMATION

Application Procedure
*This section will include the Application deadline and process. Applications must be received by **[insert time and date]**. Please submit an electronic copy of the application to **[insert contact information]**.*

Timeline

- *Date: RFP released*
- *Date and Time (Eastern): Deadline for submission of grant proposals*
- *Date: Contract award announced*
- *Date: Contract period commences*
- *Date: Reporting or deliverable due dates*

In the Submission section, consider including how applicants can ask questions and receive guidance (see sample language below):

Applicant Questions and Guidance

*Describe process for how applicants can submit questions about RFP. **[Your organization]** can schedule a call on **[list date, time, call-in information]**. Interested parties may contact **[insert contact information]**. In addition, frequently asked Q&A questions will be posted regularly.*

Disclaimer Notice:

This RFP is not binding on your organization, nor does it constitute a contractual offer. Without limiting the foregoing, your organization reserves the right, in its sole discretion, to reject any or all proposals; to modify, supplement, or cancel the RFP; to waive any deviation from the RFP; to negotiate regarding any proposal; and to negotiate final terms and conditions that may differ from those stated in the RFP. Under no circumstances shall your organization be liable for any costs incurred by any person in connection with the preparation and submission of a response to this RFP.

THE ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS

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