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NEONATAL ABSTINENCE SYNDROME (NAS)

**Environmental Scan and Key Informant
Interview Analysis Report**

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Background

Neonatal abstinence syndrome (NAS) is a newborn syndrome comprised of a constellation of signs of *in utero* exposure to, and withdrawal from, one or more medications, drugs, and other substances known to cause withdrawal in adults (1-3). Common sources of *in utero* exposure are prescription and non-prescription non-synthetic and synthetic opioids and opioid metabolites (such as oxycodone, methadone, buprenorphine, heroin, and fentanyl), as well as anxiolytics and sedatives such as benzodiazepines (e.g., diazepam and alprazolam) and barbiturates (e.g., phenobarbital). Although withdrawal can be effectively managed with nonpharmacologic means or pharmacologically treated, neonates with signs of withdrawal may have increased lengths of stay and increased costs of care. NAS is not a nationally notifiable condition and is not a reportable condition in most states. Hospital discharge data show that the incidence of NAS has increased by 400% between 2000 and 2012 (3) and is likely to have increased even further since 2012.

Opioid use among women of reproductive age and NAS are important emerging public health problems. 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 standardized case definitions. The Council of State and Territorial Epidemiologists (CSTE) therefore formed a NAS Workgroup (the Workgroup) in 2017 with the purpose of better understanding how states define and operationalize a definition of NAS, the sources of data used to report NAS incidence and if there would be value in developing a standardized case definition. Co-leads for the Workgroup were drawn from the Substance Use and Mental Health Subcommittee and the Maternal Child Health Subcommittee. To assess the need for and inform the development of a standardized definition of NAS and a CSTE position statement to be presented at the June 2019 Annual Conference, the Workgroup conducted a Neonatal Abstinence Syndrome (NAS) Definition Environmental Scan (the “Environmental Scan”) during September and October 2018 to understand the current ways in which states define and operationalize NAS surveillance and the data sources that were being used. Specifically, the Environmental Scan asked states about the following:

- Enabling legislation, regulation, or authority for NAS reporting;
- Definitions of NAS as a reportable condition;
- Reporting requirements relating to NAS;
- Data sources used to identify NAS cases;
- International Classification of Diseases (ICD)-9-CM and ICD-10-CM diagnosis codes or keywords/phrases (newborn and maternal) employed for identifying NAS cases (and which data sources states would like to use if they could gain access);
- Use of symptom scoring tools, laboratory results, and neonatal treatment histories for NAS case identification
- Information about whether maternal and infant records were linked or if maternal characteristics and exposure status were documented;
- Description of how NAS definition was operationalized;
- Which NAS definitions the jurisdictions would favor.

In addition to the Environmental Scan, key informant interviews were conducted in six states with enabling legislation, regulation or authority for NAS reporting and two without such authority. The purpose of the interviews was to gather more in-depth information of use to states that are interested in further developing and implementing NAS surveillance and practical lessons learned from the operationalization process.

Methods

NAS Environmental Scan

The NAS Definition Environmental scan was developed and fielded in the fall of 2018 and initial analysis was used to inform the development of the CSTE NAS Standardized Surveillance Case Definition Position Statement. A Qualtrics-based instrument was developed by members of the NAS Workgroup and field tested in six states. A link to the final instrument was sent to the 50 states and the District of Columbia and one tribal health authority, with the instructions to have it filled out by those most familiar with NAS or NAS surveillance. States were encouraged to collect relevant information from hospitals or external stakeholders as needed or to have the hospitals themselves respond to the scan. Additionally, if data were obtained from different sources or there were multiple experts in NAS, states could have more than one respondent. Thus, multiple responses from each state were possible, although data were collected on whether the respondent was the key contact for the state. The quantitative analysis presented in this document is limited to the key respondent in the 50 states, DC, and the Northwest Portland Area Tribal Health Board, although open-ended responses from other respondents were also examined.

Part 1 consisted of an initial screening section concerning basic information about the respondent, the authority to mandate NAS reporting, and current and desired data sources used in monitoring or conducting surveillance of NAS.

Part 2 consisted of seven sections. Section A gathered further information on states with a reporting mandate, including case definition and data sources. All states that reported in Part 1 that they had used at least one data source were directed to Sections 2B to 2G depending on the data sources selected. Section 2B asked about case definition elements and sources for Electronic Health Records (EHR) Data / Medical Record Reviews (MRR) or Birth Defects Registry (BDR) or Extractions / Perinatal Quality Collaboratives (PQCs) / Hospital-based Quality Improvement (QI); Section 2C about vital and birth records, Section 2D about hospital discharge, Medicaid, all-payer and insurance data; Section 2E about syndromic surveillance; and Sections 2F and 2G about other data sources. Most of these sections included questions on the use of ICD-9-CM and ICD-10-CM diagnosis codes, on other elements included in the case definition (i.e., laboratory testing, scoring tools, and whether the infant had been treated for signs of withdrawal), on whether maternal-infant record linkage was available, and on how the case definition had been operationalized. For sources that potentially used record searches using key terms, questions were also asked about search terms. Because states interpreted “operationalization” in many different ways, the data were not readily analyzable; the topic was instead addressed in the key informant interviews.

Part 3 was completed by all respondents and asked about general comments useful in understanding the current state surveillance process and preferred content of a potential case definition.

States were asked to provide evidence of legislation, policies, and regulations (henceforth referred to as legislative mandates), and all were validated based on original sources and links cited or direct queries by the Workgroup co-leads with the key respondent for the state. Because of issues in skip patterns and the collection of the same information in different parts of the questionnaire based on the different data sources, there were some inconsistencies and duplication in many of the responses across Parts 1 and 2. For this reason, composite variables were created to examine, for example, which ICD-CM codes had been used in surveillance definitions across the entire assessment .

Data were analyzed using Excel 2007 and Epi Info 7. Where relevant, results are first reported for all states and for the 16 states with a legislative mandate. In keeping with CSTE policies, data are presented only in composite fashion without mention of specific jurisdictions.

Key Informant Interviews

The quantitative findings from the NAS Definition Environmental scan were presented to NAS Leadership Group in December 2018 and used to inform the development of the CSTE NAS Standardized Surveillance Case Definition Position Statement. Based on the quantitative findings and a discussion with Workgroup members, an interview guide was developed to further explore several issues in greater depth.

Eight states were identified by the Workgroup co-leads, six that reported legislative mandates for NAS surveillance at the time of the Environmental Scan (Alaska, Georgia, Minnesota, Pennsylvania, Tennessee, and West Virginia) and two that did not (Missouri and Wyoming).

Topics covered in the qualitative interviews included:

- How the state mandate for reporting came about;
- Key partners in developing and implementing reporting;
- Issues the states faced in implementation of reporting;
- Data use -- who is using the data and for what purposes;
- Advice to states that want to mandate NAS reporting;
- State views on the use of administrative and electronic medical records-based data collection for NAS;
- State views on the scope of surveillance (which substances, exposure in addition to clinical signs); and
- How CSTE could best help states.

For those states without a legislative mandate, the first question was modified to ask if they felt a need for mandating reporting and what might change as a result.

Structured in-depth interviews were conducted in early 2019; each lasted approximately 45 minutes. The interviews were recorded with permission of the persons included in the interview. Detailed notes were made of the content at the time of the interviews, the audiotapes were reviewed, and selected quotes were transcribed.

Results

NAS Environmental Scan

Response rate

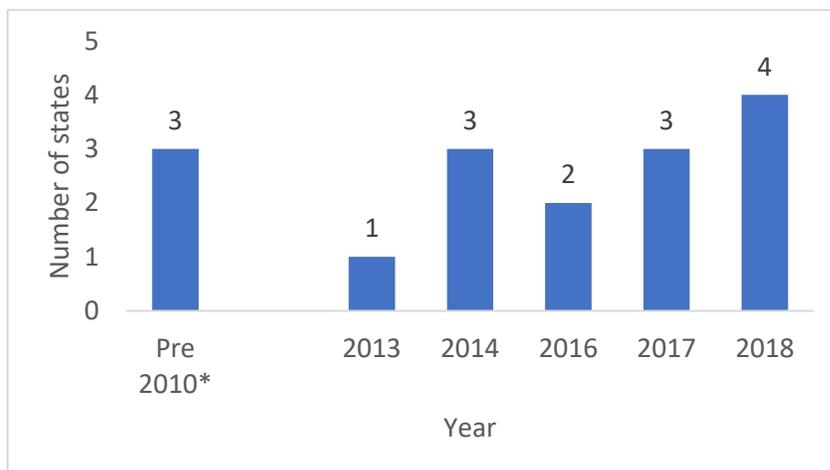
All 50 states, the District of Columbia, the Northwest Portland Area Indian Health Board, two city/county health departments from two states, and four hospitals from a single state responded to the scan. In four states, more than one individual from the health department responded. The city and hospital responses were not considered in the overall analysis, and in those states with more than one respondent, only the response from the person who reported being the key contact for NAS was included. However, details of operationalization provided by these additional sources have been included where relevant.

How many states have enabling legislation, regulation, or authority, when did it come into effect, what wording is used to describe NAS, and what are the reporting requirements?

Number of states with enabling legislation and year reporting began

Sixteen of the 52 responding jurisdictions (31%) had legislation, policies, or regulatory authority to collect NAS data. In 13 of the 16 states with a legislative mandate (81%), reporting is mandatory. In three states, reporting began prior to 2004. Seven of the remaining 13 have initiated reporting in 2017 and 2018 (Figure 1).

Figure 1. Year reporting began in states with NAS as a reportable condition, NAS Definition Environmental Scan (n = 16)



What wording is used to describe NAS?

Of the 16 states with a legislative mandate, 9 (56%) used the term *neonatal abstinence syndrome* as the condition to be reported, while three (19%) used *substance exposed infants or newborns*, and one used both (6%). Of the remaining three, the terms or phrases used to denote NAS were *infants born to opioid-dependent mothers*, *substance-affected infants*, and *group of physical problems that occur in a newborn infant who was exposed to addictive illegal or prescription drugs while in the mother's womb*.

What are the reporting requirements?

Reporting requirements differ greatly between jurisdictions, though the open-ended nature of the Environmental Scan question on this topic makes it difficult to conduct quantitative comparisons. The

reporting entity may be a physician or other health care provider, or it may be a hospital or birthing facility. In some cases, a detailed case report form is filled out by the provider of a facility; in others, reporting consists of hospitals or birth defects registries providing the number of infants with specific ICD-9/10-CM diagnosis codes or birth scores. Reports generally are sent to health departments, although in some cases, child protective services is the receiving entity. Some jurisdictions require reporting within days of diagnosis, while others require monthly reporting or periodic examination of existing databases. Similarly, the case definition for reporting purposes varies widely. Jurisdictions use clinical signs alone with or without laboratory confirmation, while others include newborns with exposure history or a positive toxicology screen who may or may not have signs of withdrawal. For those using hospital discharge records or birth defects registries, cases are defined as newborns/infants with specific ICD-9-CM or ICD-10-CM codes or whose birth mothers have ICD-9/10-CM diagnosis codes related to drug use. Some states specify the type of drug exposure (e.g., illicit, prescribed), and a small number also include alcohol in their reporting systems. The amount of information collected on each reported case varies; jurisdictions with electronic notification systems collect considerable demographic, clinical, and laboratory information, while others have only basic information on each case that can be ascertained from discharge records.

What data sources are currently being used to identify NAS cases, and what sources would jurisdictions like to use if they could gain access?

Individual data sources

The data sources used by the 52 participating jurisdictions are shown in Table 1. The most common source was hospital discharge records (46 jurisdictions; 88%), followed by vital records (17 jurisdictions; 32%), reportable condition notifications and Medicaid claims (each reported by 13 jurisdictions; 24%), and birth defects registries (8 jurisdictions, 15%). Of note, medical record reviews and electronic medical records, as well as all-payer claims and private insurance were each used by <15% of the 52 jurisdictions.

Table 1. Current and potential NAS data sources, overall and by reporting status, 52 jurisdictions*, NAS Definition Environmental Scan, 2018

Source	Currently use for NAS surveillance						Would use for NAS surveillance if access granted					
	All* (n =52)		Reportable (n=16)		Not reportable (n=36)		All* (n=52)		Reportable (n=16)		Not reportable (n =36)	
	n	%	n	%	n	%	n	%	n	%	n	%
Hospital discharge data	43	81.1%	10	62.5%	33	91.7%	4	7.7%	0	0.0%	4	11.1%
Vital records / birth data	17	32.1%	8	50.0%	9	25.0%	1	1.9%	0	0.0%	1	2.8%
Medicaid claims data	13	24.5%	4	25.0%	9	25.0%	9	17.3%	0	0.0%	9	25.0%
Reportable condition	13	24.5%	13	81.3%	0	0.0%	5	9.6%	0	0.0%	5	13.9%
Birth defects registry	8	15.1%	5	31.3%	3	8.3%	4	7.7%	0	0.0%	4	11.1%
Child & family services data	6	11.3%	1	6.3%	5	13.9%	10	19.2%	3	18.8%	7	19.4%
Medical record reviews	6	11.3%	2	12.5%	4	11.1%	8	15.4%	2	12.5%	6	16.7%
Treatment program data	4	7.5%	2	12.5%	2	5.6%	8	15.4%	1	6.3%	7	19.4%
All payer claims	3	5.7%	1	6.3%	2	5.6%	10	19.2%	1	6.3%	9	25.0%
Syndromic surveillance	3	5.7%	1	6.3%	2	5.6%	3	5.8%	1	6.3%	2	5.6%
Electronic medical record	2	3.8%	1	6.3%	1	2.8%	13	25.0%	3	18.8%	10	27.8%
Perinatal quality improvement	2	3.8%	2	12.5%	0	0.0%	5	9.6%	0	0.0%	5	13.9%
Private insurance claims	1	1.9%	0	0.0%	1	2.8%	12	23.1%	3	18.8%	9	25.0%
Other	10	18.9%	4	25.0%	6	16.7%	3	5.8%	0	0.0%	3	8.3%

* 50 states, DC, and NW Portland Area Indian Health Board

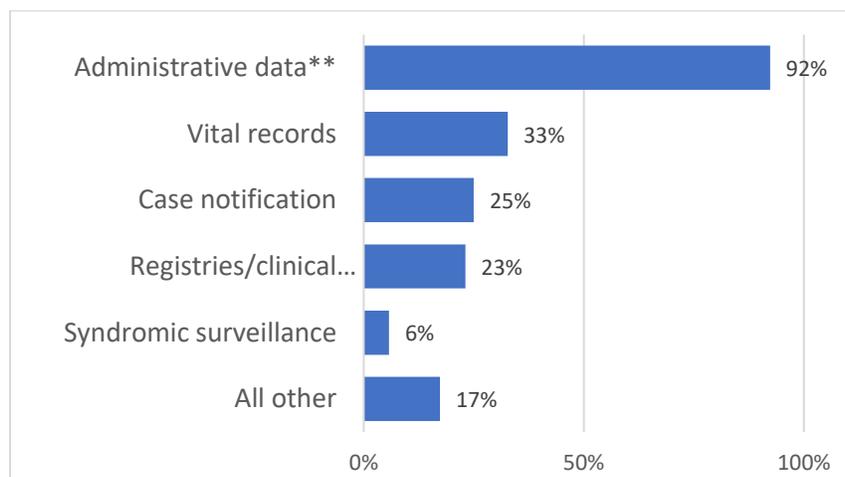
Patterns were similar for jurisdictions in which NAS is reportable and those in which it is not reportable. Although hospital discharge data were the most common source for both groups, the percentage was higher in states where NAS is not reportable.

Categories of sources currently used

Sources were further grouped into six broad categories. They consisted of 1) administrative data (hospital discharge, Medicaid, all-payer, and private insurance data), 2) case notification of reportable conditions, 3) vital records, 4) registries and other clinical records (birth defects registry, electronic medical records, medical records, and perinatal quality improvement data), 5) syndromic surveillance, and 6) all other.

As shown in Figure 2, 48 of the 52 jurisdictions (92%) use administrative/claims-based data sources, while approximately a quarter used reportable condition notification, registries and other clinical sources, and vital records data. The order was similar when the analysis was limited to jurisdictions in which NAS is a reportable condition; 14 of the 16 (88%) used administrative /claims-based data sources, 8 (50%) used registries and other clinical records, and 7 (43%) used vital records. As would be expected, all 13 of the 16 jurisdictions in which NAS is reportable were using reportable condition notification.

Figure 2. Category of data used for NAS surveillance the 52 jurisdictions*, NAS Definition Environmental Scan, 2018



* 50 states, DC, and NW Portland Area Indian Health Board
 **hospital discharge, Medicaid, all-payer, and private insurance data

Additional data sources that could be used if access granted

Jurisdictions were also asked, “Are there any data sources in your jurisdiction that you would use for NAS surveillance, but to which you do not have access?” Overall, the data sources of greatest interest were electronic medical records (25%), private insurance (23%), child and family services (19%), Medicaid claims data (17%), and medical record review and treatment center data (each 15%) (Table 1). For those with NAS as a reportable condition, child and family services, private insurance claims, and electronic medical records were each of interest to 19% of the jurisdictions. In jurisdictions in which

NAS is not reportable, the data sources of greatest interest were electronic medical records (28%) and Medicaid, private insurance, and all-payer claims data (each 25%).

For the data sources, which ICD-9-CM and ICD-10-CM newborn and maternal codes are jurisdictions currently using, which search terms have been employed for reviewing electronic medical records, and which other diagnostic elements are included in NAS case definitions?

ICD-9-CM diagnosis codes

With respect to the use of ICD-9-CM diagnosis codes, the most commonly used newborn diagnosis codes were 779.5, used by 41 (79%) of the 52 jurisdictions, and 760.72, used by 13 (25%). Twelve (23%) jurisdictions did not use ICD-9-CM diagnosis codes. The 760.72 code was used alone in one jurisdiction and in combination with 779.5 in the remaining 12 jurisdictions.

ICD-10-CM diagnostic codes

ICD-10-CM diagnosis codes have been used since the ICD-9-CM to ICD-10-CM transition on October 1, 2015, and are the basis of NAS surveillance in those jurisdictions using administrative records for surveillance purposes. As shown in Table 2, the most commonly used diagnosis code is P96.1, which includes “withdrawal symptoms from therapeutic use of drugs in newborn; neonatal drug withdrawal syndrome, maternal therapeutic drug; neonatal drug withdrawal syndrome, mother prescription.” It is used by 83% of the 52 jurisdictions and by all 43 of the jurisdictions which report using ICD-10-CM codes for surveillance purposes.

Table 2. ICD-10-CM newborn codes used in NAS surveillance for the 52 jurisdictions*, overall and by reporting status, NAS Diagnosis Environmental Scan, 2018

ICD-10-CM newborn code	All jurisdictions (N = 52)		Reportable (N=16)		Not reportable (n=36)	
	n	%	n	%	n	%
P96.1 (neonatal withdrawal symptoms from maternal use of drugs of addiction; drug withdrawal syndrome in infant of dependent mother; neonatal abstinence syndrome)	43	82.7%	14	87.5%	29	80.6%
P96.2 (withdrawal symptoms from therapeutic use of drugs in newborn; neonatal drug withdrawal syndrome, maternal therapeutic drug; neonatal drug withdrawal syndrome, mother prescription)	9	17.3%	2	12.5%	7	19.4%
P04.49 (newborn affected by maternal use of other drugs of addiction, excluding P96.1, maternal anesthesia and analgesia, and maternal use of cocaine)	9	17.3%	3	18.8%	6	16.7%
P04.40 (newborn affected by maternal use of unspecified drugs of addiction)	3	5.8%	0	0.0%	3	8.3%
P04.41 (newborn affected by maternal use of cocaine)	1	1.9%	0	0.0%	1	2.8%
P04.42 (newborn affected by maternal use of hallucinogens)	1	1.9%	1	6.3%	0	0.0%
Other (P04.1, P04.14, P04.15, P04.16, P04.18, P04.19, P04.3, P04.81, P04.89, P04)	1	1.9%	1	6.3%	0	0.0%
Do not use ICD-10 codes	9	17.3%	2	12.5%	7	19.4%

* 50 states, DC, and NW Portland Area Indian Health Board

The combinations of newborn diagnosis codes used by the 52 jurisdictions are shown in Table 3. Twenty-four (46%) used a single code (P96.1), while an additional five used both P96.1 and P96.2. Four jurisdictions used P96.1 and P04.49. Only five jurisdictions used more than three diagnosis codes.

Use of maternal diagnosis codes to identify NAS cases is rare. Only one jurisdiction, in which NAS is not currently a reportable condition, uses maternal diagnosis codes as part of the NAS definition. The codes used by this state include F11.20 (opioid dependence, uncomplicated); F10-F19 (disorders due to psychoactive substance use); and codes for drug poisoning or adverse effects (e.g., T42.4 [benzodiazepines]).

Table 3. Newborn and maternal ICD-10-CM diagnosis codes and other case-definition elements in 52 jurisdictions*, NAS Definition Environmental Scan, 2018.

Newborn codes	N	Maternal codes	Other elements
P96.1	29	--	--
P96.1 + P96.2	5	--	--
P96.1 + P04.49	4	--	Lab (1); clinical (2)
P96.1 + P96.2 + P04.49	2	F11.20 + F10-19 + maternal poisoning (1)	--
As above + P04.40/P04.40-4.42	2	--	--
P96.1 + P04.49 + others	1	--	Lab (1)
Did not use/no response	9	--	Score (1); clinical (1)

* 50 states, DC, and NW Portland Area Indian Health Board

Electronic medical record search terms

Only two jurisdictions reported using electronic medical records, and neither elaborated on the search terms used.

Other diagnostic elements: Scoring tools, clinical signs, and laboratory confirmation

As shown in Table 3, a limited number of jurisdictions use scoring tools, clinical signs, and laboratory confirmation in their NAS reporting. Three use clinical signs, two use laboratory confirmation, and one uses a state-developed birth score system. The two states using only scores and clinical signs are states with NAS as a reportable condition.

Maternal-infant record linkage

Linkage of maternal and infant records provides the opportunity to further examine and possibly confirm maternal history of substance use and obtain additional sociodemographic information on both mother and infant. Seventeen of the 52 jurisdictions (33%) report that mother and infant records can be linked. Among the 16 in which NAS is reportable, 7 (44%) have the capacity for record linkage.

Which NAS definitions would the jurisdictions favor?

Jurisdictions were asked, “How would you propose to standardize the NAS case definition?” As shown in Table 4, there was no consensus. Approximately a third (32.7%) responded, “NAS should be a definition capturing neonatal withdrawal symptoms from maternal use of drugs of addiction and prescription medications (e.g., SSRIs) that may be linked to symptoms of withdrawal”. Although about 20% wanted a

broader definition involving ALL drugs of addiction, a nearly equal number felt it should be limited to opioids. There also seemed to be no consensus on the need to include maternal history of substance use in the definition.

Table 4. Preferred case definitions for NAS, NAS Definition Environmental Scan, 2018

Possible case definition (MORE THAN 1 RESPONSE POSSIBLE)	n	%
NAS should be a definition capturing neonatal withdrawal symptoms from maternal use of drugs of addiction and prescription medications (e.g., SSRIs) that may be linked to symptoms of withdrawal	17	32.7%
NAS should be a broad definition capturing neonatal withdrawal symptoms from ALL maternal use of drugs of addiction	11	21.2%
NAS should be a definition capturing neonatal withdrawal symptoms from maternal use of opioids	10	19.2%
NAS should be a definition capturing neonatal withdrawal symptoms even in the absence of evidence of maternal exposure	9	17.3%
NAS should be a broad definition capturing neonatal withdrawal symptoms from MOST maternal use of drugs of addiction (but excludes some drugs such as tobacco and alcohol)	8	15.4%
NAS should be a definition capturing neonatal withdrawal symptoms from SOME maternal use of drugs of addiction, such as (please specify)	1	1.9%
Other	11	21.2%

Additional comments

Themes that emerged in the additional general comments included whether the definition should also include substance-exposed infants, the problems of including maternal testing and history, what drugs should be included in a standardized definition, and the need to identify specific drug exposures (e.g., opioids).

Key Informant Interviews

How did the six states with mandates for NAS reporting come about and what were the motivating factors for reporting?

The process of mandating NAS reporting differed between states, reflecting the variation and nuances in state laws regarding reportable conditions and how a condition can be made reportable in that state. In the six states that have data collection mandates, only one had a formal legislative mandate. In a second state, NAS was made reportable by the public health commissioner. In two states reporting was mandated, but not on a permanent basis: NAS reporting was added by the state health officer to a renewable list of conditions warranting epidemiologic investigation as part of public health practice; and in the other, NAS reporting was part of an emergency mandate by the state governor concerning the

opioid epidemic that requires periodic renewals. In the remaining two states, NAS reporting involved modification of an existing mandate for a birth scoring tool that had been in place for several decades and the addition of NAS to the state's existing birth defects registry.

The stimulus for obtaining some form of mandate for data collection/reporting also varied by state. In some, it came from within the health department in response to apparent trends or a perceived need for data on an emerging problem, while in others the stimulus was partially externally based on increased requests for information to programs within the health department. In two of the states particularly affected by the opioid epidemic, the impetus for reporting was requested by stakeholders and champions in the pediatric and public health communities. Most notably, in one of these states, the impetus came from neonatal care nurses in a part of the state that had seen a dramatic increase in cases. Finally, in one state, the decision appeared to be more opportunistic, taking advantage of a broader opioid emergency data mandate.

The need for more timely data was cited as an important motivation for having a mandate in states that established NAS reporting systems or added it to their reportable disease or screening tool data collection systems. In those states whose reporting is based on hospital discharge records, completeness of data was also seen as an advantage to having a mandate since it provided motivation for reporting by hospitals which had not previously reported, or only periodically reported, as part of the state hospital discharge system.

How did the two states without a mandate for NAS reporting view the need for a mandate and what might change as a result?

One of the states that does not have a mandate has few births and to date has experienced few cases of NAS. NAS is therefore not considered a priority for additional monitoring beyond the use of hospital discharge records. The other state does not have a mandate for NAS reporting, but it does have a state mandate that hospitals report all hospital discharges to the state that is being used for NAS surveillance. NAS is also captured in the state birth defects registry, with a review of records triggered by certain ICD-10-CM codes. This has allowed the state to gather additional data on each case, though it is costly, labor-intensive, and is not timely and state coverage remains incomplete. Although the state reported that a mandate would have the advantage of being able to potentially gather additional information on each case and to allow for electronic transfer of medical records of those infants flagged by the birth defects registry, there were also some potential drawbacks. The first concerned the specificity in the language required as part of the legislative process, which would limit the flexibility of the system as new drugs emerged or ICD codes changed. More importantly, there were concerns about having records with personally identifiable information, which could be subpoenaed if proposed legislation to penalize women who use drugs during pregnancy is passed by the state legislature:

“We don’t want people not to seek treatment...if they are pregnant...We want an accurate measure of the epidemic, but we also don’t want to be the Big Brother and make the population uncomfortable.”

What data sources and methods do states use?

As with the motivations for NAS surveillance, the sources and methods of data collection varied widely. The following strategies were used:

- Data are collected as part of a screening of all newborns for a variety of conditions, including heart defects, and must be completed at the time of discharge.
- NAS was added to a long-standing hospital-based notifiable disease system in which providers or their delegates enter information through a protected web portal within a month of diagnosis; in this system, a case may be defined as either the presence of NAS symptomatology or a positive newborn drug screen.
- Stand-alone data collection systems dedicated to NAS were developed. The systems were created using REDCap (a secure web application for building and managing online surveys and databases) and allowed the states to tailor the data collection and format to their needs and interests.
- The ICD-10-CM code for NAS (P96.1) was added to the state's birth defects registry, which requires mandatory reporting.
- Existing data from the state's hospital association, which covered virtually all hospitals, began routinely examining data on ICD-10-CM code P96.1 from hospitals.
- The state without a specific NAS mandate that nonetheless has a generic mandate to access all hospital discharges, examines multiple ICD-10-CM codes (P96.1, P96.1, P04.40, and P04.49) and has also added these diagnosis codes to the birth defects registry.
- Of note, several states with separate data collection systems also continue to examine hospital discharge databases. Some also examine Medicaid data and the state's birth defects registry, although their new data collection systems are generally considered to be more complete and reliable.

What was involved in the implementation of data collection and reporting?

In most of the states with mandated reporting, there was enough lead time to develop plans for a system or modify an existing system, which facilitated implementation. In the state with the emergency mandate, however, implementation was more rushed. One state delayed full implementation for several months after the addition of NAS to its data collection system, to allow for additional planning and training prior to implementation.

Although implementation generally went well, states reported that it took considerable time, effort, and staff. This was especially true in those establishing new reporting systems or adding NAS to existing reporting systems.

Most states went through similar steps in initiating mandated surveillance. The initial step in the design and implementation process included deciding on a case definition and whether it will rely on ICD-CM codes or some combination of signs and laboratory findings and a determination of the scope of the surveillance (e.g., opioids or a broader range of drugs; exposure versus clinical syndrome). States heavily involved clinical partners, perinatal quality improvement collaboratives, and other key partners in the process.

A second critical design step was identifying possible existing data sources or surveillance systems that might be modified to include NAS. These decisions were partially driven by the feasible options for data collection in the state as well as input from key partners in the clinical realm and other areas in the health department.

An additional component of the early design process, especially for those states not using administrative records, was deciding how much additional demographic and medical information was necessary and feasible to collect, considering the potential burden on those responsible for reporting and what was already available from the existing sources and, in some cases, from potentially linkable data sources such as birth certificates.

From the point of view of systems design, new software had to be developed or the existing systems modified. For states that developed new reporting software, there was a learning curve, though reportedly reporting in REDCap can be developed relatively quickly. As part of system development, states almost universally reported the importance of identifying who will perform data management and who will be responsible for monitoring and following up on incomplete records or facilities that do not report regularly. The health departments also had to decide on frequency and methods of disseminating data as well as what to report beyond overall incidence rates, the target audience, and methods of dissemination.

Steps involved in the actual implementation included identifying all relevant hospitals and birthing facilities and eliciting their collaboration, informing all providers who may be seeing cases, and conducting training of relevant personnel and providing support and advice during the initial months of the new systems.

What lessons were learned in designing and implementing a NAS surveillance system?

The following represents a summary of advice from the states with a reporting mandate to other states and jurisdictions that may want to implement NAS surveillance:

- Think carefully about the design of your system and what resources will be needed to implement and maintain it. Consider sustainability and adaptability to include other exposures.
- Develop a good working relationship with public health, the clinical communities, and other key stakeholders, and involve them in the development of the system and data collection instruments.

“Bring your champions to the table, let them be your voice. They are the ones that are driving. When they relate to us what they need then we can tell them what tools we have to meet their need.”

- Be aware of burden and try to minimize the amount of data collected. Some data can be obtained through linkage with birth records; where possible, build in the capacity for data linkage.
- If the system is electronic, consider also having a paper-based worksheet that can be used to compile the data, especially if it involves data from different sources.
- Pilot the system to work out bugs.
- Realize that it will take time to ramp up the system and initially the data may not be complete, especially in large or decentralized states where there are many parties involved.

“[It] took a while to get facilities on board. [States] really can’t underestimate the amount of energy and wherewithal, and time it will take to... get everybody on board... especially when the state is decentralized and there are districts within the state and perinatal regions and everyone

kind of views themselves as an authority...To convince everyone to participate, it takes a lot of time.”

- Develop a comprehensive list of the facilities and facility contacts. Keep the contact list up-to-date as there is likely to be considerable turnover.
- Do not underestimate the resources needed for training, both initially and as staff turnover in health facilities occurs.
- Monitor data reporting. If numbers from a specific facility decline dramatically, it may be the result of staff turnover, if so, identify a new contact and provide the necessary training.
- Try to keep facilities engaged through frequent summary reports and ongoing contact—otherwise, there is a risk of reporting fatigue.

What should be included in a NAS surveillance system?

Most states seem to favor a NAS surveillance system that is not limited to opioids, including states where the mandate focuses only on opioids. The reasons for expanding the surveillance include substantial problems with other drugs of addiction in the state (e.g., methamphetamine), the finding that many women are polysubstance /users, the possibility of emerging and equally dangerous drugs over time, and the importance of a comprehensive picture of the epidemiology of neonatal substance withdrawal for prevention and intervention activities. Maintaining a flexible system allows states to be responsive to new threats/substances.

“Once opioids are under control, there certainly will be something else.”

“As a program person, not as an epidemiologist, the reason why we do all this is to try to not only understand the impact of NAS but also to do something about [it] and having a good understanding of what substances as a whole impact women of reproductive age is key in decreasing the number of [affected] babies down the line. As a program person, I feel extending the definition beyond opioids would be helpful.”

Although some felt it would be useful to also look at exposures and asymptomatic infants, it remains beyond the resources that most have available. One state suggested, however, that the Pregnancy Risk Assessment Monitoring System (PRAMS) opioid module provides a rich potential source of exposure data that could be exploited to examine exposure trends.

In terms of which ICD-10-CM codes should be used, several states are currently using only P96.1 to examine their hospital discharge records, although others use additional codes to cast the net more broadly or to try to capture exposure. Some states have compared data from their specific NAS surveillance systems with data from administrative data sets. Compared with screening or facility-based reporting systems, the administrative database systems may pick up either fewer or more cases, although trends tend to be similar. When investigations of cases triggered by certain ICD-10-CM codes are carried out as part of the birth defects registry review process, some states find records that have been coded in error but have no way of estimating how many cases are missed.

In one state that does use three ICD-10-CM codes, most (79%) cases were P04.49, while only 19% were P96.1. Using the wider definition obviously increases the number of reported cases. With the decision to

move to a P96.1-based definition, the number of reported cases would clearly undergo a substantial decline:

*“It looks like based on where the CSTE position statement is going our numbers are going to decrease a lot, so it’s going to be interesting times trying to explain these changes and come to a point where everyone is comfortable with what we are reporting... **We may consider adopting** some sort of hybrid for a while so there is a nice period of transition.”*

What are some of the issues and limitations of using administrative data and ICD-CM diagnosis codes?

Although it is generally considered a relatively simple way of gathering data on trends, states identified several problems with its use. They include the following:

- The quality of the data is unknown and may be unknowable. The diagnosis for various reasons may not make it to the medical record (e.g., human error or an intentional exclusion based on a fear of creating stigma).
- Coding practices may vary widely within a state and are likely to vary considerably between states as well.
- Not all states have ready access to the state hospital association databases, some of which require contracts, and not all hospitals that care for mothers and infants may participate in the system.
- The ICD-10-CM codes are not very specific, although the additional P04 coding may help somewhat. (For example, in October 2018 a new ICD-10-CM code [P04.14 *newborn affected by maternal use of opiates*] was one of a suite of more specific newborn exposure codes released.)
- The data are not timely and real-time monitoring is not possible. At best, they are reported on a quarterly basis, but in provisional form, and it takes time for the data sets to be finalized. Hospital discharge data and all-payer claim data may lag up to 18 months or more.
- Hospital discharge data sets and all-payer claim data represent encounters and often limit access to demographic data elements and identifiers that can be used to better target services.
- State and HIPAA/42 CFR Part 2 policies regarding the removal of demographic information on patients with certain conditions involving drugs or alcohol make it difficult to characterize cases, but also to avoid duplicates. In some states, entire records with any mention of drugs or alcohol may be redacted from the hospital discharge, all-payer, and Medicaid claims records. On the other hand, having detailed demographic information may risk subpoenas in states with punitive policies toward substance users.

How did the states that were interviewed feel about the use of a clinical definition with case identification through electronic medical records?

The limitations of administrative records are clearly recognized; infants could be missed because the physician forgets to record the diagnosis or fears stigmatizing mothers and infants. Conversely, infants may be erroneously be counted as cases of NAS because of clerical error. Although most states consider searching electronic medical records (EMR) for key words of interest for the future, most do not feel that it is feasible at present.

“If [an EMR-based system] ever happens, it would probably need to be part of a much larger surveillance effort—it would get rolling because of a different purpose but we could wrap NAS into the system.”

A series of issues were raised about why its use would be problematic, as detailed below:

- The use of EMR is not yet universal in some states.
- Even if there are EMR, states may not be able to obtain access or may not be able to gain remote access, which massively increases the volume of work.
- Use of terminology is not uniform, making word search difficult.
- Physicians may avoid putting in certain terms because of fear of stigmatizing their patients.
- With a few exceptions, different hospitals and hospital systems have used different EMR vendors, further complicating any search process.

How are NAS surveillance data being used?

States were asked who was using their data and for what purposes. Most states reported results on their websites or dashboards, though the periodicity of reporting varies. A few states have gotten inquiries from their legislatures, some civic leaders have requested information as part of grant proposals, and universities have expressed interest in data access.

What further can CSTE do?

CSTE’s efforts to develop a NAS case definition is widely supported and eagerly awaited by the states that were interviewed, although as noted above, some are concerned about the implications of the definition for monitoring of trends in their states. States also mentioned that participating in working groups and conference calls provides the opportunity to learn from other states.

“What CSTE is doing in forming a more formal case definition is great. It’s difficult from our side to be doing surveillance like we are without something to harken back on as a standard. It’s been helpful in other areas where CSTE has developed a case definition....It’s easier to strategize both in terms of how your surveillance system works and what you are communicating out to the stakeholders and persons who might be reporting this data to you.”

“I find it helpful when CSTE has working groups and calls. I learn a lot from other states that have implemented systems or ways of doing things.”

Discussion

Findings

The environmental scan demonstrated that a minority of states have some form of a legislative mandate to conduct NAS surveillance. Many that do have such a mandate are states that have been heavily impacted by the opioid epidemic; in 2017, 12 of the 16 had drug overdose deaths in excess of 1500, and two additional small states with a mandate had among the highest drug overdose mortality rates in the country (4). Several have set up innovative methods of collecting surveillance data, either by adapting existing surveillance systems, state-based score tools, and birth defects registries to include NAS or by creating dedicated systems for facility reporting. The advantages of having a mandate include more complete coverage, and where new systems have been set up, far timelier data than is currently available through administrative records. Even states without mandates, however, have managed to establish data collection systems that provide useful data for program purposes.

Universal to virtually all states is the use of hospital discharge records, although not all states are conducting routine reporting of the findings, especially after the changeover to ICD-10-CM codes. While these data are not timely, in many states they cover most of the facilities where deliveries are conducted. Issues remain, however, with limited coverage in some states, lack of access to these data, which are usually consolidated by the state hospital association, lack of sociodemographic information, and in some cases, identifiers that can be used to remove duplicates, and redaction or restriction of records in which alcohol and substance use diagnostic codes appear in the insurance claim. Furthermore, there are concerns about whether information is getting recorded at hospital discharge, either because of error or concerns over creating stigma. Most of the states currently using ICD-10-CM codes employ a single code (P96.1), which by itself was not felt to be ideal. The October 2018 modifications that also allow identification of the substance of exposure should allow greater specificity.

Other administrative data sources have sometimes been used, but generally not in a systemic way. Adding NAS to birth defects registries, which involve extensive medical record reviews of infants and children with congenital anomalies, is becoming an increasingly common source of data, but it is reportedly a time-consuming process to conduct the detailed review of records that is necessary, especially if states lack electronic access to hospital records. Essentially none of the states are using electronic medical records as a primary data source, although some see it as a direction for the future as part of broader surveillance efforts to use such sources especially in states that have a single provider of the electronic record software.

In terms of the content of the case definition, 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 also favored adding tobacco and alcohol to a surveillance system. Although the value of including exposure was recognized by many, the difficulties of obtaining exposure data from existing records, issues of creating stigma, and the priority of gathering reliable information on clinical illness contribute to the relatively low interest in surveillance of exposure.

Limitations

The environmental scan and key informant interviews had several limitations. First, the scan instrument was long and complex, and some of the skip patterns resulted in the absence of data on certain

variables. In addition, some of the questions were not clear and resulted in some confusion and ambiguity in some responses. For example, in the question concerning whether NAS was a reportable condition at state level, there may have been confusion with the reporting required by the Comprehensive Addiction and Recovery Act (CARA) and Child Abuse Prevention and Treatment Act (CAPTA). Finally, in some states, the person who completed the scan may not have been the person with the greatest knowledge of NAS reporting practices in the state.

The key informant interviews did not include all states with a legislative mandate, and only two states without a mandate were interviewed. Thus, the information presented may not represent the full range of experiences for the states they were meant to represent, especially for states without a current mandate.

Conclusions and recommendations

Legislative mandates

A minority of states (16) have some form of a legislative mandate to conduct NAS surveillance. In most cases, they are not based on specific legislation but result from actions permitted under previous legislation that allows state health officers and others to add NAS to the list of reportable conditions in the state. There were several obvious advantages to mandates, including timeliness, completeness of reporting, and the ability to collect sociodemographic and clinical information not available from administrative sources, but in some cases, legislation may limit surveillance flexibility as other causes of NAS emerge, and having additional data may increase the likelihood of subpoenas in states with punitive policies towards substance use in pregnancy.

Recommendations, legislative mandates

Most importantly, jurisdictions should use a standardized case definition and conduct surveillance. If they choose to pursue legislation, policies, or regulations that mandate NAS surveillance, they should explore existing policies and regulations to see if NAS can simply be added to an existing mandate rather than going through the many steps of passing a law. If they seek to develop a specific law, it should be made flexible so that other substances can be added in the future.

Sources and methods of surveillance

Virtually all states have access to administrative data, and many use hospital discharge records as the primary data source for NAS surveillance. A single ICD-10-CM code, P96.1, is generally used.

Although such administrative data have the advantage of near-universal availability, they have many disadvantages:

- Real-time monitoring is not possible, and although provisional counts may be available quarterly, the final data set is generally not available until early in the next calendar year.
- The data may not be complete since state hospital associations do not always cover all the hospitals in the state.
- States may lack financial access to the hospital discharge records, which may require payment to the hospital association.
- The quality of the data is unknown, and probably unknowable. States report wide variations in reporting even within the state based on individual clinician and hospital practices, and not all NAS cases will have the condition recorded in as a discharge diagnosis, either through error or because providers perceive that it may create stigma. The amount of information that can be used to better target services is often limited, and depending on the state, it may not be possible to easily eliminate duplicate records. Furthermore, because of HIPAA rules, data may not be available on persons with diagnoses related to alcohol or substance abuse. The current ICD-10-CM code is not very specific, leading to possible over- and under-classification of cases.

A number of other alternatives exist for NAS surveillance which can be used to collect more detailed, and, in many cases, more timely data. Adding NAS to birth defects registries that are considered to have fairly complete reporting is one solution, but the necessary record abstraction may be labor-intensive and is unlikely to be timely. States may consider adding NAS existing reportable disease hospital-based reporting systems, which can be done relatively quickly and with minor software modifications, although

training at the reporting facilities will also be necessary. A variant in those states which are using a birth scoring tool is to add NAS to the existing reporting system. Finally, states may create standalone systems, which are generally more time and labor intense to create and manage than adding on to existing systems.

Using electronic medical records may be a promising strategy in the future but is not yet in widespread use and may not be feasible in the short term in those states where there are multiple electronic record software providers or where states do not have online access (or any access) to hospital electronic records. Many other surveillance groups are interested in their use, and when the techniques for their use have been further refined, it will be worthwhile to revisit their usefulness as a NAS surveillance tool.

Sources and methods of surveillance, recommendations

For national surveillance purposes, the priorities of each state and the need for detailed NAS surveillance, and state resources should be considered. However, at a minimum, it should be possible to collect ICD-10-CM data from virtually all states. Clearly, any national indicator used to compare NAS incidence between states will require the collection of data from all or virtually all hospitals and birthing centers. It will also require working with providers to ensure use of a common standard and with hospitals to ensure that it is reported at the time of discharge and that the coding is complete and accurate. Jurisdictions can later make modifications to meet their particular needs, taking into account local resources.

States with a high or rising number of cases, where detailed and more timely data are needed to target and deliver services, should consider additional NAS surveillance activities, such as adding NAS to an existing reportable system or creating a standalone system that will allow them to collect the data that would be needed to clinically confirm a case and identify populations at risk. Such systems would also have the advantage of timeliness, which can be critical to the effectiveness of interventions. It should be noted, however, that considerable resources will need to be dedicated to training, and periodically re-training facility staff to ensure continuous and complete reporting. Additionally, the challenges of developing software or a case-reporting application should not be underestimated, nor should the need for staff to follow through with non-reporting or incomplete records and to maintain the motivation of reporting staff at the participating facilities.

Electronic medical records are not a feasible source of surveillance at present, but if successful techniques for their use are developed for other diseases and conditions, additional pilot projects should be undertaken to re-evaluate their use in NAS surveillance.

Content of NAS surveillance

Most states prefer a definition of NAS that extends beyond opioids, especially since it is likely that new substances that cause neonatal withdrawal will appear in the future. There are mixed opinions on surveillance of exposure. Although it would provide a more comprehensive picture of substance use in pregnancy, it also would involve obtaining information from maternal records and laboratory records, which may be beyond the scope and means of many health departments, who may prefer to concentrate on obtaining reliable information on the clinical syndrome.

Content of NAS surveillance, recommendations

There seems to be a consensus that the surveillance system should concentrate on clinically apparent NAS, although some states may wish to also collect exposure data to better define the extent and breadth of neonatal substance exposure.

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