

Neonatal Abstinence Syndrome (NAS) Standardized Surveillance Case Definition Position Statement



Council of State and Territorial Epidemiologists

What is CSTE?



- CSTE is the Council of State and Territorial Epidemiologists
 - is an organization of member states and territories representing public health epidemiologists
 - works to advance public health policy and epidemiologic capacity
 - provides information, education, and developmental support of practicing epidemiologists
- CSTE members include
 - state epidemiologists – these are the representatives from the states who get to vote on position statements about how disease case definitions are determined and whether reporting of diseases should be recommended
 - applied public health epidemiologists and related professions
- CSTE members work in government, private-sector, non-profit, and academic contexts throughout the nation

Why is CSTE Interested in NAS?



- Variation in incidence of NAS of great concern
 - NAS incidence did not necessarily correspond to rates of opioid use disorder among pregnant women
- Uncertainty about how NAS is being defined
- No clear understanding of how NAS is being diagnosed / how a clinically compatible presentation is being made
- No clear understanding of what is documented in the newborn record
- ICD-9-CM and ICD-10-CM codes do not allow for clear cut case definitions

- Led to the formation of an epidemiologic workgroup at CSTE

Timeline

June 2017	CSTE identified need for a workgroup on NAS and identifies co-leads for the workgroup
September 2017	CSTE convened NAS definition workgroup and leadership group
June 2018	CSTE conducted 50-state Environmental Scan on NAS definitions, data sources and reporting
December 2018	CSTE convened multi-state NAS Leadership group in-person meeting; state representatives vote to draft a position statement
January-March 2019	CSTE and state representatives consulted with CSTE staff, epidemiologists, neonatologists, obstetricians, addiction medicine specialists, laboratorians on aspects of NAS to come to a consensus on a case definition
March 2019	State representative CSTE members submitted position statement on a standardized case definition of NAS

Surveillance Goals



- Estimate incidence
- Track trends for planning and comparison across areas
- Evaluate effectiveness of neonatal interventions
- Monitor impact of *in utero* exposure on long-term health and development of infants
- Identify women with chronic opioid use and link to treatment
- Plan for public health and clinical resources for families
- Connect families with health and social services

Surveillance Challenges



- Develop case definition all states can use given needs and resources
- Advance definitions amidst lack of clinical consensus
- Advance definitions using current ICD-10-CM codes
- Address NAS in context of substance exposure in pregnancy
- Desire to not contribute to further stigmatization of women

Neonatal abstinence syndrome (NAS) is withdrawal in neonates following chronic *in utero* exposure to medications or illicit drugs, most commonly opioids, benzodiazepines and barbiturates

- Withdrawal signs:

- central nervous system (high pitched cry, hypertonia, tremors, seizures, hyperactive Moro reflex, poor sleep, seizures, poor feeding)
- autonomic nervous system (sneezing, nasal congestion, frequent yawning, fever, mottling)
- gastrointestinal (regurgitation, vomiting, loose stools)
- respiratory dysregulation (tachypnea, respiratory distress)

- Two-tiered approach to accommodate state needs and resources
 - Tier 1
 - Case reporting to public health legal authorities
 - Based on clinical records
 - Reporting by providers, laboratories
 - Tier 2
 - Case reporting based on administrative data
 - Uses ICD-10-CM codes
 - Reporting by providers, facilities

PROPOSED CASE DEFINITIONS



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Tier 1 NAS Case Definitions: CONFIRMED CASE



- Hospitalized neonate <28 days of age
- Presentation / clinical signs not explained by another etiology*

<i>In utero exposure**</i>	Diagnosis, Chief Complaint or Clinically Compatible Presentation	Neonatal Confirmatory Laboratory Evidence
opioids, barbiturates, benzodiazepines	Diagnosis of NAS	Positive
opioids, barbiturates, benzodiazepines	Chief complaint of NAS	Positive
opioids, barbiturates, benzodiazepines	Clinically compatible presentation of 3 or more signs of withdrawal***	Positive

*e.g., sepsis, intracranial hemorrhage, hypocalcemia

**opioids (any level) including natural (e.g., morphine, codeine), semi-synthetic (e.g., heroin), and synthetic (e.g., fentanyl, or fentanyl analogs), or opioid metabolites (e.g., 6-monoacetylmorphine), benzodiazepines (e.g., diazepam, alprazolam), or barbiturates (e.g., phenobarbital)

***Withdrawal signs:

central nervous system (high pitched cry, hypertonia, tremors, seizures, hyperactive Moro reflex, poor sleep, seizures, poor feeding)

autonomic nervous system (sneezing, nasal congestion, frequent yawning, fever, mottling)

Tier 1 NAS Case Definitions: PROBABLE CASE – Types 1 & 2



- Hospitalized neonate <28 days of age
- Presentation / clinical signs not explained by another etiology*

Type	Maternal History of Chronic Substance** Use in the 4 Weeks Prior to Delivery	Diagnosis, Chief Complaint or Clinically Compatible Presentation	Maternal Confirmatory Laboratory Evidence	Neonatal Confirmatory Laboratory Evidence
1	#	Diagnosis of NAS		No/unknown
1	#	Chief complaint of NAS		No/unknown
1	#	Clinically compatible presentation of 3 or more signs of withdrawal***		No/unknown
2		Diagnosis of NAS	Positive##	No/unknown
2		Chief complaint of NAS	Positive##	No/unknown

Tier 1 NAS Case Definitions: SUSPECT CASE – Types 1 - 7



- Hospitalized neonate <28 days of age
- Presentation / clinical signs not explained by another etiology*

Type	Maternal History of Chronic Substance Use in the 4 Weeks Prior to Delivery	Diagnosis, Chief Complaint or Clinically Compatible Presentation/Clinical Presentation	Maternal Confirmatory Laboratory Evidence	Neonatal Confirmatory Laboratory Evidence
1	Non-opioid, non-benzodiazepine or non-barbiturate	Diagnosis of NAS	No/unknown	No/unknown
1	Non-opioid, non-benzodiazepine or non-barbiturate	Chief complaint of NAS	No/unknown	No/unknown
1	Non-opioid, non-benzodiazepine or non-barbiturate	Clinically compatible presentation of 3 or more signs of withdrawal***	No/unknown	No/unknown
2	Unknown type	Diagnosis of NAS	No/unknown	No/unknown
2	Unknown type	Chief complaint of NAS	No/unknown	No/unknown

Tier 1 NAS Case Definitions: SUSPECT CASE – Types 1 – 7, cont.



- Hospitalized neonate <28 days of age
- Presentation / clinical signs not explained by another etiology*

Type	Maternal History of Chronic Substance Use in the 4 Weeks Prior to Delivery	Diagnosis, Chief Complaint or Clinically Compatible Presentation/Clinical Presentation	Maternal Confirmatory Laboratory Evidence	Neonatal Confirmatory Laboratory Evidence
3		Diagnosis of NAS	Positive§	No/unknown
3		Chief complaint of NAS	Positive§	No/unknown
3		Clinically compatible presentation of 3 or more signs of withdrawal***	Positive§	No/unknown
4	Opioid, benzodiazepine or barbiturate	Clinical presentation of 1 or 2 signs of withdrawal***	No/unknown	No/unknown
5		Clinical presentation of 1 or 2 signs of withdrawal***	Positive§§	No/unknown

Tier 1 NAS Case Definitions: SUSPECT CASE – Types 1 – 7, cont.



- Hospitalized neonate <28 days of age
- Presentation / clinical signs not explained by another etiology*

Type	Maternal History of Chronic Substance Use in the 4 Weeks Prior to Delivery	Diagnosis, Chief Complaint or Clinically Compatible Presentation/Clinical Presentation	Maternal Confirmatory Laboratory Evidence	Neonatal Confirmatory Laboratory Evidence
6	Opioid, benzodiazepine or barbiturate	Clinical presentation of a well newborn with 0 signs of withdrawal***	No/unknown	No/unknown
7		Clinical presentation of a well newborn with 0 signs of withdrawal***	Positive§	No/unknown

*,***See Tier 1 Confirmed Case Slide

§Chronic opioid, benzodiazepine or barbiturate use in the 4 weeks prior to delivery

Note: Positive maternal history is considered stronger evidence of chronic *in utero* substance exposure than laboratory findings due to variability in who is tested, when testing occurs with respect to delivery, and the sensitivity and specificity immunoassay screening tests.

Immunoassay tests are commonly used in hospitals without confirmatory testing due to costs, and the length of time to receive confirmatory results. Laboratory evidence is supportive.

Laboratory evidence without newborn signs will only be considered a suspect case. It is not the

Tier 2 NAS Case Definitions: CONFIRMED CASE



Confirmed	A neonate whose healthcare record contains any diagnosis of neonatal drug withdrawal within the birth hospitalization or a hospitalization or similar clinic admission before 28 days of age.	ICD-10-CM Code P96.1
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Notes: Current ICD-10-CM codes are not specific enough to capture withdrawal signs solely due to opioids, benzodiazepines, or barbiturates. For this reason, Tier 1 Confirmed and Probable cases and Tier 1 Type 1, Type 2 and Type 3 Suspect cases will be categorized as Confirmed cases under Tier 2.

Recommendations for use of ICD-10-CM codes to promote consistency relevant to Neonatal Abstinence Syndrome/NAS: In a hospital setting, the healthcare provider will state clinical signs and findings based on their expertise. Neonatal laboratory results, maternal laboratory results and maternal history will be used to inform clinical decision-making. In classifying cases of NAS using ICD-10-CM codes, we recommend the following guidelines to promote consistency in reporting for coding infants with neonatal abstinence syndrome and/or *in utero* exposure to opioids, benzodiazepines, or barbiturates.

Confirmed and Probable NAS:

For neonates with clinical signs of withdrawal and confirmed neonatal or maternal laboratory results or maternal history, the following ICD-10-CM hospital discharge code should be reported:

P96.1

Neonatal abstinence syndrome

Tier 2 NAS Case Definitions: SUSPECT CASE



Suspect	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	ICD-10-CM Codes P04.14, P04.17, or P04.1A
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Recommendations for use of ICD-10-CM codes to promote consistency relevant to Neonatal Abstinence Syndrome/NAS

Suspect NAS:

Presence of the clinical signs compatible with NAS without a history for or laboratory confirmation of maternal opioid use. For these infants, there are no ICD-10-CM codes available.

Exposed but no clinical signs of withdrawal:

When an infant has been exposed prenatally to drugs/substances that can cause withdrawal signs (known via maternal history/laboratory testing or neonatal laboratory testing), but does not show signs of withdrawal, one of the following ICD-10-CM discharge codes should be reported. These ICD-10-CM codes were new in October 2018 (FFY 2019) to designate *in utero* exposure:

- P04.14 Newborn affected by maternal use of opiates
- P04.17 Newborn affected by maternal use of sedative-hypnotics
- P04.1A Newborn affected by maternal use of anxiolytics

- For neonates who require opioids to prevent or to treat signs of withdrawal following prolonged use of opioids due to postnatal exposure (i.e., for neonatal medical conditions such as extracorporeal life support, treatment of pain after major surgical procedures), the following ICD-10 hospital discharge code should be reported:

P96.2 Withdrawal after therapeutic use of drugs

- **These infants are not considered to experience Neonatal Abstinence Syndrome/NAS according to the case definition of this position statement as it only includes *in utero* exposures.**

Confirmatory laboratory evidence -- NEONATE

Detection of opioids (any level) including natural (e.g., morphine, codeine), semi-synthetic (e.g., heroin), and synthetic (e.g., fentanyl, or fentanyl analogs), or opioid metabolites (e.g., 6-monoacetylmorphine), benzodiazepines (e.g., diazepam, alprazolam), or barbiturates (e.g., phenobarbital) in any clinical specimen from a screening or other laboratory test (See Appendix 3 for exact laboratory criteria). This would include positive immunoassay results as well as confirmatory testing based on liquid or gas chromatography-mass spectrometry.

Presumptive laboratory evidence -- MOTHER

Detection of opioids (any level) including natural (e.g., morphine, codeine), semi-synthetic (e.g., heroin), and synthetic (e.g., fentanyl, or fentanyl analogs), or opioid metabolites (e.g., 6-monoacetylmorphine), benzodiazepines (e.g., diazepam, alprazolam), or barbiturates (e.g., phenobarbital) in blood or urine from a screening or other laboratory test in the four weeks prior to delivery (See Appendix 3 for exact laboratory criteria). This would include positive immunoassay results as well as confirmatory testing based on liquid or gas chromatography- mass spectrometry.

Supportive laboratory evidence -- MOTHER

Detection of a non-opioid, non-benzodiazepine, or non-barbiturate drug of abuse, including cocaine, methamphetamine, amphetamine, or cannabinoid in blood or urine from a screening or other laboratory test in the four weeks prior to delivery (See Appendix 3 for exact laboratory criteria). This would include positive immunoassay results as well as confirmatory testing based on liquid or gas

Specificity of ICD-10-CM codes:

- New ICD-10-CM neonatal drug withdrawal codes specific to opioids, benzodiazepines, barbiturates
- Suspect cases and some Probable cases identified under Tier 1, would be categorized as confirmed cases under Tier 2
- Appendix 5 provides guidance on coding consistent with case definition
- Appendix 6 identifies where additional codes would promote greater specificity of *in utero* exposure

Laboratory reporting of drug exposures:

- Supportive information only
- ANY level confirmed positive result is acceptable
- Immunoassays are commonly used for screening – varying sensitivity.
- Cross reactivity with medications or poppy seeds can result in false positives.
- Tests capture varying time frames of exposure.

Polysubstance exposure

- Alcohol, nicotine, medications, other drugs may influence withdrawal timing and severity
- Recommend capturing substances / substance types and positive drug screens and self-reports on case report form:
 - opiates, sedative-hypnotics, anxiolytics
 - cocaine, methamphetamine, amphetamine, cannabinoid
 - alcohol, nicotine
 - self-reported medications
- Will make recommendation of ICD-10-CM codes that would facilitate report of polysubstance exposure

All in utero exposure vs NAS

- Would be helpful for public health goals to capture all *in utero* opioid, benzodiazepine, barbiturate exposure and determine no, mild, moderate, severe withdrawal in neonate
- Current position statement framework will support states' moving towards this approach
- Position statement can be revised as clinical consensus builds

- Two-tiered case definition not perfect, but hope to move field forward and promote more consistent diagnostic and coding practices while pediatric clinicians develop consensus.
- With improved clinical consistency and coding over time, hope to combine tiers into single case definition with guidance for using either clinical or administrative records.

Position Statement (PS) Next Steps



Date	Action
3-7-2019	NAS PS submitted
3-9-2019 -- 3-21-2019	CSTE National Office Internal Review
3-21-2019	Submission shared with PS SMEs for review
3-21-2019	Submission shared with Steering Committee Chairs
3-21-2019 – 4-4-2019	Steering Committee Chair Review and approval
4-4-2019	Feedback shared with authors
4-4-2019 – 4-18-2018	Authors reconcile feedback
4-18-2019	Final versions shared with the CSTE National Office
4-25-2019	PS posted to CSTE website for member review
5-7-2019 at 3:30-4:30 Eastern	NAS PS webinars
5-10-2019 at 3:00-4:30	

Position Statement (PS) Next Steps



Date	Action	Opportunities to Learn and Advocate
6-2-2019	SU/MH Conf Workshop	3:30-4:25 Discussion and Q&A
6-2-2019	MCH Conf Workshop	Discussion and Q&A
6-3-2019	NAS PS Roundtable	Discussion and Q&A
6-TBD-2019	SU/MH Meeting	Report and Discussion
6-TBD-2019	CD/MCH/OH Meeting	Report and Discussion
6-5-2019	CSTE Position Statement Discussions	Presentation, Discussion and Q&A
6-6-2019	CSTE Business Meeting	Please attend / Make sure your state epidemiologist is prepared to vote

For Questions or Comment Submissions,

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Definition of NAS

- CSTE defines **confirmed, probable** or **suspect NAS**
- There is a use of “diagnosis of NAS, or chief complaint of NAS, or a clinically compatible presentation of 3 or more signs of withdrawal” in the definition
- It is difficult for clinicians to be consistent with their diagnosis, when the actual diagnosis is used in the definition.
- We propose use of the Florida definition of NAS for Kansas.
- To be the true NAS code 96.1
 - Documented or known exposure to opioid, benzo or barbiturate
 - Signs of NAS requiring some care different than routine observation:
 - Medical treatment or
 - Prolonged hospital stay for comfort cares beyond normal observation period:
 - 72 hours : exposure to short acting opiate
 - 5 days: exposure to long acting opiate
 - Excessive need for comfort cares during hospitalization (i.e. 24/7 holding)
- Always start with the known exposure code



Codes to be used when there is a known exposure but no clinical signs of withdrawal; classified as “suspect” (exposure) by CSTE

These ICD-10-CM codes were new in October 2018 to designate in utero exposure:

- Could possibly be coded as 96.1:
 - P04.14 Newborn affected by maternal use of opiates
 - P04.17 Newborn affected by maternal use of sedative-hypnotics
 - P04.1A Newborn affected by maternal use of anxiolytics
 - P04.13 Newborn affected by maternal use of anticonvulsants
- Cannot be coded as 96.1:
 - P04.11 Newborn affected by maternal antineoplastic chemotherapy
 - P04.12 Newborn affected by maternal cytotoxic drugs
 - P04.15 Newborn affected by maternal use of antidepressants
 - P04.16 Newborn affected by maternal use of amphetamines
 - P04.18 Newborn affected by other maternal medication
 - P04.19 Newborn affected by maternal use of unspecified medication
 - P04.41 Newborn affected by maternal use of cocaine
 - P04.42 Newborn affected by maternal use of tobacco
 - P04.81 Newborn affected by maternal use of cannabis



CSTE Definitions

- Confirmed NAS; code 96.1
 - + infant drug screen for opioids, benzos or barbiturates
 - Symptoms requiring increased care (as defined slide 1)
 - Probable NAS; code 96.1
 - History of exposure to above meds
 - Symptoms requiring increased care (as defined slide 1)
 - Suspected NAS; coded by exposure code P04.xx
 - All other drug exposures with or without symptoms
 - Exposure to opioids, benzo or barbiturates without significant symptoms
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- See slides for many more details!

