VERMONT OXFORD NETWORK

Neonatal Encephalopathy Registry
Manual of Operations For Infants Born in 2011

Release 5.0
Published November 2010
Revisions for 2011

Changes in Eligibility Criteria: The NER eligibility criteria have changed for infants born in 2011. Please see chapter 2 for details on eligibility. Infants born in 2011 are only eligible for the Neonatal Encephalopathy Registry if they receive hypothermic therapy. Infants who die in the delivery room or initial resuscitation area following birth are not eligible. These changes do not affect infants born in 2010 or previous years. For infants born prior to 2011, apply the eligibility criteria in the NER Manual of Operations applicable to the birth year of the infants.

There are no changes to the data items for infants born in 2011, as compared to previous years.
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CHAPTER 1

Introduction, Background and Methods

Introduction

The Vermont Oxford Network Neonatal Encephalopathy Registry enrolls newborn infants who receive hypothermic therapy for neonatal encephalopathy. The Registry includes demographic characteristics, associated perinatal factors, medical treatments, co-morbidities and outcomes. Its purpose is to provide data to characterize the population of infants with encephalopathy, evaluate variations in current practice, identify opportunities for improvement in the quality and safety of care for infants with encephalopathy, monitor the introduction and dissemination of neuroprotective hypothermia, assess selection criteria for neuroprotective therapy, define important questions for clinical research, and plan prospective research and randomized trials.

Background

Neonatal encephalopathy has been defined as a “syndrome of disturbed neurological function in the earliest days of life in the term infant, manifested by difficulty with initiating and maintaining respiration, depression of tone and reflexes, subnormal level of consciousness, and often by seizures.” ¹

The prevalence of neonatal encephalopathy has been estimated to be 3.8 per 1000 live term births. ² ³ In the past it was accepted that fetal asphyxia during labor and delivery was the predominant cause of neonatal encephalopathy and cerebral palsy, leading to the diagnosis of hypoxic-ischemic encephalopathy (HIE) for most infants presenting with encephalopathy soon after birth. More recently, it has been recognized that there may be multiple etiologies for neonatal encephalopathy, that the proportion of cases attributable to perinatal hypoxic-ischemic injury is unclear, and that the significant predisposing factors and those contributing to unfavorable long-term outcome are for the most part unknown. ⁴ Data from a large multicenter registry will be needed to address these critical questions.

Two additional arguments support the need for a registry of neonatal encephalopathy. First, given the paucity of scientific data, variation in routine practice for the diagnosis and management of neonatal encephalopathy is likely to be great leading to deficiencies in the quality and safety of medical care for these high risk infants. ⁵ Second, if new therapies such as hypothermia and neuroprotective agents are to be tested appropriately and used effectively, selection criteria for treatment must be developed and assessed, and prospective studies planned and designed.⁶
Methods

Data Collection and Monitoring: Data will be collected and submitted using the Vermont Oxford Network eNICQ software. A special data module for the eNICQ application has been created to support collection, editing, and electronic submission of data to the Registry. The software is available at no additional charge to participating units. The data submitted will become the property of the Vermont Oxford Network. The Network may use these data for research and reporting, but will maintain the confidentiality of individual hospital data.

Patient Confidentiality and Human Subjects: The confidentiality of individual patients will be protected. No protected healthcare information will be submitted to Vermont Oxford Network for the Registry. Although some patient identifiers are maintained locally at participating units using the eNICQ software, no protected healthcare information is transmitted or submitted to the Vermont Oxford Network. Only de-identified data are submitted. All patients will receive the current standard of care at their institution. The Registry does not require any interventions, or protocols for treatment.

Institutional Review Board (IRB) Considerations: The Registry data collection plan has been reviewed by the IRB at the University of Vermont. Because the Registry data are expected to be used to perform observational research, participating hospitals must submit the project to their local IRBs for review. Since there is no anticipated additional risk for individual patients, and only de-identified data are submitted to the Registry, it is not anticipated that individual patient consent will be required. However, the conditions for approval of Registry participation are the responsibility of each participating site. A letter of IRB approval from your hospital is required before your center can participate in the Registry.

Routine Reporting to Participating Hospitals: Participating hospitals will receive confidential reports comparing their own data with those of all hospitals participating in the Registry.

Quality Improvement Opportunities: Data from the Registry will be used to identify opportunities for improvements in the quality and safety of the diagnosis, care and follow-up of infants with neonatal encephalopathy. These opportunities will be explored through the Vermont Oxford Network NICQ Quality Improvement Collaboratives, and Registry Internet sessions. Case studies of improvements will be disseminated at the Network’s Annual Quality Congress for Neonatology and through interactive Internet conferences.

Observational Research: The Registry may be used to perform observational research including describing the population of infants with encephalopathy, associated perinatal factors, medical treatments, co-morbidities and outcomes. A planned focus of observational research will be to monitor the introduction and dissemination of new neuroprotective therapies such as hypothermia, assess selection criteria for neuroprotective therapy, and to identify variations in routine practices and outcomes. Each observational study will require approval by the
Steering Committee. Data from individual hospitals would not be identifiable in these study reports, although hospitals participating in the Registry would be identified in an Appendix to the manuscripts. No personal patient identifiers or protected healthcare information would be included in any study reports.

Planning for Prospective Research: Individual hospitals care for relatively few infants each year with neonatal encephalopathy. Many of these infants are born at outlying hospitals and often there is significant delay between birth and transfer to a referral center. These factors present challenges to the design and performance of prospective multi-center studies of interventions for neonatal encephalopathy. The Registry will provide valuable information for generating hypotheses for prospective studies and randomized trials, and for estimating the sample sizes and feasibility of such studies.

Other reporting: The Vermont Oxford Network has contracted with Natus Medical to provide reports based on the Registry related to the post marketing surveillance of their head cooling equipment. Natus Medical may at their discretion submit information to the FDA that uses information from these reports. Vermont Oxford Network will not have any responsibility for reporting to the FDA. Any reports provided by Vermont Oxford Network to Natus Medical or to other parties will include aggregate data only and will not identify data from individual hospitals or patients.

Personnel

Registry Director: Jeffrey D. Horbar, MD
Co-Directors: Jerold F. Lucey, MD, Roger F. Soll, MD
Statistician: Joseph H. Carpenter, MS
Steering Committee: Peter Bingham, MD, Univ. of VT College of Medicine
Terrie Inder, MD, Washington University
Karin B. Nelson, MD, Senior Investigator, NIH
Tonse Raju, MD, NICHD
References


Eligibility for the Neonatal Encephalopathy Registry

Infants born in 2011 are eligible for the Registry if they are eligible either for the Network VLBW Database or the Network Expanded Database and if they receive hypothermic therapy for neonatal encephalopathy prior to discharge home or death.

In cases where local institutional review boards require individual consent prior to enrolling infants in the Registry, infants may only be considered eligible when individual consent is obtained.

<table>
<thead>
<tr>
<th>Birth Weight</th>
<th>Gestational Age (Wks/Days)</th>
<th>Eligible for VLBW DB?</th>
</tr>
</thead>
<tbody>
<tr>
<td>350</td>
<td>22/0</td>
<td>Yes</td>
</tr>
<tr>
<td>400</td>
<td>21/6</td>
<td>No</td>
</tr>
<tr>
<td>401</td>
<td>21/6</td>
<td>Yes</td>
</tr>
<tr>
<td>400</td>
<td>22/0</td>
<td>Yes</td>
</tr>
<tr>
<td>1500</td>
<td>30/0</td>
<td>Yes</td>
</tr>
<tr>
<td>1501</td>
<td>30/0</td>
<td>No</td>
</tr>
<tr>
<td>1501</td>
<td>29/6</td>
<td>Yes</td>
</tr>
<tr>
<td>1600</td>
<td>28/4</td>
<td>Yes</td>
</tr>
<tr>
<td>1600</td>
<td>30/0</td>
<td>No</td>
</tr>
</tbody>
</table>

Figure 2.1: VLBW Database Eligibility Criteria
Eligibility criteria for the VLBW and Expanded Databases are shown in Figures 2.1 and 2.2. If the infant meets the eligibility criteria for the VLBW or Expanded Database and meets the criteria of the definition for a “Yes” response to Item EL1 on the NER Eligibility Form, the infant is eligible for the Registry.

### Expanded Database Eligibility

All infants eligible for the VLBW Database are also eligible for the Expanded Database. In addition, the following infants are also eligible for the Expanded Database only:

1. Any infant whose birth weight is over 1500 grams and who is admitted to a neonatal intensive care unit (NICU) in your hospital within the first 28 days of life without first having gone home, regardless of gestational age. A NICU is any location within the hospital in which newborn infants receive continuous positive airway pressure (CPAP) or intermittent mandatory ventilation (IMV). When applying this definition, do not include those areas in which these modalities of respiratory support are used only for brief periods of stabilization prior to transfer to another location. The intent is that units designated as a NICU routinely provide these services for ongoing care beyond an initial period of stabilization.

2. Any infant whose birth weight is over 1500 grams and who dies at any location in your hospital within 28 days of birth without first having gone home. This includes inborn and outborn infants.

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**Figure 2.2: Expanded Database Eligibility Criteria**
Completing Registry Forms

The Neonatal Encephalopathy Registry includes five forms as shown in Appendix B. Complete these forms for all infants who receive hypothermic therapy for neonatal encephalopathy. The name and purpose of each form, and the chapter in this manual which includes the definitions are shown in Table 3.1. None of these forms includes personal patient identifiers or protected health care information. All NER data are submitted to the Vermont Oxford Network using the Network eNICQ software. Patient data that is recorded in eNICQ is retained in your hospital and is not exported to the Network.

<table>
<thead>
<tr>
<th>NER Form</th>
<th>Purpose</th>
<th>Chapter</th>
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<tr>
<td>Eligibility</td>
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<td>OB/Initial Status</td>
<td>Obstetric history and initial clinical status</td>
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<tr>
<td>Neurological</td>
<td>Neurological indicators, electrophysiology, seizures, anticonvulsants and neuroimaging</td>
<td>6</td>
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<tr>
<td>Diagnosis and Discharge</td>
<td>Outcomes relevant to conditions diagnosed prior to discharge from your center, as well as indicators of the infant’s status at discharge.</td>
<td>7</td>
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<tr>
<td>Hypothermic Therapy</td>
<td>Methods of hypothermic therapy used and adverse events, as well as the dates and times of cooling</td>
<td>8</td>
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</tbody>
</table>

Table 3.1: NER Data Forms

Only complete the NER forms for eligible infants (see Chapter 2). Do not record events on the NER data forms that occur after the infant is discharged home. Do not record events that occur after the infant’s first birthday.

Refer to Table 3.2 and the rules below to determine how and when to record events on the NER data forms.

Complete the Eligibility Form for all eligible infants who receive hypothermic therapy for neonatal encephalopathy. Record all events on the Hypothermic Therapy Form that occur prior to discharge home or death. This includes events that occur at your hospital, in transit to or from your hospital or at another hospital to which the infant is transferred.

For the OB/Initial Status Form, Neurological Form and Diagnosis and Discharge Form, record all events that occur prior to discharge from your hospital, including events which occur prior to admission to your hospital. If the infant is transferred...
to another hospital and is readmitted to your hospital, record events that occur at the hospital to which the infant was transferred as well as events that occur following readmission. Do not record events on these forms that occur after transfer to another hospital if the infant is not readmitted to your hospital.

<table>
<thead>
<tr>
<th>Where/When Events Occur</th>
<th>Type of Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>In any hospital prior to admission to your hospital (outborn only)</td>
<td>Eligibility, Hypothermic Therapy: Record all events that occur at other hospital(s).</td>
</tr>
<tr>
<td>In your hospital prior to discharge home, transfer or death (whichever is first)</td>
<td>Record all events that occur at your hospital.</td>
</tr>
<tr>
<td>In “transferred to” hospital</td>
<td>Record all events that occur at other hospital(s).</td>
</tr>
<tr>
<td>In your hospital after readmission following initial transfer</td>
<td>Record all events that occur at your hospital.</td>
</tr>
<tr>
<td>In any hospital following second transfer</td>
<td>Record all events at your hospital or other hospital(s)</td>
</tr>
</tbody>
</table>

Table 3.2: Recording Events on NER Data Forms

**NOTE:** Readmitted after initial transfer means that the infant’s Initial Disposition is “transferred to another hospital” and that the infant was readmitted to your center after this initial transfer without having gone home or transferred again prior to readmission. For example, if the infant transferred from your center to hospital B and was readmitted to your center from hospital B, the infant was readmitted after initial transfer. But if the infant transferred from hospital B to hospital C prior to being readmitted to your center, the infant would not be considered to have been readmitted after initial transfer.
Chapter 4

Eligibility Form Definitions

Item El1: Hypothermic Therapy Received?

Hypothermic therapy may include selective head cooling or whole body cooling for encephalopathy. Selective head cooling is active cooling restricted to the head and brain; it is an intervention to reduce the temperature of the head and brain by exposing the head to lower than environmental temperature. Specially designed head cooling devices, other cooling devices and ice packs applied to the head would be considered active cooling of the head and brain. Whole body cooling is active cooling of the body that is not restricted to the head and brain; it is an intervention to reduce the core body temperature and temperature of the brain by exposing the body to lower than environmental temperature. Whole body cooling may include cooling of the head in addition to the rest of the body. Cooling blankets, other cooling devices and ice packs applied to the body would be considered active cooling of the whole body.

NOTE: Passive exposure to environmental temperature or cooling of the face for the treatment of supraventricular tachycardia is not considered active cooling of the head and brain.

Passive exposure to environmental temperature is not considered active cooling of the whole body.

Answer “Yes” if the infant was treated with selective head and/or whole body cooling for encephalopathy prior to discharge home or death. If an eligible outborn infant was cooled at another hospital or during transport prior to admission to your center, answer “Yes”. If, prior to discharge home or death, the infant received hypothermic therapy at your center or was transferred to another hospital and received hypothermic therapy during transport to or at the other hospital, answer “Yes”.

Answer “No” if the infant was not treated with head and/or whole body cooling for encephalopathy at any time prior to discharge home or death. Answer “No” if it is not known whether or not the infant was treated with head and/or whole body cooling at any time prior to discharge home or death.
ITEM EL2: Gestational Age ≥ 36 Weeks, 0 Days or More?

Answer “Yes” if the infant’s gestational age in completed weeks is 36 weeks, 0 days or more.

Answer “No” if the infant’s gestational age in completed weeks is less than 36 weeks, 0 days.

Answer “Unknown” if the infant’s gestational age is not known.

ITEM EL3: Major CNS Congenital Malformation?

Lethal or life threatening central nervous system (CNS) congenital malformations include birth defect codes 101 through 105 and code 901 in Appendix C of the 2011 Vermont Oxford Network Manual of Operations. The code 901, other lethal or life threatening CNS defects, means that the defect is either the primary cause of death or is treated prior to discharge with specific surgical or medical therapy to correct a major anatomic defect or a life threatening physiologic dysfunction.

Answer “Yes” if the infant has a major CNS congenital malformation, syndrome or chromosomal defect involving the central nervous system that is lethal or life threatening.

Answer “No” if the infant does not have a major CNS congenital malformation, syndrome or chromosomal defect involving the central nervous system that is lethal or life threatening.

Answer “Unknown” if it is not known whether the infant has a major CNS congenital malformation, syndrome or chromosomal defect involving the central nervous system that is lethal or life threatening.

ITEM EL4: Stupor or Coma within 72 Hours?

Stupor is defined as “no spontaneous eye opening, and tactile stimulation elicits poorly sustained eye opening”. Coma is defined as “no eye opening to vigorous tactile stimulation”.

Answer “Yes” if the infant had stupor or coma within 72 hours of birth, and the stupor or coma lasts continuously for at least six hours.

Answer “No” if the infant did not have stupor or coma lasting continuously for at least six hours within 72 hours of birth.

Answer “Unknown” if it is not known whether the infant had stupor or coma lasting continuously for at least six hours within 72 hours of birth.
**ITEM EL5: Seizures within 72 Hours?**

Clinical seizures are present if there is paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/pupillary dilation).

Answer “Yes” if the infant had at least one clinical or electroencephalographic (EEG) seizure at any time within 72 hours of birth.

Answer “No” if the infant did not have any clinical or EEG seizures at any time within 72 hours of birth.

Answer “Unknown” if it is not known whether the infant had any clinical or EEG seizures within 72 hours of birth.

**ITEM EL6: Paralysis Induced for First 72 Hours?**

Answer “Yes” if the infant was paralyzed with pancuronium or other muscle relaxant starting within 4 hours of birth and continuing until 72 hours after birth.

Answer “No” if the infant was not paralyzed with pancuronium or other muscle relaxant starting within 4 hours of birth and continuing until 72 hours after birth.

Answer “Unknown” if it is not known whether the infant was paralyzed with pancuronium or other muscle relaxant starting within 4 hours of birth and continuing until 72 hours after birth.

**ITEM EL7: APGAR Score at 5 Minutes of 3 or Less?**

**NOTE:** The answer to this item should be consistent with the response to the APGAR score at 5 minutes on the 28 Day Form and is automatically calculated by the eNICQ software.

Answer “Yes” if the value of the APGAR score at 5 minutes was between 0 and 3.

Answer “No” if the value of the APGAR score at 5 minutes was between 4 and 10.

Answer “Unknown” if the value of the APGAR score at 5 minutes is not known.
CHAPTER 5

OB/INITIAL STATUS FORM Definitions

The OB/Initial Status Form includes data items for the obstetric history of the infant and the infant’s initial clinical status and is completed for all infants who are eligible for the registry.

For infants who did not transfer to another hospital, consider all events recorded in the medical record which occur prior to death, discharge home or first birthday, whichever is soonest. For outborn infants, this includes events which occurred in the hospital from which the infant transferred.

PART A, OBSTETRIC-PERINATAL HISTORY

ITEM OB1: Mode of Delivery

Answer one of the following which best describes the mode of delivery as recorded in the maternal or infant medical record.

- Vaginal without Vacuum or Forceps
- Vacuum and/or Forceps Assisted Vaginal
- C-Section before Labor Started
- C-Section after Labor Started
- C-Section after Failed Vacuum or Forceps Delivery

Answer “Unknown” if both the maternal and infant records are missing and not available for review, or if the mode of delivery is not noted in these records.

ITEM OB2: Presentation

Answer one of the following to indicate the infant’s presentation as recorded in the maternal or infant medical record.

- Vertex
- Breech
- Transverse
- Other

Answer “Unknown” if both the maternal and infant records are missing and not available for review, or if the infant’s presentation is not noted in these records.
**ITEM OB3: Ruptured Membranes 24 Hours or More Prior to Delivery?**

Answer “Yes” if the mother’s membranes ruptured either spontaneously or artificially 24 hours or more before the infant was delivered, as recorded in either the maternal or infant medical record.

Answer “No” if the mother’s membranes were not ruptured either spontaneously or artificially 24 hours or more before the infant was delivered, as recorded in either the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

**ITEM OB4: Cord Prolapse?**

Answer “Yes” if there was a record of umbilical cord prolapse in either the maternal or infant medical record.

Answer “No” if there was no record of cord prolapse in either the maternal or infant record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

**ITEM OB5: Uterine Rupture?**

Answer “Yes” if there was a record of uterine rupture in either the maternal or infant medical record.

Answer “No” if there was no record of uterine rupture in either the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

**ITEM OB6: Antepartum Hemorrhage?**

Answer “Yes” if placenta previa, abruption or threatened abortion resulting in bleeding that can be external (vaginal bleeding in the absence of a vaginal or cervical source) or occult (retroplacental clot) other than bloody show was documented after 20 weeks of pregnancy in the maternal or infant medical record.

Answer “No” if placenta previa, abruption or threatened abortion resulting in bleeding that can be external (vaginal bleeding in the absence of a vaginal or cervical source) or occult (retroplacental clot) other than bloody show was not documented after 20 weeks of pregnancy in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.
ITEM OB7: Chorioamnionitis?

Answer “Yes” if a diagnosis of chorioamnionitis was recorded in the maternal or infant medical record.

Answer “No” if a diagnosis of chorioamnionitis was not recorded in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

ITEM OB8: Maternal Temperature during Labor and Delivery

a. Maternal Temperature Recorded?

Answer “Yes” if a maternal temperature obtained during labor and delivery was recorded in the maternal or infant record.

Answer “No” if a maternal temperature obtained during labor and delivery was not recorded in the maternal or infant record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

If “Yes” to a., answer question b. below.

b. Temperature of Mother

If maternal temperature was recorded during labor and delivery, enter the highest maternal temperature recorded during labor in degrees Centigrade, as documented during labor in the maternal or infant medical record. Use a single decimal place, e.g. 36.7° C.

ITEM OB9: Antenatal Magnesium Exposure?

Answer “Yes” if it is noted in the infant or maternal record that magnesium was administered to the mother prior to delivery for any indication.

Answer “No” if it is not noted in the infant or maternal record that magnesium was administered to the mother prior to delivery for any indication.

Answer “Unknown” if both the infant or maternal records are missing and not available for review.

ITEM OB10: Maternal Hypertension, Pre-eclampsia, or Eclampsia?

Answer “Yes” if maternal hypertension, chronic or pregnancy induced, with or without edema and proteinuria, was recorded in the maternal or infant medical
record, or if a maternal blood pressure above 140 systolic or 90 diastolic was recorded prior to or during the present pregnancy.

Answer “No” if maternal hypertension, chronic or pregnancy induced, with or without edema and proteinuria, was not recorded in the maternal or infant medical record, and if a maternal blood pressure above 140 systolic or 90 diastolic was not recorded prior to or during the present pregnancy.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

**ITEM OB11: Maternal Diabetes?**

Answer “Yes” if maternal diabetes mellitus treated with insulin and/or an oral hypoglycemic agent during or prior to the present pregnancy was recorded in the maternal or infant medical record.

Answer “No” if maternal diabetes mellitus treated with insulin and/or an oral hypoglycemic agent during or prior to the present pregnancy was not recorded in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

**ITEM OB12: Maternal Hypothyroidism?**

Answer “Yes” if a diagnosis of maternal hypothyroidism during or prior to the present pregnancy was recorded in the maternal or infant medical record.

Answer “No” if a diagnosis of maternal hypothyroidism during or prior to the present pregnancy was not recorded in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.
ITEM OB13: Non-Reassuring Fetal Assessment

Record any abnormalities noted in the maternal or infant medical record based on fetal heart rate monitoring prior to delivery. Answer all that apply.

**a. Bradycardia Prior to Delivery?**

Answer “Yes” if a baseline fetal heart rate < 110 beats per minute on fetal heart rate monitoring (electronic or auscultation) prior to delivery was noted in the maternal or infant medical record.

Answer “No” if a baseline fetal heart rate < 110 beats per minute on fetal heart rate monitoring (electronic or auscultation) prior to delivery was not noted in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

**b. Tachycardia Prior to Delivery?**

Answer “Yes” if a baseline fetal heart rate > 160 beats per minute on fetal heart rate monitoring prior to delivery (electronic or auscultation) was noted in the maternal or infant medical record.

Answer “No” if a baseline fetal heart rate > 160 beats per minute on fetal heart rate monitoring prior to delivery (electronic or auscultation) was not noted in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

**c. Decreased FHR Variability Prior to Delivery?**

Answer “Yes” if minimal (amplitude range detectable but less than 5 beats per minute or fewer) or absent (amplitude range undetectable) fetal heart rate variability on electronic fetal heart rate monitoring prior to delivery was noted in the maternal or infant medical record.

Answer “No” if minimal (amplitude range detectable but less than 5 beats per minute or fewer) or absent (amplitude range undetectable) fetal heart rate variability on electronic fetal heart rate monitoring prior to delivery was not noted in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.
d. Prolonged or Recurrent Decelerations Prior to Delivery?

Answer “Yes” if either prolonged or recurrent decelerations on electronic fetal heart monitoring prior to delivery was noted in the maternal or infant medical record.

Answer “No” if neither prolonged nor recurrent decelerations on electronic fetal heart monitoring prior to delivery was noted in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

ITEM OB14: Umbilical Cord Blood Sampling

a. Umbilical Cord Blood Sampling Performed?

Answer “Yes” if the performance of either arterial or venous umbilical cord blood sampling was noted in the maternal or infant medical record.

Answer “No” if the performance of either arterial or venous umbilical cord blood sampling was not noted in the maternal or infant medical record.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.

NOTE: If multiple cord blood samples were obtained, the lowest pH and worse base deficit values, defined below, may be from different cord blood specimens.

If “Yes” to a., answer questions b. and c. below.

b. pH from Cord Blood Sample

If either arterial or venous umbilical cord blood sampling was performed, record the pH observed to two decimal places. If multiple umbilical cord samples were obtained, record the lowest pH observed to two decimal places.
c. Base Deficit from Cord Blood Sample

If either arterial or venous umbilical cord blood sampling was performed, record the base deficit observed in mmoles/liter to the nearest tenth. If multiple umbilical cord samples were obtained, record the worst (highest) base deficit measured or calculated in mmoles/liter.

NOTE: Record the Base Deficit. Some laboratories report Base Excess rather than Base Deficit. This can be confusing. Infants with acidosis usually have a positive Base Deficit. That means that they have a deficit of Base. The same infant would have a negative Base Excess meaning that there is a negative excess or a deficit. Take the following steps when recording Base Deficit for the Registry:

1. Determine whether your laboratory is reporting results to you as Base Excess or Base Deficit.
2. If the laboratory is reporting Base Deficit, record the value exactly as reported by the laboratory.
3. If your laboratory is reporting Base Excess, you must change the sign in front of the number before recording it for the Registry. For example, if your laboratory reports a Base Excess of -6 (negative 6), the Base Deficit would be +6 (positive 6). You would enter 6 in eNICQ. If your laboratory reports a Base Excess of +3 (positive 3), the Base Deficit would be -3 (negative 3). You would enter -3 in eNICQ. The number stays the same; only the sign in front of the number changes.

ITEM OB15: Assisted Reproduction?

Answer “Yes” if it is documented in the maternal or infant medical record that this pregnancy was the product of artificial or assisted reproductive technology. This may include medications to induce ovulation (clomid) and/or procedures to assist fertilization (artificial insemination, in vitro fertilization).

Answer “No” if it is not documented in the maternal or infant medical record that this pregnancy was the product of artificial or assisted reproductive technology.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.
ITEM OB16: Placenta Sent for Pathology?

Answer “Yes” if it is recorded in the maternal or infant medical record that the placenta was sent for pathological examination.

Answer “No” if it is not recorded in the maternal or infant medical record that the placenta was sent for pathological examination.

Answer “Unknown” if both the maternal and infant records are missing and not available for review.
OB/INITIAL STATUS FORM
PART B, INFANT'S INITIAL CLINICAL STATUS

ITEM OB17: Infant Admitted to Your NICU?

a. Infant Admitted to Your NICU?

Answer “Yes” if the infant was admitted to your NICU.
Answer “No” if the infant was not admitted to your NICU.

If “Yes” to a., answer questions b., c., and d. below. If the date is known but
the time is uncertain, enter the best estimate for time.

b. Age at Admission, Days

Age at Admission, Days, is automatically calculated in eNICQ by subtracting
the date and time of birth from the date and time of admission to your NICU.
For example, if more than 48 hours and less than 72 hours elapsed between
these two date/time values, the number of days would be 2. If less than 24
hours elapsed, the value would be zero.

c. Age at Admission, Hours

Age at Admission, Hours, is automatically calculated in eNICQ by subtracting
the date and time of birth from the date and time of admission to your NICU.
The number of hours can vary between 0 and 23.

d. Age at Admission, Minutes

Age at Admission, Minutes, is automatically calculated in eNICQ by subtracting
the date and time of birth from the date and time of admission to your NICU.
The number of minutes can vary between 0 and 59.

NOTE: The date and time of birth and date and time of admission are protected
health care data items. These items will not be exported to the Vermont
Oxford Network. They will be stored on your local computer.
ITEM OB18: APGAR Score at 10 Minutes

Enter the **10 minute APGAR** score if the score was recorded in either the maternal or infant medical record.

Enter “**Unknown**” if the APGAR score at 10 minutes was not recorded in either the maternal or infant medical record.

**ITEM OB19: Assisted Ventilation at 10 Minutes?**

Answer “**Yes**” if it is documented in the infant’s record that assisted ventilation by either bag-mask or endotracheal tube was provided to the infant at 10 minutes of life.

Answer “**No**” if it is not documented in the infant’s record that assisted ventilation by either bag-mask or endotracheal tube was provided to the infant at 10 minutes of life.

Answer “**Unknown**” if the infant record is missing and not available for review.

**ITEM OB20: Arterial, Venous, or Capillary Blood Gas**

**a. Arterial, Venous, or Capillary Blood Gas Obtained during First Hour of Life?**

Answer “**Yes**” if it is documented in the infant record that an arterial, venous, or capillary blood gas was obtained within the first hour after birth.

Answer “**No**” if it is not documented in the infant record that an arterial, venous, or capillary blood gas was obtained within the first hour after birth.

Answer “**Unknown**” if the infant record is missing and not available for review.

**NOTE:** If multiple blood gases were obtained, the lowest pH and worst base deficit values, defined below, may be from different blood gas specimens.

**b. pH from Arterial, Venous, or Capillary Blood Gas**

Enter the lowest pH from an arterial, venous, or capillary blood gas obtained within the first hour after birth to two decimal places. If multiple capillary cord samples were obtained, record the lowest pH observed to two decimal places.
c. Base Deficit from Arterial Venous, or Capillary Blood Gas within the First Hour of Life

If arterial, venous, or capillary blood gas was obtained within the first hour after birth, record the base deficit observed in mmoles/liter to the nearest tenth. If multiple blood gas samples were obtained, record the worst (highest) base deficit measured or calculated in mmoles/liter to the nearest tenth.

NOTE: Record the Base Deficit. Some laboratories report Base Excess rather than Base Deficit. This can be confusing. Infants with acidosis usually have a positive Base Deficit. That means that they have a deficit of Base. The same infant would have a negative Base Excess meaning that there is a negative excess or a deficit. Take the following steps when recording Base Deficit for the Registry:

1. Determine whether your laboratory is reporting results to you as Base Excess or Base Deficit.
2. If the laboratory is reporting Base Deficit, record the value exactly as reported by the laboratory.
3. If your laboratory is reporting Base Excess, you must change the sign in front of the number before recording it for the Registry. For example, if your laboratory reports a Base Excess of -6 (negative 6), the Base Deficit would be +6 (positive 6). You would enter 6 in eNICQ. If your laboratory reports a Base Excess of +3 (positive 3), the Base Deficit would be -3 (negative 3). You would enter -3 in eNICQ. The number stays the same; only the sign in front of the number changes.

ITEM OB21: Infant Temperature Recorded?

a. Infant Temperature Recorded within 72 Hours of Birth?

Answer “Yes” if at least one measurement of the infant’s temperature obtained within the first 72 hours of birth was recorded in the infant record.

Answer “No” if no measurement of the infant’s temperature obtained within the first 72 hours of birth was recorded in the infant record.

Answer “Unknown” if the infant records are missing and not available for review.

If “Yes” to Item a, answer question b and c below.
b. Highest Temperature of Infant

If the infant body temperature was recorded during the first 72 hours after birth (rectal, esophageal, tympanic, or axillary), enter the highest temperature recorded during this period in degrees Centigrade. In recording the temperature, use a single decimal place and indicate that the temperature is in degrees Centigrade, e.g. 36.7° C.

c. Lowest Temperature of Infant

If the infant body temperature was recorded during the first 72 hours after birth (rectal, esophageal, tympanic, or axillary), enter the lowest temperature recorded during this period in degrees Centigrade. In recording the temperature, use a single decimal place and indicate that the temperature is in degrees Centigrade, e.g. 36.7° C
NEUROLOGICAL FORM Definitions

The Neurological Form includes data items for neurological indicators, electrophysiology, seizures, anticonvulsants and neuroimaging. The form includes three parts:

- Part A: Neurological Examination (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 and Day 7 ± 1 day)
- Part B: Electrophysiology, Seizures and Anticonvulsants
- Part C: Neuroimaging

PART A, Neurological Indicators

Answer the items in Part A of the Neurological Form for each examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 and Day 7 of life). Two examination periods are reported for Day 1 as indicated; Day 3 includes the period 48 to 72 hours of age; Day 7 ± 1 day includes the period of day 7 of life plus or minus 1 day (120 to 192 hours of age).

ITEM NU1: Infant Alive During Examination Period?

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day),

Answer “Yes” if the infant was alive in your hospital or, if outborn, was in the hospital from which the infant was transferred for some or all of the applicable examination period. If the infant was transferred and readmitted to your hospital, and the infant was in your hospital or in the “transferred to” hospital during the examination period, answer “Yes”.

Answer “No” if the infant was not alive in your hospital and, if outborn, was not alive in the hospital from which the infant was transferred, at any time during the applicable examination period. If the infant was transferred prior to an examination period and not readmitted, answer “No”.

NOTE: The answer to Item NU1 for Day 1 ≤ 6 Hours must always be “Yes”. If the answer to Item NU1 for the other time periods is “No”, do not answer the other questions in Part A of the Neurological Form for the applicable examination period. If the answer to Item NU1 is “Yes”, answer Item NU2 below for the applicable examination period.
ITEM NU2: Paralysis for the Entire Examination Period?

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day),

Answer “Yes” if Paralysis with pancuronium or other muscle relaxant was pharmacologically induced during the entire period for which the examination is applicable (0 to 24 hours for Day 1, 48 to 72 hours for Day 3 and 120 to 192 hours for Day 7 ± 1 day).

Answer “No” if Paralysis with pancuronium or other muscle relaxant was not pharmacologically induced during the entire period for which the examination is applicable.

NOTE: If the answer to Item NU2 is “Yes”, do not answer the other questions in Part A of the Neurological Form for the applicable examination period. If the answer to Item NU2 is “No”, answer all the other questions in Part A of the Neurological Form for the applicable examination period.

ITEM NU3: Conscious State

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day), select the worst conscious state during the period (from best to worst, states are normal, irritability, lethargy, stupor and coma):

Answer “Normal” if the infant is in the normal conscious state during the entire examination period.

Answer “Irritability” if there is excessive, often high-pitched cry with little sustained quiet (which may be associated with spontaneous tremors).

Answer “Lethargy” if the infant sleeps excessively with occasional spontaneous eye opening.

Answer “Stupor” if there is no spontaneous eye opening, and tactile stimulation elicits poorly sustained eye opening.

Answer “Coma” if there is no eye opening with vigorous tactile stimulation.

Answer “Unknown” if the conscious state was not known.
ITEM NU4: Brainstem Function

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day),

Answer “Normal” if brainstem function was normal during the entire examination period.

Answer “Abnormal” if any of the following abnormalities were observed at any time during the examination period: decreased facial movements; eyes not normally aligned or incomplete eye movements to Doll’s eye maneuver; poor suck, excess drooling, decreased swallow, or depressed gag reflex; depressed corneal reflex; sustained periodic hyperventilation or ‘gassing’ patterns.

Answer “Unknown” if it is not known whether brainstem function was normal or abnormal.

ITEM NU5: Movements

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day),

Answer “Normal” if the infant’s movements were normal in frequency and amplitude throughout the examination period.

Answer “Abnormal” if the infant’s movements were decreased in frequency or amplitude at any time during the examination period.

Answer “Unknown” if it is not known whether the infant’s movements were normal or abnormal.

ITEM NU6: Posturing

Posturing is sustained abnormal position such as tonic extension or flexion of limbs or trunk, e.g., opisthotonus (extension of neck and trunk); retrocollis (extension of neck); decerebrate posturing (extension of arms and legs); decorticate posturing (extension of legs/ flexion of elbows).

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Answer “Present” if posturing was observed at any time during the examination period.

Answer “Absent” if posturing was not observed during the examination period.

Answer “Unknown” if it is not known whether posturing was present or absent.
ITEM NU7: Tone

Tone is abnormal if it is either increased (shows increased resistance to passive movement) or decreased (shows decreased resistance to passive movement, which may be associated with frog-leg posturing with arms and legs lying flaccid in abduction).

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Answer “Normal” if the tone was normal during the entire examination period.

Answer “Abnormal” if the infant’s tone was observed to be abnormal at any time during the examination period.

Answer “Unknown” if it is not known whether tone was normal or abnormal.

ITEM NU8: Reflexes

Reflexes are abnormal if they (1) are hyperactive e.g., exaggerated response to tendon tap (which may be associated with sustained clonus of > 5 beats at the ankles) or (2) show crossed adductor response of opposite knee when tapping medial aspect of knee or (3) are hypoactive, e.g., when there is reduced or absent response to tendon tap.

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Answer “Normal” if the infant’s deep tendon reflexes were normal during the entire examination period.

Answer “Abnormal” if the infant’s deep tendon reflexes are observed to be abnormal at any time during the examination period.

Answer “Unknown” if it is not known whether reflexes were normal or abnormal.
ITEM NU9: Feeding

NOTE: Feedings by mouth include nipple feeding from the breast, nipple feeding from a bottle of human or formula milk, and feedings of human or formula milk by mouth using a feeding cup or spoon.

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Answer “No Enteral Feedings” if there are no enteral feedings at all, including feedings by mouth or tube feedings. The infant may receive feedings by parenteral routes.

Answer “Enteral Feedings, No Feedings by Mouth” if the infant is receiving enteral feedings but none of the enteral feedings are by mouth as defined above. All enteral feedings are by tube.

Answer “Enteral Feedings, Some Feedings by Mouth” if the infant is receiving enteral feedings, and some of the enteral feedings are by mouth as defined above, with supplementation by enteral tube feedings and/or parenteral nutrition.

Answer “Enteral Feedings, All Feedings by Mouth” if all feedings are by mouth as defined above. There are no supplemental tube feedings or supplemental parenteral nutrition. Infant may receive IV fluids for medications but not for parenteral nutrition or supplemental hydration.

Answer “Unknown” if the feeding method is not known.

ITEM NU10: Assisted Ventilation?

NOTE: Intermittent positive pressure ventilation via nasal prongs and synchronized intermittent positive pressure ventilation via nasal prongs are not considered assisted ventilation.

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Answer “Yes” if the infant was given intermittent positive pressure ventilation through an endotracheal tube with a ventilator (conventional or high frequency) at any time on the applicable day of life.

Answer “No” if the infant was not given intermittent positive pressure ventilation through an endotracheal tube with a ventilator (conventional or high frequency) at any time on the applicable day of life.

Answer “Unknown” if it is not known whether the infant received assisted ventilation during the examination period.
ITEM NU11: Clinical Seizures?

A clinical seizure is defined as “paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/papillary dilation).”

For the applicable examination period (Day 1 ≤ 6 Hours, Day 1 > 6 to 24 Hours, Day 3 or Day 7 ± 1 day):

Answer “Yes” if one or more clinical seizures as defined above were recorded in the infant medical record on the applicable day of life.

Answer “No” if no clinical seizure as defined above was recorded in the infant medical record during the examination period.

Answer “Unknown” if the infant medical record is missing and unavailable.
NEUROLOGICAL FORM
PART B, Electrophysiology, Seizures and Anticonvulsants

NOTE: When answering questions in Part B of the Neurological Form, “prior to discharge from your hospital” includes diagnoses made prior to admission to your hospital if the infant was outborn. If the infant transfers to another hospital and is readmitted to your center without having gone home, include diagnoses following transfer until the infant is discharged home, died or transfers again, whichever is soonest.

ITEM NU12: Full Channel EEG

a. Full Channel EEG Performed?
Answer “Yes” if a full channel electroencephalogram (EEG) was performed at any time prior to discharge from your hospital.
Answer “No” if a full channel EEG was not performed at any time prior to discharge from your hospital.
Answer “Unknown” if it is not known whether a full channel EEG was performed at any time prior to discharge from your hospital.

b. EEG Background Pattern
If a full channel EEG was performed at any time prior to discharge from your hospital, select the one category that most closely describes the worst EEG background pattern observed on any full channel EEG prior to discharge from your hospital, including EEGs performed prior to admission for outborn infants (from best to worst, patterns are normal, excessively discontinuous, depressed amplitude, burst suppression and background iso-electric).
Answer “Normal” if the background pattern is normal in continuity, amplitude and frequency for gestational age.
Answer “Excessively Discontinuous” if the background pattern is excessively discontinuous (‘dysmature’) for gestational age.
Answer “Depressed Amplitude” if the background pattern shows depressed amplitude and/or slowing.
Answer “Burst Suppression Pattern” if a burst suppression pattern is present or a severely depressed background is present.
Answer “Background Iso-Electric” if the background pattern shows no recognizable electro-cortical activity.
Answer “Unknown” if the worst background pattern is not known.
ITEM NU13: Bedside aEEG

a. Bedside aEEG Performed

Answer “Yes” if a bedside amplitude integrated EEG (aEEG) monitor was used at any time prior to discharge from your hospital.

Answer “No” if a bedside aEEG monitor was not used at any time prior to discharge from your hospital.

Answer “Unknown” if it is not known whether a bedside aEEG monitor was used at any time prior to discharge from your hospital.

b. Bedside aEEG Background Pattern

If a bedside aEEG was performed at any time prior to discharge from your hospital, select the one category that most closely describes the worst background pattern observed at any time prior to discharge from your hospital, including bedside monitor tracings performed prior to admission for outborn infants (from best to worst, patterns are normal, moderately abnormal or discontinuous, and severely abnormal).

NOTE: A minimum of one hour recording with low electrode impedance and the absence of continuous EEG seizures should be available in order to classify the worst background. The output appears as a thick dense band on the chart. The lower margin of the dense band represents the minimum degree of cerebral activity and the upper margin represents the maximum cerebral activity.\(^1\) A line is drawn through the upper margin and the lower margin of the dense band of the aEEG and the voltage measured from these marked lines with the scale on the printed record.\(^2\)


Answer “Normal” if the upper margin of the dense aEEG band is greater than 10µv and the lower margin is greater than 5µv.

Answer “Moderately Abnormal or Discontinuous” if the upper margin of the dense aEEG band is greater than 10µv and the lower margin is less than 5µv.
Answer “Severely Abnormal” if the upper margin of the dense aEEG band is less than 10μv and the lower margin is less than 5μv.

Answer “Unknown” if the worst aEEG background pattern is not known. If there is less than one hour of recording with low electrode impedance and absence of continuous EEG seizures is available, the worst background cannot be determined, answer “Unknown”.

**ITEM NU14: Seizures Prior to Discharge**

**a. Seizures Occurred Prior to Discharge?**

Answer “Yes” if one or more seizures were documented in the infant medical record at any time prior to discharge from your hospital. The diagnosis may be made by clinical observation, full channel EEG or bedside aEEG monitor.

Answer “No” if one or more seizures were not documented in the infant medical record at any time prior to discharge from your hospital.

Answer “Unknown” if the infant medical record is missing and unavailable for review.

**NOTE:** If seizures were documented at any time prior to discharge from your hospital, indicate in b. through d. below the evidence used to determine that seizures occurred; record the age seizures first occurred in e. below.

**b. Evidence of Clinical Seizure?**

A clinical seizure is defined as “paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/papillary dilation)”.

Answer “Yes” if one or more clinical seizures as defined above were recorded in the infant medical record at any time prior to discharge from your hospital.

Answer “No” if clinical signs of seizures as defined above were not recorded in the infant medical record at any time prior to discharge from your hospital.
c. Full Channel EEG Evidence of Seizure?

Answer “Yes” if electroencephalographic evidence of seizures was detected on a full channel EEG performed at any time prior to discharge from your hospital.

Answer “No” if electroencephalographic evidence of seizures was not detected on a full channel EEG performed at any time prior to discharge from your hospital.

d. Bedside aEEG evidence of seizure?

Answer “Yes” if electroencephalographic evidence of seizures was detected on a bedside aEEG recording performed at any time prior to discharge from your hospital.

Answer “No” if electroencephalographic evidence of seizures was not detected on a bedside aEEG recording performed at any time prior to discharge from your hospital.

e. Age Seizures First Observed

If seizures were documented at any time from birth until discharge from your hospital, enter the date and time that seizures were first observed by any method (clinically, full channel EEG, or bedside EEG).

NOTE: The date and time seizures were first observed is protected health care information. This item will not be exported to the Vermont Oxford Network. It will be stored on your local computer. Only the age of the infant when seizures were first observed will be exported to VON. The infant's age in days, hours and minutes is automatically calculated by the eNICQ software.

(1) Age Seizures First Observed, Days

The age seizures were first observed, days, is automatically calculated by eNICQ by subtracting the date and time of birth from the date and time seizures were first observed. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

(2) Age Seizures First Observed, Hours

The age seizures were first observed, hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time that seizures were first observed. The number of hours can vary between 0 and 23.
**3) Age Seizures First Observed, Minutes**

The age seizures were first observed, minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time seizures were first observed. The number of minutes can vary between 0 and 5.

**ITEM NU15: Anticonvulsants Prior to Discharge**

| NOTE: See Appendix C for complete list of anticonvulsant generic and trade names. If anticonvulsants were documented at any time prior to discharge from your hospital, indicate in b. through h. below all of the anticonvulsants that were received. |

**a. Anticonvulsants Received Prior to Discharge?**

Answer “Yes” if the infant received anticonvulsant treatment at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant did not receive anticonvulsant treatment at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “Unknown” if the infant medical record is missing and unavailable for review.

If Item a. is answered “Yes”, answer questions b. through h. below.

**b. Phenobarbital Prior to Discharge?**

Answer “Yes” if the infant received Phenobarbital at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant did not receive Phenobarbital at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “Unknown” if it cannot be determined whether Phenobarbital was received prior to discharge.

**c. Phenytoin or Fosphenytoin Prior to Discharge?**

Answer “Yes” if the infant received Phenytoin or Fosphenytoin at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant did not receive Phenytoin or Fosphenytoin at any time prior to discharge from your hospital, as recorded in the infant medical record.
Answer “Unknown” if it cannot be determined whether Phenytoin or Fosphenytoin was received prior to discharge.

d. Lorazepam Prior to Discharge?

Answer “Yes” if the infant received Lorazepam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant did not receive Lorazepam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “Unknown” if it cannot be determined whether Lorazepam was received prior to discharge.

e. Diazepam Prior to Discharge?

Answer “Yes” if the infant was receiving Diazepam at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant was not receiving Diazepam at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving Diazepam at discharge.

f. Midazolam Prior to Discharge?

Answer “Yes” if the infant received Midazolam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant did not receive Midazolam at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “Unknown” if it cannot be determined whether Midazolam was received prior to discharge.

g. Topiramate Prior to Discharge?

Answer “Yes” if the infant received Topiramate at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant did not receive Topiramate at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “Unknown” if it cannot be determined whether Topiramate was received prior to discharge.
h. Other Anticonvulsant Prior to Discharge?

Answer “Yes” if the infant was receiving any other anticonvulsant not mentioned above at the time of discharge from your hospital, as recorded in the infant medical record. If “Yes”, record the name of the other anticonvulsant received in the space provided.

Answer “No” if the infant was not receiving any other anticonvulsant at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving other anticonvulsants at discharge.

If “Yes” to this item, specify which other anticonvulsants were received at discharge (see Appendix C).
NEUROLOGICAL FORM
PART C, NEUROIMAGING

NOTE: Prior to completing Part C of the Neurological Form, first review all reports of neuroimaging studies (Cranial Ultrasounds, CT Scans, and MRI Scans) performed prior to discharge from your hospital, including studies performed prior to admission for outborn infants. Refer to the actual neuroimaging reports when completing these items. It would be advantageous to share Part C of the Neurological Form and review cases with your local neuro-radiologist/ radiologist who reports most of the neuroimaging for your NICU. This will assist you as the radiologist will understand what codings are being used and you may find it easier to approach them for any assistance in recording the findings of neuroimaging studies. Abbreviations for the studies used below are US for cranial ultrasound, CT for CT scan and MRI for MRI scan.

ITEM NU16: Exam or Scan Performed?

For each type of exam performed (US, CT or MRI),

Answer **“Yes”** if one or more exams/scans were performed prior to discharge from your hospital.

Answer **“No”** if one or more exams/scans were not performed prior to discharge from your hospital.

Answer **“Unknown”** if the maternal and infant records and the neuroimaging reports are missing and not available for review.

NOTE: If the answer to Item NU16 is **“No”**, do not answer the other questions in Part C of the Neurological Form for the applicable exam or scan. If the answer to Item NU16 is **“Yes”**, complete all of the other questions in Part C of the Neurological Form for the applicable exam or scan.
ITEM NU17: Day of First Exam/Scan

**NOTE:** The dates of the first cranial ultrasound exam, CT scan and MRI scan are protected health care information. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer. The eNICQ software will automatically calculate the day of first exam in days, and this data item will be exported to the Network.

For each type of exam performed (US, CT or MRI), enter the day of life that the first exam/scan of that type was performed.

ITEM NU18: Day of Last Exam/Scan

**NOTE:** The dates of the last cranial ultrasound exam, CT scan and MRI scan are protected health care information. These items will not be exported to the Vermont Oxford Network. They will be stored on your local computer. The eNICQ software will automatically calculate the day of first exam in days, and this data item will be exported to the Network.

For each type of exam performed (US, CT or MRI), enter the day of life that the last exam/scan of that type was performed.

ITEM NU19: Intraventricular Hemorrhage?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if intraventricular hemorrhage was recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if intraventricular hemorrhage was not recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether an intraventricular hemorrhage was recorded for the type of exam/scan.
ITEM NU20: Extra-Axial, Subdural or Subarachnoid Hemorrhage?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if extra-axial, subdural or subarachnoid hemorrhage was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if extra-axial, subdural or subarachnoid hemorrhage was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether extra-axial, subdural or subarachnoid hemorrhage was recorded for the type of exam/scan.

ITEM NU21: Intraparenchymal Hemorrhage?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if intraparenchymal hemorrhage was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if intraparenchymal hemorrhage was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether an intraparenchymal hemorrhage was recorded for the infant for the type of exam/scan.

ITEM NU22: Subependymal Hemorrhage?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if subependymal hemorrhage was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if subependymal hemorrhage was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether a subependymal hemorrhage was recorded for the infant for the type of exam/scan.
ITEM NU23: Abnormality in Deep Nuclear Gray Matter?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if an abnormality in the deep nuclear gray matter was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if an abnormality in the deep nuclear gray matter was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether an abnormality in deep nuclear gray matter was recorded for the type of exam/scan.

ITEM NU24: Cystic White Matter Injury?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if a cystic white matter injury was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital. Cystic white matter injury may be focal, multifocal or diffuse but must include the presence of cysts.

Answer “No” if a cystic white matter injury was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether a cystic white matter injury was recorded for the type of exam/scan.

ITEM NU25: Diffuse White Matter Injury?

Note: this item only applies to MRI scans.

Answer “Yes” if diffuse white matter injury was indicated in a MRI scan performed at any time prior to discharge from your hospital. This form of white matter injury should have no cystic changes.

Answer “No” if diffuse white matter injury was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether a diffuse white matter injury was recorded on an MRI scan.
ITEM NU26: Ventriculomegaly?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if ventriculomegaly was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if ventriculomegaly was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether ventriculomegaly was recorded for the type of exam/scan.

ITEM NU27: Veno-Occlusion?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if veno-occlusion was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if veno-occlusion was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether veno-occlusion was recorded for the type of exam/scan.

ITEM NU28: Arterial Occlusion?

For each type of exam performed (US, CT or MRI),

Answer “Yes” if arterial occlusion was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “No” if arterial occlusion was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “Unknown” if it cannot be determined whether arterial occlusion was recorded for the type of exam/scan.
**ITEM NU29: Brainstem Injury?**

**Note:** This item only applies to CT scans and MRI scans.

Answer “**Yes**” if brainstem injury was indicated in one or more CT or MRI scans performed at any time prior to discharge from your hospital.

Answer “**No**” if brainstem injury was not indicated in one or more CT or MRI scans performed at any time prior to discharge from your hospital.

Answer “**Unknown**” if it cannot be determined whether brainstem injury was recorded for the type of scan.

**ITEM NU30: Cerebellar Injury?**

For each type of exam performed (US, CT or MRI),

Answer “**Yes**” if cerebellar injury was indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “**No**” if cerebellar injury was not indicated in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “**Unknown**” if it cannot be determined whether cerebellar injury was recorded for the type of exam/scan.

**ITEM NU31: Diffuse Cortical Signal Abnormality?**

**Note:** This item only applies to MRI scans.

Answer “**Yes**” if diffuse cortical signal abnormality was indicated in a MRI scan performed at any time prior to discharge from your hospital.

Answer “**No**” if diffuse cortical signal abnormality was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Answer “**Unknown**” if it cannot be determined whether diffuse cortical signal abnormality was recorded on an MRI scan.
ITEM NU32: Parasagittal Watershed Cortical Gray Matter Injury?

**Note:** This item only applies to MRI scans.

Answer “**Yes**” if parasagittal watershed cortical gray matter injury was indicated in a MRI scan performed at any time prior to discharge from your hospital.

Answer “**No**” if parasagittal watershed cortical gray matter injury was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Answer “**Unknown**” if it cannot be determined whether parasagittal watershed cortical gray matter injury was recorded on an MRI scan.

ITEM NU33: Absence of Posterior Limb of the Internal Capsule?

**Note:** This item only applies to MRI scans.

Answer “**Yes**” if absence of the posterior limb of the internal capsule was indicated in a MRI scan performed at any time prior to discharge from your hospital.

Answer “**No**” if absence of the posterior limb of the internal capsule was not indicated in a MRI scan performed at any time prior to discharge from your hospital.

Answer “**Unknown**” if it cannot be determined whether absence of posterior limb of the internal capsule was recorded on an MRI scan.

ITEM NU34: Other Intracranial Abnormalities?

For each type of exam performed (US, CT or MRI),

Answer “**Yes**” if any other intracranial abnormalities are recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital. If “Yes”, describe the other abnormalities in the space provided.

Answer “**No**” if any other intracranial abnormalities are not recorded in one or more of the reports for the specific type of exam or scan performed at any time prior to discharge from your hospital.

Answer “**Unknown**” if it cannot be determined whether other intracranial abnormalities were recorded for this type of exam/scan.
CHAPTER 7

DIAGNOSES AND DISCHARGE FORM Definitions

The Diagnoses and Discharge Form includes data items which identify infant outcomes relevant to conditions diagnosed prior to discharge from your center, as well as indicators of the infant’s status at discharge. The form includes two parts:

- Part A: Diagnoses
- Part B: Discharge Status

PART A, DIAGNOSES

ITEM DD1: Persistent Pulmonary Hypertension of the Newborn, PPHN?

Answer “Yes” if a diagnosis of Persistent Pulmonary Hypertension of the Newborn (PPHN), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Answer “No” if the infant medical record did not include documentation that a diagnosis of PPHN occurred prior to discharge from your hospital.

Answer “Unknown” if the infant medical record was missing and unavailable for review.

ITEM DD2: Renal Failure?

Answer “Yes” if a diagnosis of renal failure (acute or chronic), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Answer “No” if the infant medical record did not include documentation that a diagnosis of renal failure (acute or chronic) occurred prior to discharge from your hospital.

Answer “Unknown” if the infant medical record was missing and unavailable for review.

ITEM DD3: Syndrome of Inappropriate Secretion of Antidiuretic Hormone (SIADH)?

Answer “Yes” if a diagnosis of Syndrome of Inappropriate Secretion of Antidiuretic Hormone (SIADH), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.
Answer “No” if the infant medical record did not include documentation that a diagnosis of SIADH occurred prior to discharge from your hospital.

Answer “Unknown” if the infant medical record was missing and unavailable for review.

ITEM DD4: Disseminated Intravascular Coagulation, DIC?

Answer “Yes” if a diagnosis of Disseminated Intravascular Coagulation (DIC), occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Answer “No” if the infant medical record did not include documentation that a diagnosis of DIC occurred prior to discharge from your hospital.

Answer “Unknown” if the infant medical record was missing and unavailable for review.

ITEM DD5: Hepatic Dysfunction?

NOTE: Apartate aminotransferase (AST) was formerly called serum glutamic oxaloacetic transaminase (SGOT). Alanine aminotransferase (ALT) was formerly called serum glutamic pyruvic transaminase (SGPT).

Answer “Yes” if serum AST (SGOT) and/or ALT (SGPT) were obtained prior to discharge from your hospital and one or both values were elevated above local normal laboratory values.

Answer “No” if serum AST (SGOT) and/or ALT (SGPT) were obtained prior to discharge from your hospital and the values were not elevated above local normal laboratory values.

Answer “Unknown” if neither serum AST (SGOT) nor ALT (SGPT) was measured, or if the results are unknown.
ITEM DD6: Hyperbilirubinemia within 7 Days of Birth?

**NOTE:** The date of birth counts as Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, then Day 7 would be September 7 - all bilirubin values from September 1 to 7 would be evaluated in answering this question.

Answer **“Yes”** if a serum indirect bilirubin level $\geq 20$ mg/dl (342 micromoles/L) was recorded in the infant medical record for a specimen obtained at any time within 7 days of birth.

Answer **“No”** if a serum indirect bilirubin level $\geq 20$ mg/dl (342 micromoles/L) was not recorded in the infant medical record for a specimen obtained at any time within 7 days of birth.

Answer **“Unknown”** if the infant medical record is missing or not available for review.

ITEM DD7: Cardiac Dysfunction?

Evidence of cardiac dysfunction includes myocardial dysfunction and/or tricuspid insufficiency on physical exam, echocardiogram, or cardiac catheterization. Arrhythmias do not count as evidence of cardiac dysfunction for this question.

Answer **“Yes”** if a diagnosis of cardiac dysfunction, occurring at any time prior to discharge from your hospital, was documented in the infant medical record.

Answer **“No”** if the infant medical record did not include documentation that a diagnosis of cardiac dysfunction occurred prior to discharge from your hospital.

Answer **“Unknown”** if the infant medical record was missing and unavailable for review.

ITEM DD8: Prenatal TORCH Infection

a. Prenatal TORCH Infection Present?

Answer **“Yes”** if a diagnosis of prenatal infection with toxoplasmosis, rubella, syphilis, cytomegalovirus, or Herpes Simplex was documented in either the infant or maternal medical record.

Answer **“No”** if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with toxoplasmosis, rubella, syphilis, cytomegalovirus, or Herpes Simplex.

Answer **“Unknown”** if the infant and maternal medical records were missing and unavailable for review.
NOTE: If a prenatal TORCH infection was present, answer questions b. through f. below. Do not answer these questions if a prenatal TORCH infection was not present.

b. Toxoplasmosis?
Answer “Yes” if a diagnosis of a prenatal infection with toxoplasmosis was documented in either the infant or maternal medical record.
Answer “No” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with toxoplasmosis.
Answer “Unknown” if it cannot be determined whether toxoplasmosis was present.

c. Rubella?
Answer “Yes” if a diagnosis of a prenatal infection with rubella was documented in either the infant or maternal medical record.
Answer “No” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with rubella.
Answer “Unknown” if it cannot be determined whether rubella was present.

d. Syphilis?
Answer “Yes” if a diagnosis of a prenatal infection with syphilis was documented in either the infant or maternal medical record.
Answer “No” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with syphilis.
Answer “Unknown” if it cannot be determined whether syphilis was present.

e. Cytomegalovirus?
Answer “Yes” if a diagnosis of a prenatal infection with cytomegalovirus was documented in either the infant or maternal medical record.
Answer “No” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with cytomegalovirus.
Answer “Unknown” if it cannot be determined whether cytomegalovirus was present.
f. Herpes Simplex?

Answer “Yes” if a diagnosis of a prenatal infection with herpes simplex was documented in either the infant or maternal medical record.

Answer “No” if the infant and maternal medical records did not include documentation of a diagnosis of prenatal infection with herpes simplex.

Answer “Unknown” if it cannot be determined whether herpes simplex was present.

ITEM DD9: Congenital Neuromuscular Disorder?

a. Congenital Neuromuscular Disorder Present?

Answer “Yes” if a diagnosis of congenital neuromuscular disorder was documented in the infant medical record. If a diagnosis of congenital neuromuscular disorder was made, describe the specific disorder in the space provided.

Answer “No” if the infant medical record did not include documentation of a diagnosis of congenital neuromuscular disorder.

Answer “Unknown” if the infant medical record was missing and unavailable for review.

b. Describe the congenital neuromuscular disorder if present.

If the infant has a congenital neuromuscular disorder, please describe.

ITEM DD10: Birth Trauma

a. Traumatic Birth Injury?

Answer “Yes” if one or more of the injuries in questions b. through h. below were diagnosed and documented in the maternal or infant record.

Answer “No” if the infant and maternal medical records did not include documentation of any of the injuries in questions b. through h. below.

Answer “Unknown” if the maternal and infant medical records were missing and unavailable for review.

NOTE: If a traumatic birth injury occurred, answer questions b. through h. below. Do not answer these questions if no traumatic birth injury occurred.
b. Spinal Cord Injury?
Answer “Yes” if a spinal cord injury was present at birth.
Answer “No” if a spinal cord injury was not present at birth.
Answer “Unknown” if it cannot be determined whether spinal cord injury occurred.

c. Brachial Plexus Injury?
Answer “Yes” if a brachial plexus injury was present at birth.
Answer “No” if a brachial plexus injury was not present at birth.
Answer “Unknown” if it cannot be determined whether brachial plexus injury occurred.

d. Skull Fracture?
Answer “Yes” if a skull fracture was present at birth.
Answer “No” if a skull fracture was not present at birth.
Answer “Unknown” if it cannot be determined whether skull fracture occurred.

e. Long Bone Fracture?
Answer “Yes” if a long bone fracture was present at birth.
Answer “No” if a long bone fracture was not present at birth.
Answer “Unknown” if it cannot be determined whether long bone fracture occurred.

f. Clavicle Fracture?
Answer “Yes” if a clavicle fracture was present at birth.
Answer “No” if a clavicle fracture was not present at birth.
Answer “Unknown” if it cannot be determined whether clavicle fracture occurred.
g. Cephalhematoma?
Answer “Yes” if a cephalhematoma was present at birth.
Answer “No” if a cephalhematoma was not present at birth.
Answer “Unknown” if it cannot be determined whether cephalhematoma occurred.

h. Other Traumatic Birth Injury?
Answer “Yes” if any traumatic birth injury was present at birth which is not listed in questions b. through g. above. Do not record lacerations. Describe the injuries in the space provided.
Answer “No” if no other traumatic birth injury was present at birth.

ITEM DD11: Meningitis or Encephalitis

a. Meningitis or Encephalitis Suspected or Proven?
Answer “Yes” if the infant was suspected or proven to have bacterial, fungal or viral meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record. Suspected meningitis or encephalitis includes cases in which no organism was recovered from the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest meningitis or encephalitis.
Answer “No” if the infant was not suspected or proven to have bacterial, fungal or viral meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.
Answer “Unknown” if the infant medical record was missing and unavailable for review.

NOTE: If meningitis or encephalitis was suspected or proven, answer questions b. through d. below. Do not answer these questions if meningitis or encephalitis was not suspected or proven.

b. Bacterial Meningitis or Encephalitis
Answer “None” if the infant did not have suspected or proven bacterial meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.
Answer “Suspected” if the infant had suspected bacterial meningitis or encephalitis recorded in the infant medical record at any time prior to discharge.
from your hospital. Suspected bacterial meningitis or encephalitis includes cases in which no organism was recovered from the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest bacterial meningitis or encephalitis.

Answer “Proven” if the infant had bacterial meningitis or encephalitis documented in the medical record at any time prior to discharge from your hospital, with a positive culture of the CSF or brain biopsy specimen.

**NOTE:** If bacterial meningitis or encephalitis was suspected, only answer question (1) below. If bacterial meningitis or encephalitis was proven, answer both questions (1) and (2) below. Do not answer these questions if bacterial meningitis or encephalitis was not suspected or proven.

(1) **Onset of Bacterial Meningitis or Encephalitis**

**NOTE:** Answer based on the first episode if there are multiple episodes. The date of birth is Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, 2006, Day 3 will be September 3, 2006. Any infection occurring on September 1, 2 or 3 would be counted as “Early”, and any infection after September 3 as “Late”.

Answer “Early” if the onset of bacterial meningitis or encephalitis was within 3 days of birth.

Answer “Late” if the onset of bacterial meningitis or encephalitis was more than 3 days after birth.

Answer “Unknown” if the onset of bacterial meningitis or encephalitis was unknown.

(2) **Name of Bacterial Meningitis or Encephalitis Organism**

If a proven bacterial meningitis or encephalitis organism was recovered, record the name of the organism in the space provided.

c. **Fungal Meningitis or Encephalitis**

Answer “None” if the infant did not have suspected or proven fungal meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.
Answer “**Suspected**” if the infant had suspected fungal meningitis or encephalitis recorded in the infant medical record at any time prior to discharge from your hospital. Suspected fungal meningitis or encephalitis includes cases in which no organism was recovered from the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest fungal meningitis or encephalitis.

Answer “**Proven**” if the infant had fungal meningitis or encephalitis documented in the medical record at any time prior to discharge from your hospital, with a positive culture of the CSF or brain biopsy specimen.

**NOTE:** If fungal meningitis or encephalitis was suspected, only answer question (1) below. If fungal meningitis or encephalitis was proven, answer both questions (1) and (2) below. Do not answer these questions if fungal meningitis or encephalitis was not suspected or proven.

(1) **Onset of Fungal Meningitis or Encephalitis**

**NOTE:** Answer based on the first episode if there are multiple episodes. The date of birth is Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, 2011, Day 3 will be September 3, 2011. Any infection occurring on September 1, 2 or 3 would be counted as “Early”, and any infection after September 3 as “Late”.

Answer “**Early**” if the onset of fungal meningitis or encephalitis was within 3 days of birth.

Answer “**Late**” if the onset of fungal meningitis or encephalitis was more than 3 days after birth.

Answer “**Unknown**” if the onset of fungal meningitis or encephalitis was unknown.

(2) **Name of Fungal Meningitis or Encephalitis Organism**

If a proven fungal meningitis or encephalitis organism was recovered, record the name of the organism in the space provided.
**d. Viral Meningitis or Encephalitis**

Answer “None” if the infant did not have suspected or proven viral meningitis or encephalitis at any time prior to discharge from your hospital, as recorded in the infant medical record.

Answer “Suspected” if the infant had suspected viral meningitis or encephalitis recorded in the infant medical record at any time prior to discharge from your hospital. Suspected viral meningitis or encephalitis includes cases in which no organism was recovered from the CSF or brain biopsy but clinical findings, serology, and/or CSF findings suggest viral meningitis or encephalitis.

Answer “Proven” if the infant had viral meningitis or encephalitis documented in the medical record at any time prior to discharge from your hospital, with a positive culture of the CSF or brain biopsy specimen.

**NOTE:** If viral meningitis or encephalitis was suspected, only answer question (1) below. If viral meningitis or encephalitis was proven, answer both questions (1) and (2) below. Do not answer these questions if viral meningitis or encephalitis was not suspected or proven.

**(1) Onset of Viral Meningitis or Encephalitis**

**NOTE:** Answer based on the first episode if there are multiple episodes. The date of birth is Day 1 regardless of the time of birth. For example, if an infant is born at 11:59 PM on September 1, 2011, Day 3 will be September 3, 2011. Any infection occurring on September 1, 2 or 3 would be counted as “Early”, and any infection after September 3 as “Late”.

Answer “Early” if the onset of viral meningitis or encephalitis was within 3 days of birth.

Answer “Late” if the onset of viral meningitis or encephalitis was more than 3 days after birth.

Answer “Unknown” if the onset of viral meningitis or encephalitis was unknown.

**(2) Name of Viral Meningitis or Encephalitis**

If a proven viral meningitis or encephalitis organism was recovered, record the name of the organism in the space provided.
DIAGNOSES AND DISCHARGE FORM

PART B, DISCHARGE STATUS

ITEM DD12: Hearing Screen

a. Hearing Screen Exam Performed?

Answer “Yes” if one or more hearing screen exams, either otoacoustic emissions (OAE) or auditory brainstem response (ABR), were recorded in the infant medical record as having been performed prior to discharge from your hospital.

Answer “No” if no hearing screen exam (otoacoustic emissions, OAE, or auditory brainstem response, ABR) was recorded in the infant medical record as having been performed prior to discharge from your hospital.

Answer “Unknown” if the infant medical record was missing and unavailable for review.

NOTE: If a hearing screen exam was performed, answer question b. below. Do not answer question b. if no hearing screen exam was performed.

b. Hearing Screen Passed?

If one or more hearing screen exams were performed prior to discharge from your hospital, enter the results of the last exam before discharge. Consider all hearing assessments documented in the infant medical record performed prior to discharge from your hospital.

Answer “Yes” if the infant passed the last hearing screen exam administered prior to discharge from your hospital.

Answer “No” if the infant did not pass the last hearing screen exam administered prior to discharge from your hospital.

Answer “Unknown” if it is not known whether the infant passed the last hearing screen exam administered prior to discharge from your hospital.
ITEM DD13: Feeding at Discharge

**NOTE:** Feedings by mouth include nipple feeding from the breast, nipple feeding from a bottle of human or formula milk, and feedings of human or formula milk by mouth using a feeding cup or spoon.

Answer **“No Enteral Feedings”** if there are no enteral feedings at all when the infant is discharged, including feedings by mouth or tube feedings. The infant may receive feedings by parenteral routes.

Answer **“Enteral Feedings, No Feedings by Mouth”** if the infant is receiving enteral feedings at discharge but none of the enteral feedings are by mouth as defined above. All enteral feedings at discharge are by tube.

Answer **“Enteral Feedings, Some Feedings by Mouth”**, if the infant is receiving enteral feedings at discharge, and some of the enteral feedings are by mouth as defined above, with supplementation by enteral tube feedings and/or parenteral nutrition.

Answer **“Enteral Feedings, All Feedings by Mouth”** if all feedings at discharge are by mouth, i.e., there are no supplemental tube feedings or supplemental parenteral nutrition. The infant may receive IV fluids for medications but not for parenteral nutrition or supplemental hydration.

Answer **“Unknown”** if the method of feeding at discharge is unknown.

ITEM DD14: Tracheotomy at Discharge?

Answer **“Yes”** if the infant was discharged from your hospital with a tracheotomy in place.

Answer **“No”** if the infant was not discharged from your hospital with a tracheotomy in place.

Answer **“Unknown”** if it is not known whether or not the infant was discharged with a tracheotomy in place.

ITEM DD15: Discharged with Ventilator?

Answer **“Yes”** if the infant was discharged with either a conventional or high frequency ventilator, with the expectation that assisted ventilation would be provided at least intermittently after discharge.

Answer **“No”** if the infant was not discharged with either a conventional or high frequency ventilator and with the expectation that assisted ventilation would be provided at least intermittently after discharge.

Answer **“No”** if the infant’s discharge status was “Died”.

NOTE: Feedings by mouth include nipple feeding from the breast, nipple feeding from a bottle of human or formula milk, and feedings of human or formula milk by mouth using a feeding cup or spoon.
Answer “Unknown” if it is not known whether or not the infant was discharged with a conventional or high frequency ventilator, with the expectation that assisted ventilation would be provided at least intermittently after discharge.

**ITEM DD16: Anticonvulsant Medication at Discharge?**

**a. Anticonvulsant Medication at Discharge?**

Answer “Yes” if the infant was receiving anticonvulsant medication at the time of discharge from your hospital, with the expectation that anticonvulsant therapy would continue after discharge.

Answer “No” if the infant was not receiving anticonvulsant medication at the time of discharge from your hospital and there was not the expectation that anticonvulsant therapy would continue after discharge.

Answer “No” if the infant’s discharge status was “Died”.

Answer “Unknown” if it is not known whether or not the infant was discharged on anticonvulsant medication, with the expectation that anticonvulsant therapy would continue after discharge.

**NOTE:** If the infant was receiving anticonvulsant medication at the time of discharge, answer questions b. through h. below.

**b. Phenobarbital at Discharge?**

Answer “Yes” if the infant was receiving Phenobarbital at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant was not receiving Phenobarbital at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving Phenobarbital at discharge.

**c. Phenytoin or Fosphenytoin at Discharge?**

Answer “Yes” if the infant was receiving Phenytoin or Fosphenytoin at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant was not receiving Phenytoin or Fosphenytoin at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving Phenytoin or Fosphenytoin at discharge.
d. Lorazepam at Discharge?

Answer “Yes” if the infant was receiving Lorazepam at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant was not receiving Lorazepam at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving Lorazepam at discharge.

e. Diazepam at Discharge?

Answer “Yes” if the infant was receiving Diazepam at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant was not receiving Diazepam at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving Diazepam at discharge.

f. Midazolam at Discharge?

Answer “Yes” if the infant was receiving Midazolam at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant was not receiving Midazolam at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “Unknown” if it cannot be determined whether the infant was receiving Midazolam at discharge.

g. Topiramate at Discharge?

Answer “Yes” if the infant was receiving Topiramate at the time of discharge from your hospital, as recorded in the infant medical record.

Answer “No” if the infant was not receiving Topiramate at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving Topiramate at discharge.
h. Other Anticonvulsant at Discharge?

Answer “Yes” if the infant was receiving any other anticonvulsant not mentioned above at the time of discharge from your hospital, as recorded in the infant medical record. If “Yes”, record the name of the other anticonvulsant received in the space provided.

Answer “No” if the infant was not receiving any other anticonvulsant at the time of discharge from your hospital.

Answer “Unknown” if it cannot be determined whether the infant was receiving other anticonvulsants at discharge.

If “Yes” to this item, specify which other anticonvulsants were received at discharge (see Appendix C).

ITEM DD17: Autopsy Status

Answer one response regarding autopsy status.

Answer “N/A” if the infant was discharged home from your hospital, was transferred to another hospital or was still in your hospital at one year of age.

Answer “Autopsy Performed” if the infant died in your hospital prior to discharge home or first birthday and an autopsy was performed.

Answer “Autopsy Permission Requested and Denied” if the infant died in your hospital prior to discharge home or first birthday, and an autopsy was requested but parental permission for the autopsy was denied.

Answer “Autopsy Permission Not Requested” if the infant died in your hospital prior to discharge home or first birthday and no autopsy was requested.

Answer “Unknown” if it is not known whether the infant died, or if it is not known whether an autopsy was requested or performed.
CHAPTER 8

HYPOTHERMIC THERAPY FORM Definitions

The Hypothermic Therapy Form includes data items related to methods of hypothermic therapy used, adverse events and the locations, dates and times of cooling. Complete this form for infants who receive hypothermic therapy prior to discharge home, first birthday or death, whichever is soonest, regardless of where hypothermic therapy was received.

ITEM HT1: Cooling Location and Method

Indicate whether cooling occurred at the hospital from which the infant transferred (outborn infants only), during transport (outborn infants only), at your hospital (all infants), during transport to another hospital (only infants who transferred from your center to another hospital without having gone home) and at the hospital to which the center transferred (only infants who transferred from your center to another hospital without having gone home). If cooling was performed at the hospital from which the infant was transferred, during transport to your hospital, during transport from your hospital to another hospital or at the hospital to which the infant was transferred from your hospital, record the name and location of the hospital from or to which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

For each site at which hypothermic therapy was performed, indicate the method of cooling used. If no cooling at that site, indicate “None”. The following definitions of the types of hypothermic therapy apply to the selection categories for each site (questions a. through e. below).

“Selective Head” Cooling: Active cooling restricted to the head and brain. This is an intervention to reduce the temperature of the head and brain by exposing the head to lower than environmental temperature. Specially designed head cooling devices, other cooling devices and ice packs applied to the head would be considered active cooling. Passive exposure to environmental temperature and cooling of the face for treatment of supraventricular tachycardia are not considered active cooling of the head and brain.
“Whole Body” Cooling: Active cooling of the body not restricted to the head and brain. This is an intervention to reduce the core body temperature and temperature of the brain by exposing the body to lower than environmental temperature. Cooling blankets, other cooling devices and ice packs applied to the body would be considered active cooling. Passive exposure to environmental temperature would not be considered active cooling. Whole body cooling may include cooling of the head in addition to the rest of the body.

“Unknown”: It is not known whether active selective head or whole body cooling was performed.

a. Cooling at Hospital from which Infant Transferred (outborn infants only)

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

(1) Hypothermic Therapy at the Hospital from which Transferred?

Answer “Not Outborn” if the infant is inborn.

Answer “Yes” if the infant is outborn and either selective head or whole body cooling was provided at the hospital from which the infant was transferred.

Answer “No” if the infant is outborn and neither selective head nor whole body cooling was provided at the hospital from which the infant was transferred.

Answer “Unknown” if the infant is outborn and it is not known whether selective head or whole body cooling was provided at the hospital from which the infant was transferred.

If “Yes” to (1), answer questions (2) and (3) below.

(2) Cooling Method at the Hospital from which Transferred

Choose the method of cooling at the hospital from which the infant was transferred to your center. Choose “Selective Head” cooling, “Whole Body” cooling or “Unknown” using the above definitions.
(3) Hospital from which Infant Transferred
Enter the name and location of the hospital from which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

b. Cooling During Transport to Your Hospital (outborn infants only)

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

(1) Hypothermic Therapy during Transport to Your Hospital?
Answer “Not Outborn” if the infant is inborn.
Answer “Yes” if the infant is outborn and received either selective head or whole body cooling during transport to your hospital.
Answer “No” if the infant is outborn and neither selective head nor whole body cooling was provided during transport to your hospital.
Answer “Unknown” if the infant is outborn and it is not known whether the infant received either selective head or whole body cooling during transport to your hospital.

If “Yes” to (1), answer questions (2) and (3) below.

(2) Cooling Method during Transport to Your Hospital
Choose the method of cooling during transport to your hospital. Choose “Selective Head” cooling, “Whole Body” cooling or “Unknown” using the above definitions.

(3) Hospital from which Infant Transferred
Enter the name and location of the hospital from which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.
c. Cooling at Your Hospital

(1) Hypothermic Therapy at Your Hospital?
Answer “Yes” if either selective head or whole body cooling was provided at your hospital.

Answer “No” if neither selective head nor whole body cooling was provided at your hospital.

Answer “Unknown” if it is not known whether selective head or whole body cooling was provided at your hospital.

If “Yes” to (1), answer question (2).

(2) Cooling Method at Your Hospital
Choose the method of cooling at your hospital. Choose “Selective Head” cooling, “Whole Body” cooling or “Unknown” using the above definitions.

d. Cooling During Transport from Your Hospital (only infants who transfer from your center to another hospital without having gone home)

NOTE: Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

(1) Hypothermic Therapy during Transport from Your Hospital?
Answer “Not Transferred” if the infant is not transferred from your center to another hospital.

Answer “Yes” if the infant was transferred from your center to another hospital and received either selective head or whole body cooling during transport to the other hospital.

Answer “No” if the infant was transferred from your center to another hospital and did not receive either selective head or whole body cooling during transport to the other hospital.

Answer “Unknown” if the infant was transferred from your center to another hospital and it is not known whether the infant received either selective head or whole body cooling during transport to the other hospital.

If “Yes” to (1), answer question (2) and (3) below.
(2) Cooling Method during Transport from Your Hospital

Choose the method of cooling during transport from your hospital. Choose “Selective Head” cooling, “Whole Body” cooling or “Unknown” using the above definitions.

(3) Hospital to which Infant Transferred

Enter the name and location of the hospital to which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

e. Cooling at Hospital to which Infant Transferred (only infants who transfer from your center to another hospital without having gone home)

**NOTE:** Infants who are transferred from one unit to another unit within your hospital are not considered transfers.

(1) Hypothermic Therapy at the Hospital to which Transferred?

Answer “Not Transferred” if the infant did not transfer to another hospital.

Answer “Yes” if the infant was transferred from your center to another hospital and either selective head or whole body cooling was provided at the hospital to which the infant was transferred.

Answer “No” if the infant was transferred from your center to another hospital and neither selective head nor whole body cooling was provided at the hospital to which the infant was transferred.

Answer “Unknown” if the infant was transferred from your center to another hospital and it is not known whether selective head or whole body cooling was provided at the hospital to which the infant was transferred.

If “Yes” to (1), answer questions (2) and (3) below.
(2) **Cooling Method at the Hospital to which Transferred**

Choose the method of cooling at the hospital to which the infant was transferred from your center. Choose "Selective Head" cooling, "Whole Body" cooling or "Unknown" using the above definitions.

(3) **Hospital to which Infant Transferred**

Enter the name and location of the hospital to which the infant was transferred. For location, U.S. hospitals record city and state; Canadian hospitals record city and province; international centers record city and country.

**ITEM HT2: Age Hypothermic Therapy Began**

a. **Age Hypothermic Therapy Began, Days**

The Age Hypothermic Therapy Began, Days, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy began. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

b. **Age Hypothermic Therapy Began, Hours**

The Age Hypothermic Therapy Began, Hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy began. The number of hours can vary between 0 and 23.

c. **Age Hypothermic Therapy Began, Minutes**

The Age Hypothermic Therapy Began, Minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy began. The number of minutes can vary between 0 and 59.

**ITEM HT3: Age Hypothermic Therapy Stopped**

a. **Age Hypothermic Therapy Stopped, Days**

The Age Hypothermic Therapy Stopped, Days, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy stopped. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.
b. **Age Hypothermic Therapy Stopped, Hours**

The Age Hypothermic Therapy Stopped, Hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy stopped. The number of hours can vary between 0 and 23.

c. **Age Hypothermic Therapy Stopped, Minutes**

The Age Hypothermic Therapy Stopped, Minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time hypothermic therapy stopped. The number of minutes can vary between 0 and 59.

**ITEM HT4: Core Body Temperature when Hypothermic Therapy Stopped**

Hypothermic therapy is considered stopped when all active cooling is stopped. This occurs when cooling devices are turned off, removed or set to ambient temperature. At this point the process of re-warming is considered to begin, even if no additional heating is provided.

a. **Temperature Measured when Hypothermic Therapy Stopped**

Answer **“Yes”** if the core body temperature was recorded in the infant medical record at the time active cooling was stopped and re-warming began (± 10 minutes). If **“Yes”**, answer question b. below. Core body temperature can be measured as rectal, esophageal, tympanic, or axillary temperature.

Answer **“No”** if the core body temperature was not recorded in the infant medical record at the time active cooling was stopped and re-warming began (± 10 minutes). If **“No”**, do not answer question b. below.

Answer **“Unknown”** if the core body temperature when hypothermic therapy stopped cannot be determined.

b. **Temperature when Hypothermic Therapy Stopped**

If “Yes” to question a. above, record the core body temperature measured closest in time to when hypothermic therapy stopped and the units in which it was recorded (Centigrade). Record rectal, esophageal, tympanic or axillary temperature using a single decimal place, e.g. 36.7° C. If cooling is interrupted and is re-started, record the temperature when hypothermic therapy was finally stopped.
ITEM HT5: Age Re-Warming Completed

**NOTE:** if rewarming is not completed, enter “Unknown” for Age Re-Warming Completed (Days, Hours and Minutes).

a. **Age Re-Warming Completed, Days**

The Age Hypothermic Re-Warming Completed, Days, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time re-warming was completed. For example, if more than 48 hours and less than 72 hours elapsed between these two date/time values, the number of days would be 2. If less than 24 hours elapsed, the value would be zero.

b. **Age Re-Warming Completed, Hours**

The Age Re-Warming Completed, Hours, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time re-warming was completed. The number of hours can vary between 0 and 23.

c. **Age Re-Warming Completed, Minutes**

The Age Re-Warming Completed, Minutes, is automatically calculated in eNICQ by subtracting the date and time of birth from the date and time re-warming was completed. The number of minutes can vary between 0 and 59.

ITEM HT6: Cooling Interruptions

a. **Was Cooling Interrupted for More than 30 Minutes?**

Answer “Yes” if, after cooling was started, it was interrupted for more than 30 consecutive minutes for any reason and then restarted. If “Yes”, answer question b. below.

Answer “No” if, after cooling was started, it was never interrupted for more than 30 consecutive minutes for any reason and then restarted. If “No”, do not answer question b. below.

Answer “Unknown” if, after cooling was started, it is not known whether cooling was ever interrupted for more than 30 consecutive minutes for any reason and then restarted. If “Unknown”, do not answer question b. below.

b. **Number of Cooling Interruptions**

If “Yes” to question a. above, record the number of times cooling was interrupted for more than 30 minutes in the space provided.
ITEM HT7: Cooling as Part of a Randomized Controlled Trial?

Answer “Yes” if the infant was enrolled in a randomized controlled trial (RCT), in which random assignment determined the details of the cooling treatment. The RCT could compare cooling to no treatment or placebo, or could compare different methods, protocols or devices for cooling.

Answer “No” if the infant was not enrolled in a RCT in which random assignment determined the details of the cooling treatment. The RCT could compare cooling to no treatment or placebo, or could compare different methods, protocols or devices for cooling.

Answer “Unknown” if it is not known whether or not the infant was enrolled in an RCT that determined the details of the cooling treatment.

ITEM HT8: Adverse Events within 7 Days of Birth

a. Cardiac Arrhythmia within 7 Days of Birth?

Answer “Yes” if a cardiac arrhythmia occurred at any time within seven days of birth. If “Yes”, answer questions (1) through (7) below. For each question, answer “Yes” if the adverse event occurred or “No” if the adverse event did not occur.

Answer “No” if a cardiac arrhythmia did not occur at any time within seven days of birth. If “No”, do not answer questions (1) through (7) below.

Answer “Unknown” if it cannot be determined whether the adverse event(s) occurred. If “Unknown”, do not answer questions (1) through (7) below.

(1) Sinus Bradycardia?
(2) Sinus Tachycardia?
(3) Ventricular Tachycardia?
(4) Ventricular Fibrillation?
(5) Conduction Block?
(6) Prolonged QT Interval?
(7) Other Arrhythmia? If “Yes”, describe the adverse event in the space provided.
b. **Thrombosis within 7 Days of Birth?**

Answer **“Yes”** if thrombosis not related to an infusion line occurred at any time within seven days of birth.

Answer **“No”** if thrombosis not related to an infusion line did not occur at any time within seven days of birth.

Answer **“Unknown”** if it cannot be determined whether thrombosis occurred within 7 days of birth.

c. **Severe Hypotension within 7 Days of Birth?**

Answer **“Yes”** if severe hypotension requiring treatment with pressors or hydrocortisone occurred at any time within seven days of birth.

Answer **“No”** if severe hypotension requiring treatment with pressors or hydrocortisone did not occur at any time within seven days of birth.

Answer **“Unknown”** if it cannot be determined whether severe hypotension occurred within 7 days of birth.

d. **Seizure during Re-Warming within 7 Days of Birth?**

Clinical seizures are present if there is paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/pupillary dilation). Electroencephalographic (EEG) seizures may be diagnosed by full channel EEG or bedside aEEG.

Answer **“Yes”** if clinical or EEG seizures during re-warming occurred at any time within seven days of birth.

Answer **“No”** if clinical or EEG seizures during re-warming did not occur at any time within seven days of birth.

Answer **“Unknown”** if it cannot be determined whether seizure during re-warming occurred within 7 days of birth.

e. **Scalp Edema within 7 Days of Birth?**

Answer **“Yes”** if scalp edema occurred at any time within seven days of birth.

Answer **“No”** if scalp edema did not occur at any time within seven days of birth.
Answer “Unknown” if it cannot be determined whether scalp edema occurred within 7 days of birth.

f. Skin Breakdown within 7 Days of Birth?
Answer “Yes” if skin breakdown occurred at any time within seven days of birth.
Answer “No” if skin breakdown did not occur at any time within seven days of birth.
Answer “Unknown” if it cannot be determined whether skin breakdown occurred within 7 days of birth.

g. Sclerema Neonatorum within 7 Days of Birth?
Answer “Yes” if sclerema neonatorum occurred at any time within seven days of birth.
Answer “No” if sclerema neonatorum did not occur at any time within seven days of birth.
Answer “Unknown” if it cannot be determined whether sclerema neonatorum occurred within 7 days of birth.

h. Thrombocytopenia within 7 Days of Birth?
Answer “Yes” if thrombocytopenia occurred at any time within seven days of birth.
Answer “No” if thrombocytopenia did not occur at any time within seven days of birth.
Answer “Unknown” if it cannot be determined whether thrombocytopenia occurred within 7 days of birth.

ITEM HT9: Seizures Prior to Cooling?

a. Were seizures noted prior to cooling?
Answer “Yes” if clinical, aEEG, or EEG seizures were present prior to the beginning of cooling.
Answer “No” if clinical, aEEG, or EEG seizures were not present prior to the beginning of cooling.
Answer “Unknown” if it cannot be determined whether seizures occurred prior to cooling.
b. Diagnosis of Seizures Prior to Cooling

Seizures are present if there is paroxysmal tonic, clonic or myoclonic motor activity that cannot be suppressed by restraint or repositioning and/or if there are paroxysms of abnormal oromotor or oculomotor activity which may be associated with changes in autonomic function (otherwise unexplained paroxysmal tachycardia/hypertension/pupillary dilation). Electroencephalographic (EEG) seizures may be diagnosed by full channel EEG or bedside aEEG.

(1) Clinical Diagnosis of Seizures Prior to Cooling

Answer “Yes” if seizures were clinically diagnosed prior to the beginning of cooling.

Answer “No” if seizures were not clinically diagnosed prior to the beginning of cooling.

Answer “Unknown” if it is not known whether seizures were clinically diagnosed prior to the beginning of cooling.

(2) aEEG Diagnosis of Seizures Prior to Cooling

Answer “Yes” if seizures were diagnosed by bedside aEEG prior to the beginning of cooling.

Answer “No” if seizures were not diagnosed by bedside aEEG prior to the beginning of cooling.

Answer “Unknown” if it is not known whether seizures were diagnosed by bedside aEEG prior to the beginning of cooling.

(3) EEG Diagnosis of Seizures Prior to Cooling

Answer “Yes” if seizures were diagnosed by full channel EEG prior to the beginning of cooling.

Answer “No” if seizures were not diagnosed by full channel EEG prior to the beginning of cooling.

Answer “Unknown” if it is not known whether seizures were diagnosed by full channel EEG prior to the beginning of cooling.
ITEM HT10: Modified SARNAT Stage Prior to Cooling

Record the modified SARNAT Stage obtained before active cooling started. Use the table in Appendix A to determine the Modified SARNAT Stage. Record the modified SARNAT Stage as “0”, “1”, “2” or “3” based on the category that fits most closely. Normal is scored as “0”. If the score was not determined or is unknown, record “9”.

ITEM HT11: Full channel EEG Prior to Cooling

a. Full channel EEG performed Prior to Cooling?

Answer “Yes” if a full channel electroencephalogram (EEG) was performed prior to cooling.

Answer “No” if a full channel electroencephalogram (EEG) was not performed prior to cooling.

Answer “Unknown” if it is not known whether a full channel EEG was performed prior to cooling.

b. Full channel EEG performed Prior to Cooling Background Pattern

If a full channel EEG was performed at your hospital prior to cooling, select the one category that most closely describes the worst EEG background pattern observed on any EEG prior to the application of any cooling therapy.

Answer “Normal” if the background pattern is normal in continuity, amplitude, and frequency for gestational age.

Answer “Excessively Discontinuous” if the background pattern is excessively discontinuous (‘dysmature’) for gestational age.

Answer “Depressed Amplitude” if the background pattern shows depressed amplitude and/or slowing.

Answer “Burst Suppression Pattern” if a burst suppression pattern is present or a severely depressed background is present.

Answer “Background Iso-Electric” if the background pattern shows no recognizable electro-cortical activity.

Answer “Unknown” if the worst background pattern is not known.
ITEM HT12: Bedside aEEG Prior to Cooling

a. Bedside aEEG prior to cooling

Answer “Yes” if a bedside amplitude integrated EEG (aEEG) was performed prior to cooling.

Answer “No” if a bedside amplitude integrated EEG (aEEG) was not performed prior to cooling.

Answer “Unknown” if it is not known whether a bedside amplitude integrated EEG (aEEG) was performed prior to cooling.

b. Bedside aEEG Background Pattern

If a bedside aEEG was performed at your hospital prior to cooling, select the one category that most closely describes the worst EEG background pattern observed on any aEEG prior to the application of any cooling therapy.

NOTE: A minimum of one hour recording with low electrode impedance and the absence of continuous seizures should be available in order to classify the worst background. The output appears as a thick dense band on the chart. The lower margin of the dense band represents the minimum degree of cerebral activity. A line is drawn through the upper margin and the lower margin of the dense band of the aEEG and the voltage measured from these marked lines with the scale on the printed record.

Answer “Normal” if the upper margin of the dense EEG band is greater than 10µV and the lower margin is greater than 5µV.

Answer “Moderately Abnormal or Discontinuous” if the upper margin of the dense aEEG band is greater than 10µV and the lower margin is less than 5µV.

Answer “Severely Abnormal” if the upper margin of the dense aEEG band is less than 10µV and the lower margin is less than 5µV.

Answer “Unknown” if the worst aEEG background pattern is not known. The worst background pattern cannot be determined if there is less than one hour of recording with low electrode impedance and without continuous EEG seizures. Answer “Unknown” when this is the case.
APPENDIX A

Modified Sarnat Stage
<table>
<thead>
<tr>
<th>Modified Sarnat Stage *</th>
</tr>
</thead>
<tbody>
<tr>
<td>**STAGE **</td>
</tr>
<tr>
<td><strong>Level of Consciousness</strong></td>
</tr>
<tr>
<td><strong>Activity</strong></td>
</tr>
<tr>
<td><strong>Neuromuscular Control</strong></td>
</tr>
<tr>
<td>Muscle Tone</td>
</tr>
<tr>
<td>Posture</td>
</tr>
<tr>
<td>Stretch Reflexes</td>
</tr>
<tr>
<td><strong>Complex / Primitive Reflexes</strong></td>
</tr>
<tr>
<td>Suck</td>
</tr>
<tr>
<td>Moro (startle)</td>
</tr>
<tr>
<td>Tonic Neck</td>
</tr>
<tr>
<td><strong>Autonomic Function</strong></td>
</tr>
<tr>
<td>Pupils</td>
</tr>
<tr>
<td>Heart Rate</td>
</tr>
<tr>
<td>Seizures</td>
</tr>
</tbody>
</table>


** STAGE 0 = Normal
The Neonatal Encephalopathy Registry (NER) forms are provided to aid Registry participants in collecting and organizing NER patient data. **Do not submit this booklet or any of the paper forms to the Vermont Oxford Network.** Submit all NER data to the Vermont Oxford Network as electronic files using the Network’s eNICQ software. Data files submitted using the eNICQ software do not include any protected health care information, as defined by the U.S. Health Insurance Portability and Accountability Act of 1996. No dates or times will be exported to the Vermont Oxford Network. The Vermont Oxford Network does not accept protected health care information.

### Contents:

- I. Eligibility Form
- II. OR/Initial Status Form
- III. Neurological Form
- IV. Diagnoses and Discharge Form
- V. Hypothermic Therapy Form (only for infants who received hypothermic therapy.)

### I. ELIGIBILITY FORM

**EL1. Hypothermic Therapy Received?**

- ☐ Yes
- ☐ No

Only infants who are actively cooled are eligible for the Registry; do not complete this form or other forms in this booklet if EL1 is answered “No”.

**EL2. Gestational Age ≥ 36 Weeks 0 Days or More?**

- ☐ Yes
- ☐ No
- ☐ Unknown

**EL3. Major CNS Congenital Malformation?**

- ☐ Yes
- ☐ No
- ☐ Unknown

**EL4. Stupor or Coma within 72 Hours?**

- ☐ Yes
- ☐ No
- ☐ Unknown

**EL5. Seizures within 72 Hours?**

- ☐ Yes
- ☐ No
- ☐ Unknown

**EL6. Paralysis Induced for First 72 Hours?**

- ☐ Yes
- ☐ No
- ☐ Unknown

**EL7. APGAR Score at 5 Minutes of 3 or Less?**

- ☐ Yes
- ☐ No
- ☐ Unknown
II. OB/INITIAL STATUS FORM

Part A. Obstetric-Perinatal History

OB1. Mode of Delivery (select one):
- □ Vaginal without Vacuum or Forceps
- □ Vacuum and/or Forceps Assisted Vaginal
- □ C Section before Labor Started
- □ C Section after Labor Started
- □ C Section after Failed Vacuum or Forceps Delivery
- □ Unknown

OB2. Presentation (select one):
- □ Vertex
- □ Breech
- □ Transverse
- □ Other
- □ Unknown

OB3. Ruptured Membranes 24 Hours or More Prior to Delivery?
- □ Yes
- □ No
- □ Unknown

OB4. Cord Prolapse?
- □ Yes
- □ No
- □ Unknown

OB5. Uterine Rupture?
- □ Yes
- □ No
- □ Unknown

OB6. Antepartum Hemorrhage?
- □ Yes
- □ No
- □ Unknown

OB7. Chorioamnionitis?
- □ Yes
- □ No
- □ Unknown

OB8. Maternal Temperature during Labor and Delivery:
   a. Maternal Temperature Recorded?
      - □ Yes
      - □ No
      - □ Unknown
   b. Temperature of Mother: Range: 30.0-44.0 for C, 86.0-111.0 for F, 777.7=N/A, 999.9=Unknown
      Record the highest intrapartum maternal temperature and the units in which it was recorded.
      Use a single decimal place, e.g. 36.7°C or 98.2°F:
      - □ □ □ □ □ □ °C □ °F

OB9. Antenatal Magnesium Exposure:
- □ Yes
- □ No
- □ Unknown
VERMONT OXFORD NETWORK
NER Booklet for Infants Born in 2011

Center Number: _________  Network ID Number: [_____]

OB10. Maternal Hypertension, Pre-eclampsia, or Eclampsia?

☐ Yes  ☐ No  ☐ Unknown

OB11. Maternal Diabetes?

☐ Yes  ☐ No  ☐ Unknown

OB12. Maternal Hypothyroidism?

☐ Yes  ☐ No  ☐ Unknown

OB13. Non-Reassuring Fetal Assessment:

a. Bradycardia Prior to Delivery?

☐ Yes  ☐ No  ☐ Unknown

b. Tachycardia Prior to Delivery?

☐ Yes  ☐ No  ☐ Unknown

c. Decreased FHR Variability Prior to Delivery?

☐ Yes  ☐ No  ☐ Unknown

d. Prolonged or Recurrent Decelerations Prior to Delivery?

☐ Yes  ☐ No  ☐ Unknown

OB14. Umbilical Cord Blood Sampling:

a. Cord Blood Sampling Performed?

☐ Yes  ☐ No  ☐ Unknown

If “Yes” to a, answer questions b and c below.

b. pH from Cord Blood Sample: Range: 5.00-8.00, 77.77=N/A, 99.9=Unknown

Record the lowest cord blood pH to 2 decimal places: [_____]

b. Base Deficit from Cord Blood Sample: Range: -20.0 to 40.0, 77.77=N/A, 99.9=Unknown

Record the worst cord blood base deficit (mmoles/liter) to the nearest tenth (base deficit is normally a positive number): +/- [_____]

OB15. Assisted Reproduction?

☐ Yes  ☐ No  ☐ Unknown

OB16. Placenta Sent for Pathology?

☐ Yes  ☐ No  ☐ Unknown
II. OB/INITIAL STATUS FORM

Part B. Infant’s Initial Clinical Status

OB17 Age at Admission to Your NICU:
  a. Infant Admitted to your NICU?
     ☐ Yes ☐ No
     If Yes to a, enter Age at Admission:
  b. Age, Days: _____
  c. Age, Hours: _____
  d. Age, Minutes: _____

OB18. APGAR Score at 10 Minutes: Range: 0-10, 99=Unknown _______

OB19. Assisted Ventilation at 10 Minutes?
  ☐ Yes ☐ No ☐ I Unknown

OB20. Infant Arterial, Venous, or Capillary Blood Gas:
  a. Arterial, Venous, or Capillary Blood Gas Obtained During First Hour of Life?
     ☐ Yes ☐ No ☐ Unknown
     If “Yes” to a, answer questions b and c below.
  b. pH from Arterial, Venous, or Capillary Blood Gas: Range: 5.00-8.00, 77.77=N/A, 99.99=Unknown
     Record the lowest arterial, venous, or capillary pH obtained within the first hour of life to 2 decimal places: .
  c. Base Deficit from Arterial, Venous, or Capillary Blood Gas:
     Range: -20.0 to 40.0, 77.77=N/A, 99.99=Unknown
     Record the worst arterial, venous, or capillary base deficit obtained within the first hour of life to the nearest tenth (base deficit is normally a positive number): + / - .
OB21. Temperature of Infant:

a. Infant Temperature Recorded within 72 Hours of Birth?

☐ Yes  ☐ No  ☐ Unknown

If “Yes” to a, answer questions b and c below.

b. Highest Temperature of Infant:

Range: 30.0-44.0 for C, 86.0-111.0 for F, 777.7=N/A, 999.9=Unknown

Record the highest temperature within 72 hours of birth and the units in which it was recorded. Use a single decimal place, e.g. 36.7°C or 98.2°F:

☐ 36.7  ☐ °C  ☐ °F

c. Lowest Temperature of Infant:

Range: 30.0-44.0 for C, 86.0-111.0 for F, 777.7=N/A, 999.9=Unknown

Record the lowest temperature within 72 hours of birth and the units in which it was recorded. Use a single decimal place, e.g. 36.7°C or 98.2°F:

☐ 36.7  ☐ °C  ☐ °F
III. NEUROLOGICAL FORM
Part A, Neurological Indicators on Day 1 (≤ 6 hours and 6 to 24 hours)

<table>
<thead>
<tr>
<th>NU1. Infant Alive During Examination Period?</th>
<th>A Neuro Status Day 1 (≤ 6 Hours)</th>
<th>B Neuro Status Day 1 (&gt;6-24 Hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

If infant was alive and not paralyzed during the examination period, complete item NU3 through NU11 below based on the worst state during the examination period.

<table>
<thead>
<tr>
<th>NU3. Conscious State:</th>
<th>Normal</th>
<th>Stupor</th>
<th>Irritability</th>
<th>Lethargy</th>
<th>Coma</th>
<th>Normal</th>
<th>Stupor</th>
<th>Irritability</th>
<th>Lethargy</th>
<th>Coma</th>
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<tbody>
<tr>
<td>(Select the worst)</td>
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<tr>
<td>Irritability</td>
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<tr>
<td>Lethargy</td>
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<table>
<thead>
<tr>
<th>NU4. Brainstem Function:</th>
<th>Normal</th>
<th>Abnormal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td></td>
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<table>
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<th>NU5. Movements:</th>
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<table>
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<tr>
<th>NU6. Posturing:</th>
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<th>Absent</th>
</tr>
</thead>
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<tr>
<td>Present</td>
<td></td>
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<td>N/A</td>
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<table>
<thead>
<tr>
<th>NU7. Tone:</th>
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</thead>
<tbody>
<tr>
<td>Normal</td>
<td></td>
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<table>
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<th>NU8. Reflexes:</th>
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</thead>
<tbody>
<tr>
<td>Normal</td>
<td></td>
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<tr>
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<table>
<thead>
<tr>
<th>NU9. Feeding:</th>
<th>No enteral feedings</th>
<th>No feedings by mouth</th>
<th>Some feedings by mouth</th>
<th>All feedings by mouth</th>
<th>Unknown</th>
<th>No enteral feedings</th>
<th>No feedings by mouth</th>
<th>Some feedings by mouth</th>
<th>All feedings by mouth</th>
<th>Unknown</th>
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<tbody>
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<td>No enteral feedings</td>
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<td>Yes</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>No feedings by mouth</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Some feedings by mouth</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
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<tr>
<td>All feedings by mouth</td>
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<td>No</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
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<table>
<thead>
<tr>
<th>NU10. Assisted Ventilation?</th>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
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<table>
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<tr>
<th>NU11. Clinical Seizures?</th>
<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>No</th>
</tr>
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<tbody>
<tr>
<td>Yes</td>
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III. NEUROLOGICAL FORM
Part A, Neurological Indicators on Day 3 and Day 7

<table>
<thead>
<tr>
<th>Item</th>
<th>C Neuro Status Day 3</th>
<th>D Neuro Status Day 7 (±1 Day)</th>
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<tbody>
<tr>
<td>NU1. Infant Alive During Examination Period?</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>No</td>
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<tr>
<td>NU2. Paralysis for the Entire Examination Period?</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
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</table>

If infant was alive and not paralyzed during the examination period, complete item NU3 through NU11 below based on the worst state during the examination period.

<table>
<thead>
<tr>
<th>NU3. Conscious State: (Select the worst)</th>
<th>C</th>
<th>D</th>
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<tbody>
<tr>
<td>Normal</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Stupor</td>
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<tr>
<td>Irritability</td>
<td>☐</td>
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<tr>
<td>Lethargy</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>Coma</td>
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<td></td>
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<th>NU10. Assisted Ventilation?</th>
<th>Yes</th>
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<th>Yes</th>
<th>No</th>
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<th>Yes</th>
<th>No</th>
<th>Yes</th>
<th>No</th>
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</table>
III. NEUROLOGICAL FORM

Part B. Electrophysiology, Seizures and Anticonvulsants

NU12. Full Channel EEG:
   a. Full Channel EEG Performed?
      □ Yes   □ No   □ Unknown

   b. EEG Background Pattern:
      If “Yes” to a, select worst observed background pattern (select one):
      □ Normal
      □ Excessively Discontinuous
      □ Depressed Amplitude
      □ Burst Suppression Pattern
      □ Background Iso-Electric
      □ Unknown
      □ N/A

NU13. Bedside aEEG:
   a. Bedside aEEG Performed?
      □ Yes   □ No   □ Unknown

   b. Bedside aEEG Background Pattern:
      If “Yes” to a, select worst observed background pattern (select one):
      □ Normal
      □ Moderately Abnormal or Discontinuous
      □ Severely Abnormal
      □ Unknown
      □ N/A

NU14. Seizures Prior to Discharge:
   a. Seizures Occurred Prior to Discharge?
      □ Yes   □ No   □ Unknown

      If “Yes” to a, answer questions b through e below.
   b. Evidence of Clinical Seizure?
      □ Yes   □ No   □ Unknown   □ N/A
VERMONT OXFORD NETWORK
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Network ID Number: □□□□

c. Full Channel EEG Evidence of Seizure?
   □ Yes □ No □ Unknown □ N/A

d. Bedside aEEG Evidence of Seizure?
   □ Yes □ No □ Unknown □ N/A

e. Age Seizures First Observed:
   (1) Days: ______ (2) Hours: _____ (3) Minutes: ______

NU15. Anticonvulsants Prior to Discharge:

a. Anticonvulsants Received Prior to Discharge?
   □ Yes □ No □ Unknown

If "Yes" to a, answer questions b through h below.

c. Phenobarbital Prior to Discharge?
   □ Yes □ No □ Unknown □ N/A

d. Phenytoin or Fosphenytoin Prior to Discharge?
   □ Yes □ No □ Unknown □ N/A

e. Lorazepam Prior to Discharge?
   □ Yes □ No □ Unknown □ N/A

f. Diazepam Prior to Discharge?
   □ Yes □ No □ Unknown □ N/A

g. Midazolam Prior to Discharge?
   □ Yes □ No □ Unknown □ N/A

h. Topiramate Prior to Discharge?
   □ Yes □ No □ Unknown □ N/A

i. Other Anticonvulsants Prior to Discharge:
   (1) Were Other Anticonvulsants Given Prior to Discharge?
      □ Yes □ No □ Unknown □ N/A

   (2) If "Yes", specify which other anticonvulsants: ____________________________

   (See Appendix C of NER Manual of Operations)
**VERMONT OXFORD NETWORK**
**NER Booklet for 2011**

Center Number: __________  Network ID Number: [blank lines]

**NEUROLOGICAL FORM Part C. Neuroimaging**

<table>
<thead>
<tr>
<th></th>
<th>A Cranial US Exam(s)</th>
<th>B CT Scan(s)</th>
<th>C MRI Scan(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NU16</td>
<td>Exam or Scan Performed?</td>
<td>[Yes, No, Unknown]</td>
<td>[Yes, No, Unknown]</td>
</tr>
<tr>
<td>NU17</td>
<td>Day of First Exam/Scan:</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>NU18</td>
<td>Day of Last Exam/Scan:</td>
<td>[ ]</td>
<td>[ ]</td>
</tr>
<tr>
<td>NU19</td>
<td>Intraventricular Hemorrhage?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
</tr>
<tr>
<td>NU20</td>
<td>Extra-axial, Subdural or Subarachnoid Hemorrhage?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
</tr>
<tr>
<td>NU21</td>
<td>Intraparenchymal Hemorrhage?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
</tr>
<tr>
<td>NU22</td>
<td>Subependymal Hemorrhage?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
</tr>
<tr>
<td>NU23</td>
<td>Abnormality in Deep Nuclear Gray Matter?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
</tr>
<tr>
<td>NU24</td>
<td>Cystic White Matter Injury?</td>
<td>[Yes, No, N/A]</td>
<td>[Yes, No, N/A]</td>
</tr>
<tr>
<td>NU25</td>
<td>Diffuse White Matter Injury?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU26</td>
<td>Ventriculomegaly?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU27</td>
<td>Veno-Occlusion?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU28</td>
<td>Arterial Occlusion?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU29</td>
<td>Brainstem Injury?</td>
<td>[Yes, No, N/A]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU30</td>
<td>Cerebellar Injury?</td>
<td>[Yes, No, N/A]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU31</td>
<td>Diffuse Cortical Signal Abnormality?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU32</td>
<td>Pons-Sagittal Watershed Cortical Gray Matter Injury?</td>
<td>[Yes, No, N/A]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU33</td>
<td>Absence of Posterior Limb of Internal Capsule?</td>
<td>[Yes, Unknown, No]</td>
<td>[Yes, No, N/A]</td>
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<tr>
<td>NU34</td>
<td>Other Intracranial Abnormalities if “Yes”, describe</td>
<td>[Yes, No, Unknown, N/A]</td>
<td>[Yes, No, Unknown, N/A]</td>
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**Note:** Shaded items indicate the item does not apply to this type of exam/scan.
### IV. DIAGNOSES AND DISCHARGE FORM

**Part A. Diagnoses**

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<tr>
<th>Diagnosis</th>
<th>Yes</th>
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<tbody>
<tr>
<td>DD1. Persistent Pulmonary Hypertension of the Newborn, PPHN?</td>
<td></td>
<td></td>
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<tr>
<td>DD2. Renal Failure?</td>
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<td></td>
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<tr>
<td>DD3. Syndrome of Inappropriate Secretion of Antidiuretic Hormone, SIADH?</td>
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<tr>
<td>DD4. Disseminated Intravascular Coagulation, DIC?</td>
<td></td>
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<tr>
<td>DD5. Hepatic Dysfunction?</td>
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<tr>
<td>DD6. Hyperbilirubinemia within 7 Days of Birth?</td>
<td></td>
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<tr>
<td>DD7. Cardiac Dysfunction?</td>
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<tr>
<td>DD8. Prenatal TORCH Infection:</td>
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<td></td>
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#### a. Prenatal TORCH Infection Present?

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If "Yes" to a, indicate which of the prenatal infections in b through f below were present.

#### b. Toxoplasmosis?

<table>
<thead>
<tr>
<th>Yes</th>
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#### c. Rubella?

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#### d. Syphilis?

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#### e. Cytomegalovirus?

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#### f. Herpes Simplex?

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<th>N/A</th>
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</thead>
</table>
VERMONT OXFORD NETWORK
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DD9. Congenital Neuromuscular Disorder?
   a. Congenital Neuromuscular Disorder Present?
      □ Yes □ No □ Unknown
   b. If “Yes”, describe: __________________________

DD10. Birth Trauma?
   a. Traumatic Birth Injury?
      □ Yes □ No □ Unknown
      If “Yes” to a, answer questions b through h below:
   b. Spinal Cord Injury?
      □ Yes □ No □ Unknown □ N/A
   c. Brachial Plexus Injury?
      □ Yes □ No □ Unknown □ N/A
   d. Skull Fracture?
      □ Yes □ No □ Unknown □ N/A
   e. Long Bone Fracture?
      □ Yes □ No □ Unknown □ N/A
   f. Clavicle Fracture?
      □ Yes □ No □ Unknown □ N/A
   g. Cephalhematoma?
      □ Yes □ No □ Unknown □ N/A
   h. Other Traumatic Birth Injury?
      (1) Other Traumatic Birth Injury Observed?
      □ Yes □ No □ Unknown □ N/A
      (2) If “Yes”, describe: __________________________

DD11. Meningitis or Encephalitis:
   a. Meningitis or Encephalitis Suspected or Proven?
      □ Yes □ No □ Unknown
      If “Yes” to a, complete the questions below.
   b. Bacterial Meningitis or Encephalitis:
      □ None □ Suspected □ Proven
      If suspected, only answer question (1) below. If proven, answer questions (1) & (2) below.
VERMONT OXFORD NETWORK
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Center Number: _________  Network ID Number: □□□□□

(1) Onset of Bacterial Meningitis or Encephalitis:
☐ Early  ☐ Late  ☐ Unknown  ☐ N/A

(2) Name of Bacterial Meningitis or Encephalitis Organism:

|--|---|
c. Fungal Meningitis or Encephalitis:
☐ None  ☐ Suspected  ☐ Proven  ☐ Unknown  ☐ N/A
If suspected, only answer question (1) below. If proven, answer questions (1) & (2) below.

(1) Onset of Fungal Meningitis or Encephalitis:
☐ Early  ☐ Late  ☐ Unknown  ☐ N/A

(2) Name of Fungal Meningitis or Encephalitis Organism:

|--|---|
d. Viral Meningitis or Encephalitis:
☐ None  ☐ Suspected  ☐ Proven  ☐ Unknown  ☐ N/A
If suspected, only answer question (1) below. If proven, answer questions (1) & (2) below.

(1) Onset of Viral Meningitis or Encephalitis:
☐ Early  ☐ Late  ☐ Unknown  ☐ N/A

(2) Name of Viral Meningitis or Encephalitis Organism:
IV. DIAGNOSES AND DISCHARGE FORM

Part B, Discharge Status

DD12. Hearing Screening:
   a. Hearing Screen Exam Performed?
      □ Yes □ No □ Unknown
      If “Yes” to a, enter the results of the last exam before discharge.
   b. Hearing Screen Passed?
      □ Yes □ No □ Unknown □ N/A

DD13. Feedings at Discharge:
   □ No Enteral Feedings
   □ Enteral Feedings, No Feedings by Mouth
   □ Enteral Feedings, Some Feedings by Mouth
   □ Enteral Feedings, All Feedings by Mouth
   □ Unknown

DD14. Tracheotomy at Discharge?
   □ Yes □ No □ Unknown

DD15. Discharged with Ventilator?
   □ Yes □ No □ Unknown

DD16. Anticonvulsant Medication at Discharge?
   a. Anticonvulsant Medication at Discharge?
      □ Yes □ No □ Unknown
      If “Yes” to a, complete questions b through h below:
   b. Phenobarbital at Discharge?
      □ Yes □ No □ Unknown □ N/A
   c. Phenytoin or Fosphenytoin at Discharge?
      □ Yes □ No □ Unknown □ N/A
   d. Lorazepam at Discharge?
      □ Yes □ No □ Unknown □ N/A
   e. Diazepam at Discharge?
      □ Yes □ No □ Unknown □ N/A
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f. Midazolam at Discharge?
   ☐ Yes ☐ No ☐ Unknown ☐ N/A

g. Topiramate at Discharge?
   ☐ Yes ☐ No ☐ Unknown ☐ N/A

h. Other Anticonvulsant at Discharge?
   ☐ Yes ☐ No ☐ Unknown ☐ N/A

If "Yes", specify which other anticonvulsant(s) ____________________________
(see Appendix C of NER Manual of Operations)

DD17. Autopsy Status:
   ☐ N/A
   ☐ Autopsy performed
   ☐ Autopsy Permission Requested and Denied
   ☐ Autopsy Permission Not Requested
   ☐ Unknown
V. HYPOTHERMIC THERAPY FORM

HT1. Cooling Location and Method:

a. Cooling at Hospital from which Infant Transferred (outborn infants only):

(1) Hypothermic Therapy at Hospital from which Transferred?

☐ Not Outborn  ☐ Yes  ☐ No  ☐ Unknown

If “Yes” to (1), answer questions (2) and (3) below.

(2) Cooling Method at Hospital from which Transferred:

☐ Selective Head  ☐ Whole Body  ☐ Unknown  ☐ N/A

(3) Hospital from which Infant Transferred:

(a) Name of Hospital: __________________________

(b) City: ______  (c) State/Prov./Country: ___________

b. Cooling During Transport to Your Hospital (outborn infants only):

(1) Hypothermic Therapy During Transport to Your Hospital?

☐ Not Outborn  ☐ Yes  ☐ No  ☐ Unknown

If “Yes” to (1), answer questions (2) and (3) below.

(2) Cooling Method during Transport to Your Hospital:

☐ Selective Head  ☐ Whole Body  ☐ Unknown  ☐ N/A

(3) Hospital from which Infant Transferred:

(a) Name of Hospital: ________________

(b) City: ______  (c) State/Prov./Country: ___________

c. Cooling at Your Hospital:

(1) Hypothermic Therapy at Your Hospital?

☐ Yes  ☐ No  ☐ Unknown

If “Yes” to (1), answer question (2) below.

(2) Cooling Method at Your Hospital:

☐ Selective Head  ☐ Whole Body  ☐ Unknown  ☐ N/A
d. Cooling During Transport from Your Hospital (transferred infants only):
   (1) Hypothermic Therapy During Transport from Your Hospital?
      ☐ Not Transferred   ☐ Yes      ☐ No      ☐ Unknown

   If “Yes” to (1), answer questions (2) and (3) below.

   (2) Cooling Method during Transport from Your Hospital:
      ☐ Selective Head       ☐ Whole Body       ☐ Unknown       ☐ N/A

   (3) Hospital to which Infant Transferred:
      (a) Name of Hospital: __________________________
      (b) City: ___________ (c) State/Prov./Country: ___________


e. Cooling at Hospital to which Infant Transferred (transferred infants only)
   (1) Hypothermic Therapy at Hospital to which Transferred?
      ☐ Not Transferred   ☐ Yes      ☐ No      ☐ Unknown

   If “Yes” to (1), answer questions (2) and (3) below.

   (2) Cooling Method at Hospital to which Transferred:
      ☐ Selective Head       ☐ Whole Body       ☐ Unknown       ☐ N/A

   (3) Hospital to which Infant Transferred:
      (a) Name of Hospital: __________________________
      (b) City: _____ _____ (c) State/Prov./Country: ___________

HT2. Age Hypothermic Therapy Began:

HT3. Age Hypothermic Therapy Stopped:
      a. Age, Days: _____  b. Age, Hours: _____  c. Age, Minutes: _____
VERMONT OXFORD NETWORK
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Center Number: __________  Network ID Number: □ □ □ □ □

HT4. Core Body Temperature when Hypothermic Therapy Stopped:
   a. Temperature Measured when Hypothermic Therapy Stopped?
      □ Yes  □ No  □ Unknown
      If “Yes” to a, answer question b below.
   b. Temperature when Hypothermic Therapy Stopped:
      Range: 30.0-44.0 for C, 86.0-111.0 for F, 777.7 for N/A, 999.9 for Unknown
      Record the temperature when hypothermic therapy stopped and the units in which it
      was recorded. Use a single decimal place, e.g. 36.7°C or 98.2°F
      □□□□□□□□ □°C  □°F

HT5. Age Re-Warming Completed:
   a. Age, Days: _____  b. Age, Hours: _____  c. Age, Minutes: _____

HT6. Cooling Interruptions:
   a. Was Cooling Interrupted for More than 30 Minutes?
      □ Yes  □ No  □ Unknown
      If “Yes” to a, answer question b below.
   b. Number of Cooling Interruptions: ________

HT7. Cooling Provided as Part of a Randomized Controlled Trial?
      □ Yes  □ No  □ Unknown

HT8. Adverse Events within 7 Days of Birth:
   a. Cardiac Arrhythmia within 7 Days of Birth?
      □ Yes  □ No  □ Unknown
      If “Yes” to a, indicate in (1) through (6) below, the adverse events from Cardiac Arrhythmia:
      (1) Sinus Bradycardia? □ Yes  □ No  □ Unknown  □ N/A
      (2) Sinus Tachycardia? □ Yes  □ No  □ Unknown  □ N/A
      (3) Ventricular Tachycardia? □ Yes  □ No  □ Unknown  □ N/A
      (4) Ventricular Fibrillation? □ Yes  □ No  □ Unknown  □ N/A
      (5) Conduction Block? □ Yes  □ No  □ Unknown  □ N/A
      (6) Prolonged QT interval? □ Yes  □ No  □ Unknown  □ N/A
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Center Number: ___________          Network ID Number: □ □ □ □ □

(7) Other Arrhythmia:
   (1) Other Arrhythmia Present?
      □ Yes  □ No  □ Unknown  □ N/A
   (2) If Other Arrhythmia, describe: ____________________________

b. Thrombosis within 7 Days of Birth?
   □ Yes  □ No  □ Unknown

c. Severe Hypotension within 7 Days of Birth?
   □ Yes  □ No  □ Unknown

d. Seizure during Re-Warming within 7 Days of Birth?
   □ Yes  □ No  □ Unknown

e. Scalp Edema within 7 Days of Birth?
   □ Yes  □ No  □ Unknown

f. Skin Breakdown within 7 Days of Birth?
   □ Yes  □ No  □ Unknown

g. Sclerema Neonatorum within 7 Days of Birth?
   □ Yes  □ No  □ Unknown

h. Thrombocytopenia within 7 Days of Birth?
   □ Yes  □ No  □ Unknown

HT9. Seizures Prior to Cooling?
   a. Were seizures noted prior to cooling?
      □ Yes  □ No  □ Unknown
      If “Yes” to a, complete question b below.

   b. Diagnosis of Seizures Prior to Cooling:
      (1) Clinical Diagnosis of Seizures Prior to Cooling?
         □ Yes  □ No  □ Unknown  □ N/A

      (2) aEEG Diagnosis of Seizures Prior to Cooling?
         □ Yes  □ No  □ Unknown  □ N/A

      (3) EEG Diagnosis of Seizures Prior to Cooling?
         □ Yes  □ No  □ Unknown  □ N/A

HT10. Modified SARNAT Stage Prior to Cooling: ____________

Range: 0 to 3, 4=N/A, 5=Unknown
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**Network ID Number:** __________

**HT11. Full channel EEG Prior to Cooling:**

a. **Full Channel EEG Performed Prior to Cooling?**
   
   - [ ] Yes  
   - [ ] No  
   - [ ] Unknown

   If “Yes” to a, select worst background pattern observed prior to cooling (select one).

b. **Background Pattern of Full Channel EEG Prior to Cooling:**
   
   - [ ] Normal  
   - [ ] Excessively Discontinuous  
   - [ ] Depressed Amplitude  
   - [ ] Burst Suppression Pattern  
   - [ ] Background Iso-Electric  
   - [ ] Unknown  
   - [ ] N/A

**HT12. Bedside aEEG Prior to Cooling:**

a. **Bedside aEEG Prior to Cooling?**
   
   - [ ] Yes  
   - [ ] No  
   - [ ] Unknown

   If “Yes” to a, select worst background pattern observed prior to cooling (select one).

b. **Background Pattern of Bedside aEEG Prior to Cooling:**
   
   - [ ] Normal  
   - [ ] Moderately Abnormal or Discontinuous  
   - [ ] Severely Abnormal  
   - [ ] Unknown  
   - [ ] N/A
## Anticonvulsant Drugs: Generic and Trade Names

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbamazepine</td>
<td>Tegretol®, Carbatrol®, Equetro®</td>
</tr>
<tr>
<td>Clonazepam</td>
<td>Klonopin®</td>
</tr>
<tr>
<td>Diazepam</td>
<td>Valium ®, Diastat®</td>
</tr>
<tr>
<td>Fosphenytoin</td>
<td>Cerebyx®</td>
</tr>
<tr>
<td>Lamotrigine</td>
<td>Lamictal®</td>
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<tr>
<td>Levetiracetam</td>
<td>Keppra®</td>
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<tr>
<td>Lidocaine</td>
<td>Xylocaine®, Xylocard®</td>
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<td>Lignocaine</td>
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<tr>
<td>Lorazepam</td>
<td>Ativan®, Temesta®</td>
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<tr>
<td>Midazolam</td>
<td>Dormicum®, Flormidal®, Versed®, Hypnovel®, Dormonid®</td>
</tr>
<tr>
<td>Oxcarbazepine</td>
<td>Tripleptal®, Trexapin®</td>
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<tr>
<td>Paraldehyde</td>
<td>Paral®</td>
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<tr>
<td>Phenobarbital</td>
<td>Luminal®, Solfoton®</td>
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<tr>
<td>Phenytoin</td>
<td>Dilantin®, Phenytek®, Eptoin®, Epanutin®, Diphenin®, Dipheninum®, PhydumTM®, Pyridoxine, Vitamin B6</td>
</tr>
<tr>
<td>Topiramate</td>
<td>Topamax®</td>
</tr>
<tr>
<td>Thiopental</td>
<td>Sodium Pentothal®, Farmotal®, Intraval®, Nesdonal®, Pentothiobarbital®, Pentothiobarbital®, Thiomebumal®, Thionembutal®, Thiopentobarbital®, Thiopentobarbitone®, Thiopentobarbituric Acid®, Thiopentone®, Thiothal®, Tiopentale®, Trapanal®</td>
</tr>
<tr>
<td>Valproic Acid</td>
<td>Depakote®, Depakene®, Depacon®</td>
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