VON Day Quality Audit / Neonatal Abstinence Syndrome

Manual of Operations

Thank you for participating in Vermont Oxford Network *A Universal Training Solution Improving Outcomes for Infants and Families Affected by Neonatal Abstinence Syndrome (NAS*) and the VON Day Quality Audit – NAS.

Vermont Oxford Network will support your regional perinatal collaborative, and your local team, to conduct quality improvement audits focusing on neonatal abstinence syndrome (NAS). The audits involve completion of a general "unit" data form addressing policies and guidelines at your hospital for the evaluation and treatment of infants exposed to substance abuse *in utero,* as well as completion of "patient" data forms auditing the status of all infants given pharmacological treatment for NAS in the first week of life and discharged in a specified three-month eligibility period. For centers with high volumes of NAS infants who received pharmacologic therapy, units will audit the last 30 eligible infants discharged from your hospital during the eligibility period.

The individual patient audit evaluates the pharmacologic agents used to treat NAS, the duration of treatment, the length of NICU stay, the length of hospital stay, the time between completing treatment and discharge, and the rate of providing breast milk at the time of discharge. These audits are identical to the audits conducted during the previous VON internet-based quality improvement program (iNICQ).

Goals: The goals of the VON Day Quality Audit on Neonatal Abstinence Syndrome are:

1. To assist multidisciplinary teams at participating hospitals in identifying improvement opportunities in the evaluation and treatment of neonatal abstinence syndrome.
2. To provide tools to assist hospitals, health systems, and state and regional perinatal quality improvement collaboratives to design, test, and implement changes to provide quality, safety, and efficiency in the care of infants with neonatal abstinence syndrome and their families.
3. Engage a wide range of hospitals and neonatal units in our improvement effort.

Background: The over-prescription, diversion, and illegal use of opiate medications is a major public health burden for maternal and child health. Infants exposed in utero to opiate medications may exhibit signs of withdrawal after birth leading to neonatal abstinence syndrome (NAS). There has been a dramatic increase in neonatal abstinence syndrome during the past decade (Patrick 2012). Infants with NAS have higher rates of neonatal complications, prolonged length of stay, consume substantial NICU and hospital resources, and pose a growing burden on already strained state Medicaid budgets.

The Committee on Drugs and the Committee on Fetus and Newborn of the American Academy of Pediatrics have recently published a clinical report on "Neonatal Drug Withdrawal (Hudak 2012). The report details the scope of the problem, the

pathophysiology, the evaluation, and the treatment of neonatal abstinence syndrome. Many of the issues germane to our iNICQ series are discussed in this clinical report and are summarized in the discussion below.

Opioid abuse constitutes the majority of neonatal abstinence syndrome. Maternal opioid addiction has increased dramatically in the past decade. Patrick and colleagues suggest that 5.6 % of pregnant women have abused opioids during pregnancy (Patrick 2012). Traditional treatment for opioid addiction in pregnancy includes the use of methadone although recent studies suggest that buprenorphine has some advantages to methadone as a treatment of opioid addiction in pregnant women (Jones 2010).

The clinical presentation of NAS varies with the opioid, the maternal drug history (including length of treatment and the most recent use of drug before delivery), maternal metabolism, transfer of drug across the placenta, placental metabolism, and infant metabolism. In addition, use of multiple agents, including cocaine, barbiturates, hypnotic sedatives, and cigarettes may influence the severity and duration of NAS.

Onset of signs attributable to neonatal withdrawal from heroin often begins within 24 hours of birth, whereas withdrawal from methadone usually begins at approximately 24-72 hours of age (Zelson 1971). For both opioids, evidence of withdrawal may be delayed until 5-7 days of age or later, which is typically after hospital discharge (Kandall 1974). The incidence and severity of NAS are greater in infants exposed to methadone compared with those exposed to buprenorphine or heroin (Jones 2010). In either case, withdrawal may occur in as many as 50% of exposed infants.

Studies of the relationship between maternal methadone dose and incidence and severity of NAS have arrived at contradictory findings. Some studies demonstrated that larger maternal methadone dosages in late pregnancy were associated with greater neonatal concentrations and increased risk of withdrawal, but others refuted the correlation. This lack of consensus is, in part, explained by different approaches to the antenatal management of mothers receiving methadone maintenance.

● **Assessment of narcotic withdrawal:** Several semi-objective tools are available for quantifying the severity of neonatal withdrawal. Clinicians have used discrete or serial scores to assist their therapeutic decision making (AAP 1998, Finnegan 1990, Green 1981, Kandall 1974, Lipsitz 1975).

Infants at risk for NAS should be carefully monitored in the hospital for the development of signs consistent with withdrawal. The appropriate duration of hospital observation varies and depends on a careful assessment of the maternal drug history. An infant born to a mother on a low dose prescription opiate with a short half-life may be safely discharged if there are no signs of withdrawal by 3 days of age, whereas an infant born to a mother on an opiate with a prolonged half-life (such as methadone) should be observed for a minimum of 5-7 days (Hudak 2012).

Initial treatment of infants who develop early signs of withdrawal is directed at minimizing environmental stimuli by placing the infant in a dark, quiet environment, avoiding auto stimulation by careful swaddling, adopting appropriate infant positioning and comforting techniques, and providing appropriate nutrition. The goals of therapy are to ensure that the infant achieves adequate sleep and nutrition to establish a consistent pattern of weight gain and begins to integrate into a social environment.

Maternal screening for co-morbidities, such as HIV or hepatitis C viral infections and polydrug abuse need to be performed. Where possible, and if not otherwise contraindicated, mothers who adhere to a supervised drug treatment program should be encouraged to breastfeed so long as the infant continues to gain weight. Breastfeeding or the feeding of human milk has been associated with decreased signs and symptoms of NAS and less frequent use of pharmacologic intervention (Abel-Latif 2006).

The Committee on Drugs and the Committee on the Fetus and Newborn of the American Academy of Pediatrics specifically recommends that "Each nursery should adopt a protocol for the evaluation and management of neonatal withdrawal and staff should be trained in the correct use of an abstinence assessment tool" (Hudak 2012). However, in a recent survey of accredited U.S. neonatology fellowship programs, only 55% had implemented a written NAS program and only 69% used a published abstinence scoring system" (Sarkar 2006, O'Grady 2009).

● **Pharmacologic treatment:** Multiple pharmacologic interventions have been used to treat neonatal abstinence syndrome, including opioids (tincture of opium, neonatal morphine solution, methadone and paregoric), barbiturates (phenobarbital), benzodiazepines (diazepam, lorazepam), clonidine and phenothiazine (chlorpromazine). The majority of centers in the United States (83%) use morphine or methadone as the first drug of choice and use phenobarbital as a secondary drug if the first line treatment does not adequately control the signs and symptoms of withdrawal (Sarkar 2006). Paregoric is no longer used because it contains variable concentrations of other opioids as well as toxic ingredients, such as camphor, anise oil, alcohol and benzoic acid. The use of diazepam has also fallen to disfavor because of documented lack of efficacy compared with other agents (Osborn 2005, Osborn 2005). Clonidine has been used in combination with opioids or other drugs in older children or adults to reduce withdrawal symptoms. Reported experience with clonidine as a primary or adjunctive treatment for NAS is limited but promising in a small case series (Leikin 2009).

The specific recommendations of the Committee on Drugs and the Committee on Fetus and Newborn of the American Academy of Pediatrics are listed verbatim in Appendix 1 (Hudak 2012). Importantly, the guidelines recommend that "Each nursery that cares for infants with neonatal withdrawal should develop a protocol that defines indications and procedures for screening for maternal substance abuse. In addition, each nursery should develop and adhere to a standardized plan for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal" (Hudak 2012).

The VON Day Quality Audit helps create a tool to monitor adherence to these important recommendations.

Results of Previous VON Day Quality Audits / Neonatal Abstinence Syndrome: An analysis of these results has been published in the peer reviewed literature, Improving Care for Neonatal Abstinence Syndrome (Patrick SW, Schumacher RE, Horbar JD, Buus-Frank ME, Edwards EM, Morrow KA, Ferrelli KR, Picarillo AP, Gupta M, Soll RF. Improving care for neonatal abstinence syndrome. *Pediatrics*. 2016; 137(5): e20153835. PubMed: 27244809). (Appendix 2).

The previous audits were identical to the audit available for this Collaborative. Similar data regarding institutional policies (maternal substance use screening, NAS evaluation and treatment, scoring practices, pharmacologic and nonpharmacologic treatment, breastfeeding) and patient level data (discharged on any human milk, with parent or other caretaker, on medication, length of treatment, length of stay in NICU vs. hospital) were collected.

Centers participating in the Collaborative demonstrated an increase in standardization of care, reflected in an increase in policies addressing the evaluation and treatment of infants with NAS. In addition, participating centers saw a significant

decrease in neonatal intensive care unit and hospital length of stay, as well as the number of infants discharged home on pharmacotherapy.

Conducting the VON Day Quality Audit / Neonatal Abstinence Syndrome

Methods: The VON Day Quality Audits / Neonatal Abstinence Syndrome will evaluate the care of infants with neonatal abstinence syndrome who have received pharmacologic therapy in the first seven days of life. In addition, the audit evaluates general policies and guidelines at your hospital regarding the management of mothers with substance abuse and infants exposed to substance abuse in utero. The Vermont Oxford Network provides data collection forms and operates a secure data portal website that allows for data entry without identification of individual patients. Approximately one week after completion of the VON Day Audit, each center will be able to view a report of their data, comparing them to the aggregated results of the other participating centers from the audit cohort (de-identified by site). The aggregated de-identified data may be submitted for publication in the peer-reviewed literature. In all these efforts, no specific data regarding the center or the individual patients will be identifiable. Your local team may elect to perform more frequent local serial audits to measure improvements in care over time. However, this data will not be submitted to VON.

The audits follow a common set of principles:

- The audits are performed for the sole purpose of quality improvement
- VON will provide audit related materials including IRB information, Manual of Operations, Step-by-Step Instructions for Audit data entry and report access, and standardized Data Collection Forms on the VON Learning Management System (LMS)
- Data will be collected manually (paper and pencil) by local data collectors
- VON will operate a secure password protected website for data entry
- Information will be entered by the local data collector via the secure web portal and transmitted to VON
- No individually identifiable data, no patient identifiers, and no protected health information will be transmitted to VON; further, the website will not accept any data of this nature
- Each audit will have two sections: 1) general questions about the unit practices, policies and procedures and 2) infant specific data regarding scoring, medication treatment, and length of stay
    - *If there are no eligible infants to report, only the unit questionnaire must be completed*

● **There are several steps that your center must take in order to participate in the audit:**

1. **Identify individual(s) to serve as the VON Day Audit Data Collector for the NAS Audit**. This individual will serve as the local leader for the VON Day Audit process. The VON Day Data Collector will help determine how cases will be identified at your center. The VON Day Data Collector is the key liaison to VON regarding all communications related to the VON Day Audit data collection and audit completion. Activities will include developing a local strategy for identifying eligible infants to audit, as well as performing the actual data collection (using "paper and

pencil" tools) and the submission of this data to VON via a web-based data entry system. He/she must have access to clinical logs and charts, as well as the clinical skills and capacity to review the charts and obtain the relevant data.

2. **Review Audit Status with your Institutional Review Board:** If not already done so, submit appropriate forms / materials/ applications to your local / regional / or statewide Institutional Review Board or comparable relevant human subjects' research committee. Confirm whether or not any human subjects' approvals are required by your unit for your local participation in the audit (please also refer to page 7 "Need for Human Subjects Approval").

3. **Enroll for VON Day Quality Audit:** Local centers will register for the VON Day Quality Audit through their statewide central contact. He / she will provide VON with the first name, last name, email, phone and key contact information for the VON Day Data Collector, as well as the VON Champion and key contacts at your center. During the week of the audit, the VON Day Audit Coordinator will provide access to the VON Day Audit portal through a link. Contact information: VON Days Audit Coordinator at vondays@vtoxford.org.

VON Day Quality Audit / Neonatal Abstinence Syndrome: The audit will involve completion of a general "unit" form addressing policies and guidelines at your hospital for the evaluation and treatment of infants exposed to substance abuse *in utero,* as well as completion of "patient" audit forms auditing the status of all infants given pharmacological treatment for NAS during the first seven days of life and discharged during the designated three month eligibility period. *If there are no eligible infants to report, only the unit questionnaire must be completed.*

● **Timeline:** We anticipate that you will review records of all discharged infants who were treated for NAS in the designated three-month eligibility period. For centers with a high volume of patients, we will expect you to audit only the most recent 30 patients discharged during the eligibility period. Detailed instructions regarding identifying these patients either using your available admission or discharge logs, or through work with your informatics team at the hospital, are given in Appendix 6 (Patient Identification Procedures and Worksheet). Data collection will include a series of questions regarding hospital policies and procedures, as well as questions regarding the individual infants treated for NAS within the first week of life. The VON Day Audit portal will be open for a one-week period at baseline. The audit will be repeated later in the collaborative for the post-test measure. PLEASE NOTE that it is imperative that you be prepared to enter data during this time period. The portal closes and data analysis begins after this 1 week period – therefore late data will not be accepted.

● **Data Collection:** There are two data forms and one worksheet to complete. The first is a data form addressing standard policies and procedures at your unit (Appendix 5: Unit Level Data Form). The second is a worksheet to help identify infants eligible for review (Appendix 6: Patient Identification Procedures and Worksheet). The third is a data collection form for individual patients who were discharged during the eligibility period after receiving pharmacologic treatment for NAS within the first 7 days of life. (Appendix 8: Patient Data Form). You will complete one data form for each eligible infant up to 30 infants. If you do not have any eligible infants during this time period, complete the Unit Level Data Form only.

When the data collection process is completed, data will be entered via the portal provided to the VON Day Data Collector at your center.

● **Data Submission:** see "Timeline" above.

● **Data Analysis:** After completion of the VON Day Audit, the VON Day Coordinator will notify the Data Collector that they have until 5:00pm on the Monday following the audit to review their data prior to finalization. Each center will be able to view a report of their data, comparing them to the aggregated results of the other participating centers from the audit cohort (de-identified by site). To view your VON Day Audit results, you will need access to the "VON Member's Area" section of our website. To access the VON Member's Area, you will use the same login and password that were required to perform the audit. In addition, anyone who has this access at your center will be able to view the VON Day Audit reports. Please see the "Step-by-Step Instructions for View Results" which can be found in the Materials and Resources section on the LMS NAS page.

If you are a VON data submitting center and want to look at related measures (i.e. your unit's LOS) or other measures of interest, you will need to be sure you have access to the VON reporting tool called Nightingale.

Access to Vermont Oxford reporting tool (Nightingale) is managed by your local VON Services Administrator(s). This is the person at your center who grants access to authorized staff at your center so that they can view the confidential data available. If you find that you do not have access when attempting to log on, please click the "Need a login and password?" link on the left to send a request to your VON Services Administrator.

If your center does not currently submit data to the VON VLBW and/or Expanded Database(s), your center will need to designate someone to serve as your VON Services Administrator (VSA) in your center's participation agreement. The local VSA can then provide Member's Area Access to as many team members as are appropriate to promote the use of data to forward the quality improvement work. Measures used for quality improvement efforts are detailed in Appendix 3 (Appendix 3: Audit Report Measures).

● **Patient privacy and HIPAA Compliance:** In all these efforts, no specific data regarding the center or the individuals will be shared with other centers. Only consolidated summary data will be presented.

These audits will allow centers to evaluate their ongoing efforts in establishing standard practice regarding management of neonatal abstinence syndrome.

Need for Human Subjects Approval: The primary purpose of the audit is quality improvement.

The University of Vermont Institutional Review Board has determined that, with respect to the role of the Vermont Oxford Network, the audit is "not human subjects research" as recognized by 45CFR46.102(f) and OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens. However, since the auditor may have access to protected health information and since the aggregated results of the audit may be published, you should consult with your local IRB to determine whether or not any human subjects' approvals are required by your unit for your local participation in the audit. We have posted a sample IRB letter on our Learning Management System. It is your responsibility to have any necessary human subjects' reviews and approvals from your local IRB before participating in this audit.

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APPENDICES

Appendix 1: AAP Statement on Neonatal Drug Withdrawal: Special Recommendations

Appendix 2: Improving Care for Neonatal Abstinence Syndrome abstract

Appendix 3: Audit Report Measures

Appendix 4: Unit Level Data and Definitions

Appendix 5: Unit Level Data Form

Appendix 6: Patient Identification Procedures and Worksheet

Appendix 7: Patient Data and Definitions

Appendix 8: Patient Data Form

Appendix 1: AAP Statement on Neonatal Drug Withdrawal: Special Recommendations

The VON Day Audit/ NAS was largely constructed based upon current AAP Special Recommendations for Neonatal Drug Withdrawal; thereby providing a "gap analysis" between practice recommendations and your current state.

1. Each nursery that cares for infants with neonatal withdrawal should develop a protocol that defines indications and procedures for screening for maternal substance abuse. In addition, each nursery should develop and adhere to a standardized plan for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal.

2. Screening for maternal substance abuse is best accomplished by using multiple methods, including maternal history, maternal urine testing and testing of newborn urine and/or meconium specimens that are in compliance with local laws. The screening of biological samples is an adjunct to provide additional information, helpful in the ongoing medical care of the infant. The duration of urinary excretion of most drugs is relatively short and maternal or neonatal urinary screening only addresses drug exposure in the hours immediately before urine collection. Thus, the false negative urine results may occur in the presence of significant intrauterine drug exposure. Although newborn meconium screening also may yield false negative results, the likelihood is lower than with urinary screening. The more recent availability of testing of umbilical cord samples may be considered a viable screening tool because it appears to reflect in utero exposure comparable to meconium screening.

3. Drug withdrawal should be considered in the differential diagnosis for infants in whom compatible signs develop. Physicians should be aware of other potential diagnoses that need to be evaluated and, if confirmed, treated appropriately.

4. Non-pharmacologic supportive measures that include minimizing environmental stimuli, promoting adequate rest and sleep and providing sufficient caloric intake to establish weight gain should constitute the initial approach to therapy.

5. Signs of drug withdrawal can be scored by using a published abstinence assessment tool. Infants with confirmed drug exposure who are unaffected or demonstrating minimal signs of withdrawal do not require pharmacologic therapy. Caution should be exercised before instituting pharmacologic therapy that could lengthen the duration of hospitalization and interfere with maternal infant bonding.

   Together with individualized clinical assessment, the serial and accurate use of a withdrawal assessment tool may facilitate a decision about the institution of pharmacologic therapy and thereafter can provide a quantitative measurement that can be used to adjust drug dosing.

6. The optimal threshold score for the institution of pharmacologic therapy by using any of the published abstinence assessment instruments is unknown.

7. Breastfeeding and the provision of expressed human milk should be encouraged if not contra-indicated for other reasons.

8. Pharmacologic therapy for withdrawal associated seizures is indicated. Other causes of neonatal seizures must also be evaluated.

9. Vomiting, diarrhea or both associated with dehydration and poor weight gain in the absence of other diagnoses are relative indications for treatment even in the absence of a high total withdrawal score.

10. The limited available evidence from controlled trials of neonatal opioid withdrawal supports the use of oral morphine solution and methadone when pharmacologic treatment is indicated. Growing evidence suggests that oral clonidine is also effective either as a primary or adjunctive therapy, but further prospective trials are warranted. Dosing regimens are noted in the recommendation. With respect to other drug treatments and clinical situations, several important caveats apply. Treatment with paregoric is contra-indicated because this preparation contains multiple opiates in addition to morphine as well as other potentially harmful compounds (alcohol, anise). Morphine prescription should be written as “mg of morphine per kg” and not as “ml of DTO per kg”. Tincture of opium contains a 25-fold higher concentration of morphine than do available oral morphine solutions; hence, it increases the likelihood of drug error and morphine overdose. The relative efficacy and safety of buprenorphine for the treatment of NAS requires additional comparative study. The optimal pharmacologic treatment of infants who are withdrawing from sedatives or hypnotics is unknown. Finally, there is also insufficient evidence to state whether an infant born to a mother with multiple drug abuse who meets criteria for pharmacologic therapy of withdrawal signs is best treated with an opioid, a barbiturate, medication from another drug class or a combination of drugs from different classes.

11. Physicians need to be aware that the severity of withdrawal signs, including seizures, has not been proven to be associated with differences in long term outcome after intrauterine drug exposure. Furthermore, treatment of drug withdrawal may not alter the long-term outcome.

12. Given the natural history of withdrawal, it is reasonable for neonates with known antenatal exposure to opioids and benzodiazepines to be observed in the hospital for 4-7 days. After discharge, outpatient follow-up should occur early and include reinforcement of the education of the caregiver about the risk of late withdrawal signs.

13. Neonates cared for in ICU’s who have developed tolerance to opioids and benzodiazepines as a result of extended duration of treatment can be converted to an equivalent regimen of oral methadone and lorazepam. Doses may be increased as necessary to achieve patient comfort. These medications then can be reduced by 10-20% of the initial dose every 1-2 days based on clinical response and serial assessments by using a standardized neonatal abstinence instrument.

14. Significant gaps in knowledge concern the optimal treatment strategy (including the criteria for instituting pharmacologic therapy, the drug of first choice and the strategy for weaning) of infants with neonatal withdrawal should be addressed in well-designed randomized trials that are adequately powered to assess short term outcomes and provide for long term follow-up.

Appendix 2: Improving Care for Neonatal Abstinence Syndrome

Patrick SW[1], Schumacher RE[2], Horbar JD[3], Buus-Frank ME[4], Edwards EM[5], Morrow KA[6], Ferrelli KR[6], Picarillo AP[7], Gupta M[8], Soll RF[3].

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BACKGROUND AND OBJECTIVE: Care for neonatal abstinence syndrome (NAS), a postnatal drug withdrawal syndrome, remains variable. We designed and implemented a multicenter quality improvement collaborative for infants with NAS. Our objective was to determine if the collaborative was effective in standardizing hospital policies and improving patient outcomes.

METHODS: From 2012 to 2014, data were collected through serial cross-sectional audits of participating centers. Hospitals assessed institutional policies and patient-level data for infants with NAS requiring pharmacotherapy, including length of pharmacologic treatment and length of hospital stay (LOS). Models were fit, clustered according to hospital, to evaluate changes in patient outcomes over time.

RESULTS: Among 199 participating centers, the mean number of NAS-focused guidelines increased from 3.7 to 5.1 of a possible 6 ($P < .001$), with improvements noted in all measured domains. Among infants cared for at participating centers, decreases occurred in median (interquartile range) length of pharmacologic treatment, from 16 days (10 to 27 days) to 15 days (10 to 24 days; $P = .02$), and LOS from 21 days (14 to 33 days) to 19 days (15 to 28 days; $P = .002$). In addition, there was a statistically significant decrease in the proportion of infants discharged on medication for NAS, from 39.7% to 26.5% ($P = .02$). After adjusting for potential confounders, standardized NAS scoring process was associated with shorter LOS (-3.3 days,95% confidence interval, -4.9 to -1.4).

CONCLUSIONS: Involvement in a multicenter, multistate quality improvement collaborative focused on infants requiring pharmacologic treatment for NAS was associated with increases in standardizing hospital patient care policies and decreases in health care utilization.

Appendix 3: Audit Report Measures

Vermont Oxford Network Quality Audit on Neonatal Abstinence Syndrome report will include unit feedback on the following measures:

1. Total number of infants pharmacologically treated for NAS in the first week of life
2. Total NICU length of stay
3. Total hospital length of stay
4. Total duration of treatment
5. Number of days after the treatment was stopped and the infant was discharged from your facility.
6. Percent of infants given mother's milk
7. Medications used for treatments
8. Medications administered at discharge

Appendix 4: Unit Level Data and Definitions

Policies, Guidelines and Procedures:

1. Our hospital has a policy or guideline that defines indications and procedures for screening for maternal substance abuse. Yes / No / Not applicable

   Answer "Yes" if your unit has written policies or guidelines that address the indications and procedures for screening for maternal substance abuse. This can include screening based on maternal history or toxicology.

   Answer "No" if your unit does not have written policies or guidelines that define indications and procedures for screening for maternal substance abuse.

   Answer "Not Applicable" if there is no delivery service at your hospital.

2. Our hospital has a policy or guideline for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal. Yes / No

   Answer "Yes" if your hospital has a policy or guideline for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal. This may include a policy for evaluation, non-pharmacologic treatment, pharmacologic treatment, or toxicological screening.

   Answer "No" if your hospital does not have a policy or guideline for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal.

3. Our hospital routinely uses a scoring system to evaluate signs and symptoms of drug withdrawal. Yes / No

   Answer "Yes" if your hospital routinely uses a scoring system to evaluate signs and symptoms of drug withdrawal.

   Answer "No" if your hospital does not routinely use a scoring system to evaluate signs and symptoms of drug withdrawal.

4. Which of the following scoring tools are used at your hospital to evaluate signs and symptoms of drug withdrawal?

   Note: Hospitals may or may not routinely use scoring tools to evaluate infants at risk for or having neonatal abstinence syndrome. More than one score could be used at a given hospital. Please indicate whether any of the scoring tools below are used at any facility in your hospital (including Delivery Room, Newborn Nursery, Step-Down Units or other special Pediatric Units and Neonatal Intensive Care Units). If you select "Other", please note the name of the tool utilized.

   a. Finnegan? Yes / No

   b. Modified Finnegan? Yes / No

   c. Lipsitz? Yes / No

d. Fir Square checklist? Yes / No

e. Locally Developed Instrument? Yes / No

f. Other? Yes / No

i. If yes, describe _____

5. Our hospital has guidelines or policies addressing the use of the Eat, Sleep, Console (ESC) assessment in the management of opioid exposed infants. Yes / No

   Answer "Yes" if your hospital has guidelines or policies that address the use of the Eat, Sleep, Console (ESC) assessment in the management of opioid exposed infants.
   Answer "No" if your hospital does not have guidelines or policies that address the use of the Eat, Sleep, Console (ESC) assessment in the management of opioid exposed infants.

   Note: Eat, Sleep, Console (ESC) evaluates the success of non-pharmacologic management of opioid-exposed infants (including keeping the infant with the mother; encouraging breast feeding, skin-to-skin contact, and other comfort measures; and supplementing feeds to help with weight gain) relying on the care teams assessment of 3 factors: eating, sleeping, and consolability.

6. Our hospital has a formal educational program that promotes standardization of NAS scoring among caregivers. Yes / No

   Answer "Yes" if your hospital has a formal educational program that promotes standardization of NAS scoring among caregivers. This could include educational sessions, available PowerPoint presentations, video material, etc.

   Answer "No" if your hospital does not have a formal education program that promotes standardization of NAS scoring among caregivers.

7. Our hospital has a policy or guideline for the non-pharmacological treatment of neonatal abstinence syndrome. Yes / No

   Answer "Yes" if your hospital has a policy or guideline for the non-pharmacological treatment of neonatal abstinence syndrome. This can include policies or guidelines that address the hospital environment (lighting, noise), the care practices (swaddling) or other efforts to control the symptoms of neonatal abstinence syndrome that do not include pharmacological intervention.

   Answer "No" if your hospital does not have a policy or guideline for the non-pharmacological treatment of neonatal abstinence syndrome.

8. Our hospital has a policy or guideline for the pharmacological treatment of neonatal abstinence syndrome. Yes / No

   Answer "Yes" if your hospital has a policy or guideline for the pharmacological treatment of neonatal abstinence syndrome (defined as treatment with one or more of the following agents; morphine, methadone, buprenorphine,

clonidine, phenobarbital, paregoric or Deodorized Diluted Tincture of Opium (DDTO)). This policy could include criteria for the type of pharmacologic treatment, the initiation of pharmacologic treatment or the site where pharmacologic treatment occurs.

Answer "No" if your hospital does not have a policy or guideline for the pharmacological treatment of neonatal abstinence syndrome.

9. Our hospital routinely transfers infants for initiation or maintenance of pharmacological treatment of neonatal abstinence syndrome. Yes / No

   Answer "Yes" if your hospital routinely transfers infants for initiation or maintenance of pharmacological treatment of neonatal abstinence syndrome.

   Answer "No" if your hospital does not routinely transfer infants for initiation or maintenance of pharmacological treatment of neonatal abstinence syndrome.

10. Our hospital has a policy or guideline that encourages breastfeeding or the provision of expressed human milk in substance exposed infants. Yes / No

    Answer "Yes" if your hospital has a policy or guideline that encourages breastfeeding or provision of expressed human milk in substance exposed infants.

    Answer "No" if your hospital does not have a policy or guideline that encourages breastfeeding or the provision of expressed human milk in substance-exposed infants.

Appendix 5: Unit Level Data Form

Vermont Oxford Network VON Day Quality Audit / NAS VON Center Number: _____

Policies, Guidelines and Procedures:

1. Our hospital has a policy or guideline that defines indications and procedures for screening for maternal substance abuse. Yes ☐ No ☐ Not applicable ☐

2. Our hospital has a policy or guideline for the evaluation and comprehensive treatment of infants at risk for or showing signs of withdrawal. Yes ☐ No ☐

3. Our hospital routinely uses a scoring system to evaluate signs and symptoms of drug withdrawal. Yes ☐ No ☐

4. Our hospital has guidelines or policies addressing the use of the Eat, Sleep, Console (ESC) assessment in the management of opioid exposed infants. Yes ☐ No ☐

5. Which of the following scoring tools are used at your hospital to evaluate signs and symptoms of drug withdrawal?

   Note: More than one scoring tool could be used at a given hospital.

   a. Finnegan? Yes ☐ No ☐

   b. Modified Finnegan? Yes ☐ No ☐

   c. Lipsitz? Yes ☐ No ☐

   d. Fir Square checklist? Yes ☐ No

   e. Locally Developed Instrument? Yes ☐ No ☐

   f. Other? Yes ☐ No ☐ if yes, describe _____

6. Our hospital has a formal educational program that promotes standardization of NAS scoring among caregivers. Yes ☐ No ☐

7. Our hospital has a policy or guideline for the non-pharmacological treatment of neonatal abstinence syndrome. Yes ☐ No ☐

8. Our hospital has a policy or guideline for the pharmacological treatment of neonatal abstinence syndrome. Yes ☐ No ☐

9. Our hospital routinely transfers infants for initiation or maintenance of pharmacological treatment of neonatal abstinence syndrome. Yes ☐ No ☐

10. Our hospital has a policy or guideline that encourages breastfeeding or the provision of expressed human milk in substance exposed infants. Yes ☐ No ☐

Appendix 6: Patient Identification Procedures and Worksheet

This worksheet is for local use only and will not be submitted to VON.

Vermont Oxford Network VON Day Quality Audit / NAS Center Number: _____

Please read through all patient identification procedures below before completing this patient identification worksheet.

Patient Identification Overview: In order to identify subjects for the audit, we would like you to review the records of infants given pharmacologic treatment for NAS in the first seven days of life, who were discharged in the specified three-month eligibility period. For centers with a high volume of NAS infants who received pharmacologic therapy in the first week of life, you will be asked to audit only the last 30 eligible infants discharged from your unit during the three-month eligibility period.

To start, review admission and discharge logs from your hospital's birth log. This is often the simplest and most reliable mechanism to identify all births during the time period.

In some settings, it may be possible to collaborate with your hospital informatics team to electronically search your records for infants coded as having "drug withdrawal syndrome of the newborn" (ICD-10 Code P96.1) and identify those infants who were discharged during the three-month eligibility period. Using ICD-10 codes can be complex and requires collaboration to develop and run such queries.

In some states (i.e. NH, KS, VA) mandatory reporting related to prenatal substance exposure is already in place via birth certificate or other statewide reporting mechanisms. You will need to understand what data is already being reported, by whom, and assure that the case definition aligns with the VON Day Audit inclusion criteria.

1. How many infants were identified for possible inclusion? _____ (enter number of infants)
   Enter the total number of infants retrieved from review either of admission and discharge logs or electronic search of ICD-10 Code P96.1, or other reliable data sources, for the three month eligibility period. These infants may or may not have received treatment for NAS.

2. This number was derived from:

   a. Review of NICU/Newborn Nursery admission and discharge logs? Yes / No

   b. Based on an electronic search of medical records using ICD-10 Code P96.1 Yes / No

   c. Retrieved from mandatory data reporting sources? Yes / No

   Next, review the medical record of each infant identified for possible inclusion above, to see if **the infant was treated for NAS with a pharmacologic agent during the first week of life**. (Pharmacologic agents include morphine, methadone, buprenorphine, clonidine, phenobarbital, paregoric or Deodorized Diluted Tincture of Opium (DDTO)).

3. _____ (enter number of infants)

For the audit, only include infants who were discharged during the three-month eligibility period and treated for NAS with a pharmacologic agent during the first 7 days of life. The day of birth counts as day 1.

If you have over 30 infants who meet all criteria, only include the last 30 infants discharged from your unit during the three-month eligibility period.

Appendix 7: Patient Data and Definitions

The header section of the patient data form worksheet is for your use. None of this information will be submitted to Vermont Oxford Network, except for the Case Number. The Case Number is simply a method to distinguish individual records. The first Case Number in each audit will be Case Number 1.

The Audit Number is for you to keep track of your audit sequence. If this is the second time you are doing this audit it would be Audit Number 2. The Vermont Oxford Network Center Number is the center number that has been assigned to your center by Vermont Oxford Network. The Patient ID is for your purposes only. You can fill this in with a Patient ID or medical record number if it helps you to identify the record. This ID number will NOT be transferred to Vermont Oxford Network.

1. Birth weight: _____ grams

   Record the birthweight in grams. Since many weights may be obtained on an infant shortly after birth, enter the weight from the Labor and Delivery record if available and judged to be accurate. If unavailable or judged to be inaccurate, use the weight on admission to the Neonatal Unit.

2. Gestational age at birth: ____ weeks _____ days

   Enter gestational age at birth in both weeks and days.

   Record the best estimate of gestational age in weeks and days using the following hierarchy:

   -Obstetrical measures based on last menstrual period, obstetrical parameters and prenatal ultrasound as recorded in the maternal chart

   -Clinician's estimate based on physical criteria, neurologic examination, combined physical and gestational age exam (Ballard or Dubowitz) or examination of the lens. The best estimate should be recorded in weeks and days. In instances when the best estimate of gestational age is the exact number of weeks, enter the number of weeks in the space provided for weeks and enter 0 in the space provided for days. Do not leave the number of days blank.

3. Location of birth: Inborn _____ / Outborn _____

   For location of birth inborn/outborn, answer "inborn" if the infant was delivered at your center; answer "outborn" if the infant was delivered outside your center. Any infant requiring ambulance transfer will be considered outborn. When completing the patient data forms for outborn infants, use all information available from the hospital that transferred the infant to your center, as well as from your own hospital.

4. Was toxicological screening (including urine, meconium, hair or cord) obtained on the infant to document substance exposure? Yes / No

   Answer "Yes" if any form of toxicological screening, including urine, meconium, hair or cord was obtained on the infant to document substance exposure.

Enter “No” if no toxicological screening was obtained on the infant to document substance exposure.

5. Was the infant scored for NAS at any time during hospitalization? Yes / No

   Answer “Yes” if the infant was scored for NAS at any time during hospitalization. The infant may be evaluated by any of the following scores: Finnegan, Modified Finnegan, Lipsitz, Fir Square checklist or other locally developed instruments.

   Check “No” if no scoring for NAS was obtained on the infant.

6. Was the infant assessed using the Eat, Sleep, Console (ESC) assessment at any time prior to initiating pharmacologic treatment for NAS? Yes / No

   Answer “Yes” if the infant was assessed using the Eat, Sleep, Console (ESC) assessment at any time prior to initiating pharmacologic treatment for NAS.

   Check “No” if the infant was not assessed using the Eat, Sleep, Console (ESC) assessment at any time prior to initiating pharmacologic treatment for NAS.

7. Which pharmacologic agents were administered for the treatment of NAS? Check all that apply:

   a. Morphine? Yes / No

   b. Methadone? Yes / No

   c. Buprenorphine? Yes / No

   d. Clonidine? Yes / No

   e. Phenobarbital? Yes / No

   f. Paregoric? Yes / No

   g. Deodorized Diluted Tincture of Opium (DDTO)

      Note: More than one agent may be used in an individual patient.

8. What was the total duration of pharmacologic treatment for NAS? _____ days

   Calculate the total number of hospital days that the infant received pharmacologic treatment for NAS. Count any day that the infant received any dose(s) of a pharmacologic agent prescribed for NAS (morphine, methadone, buprenorphine, clonidine, phenobarbital, paregoric or Deodorized Diluted Tincture of Opium (DDTO)).

9. What was the interval between receiving the last dose of a pharmacologic agent for NAS and discharge? _____ days

10. Calculate the interval in days between the date of the last dose of a pharmacologic agent for NAS (morphine, methadone, buprenorphine, clonidine, phenobarbital, paregoric or Deodorized Diluted Tincture of Opium (DDTO)) and the date of discharge to home or foster care. Include the first full day the infant was off treatment up until and including the day of discharge to home or foster care. If the infant was initially transferred, please obtain the day of discharge to home or foster care from the facility where the infant was transferred.

11. At the time of discharge from your hospital, was the infant receiving medications for NAS (morphine, methadone, buprenorphine, clonidine, phenobarbital, paregoric or Deodorized Diluted Tincture of Opium (DDTO))? Yes / No (if "no" skip to #11)

    Answer "Yes" if, at the time of discharge, the infant was receiving medications for NAS, (morphine, methadone, buprenorphine, clonidine, phenobarbital, paregoric or Deodorized Diluted Tincture of Opium (DDTO)).

    Check "No" if, at the time of discharge, the infant was not receiving any medications for NAS.

    If you checked "No", you can skip to Question #11.

12. At the time of discharge from your hospital, which pharmacologic agents were still being administered for the treatment of NAS? Check all that apply:

    a. Morphine? Yes / No

    b. Methadone? Yes / No

    c. Buprenorphine? Yes / No

    d. Clonidine? Yes / No

    e. Phenobarbital? Yes / No

    f. Paregoric? Yes / No

    g. Deodorized Diluted Tincture of Opium (DDTO)

       Note: More than one agent may be used in an individual patient.

13. In the 24 hours preceding discharge from your hospital, did the infant receive any of his/her mother's own milk? Yes / No / Unknown

    Answer "Yes" if, in the 24 hours preceding discharge from your hospital, the infant received any of his/ her mother's own milk, either by breastfeeding or feeding of expressed breastmilk.

    Answer "No" if the infant did not receive any of his/her mother's own milk.

    Answer "Unknown" if it is unclear from the chart whether or not the infant was receiving any of his/her mother's own breast milk.

14. Where was the infant discharged to? (check only one)

    a. Home? Yes / No

    b. Home with a guardian or foster parent? Yes / No

    c. Transferred to another hospital? Yes / No

    d. Other? Yes / No Describe: _____

    If the infant went home with either parent (mother or father), check "home". If the infant went home with a guardian (i.e. grandparent), or foster parent or adoptive parent, check "home with a guardian or foster parent". If the infant was transferred to another hospital check "transferred to another hospital". If the infant went to a special inpatient treatment program or to an agency for adoption, or any other facility, check "other" and describe.

15. What was the infant's total length of NICU stay? _____ days

    Calculate the total number of days that the infant stayed in the NICU. The first day of NICU admission counts as Day 1. Include the day of discharge as a full day.

16. What was the infant's total length of hospital stay? _____ days

    Calculate the number of days the infant stayed at any hospital. The first day of admission to any hospital counts as Day 1. If the infant was transferred to another hospital, please contact that hospital regarding total hospital length of stay. Include the day of discharge as a full day.

Appendix 8: Patient Data Form

Vermont Oxford Network **VON Day Quality Audit / NAS** **Patient Data Worksheet**	**CASE #**
Audit Number: _____ Vermont Oxford Network Center Number: _____	

Please note: All data on this portion of the worksheet will be transmitted to the Vermont Oxford Network.

1. Birth weight _____ grams
2. Gestational age at birth: _____weeks _____ days
3. Location of birth: Inborn ☐ Outborn ☐
4. Was toxicological screening (including urine, meconium, hair or cord) obtained on the infant to document substance exposure? Yes ☐ No ☐
5. Was the infant scored for NAS at any time during hospitalization? Yes ☐ No ☐
6. Was the infant assessed using the Eat, Sleep, Console (ESC) assessment at any time prior to initiating pharmacologic treatment for NAS? Yes ☐ No ☐
7. Which pharmacologic agents were administered for the treatment of NAS? Check all that apply:

   a) Morphine? Yes ☐ No ☐ d) Clonidine? Yes ☐ No ☐ g) Deodorized Diluted Tincture

   b) Methadone? Yes ☐ No ☐ e) Phenobarbital? Yes ☐ No ☐ of Opium (DDTO)? Yes ☐ No ☐

   c) Buprenorphine? Yes ☐ No ☐ f) Paregoric? Yes ☐ No ☐

   Note: More than one agent may be used in an individual patient.

8. What was the total duration of pharmacologic treatment for NAS? _____ days

   Calculate the total number of hospital days that the infant received pharmacologic treatment for NAS. Count any day that the infant received any dose(s) of a pharmacologic agent (morphine, methadone, buprenorphine, clonidine, phenobarbital, paregoric or DDTO) prescribed for NAS.

9. What was the interval between receiving the last dose of a pharmacologic agent for NAS and discharge? _____ days

   Calculate the interval in days between the date of the last dose of a NAS agent and the date of discharge. Include the first full day the infant was off treatment up until and including the day of discharge.

10. At the time of discharge from your hospital, was the infant receiving medications for NAS (morphine, methadone, buprenorphine, clonidine, phenobarbital, paregoric or DDTO)? Yes ☐ No ☐ (if no, skip to #11)
11. At the time of discharge from your hospital, which pharmacologic agents were still being administered for the treatment of NAS? Check all that apply:

a) Morphine? Yes ☐ No ☐ d) Clonidine? Yes ☐ No ☐ g) Deodorized Diluted Tincture

b) Methadone? Yes ☐ No ☐ e) Phenobarbital? Yes ☐ No ☐ of Opium (DDTO)? Yes ☐ No ☐

c) Buprenorphine? Yes ☐ No ☐ f) Paregoric? Yes ☐ No ☐

Note: More than one agent may be used in an individual patient.

12. In the 24 hours preceding discharge from your hospital, did the infant receive any of his/her mother's own milk? Yes ☐ No ☐ Unknown ☐

13. Where was the infant discharged to: (check only one)

☐ Home ☐ Transferred to another hospital

☐ Home with a guardian or foster parent ☐ Other Describe: _____

14. What was the infant's total length of NICU stay? _____ days

Calculate the total number of days that the infant stayed in the NICU. The first day of NICU admission counts as Day 1. Include the day of discharge as a full day.

15. What was the infant's total length of hospital stay? _____ days

Calculate the number of days the infant stayed at any hospital. The first day of admission to any hospital counts as Day 1. If the infant was transferred to another hospital, please contact that hospital regarding total hospital length of stay. Include the day of discharge as a full day.

