# **Vermont Oxford Network**

2023

**Global Health Neonatal Quality Improvement Database** Data Definitions & Infant Data Sheet

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# **CHAPTER 1**

# Introduction

This Manual of Operations is for the Vermont Oxford Network (VON) Global Health Neonatal Quality Improvement (QI) Neonatal Database. It includes the data definitions, data forms, instructions for data submission, and information on using reports for quality improvement.

# About VON Global Health Neonatal QI Database

The **mission** of Vermont Oxford Network is to improve the quality, safety, and value of care for newborn infants and their families through a coordinated program of data-driven quality improvement, education and research.

VON Global Health Neonatal QI Database:

- The first QI database developed uniquely for neonatal units in resource-limited settings
- Provides data on patient demographics, care practices, and outcomes
- Provides quality of care indicators for the major causes of newborn mortality
- Provides information to describe referral and transport patterns
- Serves as the foundational platform to develop and test specific quality improvement initiatives

Members submitting data to the Global Health Neonatal QI Database join Vermont Oxford Network's worldwide community of practice, comprised of over **1,400 neonatal** units around the world, dedicated to giving infants the best possible start so that every newborn and family achieves their fullest potential.

The VON Global Health Neonatal QI Database is managed and secured by Vermont Oxford Network (VON).

# **Eligibility Criteria**

The eligibility criteria for the VON Global Health Neonatal QI Database are all neonates admitted to a member center neonatal unit within 28 days of birth.

Infants who were admitted to your neonatal unit, discharged to home by your center, and return to your center are eligible at the initial hospitalization only. **Infants are only eligible once**. The infant is not eligible again at the second hospitalization. The record does not need to be updated upon readmission.

# **Data Definitions**

Each data item has its own *data definition*, a precise explanation of the information required for the item. As you enter data, use the data definitions presented in this manual as a reference. Please read the explanations carefully so that you understand the details for each item. To ensure data integrity and accuracy of reports to your hospital, it is very important that the definitions provided in this manual be followed as closely as possible.

# NOTES:

• Some definitions and sections are preceded or followed by a Notes Box, which contains notes that may be useful to you in determining how to best respond to the question.

# **Data Submission and Reporting**

Each January 1<sup>st</sup> on the Gregorian (western) calendar marks the beginning of a new cycle of data submission and reporting. Data are submitted, finalized, and reported for all eligible infants discharged during the entire calendar year. Members confirm that data for all eligible infants are submitted and that data records for each infant are accurate and up-to-date.

Vermont Oxford Network produces annual and group reports to provide participating members with feedback about their performance. Reports include:

- Patient characteristics
- Treatment practices
- Morbidity and mortality
- Length of stay at your center

# **Confidentiality and Patient Privacy**

Vermont Oxford Network strictly maintains the confidentiality of the data in its databases. Although data at Network or group levels are summarized for comparative purposes, individual center data are reported only to the submitting center. A group administrator may receive center data only with prior written authorization from the center. Your hospital must take appropriate measures to ensure that patient data stored at your hospital are protected and secure from unauthorized access.

# **Getting Help**

Your center has been assigned an Account Manager to assist you with data submission. Your Account Manager will answer any questions you may have about collecting, recording, or submitting data, as well as questions you may have about the data definitions in this manual.

If you have questions, please do not hesitate to contact your Account Manager.

Account Manager: Paula Beales Paula@vtoxford.org

Technical support is available from 9:00 A.M. to 5:00 P.M., Monday through Friday, UTC -05:00.

Tech Support

Support@vtoxford.org

# **CHAPTER 2**

# ITEM 1a: Date of Birth

Record the infant's date of birth in the Gregorian (Western) calendar in the format day-month-year (DD-MM-YYY).

# ITEM 1b: Time of Birth

Record the infant's time of birth. The time is recorded in the 24-hour clock in the format hour:minute (HH:MM). Answer "**Unknown**" if the time of birth is unknown.

# **ITEM 2: Date of Admission**

Record the infant's date of admission in the Gregorian (Western) calendar in the format day-month-year (DD-MM-YYYY). Date of admission is the day on which the infant is admitted to your hospital. If an infant is born at home or another facility, or was previously discharged home, the date of admission may be different than the date of birth.

# ITEM 3: Date of Discharge or Death

Record the infant's date of discharge or death in the Gregorian (Western) calendar in the format day-month-year (DD-MM-YYYY).

# **ITEM 4: Previously Discharged Home**

Answer **"Yes"** if the infant was previously discharged to home from any hospital or health center/clinic after birth.

Answer "**No**" if the infant was not previously discharged to home from any hospital or health center/clinic after birth.

# NOTES:

- A home birth that was admitted to your neonatal unit should be coded as "**No**" unless the infant was admitted to a hospital after the home birth, then discharged, then admitted to your neonatal unit.
- Infants who were previously discharged from your neonatal unit are not eligible again if they are readmitted. See page 3 of this manual.

# **ITEM 5: Place of Delivery**

Answer "Inborn at Same Facility" if the infant was delivered at your center.

Answer "**Other Hospital**" if the infant was delivered outside your center at another facility classified as a hospital. When completing the data collection form for outborn infants, use all information available from the hospital that transferred the infant to your center as well as from your own hospital.

Answer "**Health Center/Clinic**" if the infant was delivered outside your center at another facility classified as a health center or clinic. When completing the data collection form for outborn infants, use all information available from the hospital that transferred the infant to your center as well as from your own hospital.

Answer "**Home**" if the infant was delivered outside your center within a residential setting.

Answer "In Transit" if the infant was delivered in transit to a health center, clinic, or hospital.

Answer "Unknown" if the location of the infant's delivery is unknown.

#### **ITEM 6: Mode of Delivery**

Answer **"Vaginal"** for all vaginal deliveries that do not require manual assistance (with forceps or vacuum). Onset of labor may be spontaneous or induced with medication.

Answer "**Instrument-assisted vaginal**" for all vaginal deliveries assisted with either forceps or vacuum. Onset of labor may be spontaneous or induced with medication.

Answer "Cesarean Section" for any cesarean delivery (elective or emergent).

Answer "Unknown" if the mode of delivery is unknown.

#### **ITEM 7: Antenatal Care**

Answer "None" if the mother did not receive any prenatal obstetrical care.

Answer **"1 to 3 visits"** if the mother received 1 to 3 prenatal obstetrical care visits prior to the admission during which birth occurred.

Answer " $\geq$ 4 visits" if the mother received  $\geq$  4 prenatal obstetrical care visits prior to the admission during which birth occurred.

Answer "Unknown" if prenatal obstetrical care history is unknown.

# ITEM 8: Maternal Age

Record maternal age in years at the time of the infant's birth.

Answer "Unknown" if maternal age is unknown.

# **ITEM 9: Maternal Obstetric History**

# Maternal Gravida:

Record the total number of times the mother has been pregnant, regardless of the outcome of these pregnancies. Include the pregnancy resulting in the birth of this infant.

Answer "Unknown" if maternal gravida is unknown.

# Total Live Births:

Record the total number of previous pregnancies resulting in live birth. Do not include the birth of this infant.

Answer "Unknown" if previous total live births are unknown.

# Total Living Children:

Record the mother's total number of living children. Do not include the birth of this infant.

Answer "Unknown" if total living children are unknown.

# NOTES:

- The maternal obstetric history questions should be answered based on *status during the prenatal time period* for the pregnancy resulting in the birth of the included infant. Therefore, "maternal gravida" includes the pregnancy resulting in the birth of this infant. The answers to "total live births" and "total living children" do not include the outcome of the pregnancy resulting in the birth of this infant.
- The live birth definition supported by the World Health Organization refers to "the complete expulsion or extraction from its mother a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life (beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles) whether or not the umbilical cord has been cut or the placenta is attached. Each product of such a birth is considered liveborn." Reference: International Classification of Diseases, 10th Revision, Geneva, World Health Organization; 2004.

# ITEM 10a: Maternal HIV Status

Answer **"Positive"** if a diagnosis of maternal HIV was recorded in the maternal or infant medical record.

Answer "**Negative**" if maternal HIV was recorded as negative in the maternal or infant medical record.

Answer "**Unknown**" if a diagnosis of maternal HIV is unknown.

# ITEM 10b: If Maternal HIV Status is Positive, Did Mother Receive Anti-Retroviral Therapy

If the answer to Maternal HIV Status is "Positive":

Answer "**Yes**" if anti-retroviral therapy was administered to the mother during pregnancy at any time prior to delivery.

Answer "**No**" if anti-retroviral therapy was not administered to the mother during pregnancy at any time prior to delivery.

Answer "**Unknown**" if treatment with anti-retroviral therapy is unknown.

# ITEM 10c: If Maternal HIV Status is Positive, Did Infant Receive Prophylaxis for HIV

If the answer to Maternal HIV Status is "Positive":

Answer **"Yes"** if infant received anti-retroviral therapy as prophylaxis for HIV following delivery.

Answer "**No**" if infant did not receive anti-retroviral therapy as prophylaxis for HIV following delivery.

Answer "**Unknown**" if treatment with anti-retroviral therapy as prophylaxis for HIV is unknown.

# **ITEM 11: Receipt of Any Antenatal Corticosteroids**

Answer "**Yes**" if corticosteroids were administered IM or IV to the mother during pregnancy at any time prior to delivery. Corticosteroids include betamethasone, dexamethasone, and hydrocortisone.

Answer "**No**" if no corticosteroids were administered IM or IV to the mother during pregnancy at any time prior to delivery.

Answer "**Unknown**" if it is unknown whether corticosteroids were administered IM or IV to the mother during pregnancy at any time prior to delivery.

#### **ITEM 12: Gestational Age**

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

- Obstetrical measures based on prenatal ultrasound or assisted reproductive technology dating.
- Obstetrical measures based on last menstrual period and/or obstetrical parameters (e.g. measured fundal height) as recorded in the maternal chart.
- Neonatal unit care provider's estimate based on physical criteria, neurologic examination, combined physical and gestational age exam (Ballard or Dubowitz).

Answer "**Unknown**" if the gestational age is unknown and a best estimate is not documented in the medical record.

#### ITEM 13: Gestational Age Determined by Early Ultrasound

Answer "**Yes**" if the infant's gestational age was determined from an ultrasound that occurred in the first trimester ( $\leq$  13 6/7 weeks of gestation).

Answer **"No"** if the infant's gestational age was not determined from an ultrasound that occurred in the first trimester.

Answer "**Not Applicable**" if the gestational age was determined by dates based on assisted reproductive technology.

Answer **"Unknown"** if it is unknown if the infant's gestational age was determined from an ultrasound that occurred in the first trimester.

# ITEM 14: Birth Weight

Record the **birth weight** in grams. Since many weights may be obtained on an infant shortly after birth, enter the weight from the Labor and Delivery record if available and judged to be accurate. If unavailable or judged to be inaccurate, use the weight on admission to the neonatal unit or lastly, the weight obtained on autopsy (if the infant expired within 24 hours of birth).

### ITEM 15: Sex

Answer "Male" or "Female."

Answer "Unknown" if sex cannot be determined.

#### **ITEM 16: Multiple Gestation**

Answer "**Yes**" if two or more live fetuses were documented at any time during the pregnancy which resulted in the birth of the infant.

Answer "**No**" if one live fetus was documented at all times during the pregnancy which resulted in the birth of the infant.

Answer "**Unknown**" if it is unknown whether two or more live fetuses were documented at any time during the pregnancy which resulted in the birth of the infant.

# ITEMS 17a-f: Delivery Interventions and Initial Resuscitation at Birth

# NOTES:

- Delivery interventions and initial resuscitation at birth refer to those performed in the delivery room or in an initial resuscitation area immediately following birth and prior to admission to the neonatal unit.
- There are situations in which infants receive their initial neonatal resuscitation in locations other than a "delivery room." These include cases in which birth occurs outside of a "delivery room" (home, automobile, ambulance, hospital room, emergency room, etc.) and cases in which resuscitation is provided in locations adjacent to or close by the delivery room. In such situations, the responses to the Delivery Room Intervention items should be based on the initial resuscitation provided immediately after birth, regardless of where the resuscitation took place.

# ITEM 17a: Delayed Cord Clamping

Answer "**Yes**" if the umbilical cord was clamped at  $\geq$  1 minute after birth.

Answer "**No**" if the umbilical cord was clamped at < 1 minute after birth.

Answer "**Unknown**" if it is unknown whether delayed cord clamping was performed during delivery.

# ITEM 17b: Face Mask Ventilation

Answer "**Yes**" if the infant received any positive pressure breaths via a face mask in the delivery room or during the initial resuscitation performed immediately after birth. Positive pressure may be administered using a resuscitation bag or other device that generates intermittent positive pressure.

Answer "**No**" if the infant did not receive any positive pressure breaths via a face mask in the delivery room or during the initial resuscitation performed immediately after birth.

Answer "**No**" if a face mask was only used to administer CPAP (continuous positive airway pressure) or supplemental oxygen, and no positive pressure breaths were given.

Answer "**Unknown**" if receipt of positive pressure breaths via a face mask in the delivery room or during the initial resuscitation performed immediately after birth is unknown.

### ITEM 17c: CPAP

Answer **"Yes"** if the infant was given continuous positive airway pressure applied through the nose during the initial resuscitation performed immediately after birth.

Answer "**No**" if the infant was not given continuous positive airway pressure applied through the nose during the initial resuscitation performed immediately after birth.

Answer "**Unknown**" if treatment with continuous positive airway pressure applied through the nose during the initial resuscitation performed immediately after birth is unknown.

# NOTES:

- CPAP administered through a face mask covering the nose *without the administration of intermittent breaths* is considered CPAP for the purpose of this definition.
- If a nasal cannula is used to provide CPAP, the answer to CPAP is "Yes."

# **ITEM 17d: Intubation**

Answer **"Yes"** if the infant received ventilation through an endotracheal tube during the initial resuscitation performed immediately after birth.

Answer "**No**" if the infant did not receive ventilation through an endotracheal tube during the initial resuscitation performed immediately after birth.

Answer "**Unknown**" if ventilation through an endotracheal tube is unknown.

#### **ITEM 17e: Chest Compressions**

Answer "**Yes**" if external cardiac massage was given in the delivery room or during the initial resuscitation immediately after birth.

Answer **"No"** if external cardiac massage was not given in the delivery room or during the initial resuscitation immediately after birth.

Answer "Unknown" if external cardiac massage is unknown.

# ITEM 17f: Epinephrine (Adrenaline)

Answer "**Yes**" if epinephrine (adrenaline) was given in the delivery room or during the initial resuscitation immediately after birth via intravenous, intracardiac, or intratracheal (through an endotracheal tube) routes.

Answer "**No**" if epinephrine (adrenaline) was not given in the delivery room or during the initial resuscitation immediately after birth via intravenous, intracardiac, or intratracheal (through an endotracheal tube) routes.

Answer "**Unknown**" if epinephrine use is unknown.

#### ITEM 18: Apgar Score

Enter the Apgar score at one minute and five minutes (range for each 0-10).

Enter "Unknown" if the Apgar score is unknown.

# ITEMs 19 a-h: Admission Assessment

#### NOTES:

- Admission assessment refers to the initial assessment upon admission to the inpatient neonatal unit.
- If your neonatal unit has a physical space, such as a 'triage area', that is used to begin the admission process, assessments occurring in this physical space that are part of the admission record qualify for the answers to these items.

# ITEM 19a: Temperature Measured within the First Hour of Admission

Answer **"Yes"** if the infant's core body temperature was measured and recorded within the first hour after admission to <u>your</u> neonatal unit. Core body temperature may be measured by taking a rectal, esophageal, tympanic, or axillary temperature.

Answer "**No**" if the infant's core body temperature was not measured and recorded within the first hour after admission to your neonatal unit.

Answer **"Unknown"** if measurement of the infant's core body temperature within the first hour of admission is unknown.

# NOTES:

- This item applies to the temperature of the infant during the first hour after admission to <u>your</u> neonatal unit. Do *not* record temperature measurements taken at the transferring center for outborn infants.
- If an attempt is made to measure the temperature during the first hour after admission to <u>vour</u> neonatal unit, and the temperature of the infant is lower or higher than the thermometer can measure, answer "**Yes**" and record the lowest or highest temperature on the thermometer in part b of this item.
- If the infant's core body temperature is not measured within the first hour after admission to the neonatal unit, part b of this item is not applicable.

### ITEM 19b: If Yes, List Temperature

If the answer to Temperature Measured within the First Hour of Admission is "Yes":

If the infant's core body temperature was measured and recorded within the first hour after admission to your neonatal unit, enter the infant's temperature in degrees centigrade to the nearest tenth of a degree.

If the infant's temperature is measured multiple times within the first hour after admission to your neonatal unit, enter the value of the <u>first</u> temperature measurement.

# NOTES:

- For centers that measure temperature in degrees Fahrenheit, please use a Fahrenheit to centigrade conversion table. A conversion table is available at <a href="http://www.vtoxford.org/downloads">www.vtoxford.org/downloads</a>.
- Use a rectal temperature, or if not available, esophageal temperature, tympanic temperature, or axillary temperature, in that order.

# ITEM 19c: Pulse Oximetry Recorded

Answer "**Yes**" if the infant's pulse oximetry was recorded on admission to your neonatal unit.

Answer "**No**" if the infant's pulse oximetry was not recorded on admission to your neonatal unit.

Answer "**Unknown**" if it is unknown whether pulse oximetry was recorded on admission.

#### ITEM 19d: If Yes, List Saturation

If the answer to Pulse Oximetry Recorded is "Yes":

Record the number of the infant's pulse oximetry reading (percent saturation) at the time of admission (range 0-100).

If the infant is admitted to the neonatal unit without any respiratory support, report the pulse oximetry without respiratory support (before initiation of treatment).

If the infant is admitted to the neonatal unit already receiving respiratory support, report the first pulse oximetry reading on the initial respiratory support.

Answer "**Unknown**" if the value is not known.

# ITEM 19e: Was Admission Assessment Recorded Above When Infant Was On Oxygen/Respiratory Support?

Answer "**Yes**" if the saturation value reported was taken while the infant was on oxygen/respiratory support.

Answer "**No**" if the saturation value reported was taken while the infant was not on oxygen/respiratory support.

Answer "**Unknown**" if it is unknown whether the infant was on oxygen/respiratory support when the reported saturation value was taken.

#### **ITEM 19f: Objective Respiratory Assessment**

Answer "**Yes**" if the infant had an objective respiratory assessment completed and recorded on admission to your neonatal unit.

Answer **"No"** if the infant did not have an objective respiratory assessment completed and recorded on admission to your neonatal unit.

Answer "**Unknown**" if completion of an objective respiratory assessment on admission is unknown.

#### NOTES:

- Examples of an objective respiratory assessment include, but are not limited to, the Downes' Score or modified Downes' Score and the Silverman Andersen Score, also referred to as the Silverman Andersen Respiratory Severity Score.
- These objective respiratory assessments include a structured clinical examination with categorization of discrete components of the respiratory examination to communicate presence and severity of respiratory distress.

#### References:

Downes JJ, Vidyasagar D, Boggs TR Jr, Morrow GM 3rd. Respiratory distress syndrome of newborn infants. I. New clinical scoring system (RDS score) with acid--base and blood-gas correlations. Clin Pediatr (Phila). 1970 Jun;9(6):325-31.

Silverman WA, Andersen DH. A controlled clinical trial of effects of water mist on obstructive respiratory signs, death rate and necropsy findings among premature infants. Pediatrics. 1956 Jan;17(1):1-10.

# ITEM 19g: If Yes, List Assessment

If Objective Respiratory Assessment is "Yes":

Answer "**Downes**" if the infant had a Downes Score assessment completed and recorded on admission to your neonatal unit.

Answer "**Silverman-Andersen**" if the infant had a Silverman-Andersen Score assessment completed and recorded on admission to your neonatal unit.

Answer **"Other"** if the infant had an objective respiratory assessment other than the Downes or Silverman-Andersen Score completed and recorded on admission to your neonatal unit.

Answer "**Unknown**" if the infant had an objective respiratory assessment completed and recorded on admission to your neonatal unit, but the type is unknown.

# ITEM 19h: If Assessment is Downes or Silverman-Andersen, list score

If Assessment is Downes or Silverman-Andersen is "**Downes**" or "**Silverman-Andersen**":

Enter the value for the Downes Score or Silverman-Andersen Score completed upon admission (range for each 0-10).

Enter "**Unknown**" if the value for the score is unknown.

# **ITEM 20: Primary Reason for Admission**

# NOTES:

- List the primary reason for admission to your inpatient neonatal unit.
- The primary reason for admission may differ from the final diagnoses as this item is based on the information known at the time of admission.
- Only one item may be selected. List the most urgent reason for admission, acknowledging there are likely secondary reasons or contributing factors for admission that will not be captured here.

Answer "**Prematurity/LBW**" if the primary reason for admission was infant prematurity (less than 37 weeks' gestational age) and/or low birth weight (LBW) (birth weight of 2500 grams or less).

Answer "Birth Asphyxia" if the primary reason for admission was birth asphyxia.

Answer **"Suspected Infection"** if the primary reason for admission was suspected infection.

Answer "**Congenital Anomaly**" if the primary reason for admission was a congenital anomaly or anomalies.

Answer "Jaundice" if the primary reason for admission was jaundice.

Answer "Tetanus" if the primary reason for admission was tetanus.

Answer "**Suspected Need for Surgery**" if the primary reason for admission was a suspected need for surgery.

Answer **"Respiratory Distress"** if the primary reason for admission was respiratory distress.

Answer "**Convulsions**" if the primary reason for admission was convulsions (seizures).

Answer "Hypothermia" if the primary reason for admission was hypothermia.

Answer "**Pallor/Severe Anemia**" if the primary reason for admission was pallor/severe anemia.

Answer "Feeding Difficulty" if the primary reason for admission was feeding difficulty.

Answer "At Risk for Hypoglycemia" if the primary reason for admission was that the infant was at risk for hypoglycemia.

Answer "Birth Injury" if the primary reason for admission was birth injury.

Answer "Other" if the primary reason for admission is not listed above.

Answer "Unknown" if the primary reason for admission was unknown.

# ITEMS 21a-r: Interventions Received in the Neonatal Unit

# NOTES:

- Interventions that are received at delivery or in the initial resuscitation at birth should be noted in item #17.
- Interventions received following the initial resuscitation, and as part of the admission process to <u>your</u> inpatient neonatal unit or interventions received at any timepoint during the inpatient admission at <u>your</u> inpatient neonatal unit should be listed for item #21.
- If your neonatal unit has a physical space used to begin the admission process, such as a 'triage area', interventions occurring in this physical space that are part of the admission record qualify for the answers to these items.

# ITEM 21a: Immediate Kangaroo Care (KMC)

Answer **"Yes"** if infant was treated with immediate and continuous kangaroo care (KMC) initiated within two hours of admission to the neonatal unit.

Answer **"No"** if infant was not treated with immediate and continuous kangaroo care (KMC), initiated within two hours of admission to the neonatal unit.

Answer "Unknown" if treatment with immediate kangaroo care is unknown.

# ITEM 21b: Kangaroo Care (KMC) Initiated After 2 Hours

Answer **"Yes"** if infant was treated with intermittent or continuous kangaroo care (KMC) two hours or more after admission to the neonatal unit.

Answer **"No"** if infant was not treated with intermittent or continuous kangaroo care (KMC) two hours or more after admission to the neonatal unit.

Answer "**Unknown**" if treatment with kangaroo care two hours or more after admission to the neonatal unit is unknown.

### ITEM 21c: Oxygen

Answer "**Yes**" if the infant received any supplemental oxygen at any time after admission to the neonatal unit.

Answer "**No**" if the infant did not receive supplemental oxygen at any time after admission to the neonatal unit.

Answer "Unknown" if treatment with oxygen is unknown.

# NOTES:

• 21% oxygen is room air. This is not considered supplemental oxygen, no matter how administered.

# ITEM 21d: CPAP After Initial Resuscitation

Answer **"Yes"** if the infant was given continuous positive airway pressure (CPAP) applied through the nose at any time after admission to the neonatal unit.

Answer "**No**" if the infant was never given continuous positive airway pressure applied through the nose at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with continuous positive airway pressure (CPAP) applied through the nose at any time after admission to the neonatal unit is unknown.

# NOTES:

- CPAP administered through a face mask covering the nose *without the administration of intermittent breaths* is considered CPAP for the purpose of this definition.
- If a nasal cannula is used to provide CPAP, the answer to CPAP After Initial Resuscitation is "**Yes.**"

# **ITEM 21e: Mechanical Ventilation**

Answer **"Yes"** if the infant received mechanical ventilation through an endotracheal tube, including intermittent positive pressure ventilation with a conventional ventilator or high frequency ventilation at any time after admission to the neonatal unit.

Answer **"No"** if the infant was never mechanically ventilated through an endotracheal tube at any time after admission to the neonatal unit.

Answer "**Unknown**" if the treatment with mechanical ventilation through an endotracheal tube is unknown.

#### **ITEM 21f: Methylxanthine Medication**

Answer **"Yes"** if the infant received methylxanthine medication, including caffeine citrate, aminophylline, or theophylline, at any time after admission to the neonatal unit.

Answer "**No**" if the infant did not receive methylxanthine medication, including caffeine citrate, aminophylline, or theophylline, at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with methylxanthine medication at any time after admission to the neonatal unit is unknown.

#### ITEM 21g: Surfactant

Answer "**Yes**" if the infant received an exogenous surfactant at any time after admission to the neonatal unit.

Answer "**No**" if the infant did not receive an exogenous surfactant at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with an exogenous surfactant at any time after admission to the neonatal unit is unknown.

# NOTES:

• This item includes surfactant administered via any route, including but not limited to endotracheal tube, thin catheter, laryngeal mask airway, and aerosolized routes of administration.

# ITEM 21h: ROP Examination

Answer **"Yes"** if an indirect ophthalmologic examination for retinopathy of prematurity (ROP) was performed at any time after admission to the neonatal unit.

Answer "**No**" if an indirect ophthalmologic examination for retinopathy of prematurity (ROP) was not performed at any time after admission to the neonatal unit.

Answer "**Unknown**" if performance of an indirect ophthalmologic examination for retinopathy of prematurity (ROP) at any time after admission to the neonatal unit is unknown.

# ITEM 21i: If Yes, Worst Stage of ROP

If the answer to ROP Examination is "Yes":

Enter the <u>worst</u> stage documented on any exam in the eye with the most advanced stage. Please select from the following stages.

Stage 0: No evidence of ROP

**Stage 1**: Presence of demarcation line (+/- abnormal vascularization)

Stage 2: Presence of intraretinal ridge

**Stage 3**: Presence of a ridge with extraretinal fibrovascular proliferation

Stage 4: Partial retinal detachment

Stage 5: Total retinal detachment

Answer "Unknown" if the stage is unknown.

#### ITEM 21j: Antibiotics

Answer "**Yes**" if infant received treatment with IV or IM antibiotics at any time after admission to the neonatal unit.

Answer "**No**" if infant did not receive treatment with IV or IM antibiotics at any time after admission to the neonatal unit.

Answer **"No"** if infant received antibiotics but all doses were administered via oral route at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with IV or IM antibiotics at any time after admission to the neonatal unit is unknown.

### ITEM 21k: Phototherapy

Answer **"Yes"** if infant was treated with phototherapy at any time after admission to the neonatal unit.

Answer **"No"** if infant was not treated with phototherapy at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with phototherapy at any time after admission to the neonatal unit is unknown.

# **ITEM 21I: Blood Transfusion**

Answer "**Yes**" if infant received a transfusion with red blood cells at any time after admission to the neonatal unit.

Answer "**No**" if infant did not receive a transfusion with red blood cells at any time after admission to the neonatal unit.

Answer "**No**" if infant did not receive a transfusion with red blood cells at any time after admission to the neonatal unit but did receive a transfusion with a blood product other than red blood cells (platelets, fresh frozen plasma, cryoprecipitate, immune globulin).

Answer "**Unknown**" if red blood cell transfusion status at any time after admission to the neonatal unit is unknown.

#### ITEM 21m: Exchange Transfusion

Answer **"Yes"** if infant received an exchange transfusion with red blood cells at any time after admission to the neonatal unit.

Answer "**No**" if infant did not receive an exchange transfusion with red blood cells at any time after admission to the neonatal unit.

Answer "**Unknown**" if exchange transfusion status at any time after admission to the neonatal unit is unknown.

# **ITEM 21n: Anticonvulsant Medication**

Answer "**Yes**" if infant was treated with anticonvulsant medication at any time after admission to the neonatal unit.

Answer "**No**" if infant was not treated with anticonvulsant medication at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with anticonvulsant medication at any time after admission to the neonatal unit is unknown.

#### ITEM 210: Active Therapeutic Hypothermia

Answer "**Yes**" if the infant received active selective head or whole-body cooling at any time after admission to the neonatal unit according to a standardized protocol of 33.5 °C for 72 hours.

Answer "**No**" if the infant did not receive active selective head or whole-body cooling at any time after admission to the neonatal unit according to a standardized protocol of 33.5 °C for 72 hours.

Answer "**No**" if the infant received passive cooling only, and did not receive active selective head or whole-body cooling at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with therapeutic hypothermia at any time after admission to the neonatal unit is unknown.

#### NOTES:

• Infants may be treated with hypothermia during surgery. If hypothermic therapy is only performed during and immediately around the time of cardiac surgery or other surgery, Active Therapeutic Hypothermia should be answered "**No.**"

# ITEM 21p: Surgery

Answer "**Yes**" if infant was treated with one or more surgical operations performed by a general or specialist surgeon at any time after admission to the neonatal unit.

Answer "**No**" if the infant was not treated with a surgical operation performed by a general or specialist surgeon at any time after admission to the neonatal unit.

Answer "**Unknown**" if treatment with a surgical operation performed by a general or specialist surgeon at any time after admission to the neonatal unit is unknown.

# NOTES:

The following are <u>not</u> considered surgical operations:

- Central lines: Broviac catheters, percutaneous venous catheters, central venous catheters, PICC lines, umbilical artery lines, umbilical venous lines, or any other intravascular catheter. We recognize that some of these lines may be placed while the infant is under anesthesia for other procedures.
- Chest tube placement.
- Peritoneal dialysis and placement or removal of peritoneal dialysis catheters.

# ITEM 21q: Cranial Ultrasound

Answer "**Yes**" if infant received a cranial ultrasound at any time after admission to the neonatal unit.

Answer "**No**" if the infant did not receive a cranial ultrasound at any time after admission to the neonatal unit.

Answer "**Unknown**" if receipt of cranial ultrasound at any time after admission to the neonatal unit is unknown.

# ITEM 21r: If Yes, Worst Grade of IVH

If the answer to Cranial Ultrasound is "Yes":

Enter the <u>worst</u> grade of intraventricular hemorrhage based on any study using the criteria below:

Grade 0: No subependymal or intraventricular hemorrhage

Grade 1: Subependymal germinal matrix hemorrhage only

Grade 2: Intraventricular blood, no ventricular dilation

Grade 3: Intraventricular blood, ventricular dilation

Grade 4: Intraparenchymal hemorrhage

Answer **"Unknown"** if diagnosis of intraventricular hemorrhage is unknown in this infant.

# ITEM 22a-s: Final Diagnoses

The following items (22a-s) refer to infant diagnoses during the entire neonatal unit admission. Indicate all the following diagnoses that apply whether they were the indication for admission or subsequently diagnosed and/or treated during the neonatal unit admission.

#### ITEM 22a: Moderate to Severe HIE

Answer "**Yes**" if the infant was diagnosed with moderate to severe Hypoxic-Ischemic Encephalopathy (HIE), which is an acquired syndrome of acute brain injury characterized by moderate to severe neonatal encephalopathy and intrapartum hypoxia, as defined below. The diagnosis of moderate to severe HIE requires presence of <u>all three</u> of the following criteria:

- The presence of a clinically recognized moderate to severe neonatal encephalopathy within 72 hours of birth. Moderate to severe neonatal encephalopathy is defined as the presence of <u>seizures</u> OR <u>at least one sign in</u> <u>three or more of the six categories below</u> within the first 72 hours after birth:
  - Level of consciousness: lethargy, stupor, or coma (Thompson score for level of consciousness 2 or 3).
  - Spontaneous activity: decreased or absent.
  - Posture: distal flexion or decerebrate (arms extended and internally rotated, legs extended with feet in plantar flexion) (Thompson score component for posture 2 or 3).

- Tone: hypotonia or flaccid (Thompson score component for limb tone 2 or 3).
- Primitive reflexes: absent or weak suck, absent or incomplete Moro (Thompson score component for suck 1 or 2 OR Thompson score component for Moro 1 or 2).
- Autonomic system: pupils constricted, with skew deviation, dilated or unresponsive to light; heart rate bradycardic or variable heartrate; respiratory pattern with periodic breathing or apnea (Thompson score component for respiration 2 or 3).

# AND

- 2. The presence of supportive findings of intrapartum hypoxia, with <u>three or more</u> supporting findings from the following list below:
  - An acute intrapartum event, including hemorrhage, prolapsed cord, uterine rupture, shoulder dystocia or maternal hypoxic event.
  - Pathologic fetal heart rate or abnormal cardiotocography as per the FIGO (International Federation of Gynecology and Obstetrics) criteria:

Reference: Ayres-de-Campos D, Spong CY, Chandraharan E; FIGO Intrapartum Fetal Monitoring Expert Consensus Panel. FIGO consensus guidelines on intrapartum fetal monitoring: Cardiotocography. Int J Gynaecol Obstet. 2015 Oct;131(1):13-24. doi: 10.1016/j.ijgo.2015.06.020. PMID: 26433401.

- Bradycardia < 100 beats per minute.
- Reduced or increased variability (normal variability 5-25 beats per minute).
- o Sinusoidal pattern.
- Repetitive late decelerations (> 20 seconds after onset of contractions) or prolonged decelerations (> 3 minutes) during > 30 minutes of fetal heart rate tracing or 20 minutes if reduced variability, or one prolonged deceleration > 5 minutes at any time (decelerations are repetitive when associated with > 50% of contractions).
- Evidence of fetal ischemia and/or distress on antepartum monitoring: reversal of end-diastolic flow on Doppler flow studies of the umbilical artery, or a biophysical profile of ≤ 2.
- Acidosis on umbilical cord or neonatal blood gas (arterial or capillary sample) in the first hour of life with pH < 7.00 OR base deficit ≥ 16 mmol/L.
- APGAR score at ten minutes of ≤ 5 OR need for resuscitation including positive pressure ventilation and/or chest compressions at birth and continued for 10 minutes.
- Evidence of multiorgan system dysfunction with evidence of dysfunction of one or more of the following systems within 72 hours of birth:

- Renal: oliguria or acute renal failure.
- GI: intestinal perforation, hepatic dysfunction.
- Hematologic: thrombocytopenia, disseminated intravascular coagulopathy (DIC).
- Endocrine: hypoglycemia, hyperglycemia, hypercalcemia, syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- Pulmonary: persistent pulmonary hypertension.
- Cardiac: myocardial dysfunction, tricuspid insufficiency.
- Neurologic: amplitude integrated electroencephalogram (aEEG), cerebral function monitor (CFM) or EEG with suppressed background pattern (burst suppression, continuous low voltage or an isoelectric/flat trace).
- Evidence on CT, MRI, technetium or ultrasound brain scan performed within fourteen days of birth of diffuse or multifocal ischemia or of cerebral edema.

#### AND

3. The absence of an infectious cause, a congenital anomaly of the brain or an inborn error of metabolism, which could explain the encephalopathy.

Answer **"No"** if the infant was not diagnosed with moderate to severe HIE as defined above.

Answer "**Unknown**" if the diagnosis of moderate to severe HIE is unknown based on the above criteria.

# NOTES:

- The diagnosis of a clinically recognized moderate to severe neonatal encephalopathy within 72 hours of birth can be facilitated with a structured neurologic examination, including but not limited to, physical examination criteria for Sarnat staging and the Thompson HIE score.
- If serial examinations are completed, answer this item according to the <u>worst</u> stage of HIE reported within 72 hours of birth.
- If the examination for Sarnat staging is completed, criteria #1 refers to a Stage 2 (moderate) or Stage 3 (severe) encephalopathy.
- If the Thompson score is completed, refer to the component scores in criteria #1 for correlation of this scoring system to the listed criteria.

References:

Sarnat HB & Sarnat MS Neonatal encephalopathy following fetal distress. A clinical and electroencephalographic study. *Arch Neurol.* 33, 696–705 (1976).

Thompson CM, et al. The value of a scoring system for hypoxic ischaemic encephalopathy in predicting neurodevelopmental outcome. *Acta Paediatr.* 86, 757–761 (1997).

# ITEM 22b: Meconium Aspiration Syndrome

Answer "Yes" if all three of the following criteria are satisfied:

1. Presence of meconium-stained amniotic fluid at birth.

# And

2. Respiratory distress with onset within one hour of birth. Respiratory distress will be defined as the presence of at least one of the following signs: tachypnea (respiratory rate > 60 breaths/minute), grunting, nasal flaring, or intercostal retractions.

# And

3. Absence of culture proven early-onset bacterial sepsis or pneumonia. The diagnosis of culture proven early-onset bacterial sepsis requires a positive blood culture obtained within 72 hours of birth.

Answer "**No**" if all 3 of the criteria for Meconium Aspiration Syndrome are not satisfied.

Answer "**Unknown**" if the diagnosis of Meconium Aspiration Syndrome is unknown based on the above criteria.

# NOTES:

- If chest x-ray is available and completed, it should also be compatible with the diagnosis of meconium aspiration. Findings may include coarse irregular or nodular pulmonary densities, areas of diminished aeration or consolidation alternating with areas of hyperinflation and generalized hyperinflation.
- If a blood gas is available and completed, consistent parameters with meconium aspiration syndrome include a PaO2 < 50 mmHg in room air, central cyanosis in room air, or a requirement for supplemental oxygen to maintain PaO2 > 50 mmHg.

# ITEM 22c: Birth Injury

# NOTES:

- Birth injury refers to physical injury of an infant during the birth process, which may occur in the setting of prematurity, cephalopelvic disproportion, obstructed labor, precipitous labor, malpresentation, fetal macrosomia, version, extraction, or instrumentation.
- Types of birth injuries include injuries to the skull and scalp, intracranial injuries and hemorrhage, cervical nerve root and spinal cord injuries, fractures, intraabdominal injuries, lacerations, and tissue injury.

Answer "Yes" if infant was diagnosed with birth injury.

Answer "No" if infant was not diagnosed with birth injury.

Answer "Unknown" if the diagnosis of birth injury is unknown.

# ITEM 22d: Transient Tachypnea of the Newborn

# NOTES:

 Transient tachypnea of the newborn (TTN) is a clinical diagnosis characterized by tachypnea (respiratory rate > 60 breaths per minute) and signs of respiratory distress (grunting, nasal flaring, or intercostal retractions). The clinical features typically appear immediately after birth or within the first two hours of life, in term and late preterm newborns (at or after 34 weeks' gestational age). These findings are transient, often resolving within 48 hours of birth. A clinical diagnosis may be supported by findings from chest radiographs, such as increased lung volumes with flat diaphragms, mild cardiomegaly, prominent vascular markings in a sunburst pattern originating at the hilum, fluid seen in the lung fissure, and absence of findings of RDS or focal pathology.

Answer "Yes" if infant was diagnosed with transient tachypnea of the newborn.

Answer "**No**" if infant was not diagnosed with transient tachypnea of the newborn.

Answer "**Unknown**" if the diagnosis of transient tachypnea of the newborn is unknown.

# ITEM 22e: Pneumonia

# NOTES:

 Neonatal pneumonia may be classified as early, presenting within the first 7 days of life, and late, presenting after 7 days of life. Congenital pneumonia is one subset of early pneumonia that is acquired in utero and usually presents immediately after delivery. Congenital pneumonia is acquired through aspiration of infected amniotic fluid, ascending infection, or hematogenous spread through the placenta. Early pneumonia can also be acquired during labor secondary to aspiration of infected amniotic fluid or bacteria colonizing the birth canal. Late neonatal pneumonia, which includes ventilator-associated pneumonia (VAP) is usually a nosocomial infection and occurs most commonly in ventilated neonates, although infection through hematogenous spread can also occur. Neonatal pneumonias can be caused by bacterial, viral, and fungal pathogens.

Answer "**Yes**" if infant was diagnosed (clinically or radiographically) with early or late neonatal pneumonia.

Answer "**No**" if infant was not diagnosed with either early or late neonatal pneumonia.

Answer "Unknown" if the diagnosis of neonatal pneumonia is unknown.

# ITEM 22f: Seizure/Convulsions

Answer "**Yes**" if infant was diagnosed (clinically or electrographically) with seizure/convulsions.

Answer "No" if infant was not diagnosed with seizure/convulsions.

Answer "**Unknown**" if the diagnosis of seizure/convulsions is unknown.

# ITEM 22g: Respiratory Distress Syndrome (RDS)

Answer "Yes" if the infant had respiratory distress syndrome (RDS), defined as:

 Preterm infant (gestation age < 37 weeks) with Downes' or Silverman-Andersen score of 4 of greater, or otherwise clinically classified with moderate to severe respiratory distress based on tachypnea, retractions, decreased air entry and grunting within the first 24 hours of life OR a chest radiograph consistent with RDS (reticulogranular appearance to lung fields with or without low lung volumes and air bronchograms) within the first 24 hours of life

# AND

• Central cyanosis in room air, or a requirement for continuous positive airway pressure (CPAP), positive end expiratory pressure (PEEP) and/or supplemental oxygen to maintain a pulse oximeter saturation over 88% within the first 24 hours of life.

Answer "No" if the infant did not satisfy both of the criteria above.

Answer "**Unknown**" if the diagnosis of RDS based on the criteria above is unknown.

# ITEM 22h: Necrotizing Enterocolitis

Answer **"Yes"** if the infant had necrotizing enterocolitis (NEC) diagnosed at surgery, at postmortem examination, or with clinical and diagnostic imaging using the following criteria, consistent with Bell grade 2 or 3:

At least one of the following clinical signs present:

- Bilious gastric aspirate or emesis
- Abdominal distension or discoloration
- Occult or gross blood in stool (no fissure)

# And

At least one of the following diagnostic imaging findings present:

- Pneumatosis intestinalis
- Hepato-biliary gas
- Pneumoperitoneum

Answer **"No"** if the infant did not satisfy the above definition of necrotizing enterocolitis.

Answer "**Unknown**" if the diagnosis of necrotizing enterocolitis is unknown based on the above criteria.

# ITEM 22i: Respiratory Support on Day 28

Answer **"Yes"** if infant received supplemental oxygen and/or respiratory support (non-invasive or invasive respiratory support, regardless of fraction of inspired oxygen) on the date of Day 28.

Answer "**No**" if infant did not receive supplemental oxygen and/or respiratory support on the date of Day 28.

Answer "Unknown" if the diagnosis of respiratory support on Day 28 is unknown.

#### NOTES:

- To calculate the Date of Day 28, add 28 days to the birth date and subtract one day. The date of birth counts as day 1 regardless of the time of birth. For an infant born at 11:59pm on September 1<sup>st</sup>, Day 28 is September 28<sup>th</sup>.
- A chart showing the Date of Day 28 may be downloaded from <u>www.vtoxford.org/downloads</u>.

# ITEM 22j: Respiratory Support at 36 Weeks

### NOTES:

• Record the <u>highest level</u> of respiratory support at any time during the week that the infant was 36 weeks postmenstrual age.

Answer "**None**" if the infant received no respiratory support at any time during the week that the infant was 36 weeks postmenstrual age.

Answer "**Nasal Cannula \leq 2 L/min**" if the infant received respiratory support via nasal cannula at a flow rate of less than or equal to two liters per minute ( $\leq$  2 L/min) at any time during the week that the infant was 36 weeks postmenstrual age.

Answer "Nasal Cannula > 2 L/min or CPAP" if the infant received respiratory support via nasal cannula at a flow rate of greater than two liters per minute (> 2 L/min) or continuous positive airway pressure (CPAP) at any time during the week that the infant was 36 weeks postmenstrual age.

Answer "**Mechanical Ventilation**" if the infant received respiratory support via mechanical ventilation at any time during the week that the infant was 36 weeks postmenstrual age.

Answer "**Unknown**" if the respiratory support of infant during the week that the infant was 36 weeks postmenstrual age is unknown.

# ITEM 22k: Hypoglycemia

Answer "**Yes**" if the serum or whole blood glucose level met or exceeded the threshold for treatment (supplemental feeds, dextrose gel or use of dextrose-containing IV fluids) based on postnatal age and risk factors.

Answer "**No**" if the serum or whole blood glucose level did not meet or exceed the threshold for treatment (supplemental feeds, dextrose gel or use of dextrose-containing IV fluids) based on postnatal age and risk factors.

Answer "**Unknown**" if the diagnosis of hypoglycemia is unknown.

### ITEM 22I: Hyperbilirubinemia

Answer "**Yes**" if the total serum bilirubin level met or exceeded the threshold for treatment (phototherapy or exchange transfusion) based on postnatal age, gestation, and risk factors.

Answer "**No**" if the total serum bilirubin level did not meet or exceed the threshold for treatment (phototherapy or exchange transfusion) based on postnatal age, gestation, and risk factors.

Answer "**Unknown**" if the diagnosis of hyperbilirubinemia is unknown.

# ITEM 22m: Anemia

Answer "**Yes**" if the hematocrit or hemoglobin level met or exceeded the threshold for treatment of anemia with one or more red blood cell transfusions based on postnatal age and risk factors.

Answer "**Yes**" if the infant had an observed acute blood loss or hemorrhage that was diagnosed and treated clinically without laboratory verification of anemia.

Answer "**No**" if the hematocrit or hemoglobin level did not meet or exceed the threshold for treatment of anemia with red blood cell transfusion based on postnatal age and risk factors.

Answer "Unknown" if the diagnosis of anemia is unknown.

### **ITEM 22n: Congenital Anomaly**

Answer "**Yes**" if the infant had one or more major congenital anomalies that are considered lethal or life-threatening.

To be considered lethal or life threatening, the defect must either: (1) be the primary cause of death, or (2) require treatment in infancy with a specific surgical or medical therapy to correct a major anatomic defect or a life-threatening physiologic dysfunction.

Answer "**No**" if the infant was not diagnosed with a major congenital anomaly that is considered lethal or life threatening.

Answer "Unknown" if the diagnosis of major congenital anomaly is unknown.

### NOTES:

- Congenital anomalies, also known as birth defects, congenital disorders or congenital malformations, can be defined as "structural or functional anomalies that occur during intrauterine life and can be identified prenatally, at birth, or later in life." Congenital anomalies may be genetic, infectious, nutritional or environmental in origin, but most often it is difficult to identify the exact cause. Reference: WHO. Congenital Anomalies Fact sheet, updated April 2015. Geneva, World Health Organization.
- The following should not be considered major congenital anomalies:
  - $\circ$  Club foot
  - Congenital dislocation of the hips
  - Congenital infections
  - $\circ$  Cystic fibrosis
  - Drug exposure
  - Extreme prematurity
  - Fetal alcohol syndrome
  - o Intrauterine growth restriction
  - o Inguinal hernia
  - Limb abnormalities
  - o Patent Ductus Arteriosus
  - Persistent Pulmonary Hypertension (PPHN)
  - Polydactyly
  - Respiratory distress
  - Small size for gestational age
  - o Syndactyly
  - Transient tachypnea of the newborn

### **ITEM 220: Congenital Infection**

Answer **"Yes"** if the infant was diagnosed with one or more of the following congenital infections listed below:

- Toxoplasmosis (Toxoplasma gondii)
- Rubella virus
- Syphilis (Treponema pallidum)
- Cytomegalovirus (CMV)
- Herpes simplex virus (HSV)
- Parvovirus B19
- Zika virus
- Varicella zoster virus
- Human immunodeficiency virus (HIV)

Answer "**No**" if an infant was not diagnosed with a congenital infection on the list above.

Answer "**Unknown**" if the diagnosis of congenital infection is unknown.

### ITEM 22p: Early-Onset Sepsis

Answer "**Yes**" if an infant has clinical signs and/or symptoms of neonatal sepsis (see note below) on Day 1, 2, or 3 from birth where Day 1 is the date of birth AND any <u>one</u> (1) of the following criteria:

- At least one sepsis risk factor, including: invasive group B streptococcal (GBS) infection in a previous baby or maternal GBS colonization/bacteriuria/infection in the current pregnancy, spontaneous preterm labor in an infant ≤ 36 weeks' gestation, maternal intrapartum fever (> 38°C), prolonged rupture of membranes (≥ 18 hours) before delivery, maternal diagnosis of intraamniotic infection or amniotic fluid was foul smelling or purulent
- Positive sepsis laboratory screen including white blood cell count < 5000/mm<sup>3</sup>, absolute neutrophil count < 2000/mm<sup>3</sup>, immature to total ratio of neutrophils ≥ 0.2, or C-reactive protein > 1mg/dL (>10mg/L)
- Radiologic evidence of pneumonia

Answer **"No"** if the infant does not meet the above clinical criteria for early-onset sepsis.

Answer "Unknown" if the diagnosis of early-onset sepsis is unknown.

### NOTES:

Clinical signs and/or symptoms of neonatal sepsis are non-specific, but may include:

- Lethargy
- Temperature instability
- Feeding intolerance
- Irritability
- Glucose intolerance
- Apnea
- Respiratory distress or failure
- Hemodynamic instability
- Hypotension
- Poor perfusion
- Pallor
- Altered consciousness
- Seizure
- Hypotonia
- Abdominal distention
- Vomiting
- Disseminated intravascular coagulation

### ITEM 22q: If Yes, Culture Confirmed

If the answer to Early-Onset Sepsis is "Yes":

Answer **"Yes"** if there is evidence of pathogenic growth in culture from blood, urine, cerebrospinal fluid (CSF), or other tissue sample.

Answer **"No"** if there is not evidence of pathogenic growth in culture from blood, urine, CSF, or other tissue sample.

Answer **"Unknown"** if a blood, urine, cerebrospinal fluid (CSF), or other tissue culture was unable to be obtained.

Answer **"Unknown"** if it is not known if a bacterial pathogen was recovered from a blood, urine, CSF, or other tissue culture.

### ITEM 22r: Late-Onset Sepsis

Answer "**Yes**" if an infant has clinical signs and/or symptoms of neonatal sepsis (see note below) on Day 4 from birth or later where Day 1 is the date of birth AND any <u>one</u> (1) of the following criteria:

- Positive sepsis laboratory screen including white blood cell count < 5000/mm<sup>3</sup>, absolute neutrophil count < 2000/mm<sup>3</sup>, immature to total ratio of neutrophils ≥ 0.2, or C-reactive protein > 1mg/dL (>10mg/L)
- Radiologic evidence of pneumonia

Answer **"No"** if the infant does not meet the above clinical criteria for suspected late-onset sepsis.

Answer "Unknown" if the diagnosis of suspected late-onset sepsis in unknown.

### NOTES:

Clinical signs and/or symptoms of neonatal sepsis are non-specific, but may include:

- Lethargy
- Temperature instability
- Feeding intolerance
- Irritability
- Glucose intolerance
- Apnea
- Respiratory distress or failure
- Hemodynamic instability
- Hypotension
- Poor perfusion
- Pallor
- Altered consciousness
- Seizure
- Hypotonia
- Abdominal distention
- Vomiting
- Disseminated intravascular coagulation

### ITEM 22s: If Yes, Culture Confirmed

If the answer to Late-Onset Sepsis is "Yes":

Answer **"Yes"** if there is evidence of pathogenic growth in culture from blood, urine, cerebrospinal fluid (CSF), or other tissue sample.

Answer "**No**" if there is not evidence of pathogenic growth in culture from blood, urine, CSF, or other tissue sample.

Answer "**Unknown**" if a blood, urine, CSF, or other tissue culture was unable to be obtained.

Answer **"Unknown"** if it is not known if a bacterial pathogen was recovered from a blood, urine, CSF, or other tissue culture.

### ITEM 23: Discharge

### NOTES:

• Discharge refers to the first time that the infant was discharged or transferred from your hospital. Do not change this item based on later dispositions following transfer or readmission.

Answer "**Discharged Home Alive**" if the infant was discharged home from your hospital without ever transferring to another hospital.

Answer "**Absconded/Left Against Medical Advice**" if the infant's family left against medical advice.

Answer "**Died in Hospital**" if the infant died at your hospital prior to being discharged home or transferred.

Answer "**Referred to Another Facility**" if the infant was transferred to another hospital or chronic care facility before going home.

Answer "**Unknown**" if the status of the infant at discharge is unknown and unobtainable from the medical record.

### ITEM 24: Discharge Weight

Enter the **discharge weight** in grams as recorded in the chart or clinical flow sheets on the date of discharge, transfer to another health facility, or death. If the infant's weight was not recorded on the date of discharge and was recorded on the previous day, enter the weight in grams as recorded in the chart or clinical flow sheets from the previous day.

### ITEM 25: If Discharged Alive or Referred, Feeding at Discharge

If the answer to Discharge is "Discharged Home Alive" or "Referred to Another Facility":

Complete this item based on enteral feedings received during the 24-hour period prior to discharge, transfer, or death if the infant was discharged alive or transferred.

Answer "**Human Milk Only**" if the infant was discharged receiving human milk as the only enteral feeding, either by being breastfed and/or by receiving expressed human milk (without fortifier or formula supplementation).

Answer "Formula Only" if the infant was discharged receiving formula milk as the only enteral feeding.

Answer "**Combination**" if the infant was discharged receiving human milk (with or without fortifier), plus formula milk.

Answer "None" if the infant was discharged without any enteral feeding.

Answer **"Unknown"** if feeding is unknown and unobtainable from the medical record.

### NOTES:

- Enteral feedings may be given by any method including breast, bottle, gavage tube, gastrostomy tube, feeding cup, etc.
- Formula milk includes all standard newborn formulas, premature formulas, and special formulas.
- Please answer this question based only on the <u>enteral</u> feedings at discharge. Do not consider parenteral feedings when answering this item. For example, if an infant was discharged on IV TPN as well as human milk, the correct response would be "**Human Milk**" since human milk was the only enteral feeding.

### ITEM 26: If Discharge is Died, Cause of Death

If the answer to Discharge is "Died":

Record the primary cause of death. Only one answer is allowed. The primary cause of death may be determined by a postmortem examination/autopsy or by a clinician following a case review and examination of any tissue sampling, diagnostic and/or laboratory information if available, in that order of preference. This item does not capture secondary and/or contributing causes of death.

### Prematurity

These items apply only if the infant was born preterm (< 37 weeks' gestation).

Answer "**RDS**" if the infant was born preterm (< 37 weeks' gestation), died before the date of Day 28of respiratory failure that was not due to pneumonia or culture-positive sepsis, and the primary cause of death was determined to be respiratory distress syndrome (RDS).

Answer "**NEC**" if the infant was born preterm (< 37 weeks' gestation) and the primary cause of death was necrotizing enterocolitis (NEC).

Answer "**IVH**" if the infant was born preterm (< 37 weeks' gestation) and the primary cause of death was intraventricular hemorrhage (IVH).

Answer "**BPD**" if the infant was born preterm (< 37 weeks' gestation), died on the date of Day 28 or after of respiratory failure that was not due to pneumonia or culture-positive sepsis, and the primary cause of death was determined to be bronchopulmonary dysplasia (BPD).

Answer "**Other**" if the infant was born preterm (< 37 weeks' gestation) and the primary cause of death was some other cause related to prematurity.

### Infection

Answer **"Probable Sepsis**" if the primary cause of death was clinically suspected sepsis without positive culture.

Answer "**Culture-positive Sepsis**" if the primary cause of death was culture-positive sepsis.

Answer "**Culture-positive Meningitis**" if the primary cause of death was culture-positive meningitis.

Answer "Pneumonia" if the primary cause of death was pneumonia.

Answer "Tetanus" if the primary cause of death was tetanus.

Answer "**Other**" if the primary cause of death was some other cause related to infection.

### Intrapartum-Related

Answer **"Hypoxic Ischemic Encephalopathy**" if the primary cause of death was hypoxic ischemic encephalopathy.

Answer "**Meconium Aspiration**" if the primary cause of death was meconium aspiration.

Answer "Birth Injury" if the primary cause of death was birth injury.

Answer "**Other**" if the primary cause of death was some other intrapartumrelated cause.

### **Congenital Anomaly**

Answer "**Cardiac**" if the primary cause of death was a cardiac congenital anomaly or anomalies.

Answer "**Chromosomal**" if the primary cause of death was a chromosomal congenital anomaly or anomalies.

Answer "**Neurological**" if the primary cause of death was a neurological congenital anomaly or anomalies.

Answer "**Abdominal/Pelvic**" if the primary cause of death was an abdominal/pelvic congenital anomaly or anomalies.

Answer "**Respiratory/Airway**" if the primary cause of death was a respiratory/airway congenital anomaly or anomalies.

Answer "**Other**" if the primary cause of death was some other congenital anomaly.

### Hyperbilirubinemia

Answer **"Pathological Jaundice/Bilirubin-induced Neurologic Dysfunction**" if the primary cause of death was pathological jaundice/bilirubininduced neurologic dysfunction.

### Other Cause (Not Listed)

**Answer "Other Cause (Not Listed)"** if the primary cause of death is a cause that is not listed in the categories described above in Primary Cause of Death. List the diagnosis as a free text answer.

### NOTES:

• To be considered the primary cause of death, the answer to the same item under "Final Diagnoses" must be "Yes" where applicable. For example, if the primary cause of death was "RDS" then the answer to 22g, RDS must be "Yes."

### ITEM 27: If Discharge is "Died", Time of Death

Record the time at which the infant died. The time is recorded in the 24-hour clock in the format hour:minute (HH:MM).

# **CHAPTER 3**

## **Data Management System**

## Step 1: Organize a Multidisciplinary Team

Your center should establish a multidisciplinary team to:

- Ensure accurate and complete data submission
- Review and evaluate your center's data on the forms, in the data collection system, and in your center's annual reports
- Promote use of your center's reports across your team

This team will help direct your center's local quality improvement efforts using VON Annual Reports and the Global Health Reports website to target specific clinical practices, to identify opportunities for improvement, and to monitor quality improvement over time. Team members will work together to develop and maintain an internal system for collecting and submitting infant data to VON, as well as a process for regularly sharing and reviewing the data and annual reports with your neonatal team(s).

Each center's core team should include individuals assigned to the following roles. These individuals will communicate with VON about specific aspects of your center's participation as outlined below. An individual may have more than one role at your center.

- Team Leader
- Data Contact(s)
- Report Contact
- VON Services Administrator

A **Team Leader** coordinates the activities associated with Network participation and quality improvement. Responsibilities associated with this role include the following:

- Establishing procedures for data collection and submission, and monitoring their implementation
- Training staff to collect, submit, and correct Network data

- Educating your neonatal unit's team about your center's VON membership and the information and tools available to them
- Encouraging the participation of new and existing staff at your center by sharing reports and findings, and ensuring they have access to VON tools
- Ensuring the staff members at your center have access to the data collection application for data entry.
- Maintaining an up-to-date list of team members' names and email addresses to ensure the appropriate staff have access to VON tools and resources.

The **Data Contact** is the person responsible for collection and submission of all infant data to VON, and will receive all Network correspondence regarding data status, submission, and errors. Depending on the size of your center, the Data Contact may be the person who collects and submits the data or someone who supervises other data management staff. It is recommended that your center assign a Primary Data Contact and an Alternate Data Contact.

The **Report Contact** is responsible for sharing your Network reports with the appropriate team members at your center and for ensuring that the appropriate staff are aware of the reporting tool to monitor real-time data between the annual reporting schedule. This person should be a member of your center's peer review committee and be active in quality improvement activities.

**VON Services Administrator(s)** are responsible for ensuring staff members at your center have access to applicable Vermont Oxford Network tools and web sites by:

- Creating user accounts that staff members at your center use to access VON tools, data, reporting, and educational materials
- Assisting users with password questions
- Periodically reviewing your center's list of users who have been granted access to VON tools and removing access from users who no longer need it

VON Services Administrators are automatically granted access to the VON User Permissions Editing tool and issued a VON Web Services Login. VON recommends that your center identify more than one VON Services Administrator.

When personnel in these roles change or a new team leader is assigned, it is important to notify your Network Account Manager.

In addition to these roles, we encourage you to engage your entire interdisciplinary neonatal team. Team members may include doctors, nurses, respiratory therapists, nutritionists, pharmacists, social workers, and other healthcare professionals involved in neonatal care at your center, as well as parents.

# Step 2: Establish Procedures for Data Security and Patient Privacy

Your center must protect patient privacy and ensure that patient data are secure according to your center's policies and procedures. Patient identifier information should be protected based on applicable laws and center policies. Do not send any patient identifier information, such as name or medical record number, to VON. Do not send any patient information to VON over email.

# Step 3: Establish Procedures for Data Collection, Submission, and Correction

## **Collecting Infant Data**

Vermont Oxford Network recommends collecting data on paper, then entering the data electronically. Keeping paper copies of your data is important to allow for data audits by your center's team. To improve data accuracy, collect data for each infant while the infant is still hospitalized and when procedures are performed or events are observed.

Data in the Network database are organized into individual infant records. Each record includes all the data items on the data collection form. Examples of data items are birth weight, admission temperature, and type of feeding. Each data item is identified by an item number and an item name.

### When Data Items are Unknown

Record data items as "Unknown" only if the answer to an item is truly unknown and cannot be obtained. Do not record items as unknown to indicate temporary or pending values. Leave these items blank until an answer is known.

When data submitted by your center are coded as "Unknown," the Network reports may be incomplete and the value of the reports for quality improvement is diminished. Items should be coded as unknown only when the data are unobtainable.

## Submitting Data to the Network

Electronic data may be entered and submitted using the VON Global Health mobile application.

Data Management is an important component of data accuracy. Although data are finalized on an annual basis, keeping your center's infant records up to date throughout the year will make the annual finalization process easier for your

center. VON will contact the team leader and data contact with further details on the finalization process.

# **Submitting Data Corrections**

All errors must be corrected by your center. Make the corrections using the VON Global Health mobile application and submit the corrected records. Data submissions may include both new and updated records. Corrections will be accepted for records in the current year and the previous birth year.

# Step 4: Train Data Management Staff

Use this manual to train your center's data management staff. Staff members who are involved in data collection, data submission, and quality improvement should understand the following areas:

- Data definitions for each data item
- Procedures for filing and storing forms
- Data security and protection of patient identifier information
- Procedures for collecting, submitting, and correcting data
- Procedures for data management and data finalization
- Use of reports for monitoring and improving patient care

# The Annual Data Submission and Report Cycle

## Introduction

All centers that complete data for infants discharged in that year and fulfill the data finalization requirements will receive an Annual Report, which analyzes center data and provides comparison to all data submitted to the VON Global Neonatal QI Database in that year. Annual Reports are based on the year infants are discharged. Each January 1<sup>st</sup> marks the beginning of a new cycle, which includes data submission for all infants discharged in the calendar year. The events in this annual cycle are listed in the table below.

### The Annual Cycle for Data Submission and Reporting

- 1. Submit data for all infants over the course of the year.
- 2. Correct data as necessary as the year progresses.
- 3. Complete the annual Health Facility Membership Survey at the end of the calendar year, in preparation for the finalization process.
- 4. Finalize data for the Annual Report after confirming that data for all infants discharged from your unit in the calendar year was submitted.
- 5. Use Global Health Reports regularly to review up-to-date information on patient demographics, outcomes, and interventions to support your quality improvement activities throughout the year.

# 1. Submit Data for All Infants

For all infants admitted to your neonatal unit, collect and submit data using the data definitions in this manual.

## 2. Correct Data as Necessary

When data are submitted to the Network, extensive error checking is done to help ensure that the data are complete and correct. Make the corrections using the VON Global Health mobile application and submit the corrected records.

## 3. Complete the Annual Health Facility Membership Survey

As your team prepares for the finalization process each year, the Membership Survey must be completed based on your center characteristics for the current year. Data from the Membership surveys are summarized and reported annually. These reports allow you to compare characteristics and capabilities at your center to other centers in the Network.

The final question in the Annual Membership Survey, sources of data for neonatal unit admissions, confirms your unit's data verification plan. The data verification plan is intended to help establish a method for ensuring all infants discharged from your neonatal unit are included in your database for the current year.

The Annual Membership Survey should be completed at the end of each calendar year, before finalizing data for the annual report.

## 4. Finalize Data for the Annual Report

Data finalization is a key component of the annual data submission and reporting cycle. Your center will receive detailed Data Finalization Guidelines each year to assist with finalizing the year's data.

# 5. Use Global Health Reports for QI

One of the important benefits of membership in Vermont Oxford Network is the feedback you get through the Network's confidential, customized reports. The reports document patient characteristics, treatment practices, morbidity, mortality, and length of stay at your center. They also track performance over time, comparing your center's performance with its performance in previous years, and with that of the VON Global Neonatal QI Database as a whole.

To effectively use the center and VON Global Neonatal QI Database reports for quality improvement, we recommend that you organize a multidisciplinary team to review the data as part of the ongoing quality improvement efforts at your neonatal unit. The reports can be used as the starting point for in-depth analyses of specific clinical practices and patient outcomes at your center, as well as to develop and evaluate quality improvement activities.

We recommend you create an internal plan for how the Report Contact shares the information in the reports with the rest of the multidisciplinary team.

# **Annual Reports**

The Annual Report provides a comprehensive, confidential analysis of your center's individual data and that of the VON Global Neonatal Database as a whole. The graphs and tables allow you to confidentially compare your center's morbidity, mortality, and length of stay to the total VON Global Neonatal Database.

## **Network Database Summaries**

The Network Database Summaries report the results for all eligible infants who were discharged during the year from all VON Global Neonatal QI Database member centers. The reports summarize Database results; there are no institution-specific data included other than a list of participating institution names, cities, and countries.

VERMONT OXFORD NETWORK CORE DATASET DEVELOPED IN PARTNERSHIP WITH AFRICAN NEONATAL ASSOCIATION

Infant Name		N 4 11	Decoud Number	
Infant Name		Medica	Record Number	
				$(HH:MM 24hr clock) \square Unk$
	(DD/MM/YYYY)		3. Date of Discharge or D	eath://(DD/MM/YYYY)
4. Previously Discharged Home: Yes No				
5. Place of Delivery:  Inborn at Same Facility  Other Hospital  Health Center / Clinic  Home  In Transit  Unk G. Mode of Delivery:  Vaginal  Instrument-assisted vaginal  Cesarean section  Unk				
		-		
7. Antenatal Care: None 1 to 3				
8. Maternal Age: years 🗆 Unk	a 🗆 Umli	Tatal I	us Distate	
9. Maternal Obstetric History: Gravid			ve Births 🗌 Unk Total	Living Children 🛛 Unk
<b>10a. Maternal HIV status:</b> Opitive	-			
<b>10b If maternal HIV status is positive, did mother receive anti-retroviral therapy?</b> Yes No Unk				
<b>10c.</b> If maternal HIV status is positive, did infant receive prophylaxis for HIV?				
11. Receipt of Any Antenatal Corticosteroids: Yes No Unk				
12. Gestational Age: weeks				
				assisted reproductive technology  Unk
14. Birth Weight: grams  Unit	15.5		□ Female □ Unk <b>16. M</b>	ultiple Gestation: 🗌 Yes 🔲 No 🗌 Unk
17. Delivery Room Interventions:				
a) Delayed Cord Clamping	□ Yes □ No		d) Intubation	□ Yes □ No □ Unk
b) Face Mask Ventilation	□ Yes □ No		e) Chest Compressions	□ Yes □ No □ Unk
c) CPAP	□ Yes □ No		f) Epinephrine	🗆 Yes 🛛 No 🗆 Unk
18. Apgar Score:	1 minute:	_L Unk	5 minutes: 🗆 Unk	
19. Admission Assessment:				
a) Temperature Within 1 hour	□ Yes □ No		<i>b) If yes,</i> list temperature	Celsius 🗆 Unk
c) Pulse Oximetry Recorded	□ Yes □ No		d) <i>If yes,</i> list saturation	% 🗆 Unk
e) Was admission assessment recorde			n oxygen/respiratory support?	
f) Objective Respiratory Assessment				
g) If yes, list assessment			Andersen 🗆 Other 🗆 Unk	
h) <i>If Downes or Silverman-Andersen,</i> list score (0-10) 🗌 Unk				
20. Primary Reason for Admission (check only one):				
🗆 Prematurity/LBW 🗆 Birth Asphyxia 🗆 Suspected Infection 🗆 Congenital Anomaly 🗆 Jaundice 🗆 Tetanus 🗆 Suspected Need for Surgery				
🗆 Respiratory Distress 🗆 Convulsions 🗆 Hypothermia 🗆 Pallor/Anemia 🗆 Feeding Difficulty 🗆 Risk for Hypoglycemia 🗅 Birth Injury 🗅 Other 🗆 Unk				
21. Interventions Received in the Neo		-		
a) Immediate Kangaroo Care (KMC)			j) Antibiotics	□ Yes □ No □ Unk
b) KMC Initiated After 2hrs	□ Yes □ No		k) Phototherapy	□ Yes □ No □ Unk
c) Oxygen	□ Yes □ No		I) Blood Transfusion	□ Yes □ No □ Unk
d) CPAP	□ Yes □ No		m) Exchange Transfusion	□ Yes □ No □ Unk
e) Mechanical Ventilation	🗆 Yes 🛛 No		n) Anticonvulsant Medication	🗆 Yes 🛛 No 🗌 Unk
f) Methylxanthine Medication	🗆 Yes 🗆 No		<ul> <li>o) Active therapeutic Hypothermi</li> </ul>	
g) Surfactant	🗆 Yes 🛛 No		p) Surgery	🗆 Yes 🛛 No 🗆 Unk
h) ROP examination	🗆 Yes 🛛 No		q) Cranial Ultrasound	🗆 Yes 🔲 No 🗆 Unk
i) <i>If yes,</i> Worst Stage of ROP			r) <i>If yes,</i> Worst Grade of I	VH (0-4): 🗆 Unk
22. Final Diagnoses (answer all questions a through s)				
a) HIE	🗆 Yes 🛛 No		k) Hypoglycemia	🗆 Yes 🛛 No 🗆 Unk
b) Meconium Aspiration	🗆 Yes 🛛 No	🗆 Unk	l) Hyperbilirubinemia	🗆 Yes 🛛 No 🗆 Unk
c) Birth Injury	🗆 Yes 🛛 No	🗆 Unk	m) Anemia	🗆 Yes 🛛 No 🗆 Unk
d) Transient Tachypnea of Newborn	🗆 Yes 🛛 No	🗆 Unk	n) Congenital Anomaly	🗆 Yes 🗆 No 🗆 Unk
e) Pneumonia	🗆 Yes 🛛 No	🗆 Unk	<ul> <li>o) Congenital Infection</li> </ul>	🗆 Yes 🗆 No 🗆 Unk
f) Seizures/Convulsions	🗆 Yes 🛛 No	🗆 Unk	p) Early-onset Sepsis	🗆 Yes 🛛 No 🗆 Unk
g) RDS	🗆 Yes 🗆 No	🗌 Unk	q) <i>If yes,</i> Culture Confirme	ed 🗆 Yes 🗆 No 🗆 Unk
h) NEC	🗆 Yes 🗆 No	🗆 Unk	r) Late-onset Sepsis	🗆 Yes 🗆 No 🗆 Unk
i) Respiratory Support on Day 28	🗆 Yes 🗆 No	🗆 Unk	s) <i>If yes,</i> Culture Confirme	ed 🗆 Yes 🗆 No 🗆 Unk
				or CPAP 🛛 Mechanical Ventilation 🗆 Unk
				al $\Box$ Referred to Another Facility $\Box$ Unk
24. Discharge Weight: grams Unk				
25. If Discharged Alive or Referred, Feeding at Discharge: 🗌 Human Milk Only 🗌 Formula Only 🗌 Combination 🗌 None 🗌 Unk				
26. If Died, Primary Cause of Death (including presumed clinical diagnoses) (check only one):				
Prematurity: □ RDS □ NEC □ IVH □ BPD □ Other				
Infection:  Probable Sepsis  Culture-positive Sepsis  Culture-positive Meningitis  Pneumonia  Tetanus  Other				
Intrapartum-related:  Hypoxic Ischemic Encephalopathy Meconium Aspiration I Birth Injury Other Congenital Anomaly: Cardiac Chromosomal Neurological Abdominal/Pelvic Respiratory/Airway Other				
Hyperbilirubinemia:       Pathologic jaundice / Bilirubin-induced Neurologic dysfunction       Other Cause (Not Listed)				
27. If Died, Time of Death::				



The Vermont Oxford Network Global Health Neonatal Quality Improvement Database is owned and maintained by Vermont Oxford Network, Inc., in Burlington, Vermont. The Vermont Oxford Network Global Health Neonatal Quality Improvement Database data forms and data submitted to Vermont Oxford Network, Inc. are the property of Vermont Oxford Network, Inc.

Institutions and individuals participating in the Vermont Oxford Network Global Health Neonatal Quality Improvement Database may be identified by name in reports or descriptions of the database. Data and summaries of data from the Vermont Oxford Network Global Health Neonatal Quality Improvement Database may be published and distributed at the discretion of Vermont Oxford Network, Inc. Data specific to an individual center will not be publicly released without the center's permission.

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