NAS TASK FORCE RESPONSE TO SB 408

Neonatal Abstinence Syndrome (NAS) is a drug withdrawal syndrome that presents in newborns after birth when transfer of harmful substances from the mother to the fetus abruptly stops at the time of delivery. NAS most frequently is a result of opioid use in the mother but may also occur as a result of exposure to benzodiazepines and alcohol. Fetal exposure most frequently occurs for one of three reasons:

- The pregnant woman is dependent/addicted to opioids, either prescribed or illicit;
- The pregnant woman requires treatment with prescription opioids for another disease process; or
- The pregnant woman is receiving prescribed opiate replacement therapy.

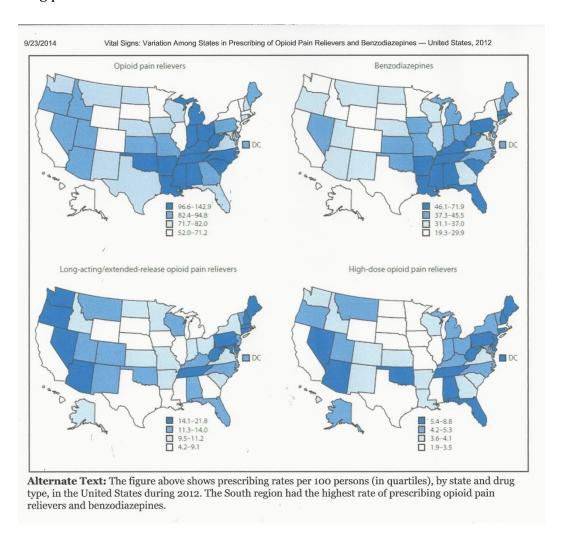
The incidence of NAS has increased significantly over the last fifteen years. In 2000, the rate per 1,000 births was 1.2. In 2009, the rate was 3.39 per 1,000 births. Maternal opiate use has increased even more dramatically. In 2000, the rate was 1.19 per 1000 births per year and in 2009 the rate was 5.63 per 1,000 births per year. The cost of care for infants diagnosed with NAS has also increased from \$190 million in 2000 to \$720 million in 2009.

In a report released by the Centers for Disease Control and Prevention (CDC),² prescribers wrote 82.5 Opioid Pain Reliever (OPR) prescriptions and 37.6 benzodiazepine prescriptions per 100 persons in the United States in 2012. The range nationally for OPR was a high of 142.9 per 100 persons for Alabama and a low of 57.0 per 100 persons for California. the range for benzodiazepine prescriptions was a high of 41.5 per 100 persons for Delaware and a low of 34.2 per 100 persons for Illinois. Only eight states had a higher prescribing rate for opioid pain relievers than Indiana's rate of 109.1 per 100 persons and 16 states had a higher prescribing rate for benzodiazepine than Indiana's rate of 42.9 per 100 persons.

¹ Patrick S, Schumacher R, Benneyworth B, *et al.* "Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009." *JAMA*. 2012. 307(18):1934-40.

² http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6326a2.htm?s_cid=mm6326a2

The following figure from the CDC report documents that status of states related to prescribing practices.



In 2014, the 118th Indiana General Assembly passed Senate Bill 408 which added Section 244.8 to Indiana Code 16-18-2 stating:

"Neonatal abstinence syndrome" and "NAS", for purposes of IC 16-19-16, refer to the various adverse effects that occur in a newborn infant who was exposed to addictive illegal or prescription drugs while in the mother's womb.

The legislation added IC 16-19-16 which required that the State Department of Health establish a task force that included, at a minimum, representatives from the Indiana Hospital Association, the Indiana Perinatal Network, the Indiana State Medical Association, the Indiana Chapter of the American Academy of Pediatrics, the Indiana Section of the

American Congress of Obstetricians and Gynecologists, and the Indiana Chapter of the March of Dimes. The task force was charged with five deliverables:

- (1) The appropriate standard clinical definition of "Neonatal Abstinence Syndrome";
- (2) The development of a uniform process of identifying Neonatal Abstinence Syndrome;
- (3) The estimated time and resources needed to educate hospital personnel in implementing an appropriate and uniform process for identifying Neonatal Abstinence Syndrome;
- (4) The identification and review of appropriate data reporting options available for the reporting of Neonatal Abstinence Syndrome data to the state department, including recommendations for reporting of Neonatal Abstinence Syndrome using existing data reporting options or new data reporting options; and
- (5) The identification of whether payment methodologies for identifying Neonatal Abstinence Syndrome and the reporting of Neonatal Abstinence Syndrome data are currently available or needed.

The Task Force was convened in May 2014 with approximately 50 members³ who met monthly to accomplish the deliverables. The committee reviewed national guidelines, relevant literature and practices related to NAS developed by other states in order to fully inform the decision-making process. After completion of the review process and substantive discussion of the issues related to NAS, the following represents the consensus position of the NAS Task Force.

Deliverable 1: The appropriate standard clinical definition of "Neonatal Abstinence Syndrome.

The Task Force has recommended that the diagnosis of NAS should be applied to babies who meet the following criteria:

³ Names and affiliations of the Task Force Members are listed in Appendix A on page 10.

- Symptomatic;
- Have two or three consecutive Modified Finnegan scores equal to or greater than a total of 24; and
- Have one of the following:
 - o A positive toxicology test, or
 - o A maternal history with a positive verbal screen or toxicology test.



Deliverable 2: The development of a uniform process of identifying Neonatal Abstinence Syndrome.

The Task Force developed a process for both pregnant women and newborns for the purpose of correctly identifying pregnant women at risk for delivering a baby with NAS.

- The **Obstetric Protocol** focuses on two points in time:
 - o The first prenatal visit; and
 - o Presentation at the hospital/birthing center for delivery.

First Prenatal Visit

At the initial prenatal visit, as part of routine prenatal screening, the primary care provider will conduct a standardized and validated verbal screening process and a urine toxicology screen. The toxicology screen is voluntary and the pregnant woman can opt out of the toxicology screen. At the discretion of the primary care provider, INSPECT and/or repeat verbal and toxicology screenings may be performed at any visit. The toxicology screen is always voluntary on the part of the pregnant woman.

Presentation at the hospital/birthing center for delivery.

When the pregnant woman arrives at the hospital for delivery, hospital personnel will conduct a standardized and validated verbal screening on all women. Medical staff will request that the woman consent to a urine toxicology screening for anyone with a positive screening result at any point during her pregnancy including presentation for delivery. Babies whose mothers had a positive verbal screen or positive toxicology screening results or babies whose mothers did not consent to the toxicology screen will be screened using urine, cord or meconium.

- The **Neonatal Protocol** focuses on three cohorts of babies:
 - Newborns with no identifiable risk;
 - Newborns at risk for NAS; and
 - o Newborns with **unknown risk.**

Mother's status	Level of Risk for infant	Suggested Action
Negative verbal and toxicology screens	Newborn with no identifiable risk	No testing recommended at birth
Positive verbal screen and/or positive toxicology screen at any time	Newborn at risk for NAS	 Perform urine and meconium or cord toxicology screening at birth Perform Modified Finnegan scoring Evaluate maternal support resources
 No known verbal or toxicology screen during pregnancy Negative verbal screen but no known toxicology screen 	Newborns with unknown risk	 Perform urine and meconium or cord toxicology screening at birth. Perform Modified Finnegan scoring

Newborns with no identifiable risk factors are babies whose mothers have had all negative verbal and toxicology screens. There is no recommendation for testing those babies. When

the mother has had a positive verbal screen and/or a positive toxicology screen, a toxicology screen of the infant's urine, cord or meconium will be conducted; additionally, a modified Finnegan scoring will be initiated.

For newborns with unknown risk, meaning that the mother has not had either verbal or toxicology screening during the pregnancy, or the mother had a negative verbal screen but no toxicology screen, the toxicology screen of the infant's urine, cord or meconium will be conducted; additionally, a modified Finnegan scoring will be initiated.

Deliverable 3: The estimated time and resources needed to educate hospital personnel in implementing an appropriate and uniform process for identifying Neonatal Abstinence Syndrome.

The Task Force identified tools and developed a process for educating hospital personnel. In order to identify a cost effective and consistent approach to the identification of NAS, the Task Force recommended that the state employ a "train the trainer" model by conducting a one day training for hospital/birthing center perinatal educators who would then return to their facility and develop a training plan that would ensure that perinatal hospital personnel have the knowledge and skills necessary to properly identify NAS. Incorporating NAS into already designated and budgeted education days limits the fiscal liability to the facilities. Incorporating NAS in future competency evaluations and nursing orientation curricula provides an already established vehicle for ongoing staff education.

Two training programs have been identified to support inter-rater reliability for Finnegan scoring necessary to make the official diagnosis of NAS. The two training modules and their costs are: NeoAdvance from Vanderbilt University (\$120 for the DVD and Manual) and the module developed by Gateway Health in Pennsylvania (\$20 for the DVD and Manual). The Task Force chose to recommend both curricula as some hospitals have already purchased materials and trained their staff.

The Task Force developed and implemented a survey⁴ of the nurse managers of ninety-one Indiana birthing hospitals to determine the extent to which hospitals were currently implementing policies and training related to NAS. The survey was conducted to get a better sense of what was happening in the state and the amount of effort that it would take to get to consistent policy implementation related to NAS. Fifty-one percent (51%) of hospitals responded to the survey. Forty percent (40%) of the respondents did not have a policy related to the diagnosis of NAS and 38% did not have a policy related to the management of NAS. Of the hospitals that indicated they had a policy, 42% indicated that the policy was always followed while an additional 30% indicated that the policy was usually followed. Only 19% of the respondents indicated they were using a recognized training program.

In addition to training hospital staff, a more comprehensive training initiative was recommended by the Task Force members that would extend beyond the initial identification process and beyond hospital personnel. This training initiative would require additional resources to reach the broader audience that is identified.⁵ A more detailed chart is provided in Appendix C.



⁴ The survey questions can be reviewed in Appendix B on page 12.

⁵ The detailed training overview can be reviewed in Appendix C on page 14.

Deliverable 4: The identification and review of appropriate data reporting options available for the reporting of Neonatal Abstinence Syndrome data to the state department, including recommendations for reporting of Neonatal Abstinence Syndrome using existing data reporting options or new data reporting options.

There was significant discussion among Task Force members related to the collection of identified versus de-identified data. While there was a real commitment to get to identified data so that supports and resources can be provided to the woman and her baby, there was real reluctance based on the variation across Indiana counties of whether NAS is addressed as a medical/public health issue or as a criminal/child protection issue. Until this issue is clarified and dealt with universally across counties, the Task Force has recommended that all data collected be de-identified.

ISDH has proposed that the portal used to collect newborn metabolic screening and newborn hearing screening be expanded to add NAS screening data. Hospitals are familiar with the process and a new data sheet to capture NAS data within the existing portal can be developed without additional expense.

The proposed data elements⁶ capture hospital information, maternal and infant basic information and diagnostic information. This minimum information would allow ISDH to obtain data on incidence and on types of drugs identified.

Hospital Information	Maternal Infant	Diagnostic Information
	Information	
Hospital Name	Maternal Age	 Method of Diagnosis:
• Department	Maternal Residence	o Maternal
o NICU	o In-state	o Infant
o Newborn Nursery	o Out-of-State	 Drugs Identified:
o Pediatrics	Third Party Coverage	o Mother
	Infant Gestational Age at	o Baby
	Birth	
	Infant Chronologic Age at	
	Diagnosis	

⁶ A detailed list of the data elements can be seen in Appendix D on page 16.

8

Deliverable 5: The identification of whether payment methodologies for identifying Neonatal Abstinence Syndrome and the reporting of Neonatal Abstinence Syndrome data are currently available or needed.

The Task Force reviewed each of the charges identified in SB 408 to determine both the cost of implementation and available reimbursement.

- <u>Toxicology Screening:</u> The cost of toxicology screening will vary based on the composition of the drug panel for which testing is being conducted. The three initial drugs that the Task Force recommends are Opioids, Alcohol, and Benzodiazepines.
 Both public and private insurance will typically cover the cost of these screenings.
 However with a universal approach, it is anticipated that there will be an increase in the number of screens and therefore an anticipated increase in cost to third party payors.
- Training: The Task Force is recommending a "train the trainer" model. ISDH would sponsor a one day training bringing in the nurse educators from all 91 birthing hospitals to provide training on NAS identification and modified Finnegan scoring. The nurse educators would be responsible for the development of a training plan and incorporating the training into already existing hospital education days. NAS training would also become part of their orientation for new staff. While there would be costs associated with the purchase of the training materials, by incorporating the training into already scheduled education events, the increased costs to hospitals would be limited.
- <u>Data Collection</u>: The development of the portal and collection sheet will be completed by ISDH staff and will have a cost of \$50,000 to support an additional <u>FTE</u> to develop, support, monitor and analyze the NAS data collection process. Estimates on the additional time that it will take for hospital staff to gather the information and enter the data cannot be confirmed until the proposed pilot process is complete.

9

⁷ NeoAdvance from Vanderbilt University (\$120 for the DVD and Manual) and the module developed by Gateway Health in Pennsylvania (\$20 for the DVD and Manual)

APPENDIX A: NAS TASK FORCE MEMBERS

First		
Name	Last Name	Affiliation
Jonell	Allen, DNP, MSN, CNS-BC, RNC-OB	Community Health Network
Ivy	Antonian, RN	Franciscan St Elizabeth East
Deb	Beynon	St Vincent Women & Children's
Bob	Bowman	Indiana State Department of Health
James	Cameron, MD	Northern IN Neonatal Associates
Kathryn	Carboneau, MD	Retired Anesthesiologist
Amelia	Clark	Meridian Health Services
Teri	Conard	Marion Co Health Dept
Mary	Degeneffe, MD	Pediatrix Medical Group
_		Indiana Counselors Association on
Stan	DeKemper	Alcohol and Drug Abuse (ICAADA)
		St. Mary's Neonatal Clinic
Maria	Del Rio Hoover, MD**	Indiana State Medical Association
Netta	Doughty	Social Worker
		Indiana State Department of Health
Ican	Duverso MD	Indiana University School of Medicine
Joan Lisa	Duwve, MD	Schneck Medical Center
John	Eagans, RNC, MSN Ellis, MD**	MHS Indiana
Donetta	Gee-Weiler, RN, BSN	Community Health Network
Donetta	Gee-Weller, KN, DSN	Indiana Chapter, American College
Mark	Gentry, MD	of Obstetrics and Gynecology
Don	Granger, MD, MPH	St. Mary's Neonatal Clinic
Laura	Haneline, MD	IU Dept of Pediatrics
Iulia	Tipton Hogan	Indiana Perinatal Network
Larry	Humbert	Indiana Perinatal Network
Vicki	Johnson, MSN, RN, NE-BC	Schneck Medical Center
Julie	Kathman, MSN, RN, CNS-BC, CPN	Bloomington Hospital
Julie	Keck, MD	Anthem
Mary Beth	Koch, NNP-BC, C-NPT	IU Health Riley
Abigail	Kuzma	Attorney General's Office
Joseph	Landwehr, MD	IU Health Ball Memorial
Bethany	Littrell, LMHC, LCAC	St. Vincent Hospital
Art	Logsdon, JD	Indiana State Department of Health
Joanne	Martin, RN DrPH	Goodwill of Central Indiana
JoAnn	Matory, MD	Eskinazi Hospital - March of Dimes

First	Lost Nove	A CC 11 - 41
Name	Last Name	Affiliation
Christina	McCaul	Community Health Network
		North Shore Community Health
Deborah	McCullough, MD	Center
Debra	McDaniel, MD	Southern Indiana Physicians
Minjoo	Morlan, MSW	March of Dimes
Ann	Morrow, MSN, RN	Columbus Regional Hospital
Olufemi	Okanlami, MD	Memorial Hospital
		Indiana University
		IN Chapter American Academy of
Lu-Ann	Papile, MD	Pediatrics
Anna	Schwartz	IU Dept of Pediatrics
Kimberly	Shimer, MD	The Women's Hospital
Andy	Shull, MD	IN Academy of Family Physicians
Anne Lise	Sullivan, RN, BSN, MA	Marion Co Public Health
Dan	Sunkel, MD	Franciscan St. Elizabeth East
Bernie	Ulrich	Indiana Hospital Association
Holly	Walpole	IN Professional Licensing Agency
John	Wareham, MD	St Vincent Women & Children's
Eric	Yancy, MD	MHS Indiana

Appendix B: NAS Survey Tool

minutes out of your very busy schedule to	arged with detern tocols for the ass	nining a process fo	r identifying the		
General Assembly. The Task Force is che to develop a consistent definition and pro minutes out of your very busy schedule to	arged with detern tocols for the ass	nining a process fo	r identifying the		
General Assembly. The Task Force is characteristic develop a consistent definition and prominutes out of your very busy schedule to any hospital. Thank you.	tocols for the ass			e extent of NAS	
minutes out of your very busy schedule to			nt women and		
to any hospital. Thank you.		ort survey. All inform			
1. Hospital:	3				
2 044 -54					
2. Contact Information:		_			
Name:		_			
Address:					
Address 2:					
City/Town:					
ZIP:					
Country:		_			
Email Address:					
Phone Number:					
3. Self-Declared Level of Care					
o. den-bediarea nevel of dare	Obstetrics	3		Neonatal	
Level I					
Level II				\Box	
Level III					
Level IV	Ħ			П	
al .	_		-		
4. Do you currently have a polic		IAS in the follo	wing areas		
Diagnosis	Yes	*		No O	
Management	\sim				
Wanagement	0	***		0	
5. How consistently is this polic	y implement	ed?			
Always					
Usually					
Infrequently					
We have no policy	11				
	250				

	n do you use to	train staff?		
Vanderbilt - NeoAdvance				
Pittsburgh - Gateway Health				
Other (please specify)				
	III-I III-II			
. What scoring tool are ye	ou currently us	ing?		
Finnegan	•	pean Total		
Modified Finnigan				
_ ,				
Other (please specify)				
6				
3. What hospital staff are o	urrently being	trained? Check al	I that apply.	
	NAS Protocols		Scoring	
NICU Nurses				
Newborn Nursery Nurses				
Labor and Delivery Nurses				
Postpartum/mother baby Nurses				
Pediatric Nurses		3		
Emergency Room Nurses				
Neonatologists				
Pediatricians				
Obstetricians				
Obstetricians Emergency Medicine				
	×			
Emergency Medicine	× _			
Emergency Medicine	, <u>U</u>	* . * .		* * *
Emergency Medicine		, ,		3
Emergency Medicine		* .		3 × ⁶ ,
Emergency Medicine		* . *		3 ·
Emergency Medicine				3 + ⁶ ,
Emergency Medicine		* .		

Page 2

Appendix C: Proposed NAS Training Overview⁸

Clinician Type	Training Topics			Trainee Locations (at the discretion of each center)		-	
	NAS General	NAS Screening	Finnegan Scoring	Data Gathering and Submission	Hospital	Office	Other: Birthing and Urgent Care Centers
Providers:							
Obstetrician	x	x			x	x	x
Pediatrician	x	x	x		x	x	x
Family Practice	x	x	x		x	x	x
Emergency Medicine	x	x			x		x
Advance Practice Nurses	x	x	x		x	x	x
Physician Assistants	х	х	X		х	х	х
Nurses and Staff:							
Labor & Delivery	х	х		x	x		x
Post-Partum	x	x	x	x	x		x
Mother-Baby	x	x	X	x	x		x
NICU	х	х	X	X	х		
Nursery	Х	Х	Х	Х	х	Clini	cal staff
Pediatrics	x	x	x	x	x	_	for infants
Emergency Department	x	x			x		
Home Health	x	x	X	X	x	X	x
Public Health	х	х	X	X	х	х	X

Potential Training Modes		
Initial (Periodic)	Ongoing (As needed)	
Self-Study	Self-Study	
Hospital	Hospital	
Train the		
Trainer		
Statewide Day		
Facility Competency Training Day	Facility Competency Training Day	
Unit Orientation	Unit Orientation	

Training Resources, Sponsors, Communicators:			
ISDH	IHA		
IPN	ISMA		
INAAP	INAAFP		
INACOG	INACEP		
March of Dimes	AWHONN		

 $^{^{\}rm 8}$ This reflects the best thinking of the Task Force prior to pilots.

Appendix D: NAS Data Collection Elements

Hospital Name:	Department where infant screening occurred:
	NICU
	☐ Newborn Nursery
	Pediatrics
Maternal Age:	Maternal Residence:
□ < 20	☐ In-state
□ 20-24	☐ Out-of-State
□ 25-29	Third Party Coverage:
□ 30-34	☐ Medicaid
35-39	☐ Private Insurance
4 0+	□ None
	□ Other:
Infant Gestational Age at Birth:	Infant Chronologic Age at Diagnosis:
25 weeks or less	□ <1 week
26 weeks through 32 weeks	☐ 1-2 weeks
33 weeks through 34 weeks	☐ 3-4 weeks
35 weeks through 38 weeks	☐ 5-6 weeks
39 weeks through 40 weeks	□ > 6 weeks
☐ 41 weeks	
☐ 42 weeks and beyond	
Method of Maternal Diagnosis:	Maternal Drugs Identified:
☐ Verbal Screen	☐ Maternal Self Report: Listing of Drugs
Toxicology Screen	and other
	☐ Toxicology Results: Listing of Drugs from
	Toxicology Report
Method of Infant Diagnosis:	Infant: Listing of Drugs from Toxicology
☐ Urine Screen	Report
☐ Cord Screen	Urine:
☐ Meconium Screen	☐ Cord:
	☐ Meconium: