Revisions for 2019

New Data Items:
- 3. Did infant die within 24 hours of admission
  *if yes, complete highlighted section of form only
- 7. Maternal Age
- 14. Method of Determination (of Gestational Age)
- 29b. if died, time of death

Modified Data Items:
- Maternal Treatments (11a-11e, 11g-11h)- added logic, items necessary only when corresponding answer to 10a-10e and 10g-10h is “yes”
- Gestational Age- response choice change, added “days”
- Feeding at Discharge- response choice change

Retired Data Items:
- Maternal blood type O
- Feedings while in NICU
- Prematurity
- Hypoxic Ischemic Encephalopathy
- Blood Group Incompatibility
- Cranial Ultrasound
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CHAPTER 1

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

About VON Global Neonatal 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 Neonatal Database:
- The first QI database developed uniquely for neonatal units in resource-limited settings
- Utilizes a web-based REDCap database, with an offline data collection feature via REDCap mobile app
- Provides baseline data on patient demographics, care practices and outcomes
- Provides quality of care indicators for the three major causes of newborn mortality: intrapartum-related events, complications of prematurity, and infections
- Provides quality of care indicators for Essential Newborn Care: immediate drying, skin-to-skin care, early initiation of breastfeeding, delayed cord clamping
- 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 Neonatal Database join Vermont Oxford Network’s worldwide community of practice, comprised of over 1,200 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 Neonatal Database is managed and secured by Vermont Oxford Network (VON).
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:**
- Please note that some definitions are 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 1st 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

For technical support regarding use of REDCap, please contact our information technology team:

Tech Support redcap@vtoxford.org

The Vermont Oxford Network Global Neonatal Database is managed by the Vermont Oxford Network Director of Global Health, Danielle Ehret MD, MPH. Dr. Ehret is available to answer quality improvement project questions at your center.

Director of Global Health Danielle Ehret Dehret@vtoxford.org

Eligibility Criteria

The eligibility criteria for the VON Global Neonatal Database are all neonates admitted to a member center neonatal unit.
ITEM 1: Date of Birth
Record the infant’s date of birth in the Gregorian (Western) calendar in the format day-month-year (DD-MM-YYYY).

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, the date of admission may be different than the date of birth.

ITEM 3: Did Infant Die Within 24 hours of Admission
Answer “Yes” if the infant was admitted to your NICU and died within 24 hours.
Answer “No” if the infant was admitted to your NICU and died 24 hours or more following admission.
Answer “No” if the infant did not die during the NICU admission.
Answer “Unknown” if the infant died, but the time between admission and death is unknown and unable to be determined from the medical record and patient history.

ITEM 4a: Place of Delivery
Answer "Inborn L&D" if the infant was delivered at your center in the labor and delivery ward.
Answer "Inborn OPD" if the infant was delivered at your center in the outpatient department.
Answer "Other Hospital" if the infant was delivered outside your center at another facility classified as a hospital. When completing the Network data forms for outborn infants, use all information available from the hospital that transferred the infant to your center as well as from your own hospital.
Answer "Health Center" if the infant was delivered outside your center at another facility classified as a health center. When completing the Network data forms for outborn infants, use all information available from the hospital that transferred the infant to your center as well as from your own hospital.
Answer "Home" if the infant was delivered outside your center within a residential setting.
Answer "Unknown" if the location of the infant's delivery is unknown.
**ITEM 4b: If Transported, From What Facility**
If the infant is outborn and transported from another health facility, enter the name of the facility from which the infant was transported. This item is not applicable if the infant is inborn, born at home, or location of birth is unknown.

**ITEM 5: Mode of Delivery**
Answer "Spontaneous 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 "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).

**ITEM 6: Antenatal Care**
Answer "≥4 visits" if the mother received ≥4 prenatal obstetrical care visits prior to the admission during which birth occurred.
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 "None" if the mother did not receive any prenatal obstetrical care.
Answer "Unknown" if prenatal obstetrical care history is unknown from the medical record and patient history.

**ITEM 7: Maternal Age**
Record the age of the mother in years at the time of birth.
Answer "Unknown" if maternal age is unknown from the medical record and patient history.

**ITEM 8: Maternal Gravida**
Record the total number of times the mother has been pregnant, regardless of the outcome of these pregnancies. The pregnancy resulting in the birth of this infant is included.
ITEM 9: Maternal Parity

ITEM 9a: Previous Live Births
Record the total number of previous pregnancies ending in live birth.

NOTES:
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.”

ITEM 9b: Previous Stillbirths/Abortions
Record the total number of previous pregnancies that ended in stillbirth or abortion.

NOTES:
- Stillbirths can occur antepartum or intrapartum.
- For purposes of international comparison, the World Health Organization defines stillbirths as “third trimester fetal deaths (≥ 1000g or ≥ 28 weeks)”. Stillbirths may be fresh (intact skin) or macerated (skin reddened or sloughing). Stillborn infants do not show any evidence of life (beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles) and do not respond to resuscitation.
- Abortions may be spontaneous or medically induced.

ITEM 10: Maternal History (current pregnancy)

ITEM 10a: Maternal HIV
Answer "Yes" if a diagnosis of maternal HIV was recorded in the maternal or infant medical record.
Answer "No" if maternal HIV was recorded as negative in the maternal or infant medical record.
Answer “Unknown” if a diagnosis of maternal HIV is unable to be ascertained from the medical record or patient history.

ITEM 10b: Maternal Hepatitis B
Answer "Yes" if a diagnosis of maternal Hepatitis B surface antigen (HBsAg) was recorded as positive in the maternal or infant medical record.
Answer "No" if HBsAg was recorded as negative in the maternal or infant medical record.
Answer “Unknown” if determination of HBsAg result is unable to be ascertained from the medical record or patient history.

NOTES:

The World Health Organization recommends routine testing for HBsAg in pregnant women in antenatal clinics in settings with a ≥ 2% or ≥ 5% HBsAg seroprevalence in the general population, with linkage to prevention, care and treatment services.

ITEM 10c: Maternal Syphilis
Answer "Yes" if a diagnosis of maternal syphilis was recorded in the maternal or infant medical record.
Answer "No" if maternal syphilis was recorded as negative in the maternal or infant medical record.
Answer “Unknown” if a diagnosis of maternal syphilis is unable to be ascertained from the medical record or patient history.

NOTES:
The World Health Organization sexually transmitted infections (STI) guideline recommends screening all pregnant women for syphilis during the first antenatal care visit.
- This applies to all settings, including settings with high or low prevalence of syphilis.

Depending on prevalence of syphilis, coverage of syphilis screening and treatment for pregnant women, quality of testing, loss to follow-up of pregnant women, and laboratory capacity, the WHO STI guideline suggests the following screening options:
- Single Rapid syphilis (treponemal) test (RST)
- RST followed by first dose of treatment; followed by lab rapid plasma reagin test (RPR)
- Single on-site RPR
- Off-site laboratory-based strategies: RPR and Treponema pallidum haemagglutination assay (TPHA) / Treponema pallidum particle agglutination assay (TPPA)


ITEM 10d: Maternal Malaria
Answer "Yes" if a diagnosis of maternal malaria was recorded as positive in the maternal or infant medical record.
Answer "No" if maternal malaria was recorded as negative in the maternal or infant medical record.
Answer “Unknown” if a diagnosis of maternal malaria is unable to be ascertained from the medical record or patient history.
**ITEM 10e: Maternal Hypertension**
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 a diagnosis of maternal hypertension is unable to be ascertained from the medical record or patient history.

**NOTES:**
- Eclampsia and pre-eclampsia should be considered forms of pregnancy-induced hypertension.

**ITEM 10f: Maternal 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 a diagnosis of chorioamnionitis is unable to be ascertained from the medical record or patient history.
ITEM 10g: Maternal Preterm Labor

Answer "Yes" if a diagnosis of maternal preterm labor was recorded in the maternal or infant medical record, or by patient history. Preterm labor is defined as spontaneous labor that starts before 37 weeks of pregnancy.

Answer "No" if labor for this pregnancy started at ≥ 37 weeks, as recorded in the maternal or infant medical record, or by patient history.

Answer "No" if labor for this pregnancy was induced at < 37 weeks for a medical indication, as recorded in the maternal or infant medical record, or by patient history.

Answer “Unknown” if a diagnosis of maternal preterm labor is unable to be ascertained from the medical record or patient history.

NOTES:

• The onset of labor prior to 37 weeks of pregnancy may be managed medically, and result in birth after 37 weeks of gestation.
• The answer to item 10g refers specifically to the initial onset of labor in this pregnancy, whether or not labor was continuous until the delivery of this infant.

ITEM 10h: Maternal Blood Type Rh Negative

Answer "Yes" if a diagnosis of maternal blood type Rh negative was recorded in the maternal or infant medical record.

Answer "No" if the maternal blood type is recorded as Rh positive in the maternal or infant medical record.

Answer “Unknown” if a diagnosis of maternal blood type Rh negative is unable to be ascertained from the medical record or patient history.
ITEM 11: Maternal Treatment (during pregnancy/labor)

ITEM 11a: Maternal Highly Active Anti-Retroviral Therapy (HAART)
Answer "Yes" if HAART was administered to the mother during pregnancy at any time prior to delivery.
Answer "No" if HAART was not administered to the mother during pregnancy at any time prior to delivery.
Answer “Unknown” if treatment with HAART is unknown from the medical record and patient history.

ITEM 11b: Maternal Hepatitis B Anti-Viral
Answer "Yes" if tenofovir was administered to the mother during pregnancy prior to delivery.
Answer "No" if tenofovir was not administered to the mother during pregnancy at any time prior to delivery.
Answer “Unknown” if treatment with tenofovir is unknown from the medical record and patient history.

NOTES:
The World Health Organization recommends treatment of Hepatitis B infected pregnant women with tenofovir.

ITEM 11c: Penicillin G for Syphilis Treatment

Answer "Yes" if at least one injection of 2.4 million units of intramuscular benzathine penicillin G was administered to the mother at least 30 days prior to delivery.

Answer "No" if at least one injection of 2.4 million units of intramuscular benzathine penicillin G was not administered to the mother at least 30 days prior to delivery.

Answer “No” if the mother was treated with erythromycin or azithromycin as they do not cross the placental barrier completely and as a result the fetus is not treated.

Answer “Unknown” if treatment with benzathine penicillin G is unknown from the medical record and patient history.

NOTES:
Adequate maternal treatment of syphilis during pregnancy is defined by the World Health Organization as at least one injection of 2.4 million units of intramuscular benzathine penicillin G was administered to the mother at least 30 days prior to delivery.

ITEM 11d: Maternal Anti-Malarial
Answer "Yes" if an anti-malarial was administered to the mother during pregnancy at any time prior to delivery.
Answer "No" if an anti-malarial was not administered to the mother during pregnancy at any time prior to delivery.
Answer “Unknown” if treatment with anti-malarial medication is unknown from the medical record and patient history.

NOTES:
- Receipt of anti-malarial can be for prevention or treatment.

The World Health Organization recommends intermittent preventive treatment in pregnancy (IPTp) with sulfadoxine-pyrimethamine (SP) in all areas with moderate to high malaria transmission in Africa.

As of October 2012, “WHO recommends that this preventive treatment be given to all pregnant women at antenatal care visits starting as soon as possible in the second trimester (i.e. not during the first trimester). Each IPTp-SP dose should be given at least 1 month apart. WHO recommends at least 3 doses during each pregnancy.”


World Health Organization Policy Brief for the Implementation of Intermittent Preventive Treatment of Malaria in Pregnancy using Sulfasocine-Pyrimethamine (IPTp-SP); April 2013 (revised January 2014)

ITEM 11e: Maternal Anti-Hypertensive
Answer "Yes" if an anti-hypertensive was administered to the mother during pregnancy at any time prior to delivery.
Answer "No" if an anti-hypertensive was not administered to the mother during pregnancy at any time prior to delivery.
Answer “Unknown” if treatment with anti-hypertensive medication is unknown from the medical record and patient history.
ITEM 11f: Maternal Antibiotics During Labor
Answer "Yes" if an antibiotic was administered to the mother at any time during labor and delivery.
Answer "No" if an antibiotic was not administered to the mother during labor and delivery.
Answer “Unknown” if treatment with an antibiotic is unknown from the medical record and patient history.

ITEM 11g: Maternal 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 treatment with corticosteroids is unknown from the medical record and patient history.

ITEM 11h: Maternal Rho (D) Immune Globulin
Answer "Yes" if Rho (D) immune globulin was administered to the mother at any time during pregnancy, prior to delivery.
Answer "No" if Rho (D) immune globulin was not administered to the mother at any time during pregnancy, prior to delivery.
Answer “Unknown” if treatment with Rho (D) immune globulin is unknown from the medical record and patient history.
ITEM 12: If Maternal HIV Status is Positive, Did Infant Receive Prophylaxis for HIV?

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 from the infant medical record.

NOTE:
This item applies only to infants born to mothers with positive HIV status, as documented in the medical record.

ITEM 13: Gestational Age

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

- Obstetrical measures based on last menstrual period, obstetrical parameters, and prenatal ultrasound as recorded in the maternal chart.
- NICU care provider’s estimate based on physical criteria, neurologic examination, combined physical and gestational age exam (Ballard or Dubowitz).

ITEM 14: Method of Determination

Record the method used to determine the gestational age of the infant based on the hierarchy in item 13. Only one option is permitted.

Answer "Sure LMP" if the infant’s gestational age was determined from the mother’s LMP and the mother was sure of the date of her LMP.

Answer "Unsure LMP" if the infant's gestational age was determined from the mother’s LMP and the mother was unsure of the date of her LMP.

Answer "Early Ultrasound" if the infant’s gestational age was determined from an ultrasound that occurred in the first trimester (≤ 13 6/7 weeks of gestation).

Answer "Late Ultrasound" if the infant’s gestational age was determined from an ultrasound that occurred in the second or third trimester (≥ 14 weeks of gestation).

Answer "Postnatal Exam" if the infant’s gestational age was determined from a postnatal examination.
ITEM 15: 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 16: Head Circumference at Birth
Enter the head circumference to the nearest tenth of a centimeter as recorded in the chart or clinical flow sheets on the day of birth. If the head circumference is not recorded on the day of birth, record the first head circumference measurement on the following day. If the head circumference is not measured on the day of birth or on the following day, record as unknown.

ITEM 17: Sex
Answer "Male" or "Female".
Answer “Unknown” if sex cannot be determined.

ITEM 18: 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.

Otherwise answer "No".

ITEMS 19-23 Initial Resuscitation

NOTES:
- Initial Resuscitation refers to interventions 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 Initial Resuscitation items should be based on the initial resuscitation provided immediately after birth, regardless of where the resuscitation took place.
ITEM 19: Delivery Attended by a Provider Trained in Helping Babies Breathe / Neonatal Resuscitation

Answer "Yes" if the delivery of the infant was attended by a provider trained in Helping Babies Breathe / neonatal resuscitation.

Answer "No" if the delivery of the infant was not attended by a provider trained in Helping Babies Breathe / neonatal resuscitation.

Answer "Unknown" if, from history and medical record, it is unknown whether the delivery of the infant was attended by a provider trained in Helping Babies Breathe / neonatal resuscitation.

ITEM 20: Received Bag-Mask Ventilation in Delivery Room

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 treatment with bag-mask ventilation is unknown from the medical record and patient history.

ITEM 21: Dried Immediately at Birth

Answer "Yes" if the infant was dried immediately at birth with a clean, dry cloth, blanket or towel.

Answer “No” if the infant was not dried immediately at birth with a clean, dry cloth, blanket or towel.

Answer “No” if the infant was dried at > 1 minute after birth.

Answer “Unknown” if treatment with immediate drying is unknown from the medical record and patient history.
ITEM 22: Placed Skin-to-Skin at Birth

Answer "Yes" if the infant was placed skin-to-skin within 10 minutes following birth.

Answer "Yes" if the infant was placed skin-to-skin immediately, but required subsequent transfer to a resuscitation area for advanced care.

Answer “No” if the infant was not placed skin-to-skin within 10 minutes following birth.

Answer “No” if the infant was not placed skin-to-skin until admission to the newborn unit.

Answer “Unknown” if treatment with skin-to-skin at birth is unknown from the medical record and patient history.

NOTES:

- “Immediate, birth, or very early skin-to-skin” refers to the practice of directly placing the infant prone skin-to-skin on the mother’s or caregiver’s bare abdomen or chest less than 10 minutes post-birth.
- The infant is dried, provided with warmth, stimulated, and if medically necessary, suctioned, while skin-to-skin.
- An infant may be placed skin-to-skin immediately, and assessed as needing transfer to a designated resuscitation area if not responding to the initial steps of warmth, drying, and stimulation.

ITEM 23: Received Delayed Cord Clamping

Answer "Yes" if the umbilical cord was clamped at ≥ 1 minute after birth.

Answer “No” if the umbilical cord was clamped at < 1 minute after birth.

Answer “Unknown” if the time of umbilical cord clamping is unknown from the medical record and patient history.

NOTES:

The World Health Organization defines late or delayed cord clamping as performed after one to three minutes after birth.

ITEM 24: Initiation of Breastfeeding Within 1 Hour of Birth

Answer "Yes" if breastfeeding was initiated < 1 hour after birth.
Answer “No” if breastfeeding was initiated at ≥ 1 hour after birth.
Answer “No” if breastfeeding was never initiated.
Answer “Unknown” if the time of breastfeeding initiation is unknown from the medical record and patient history.

NOTES:

- All mothers should be supported to initiate breastfeeding as soon as possible after birth, within the first hour after delivery.
- Mothers of infants admitted to the neonatal intensive care, or temporarily separated from their infants, may be coached on how to express breast milk soon after birth as a means of initiating, and maintaining lactation.

Ref: Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services. Geneva: World Health Organization; 2017

ITEM 25a: Temperature measured within 1-hour of admission

Answer "Yes" if the infant’s core body temperature was measured and recorded within the first hour after admission to your 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.

NOTES:

- This item applies to the temperature of the infant during the first hour after admission to your 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 your 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 25b: if measured, Temperature
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 first 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 www.vtoxford.org/downloads.
- Use a rectal temperature, or if not available, esophageal temperature, tympanic temperature, or axillary temperature, in that order.

ITEM 26: Major Clinical Diagnoses During Admission to Neonatal Unit
The following items (26a-k) refer to infant diagnoses during the entire neonatal unit admission. Indicate all the following diagnoses that apply, whether or not they were the indication for admission, or treated during the neonatal unit admission.

ITEM 26a: Respiratory Distress
Answer "Yes" if the infant had respiratory distress, defined as the presence of one of the following signs: tachypnea (respiratory rate > 60 breaths/minute), grunting, nasal flaring, or intercostal retractions.

Answer "No" if the infant did not have evidence of respiratory distress.

Answer “Unknown” if the diagnosis of respiratory distress is unknown in this infant.
ITEM 26b: Meconium Aspiration Syndrome

Answer "Yes" if ALL THREE (3) 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 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 or pneumonia requires a positive blood culture obtained within 72 hours of birth.

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.

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 for this infant based on the above criteria.

ITEM 26c: Birth Trauma

Birth Trauma 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, intra-abdominal injuries, lacerations, and tissue injury.

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

Answer “No” if infant was not diagnosed with birth trauma.

Answer “Unknown” if the diagnosis of birth trauma is unknown in this infant.
ITEM 26d: Perinatal Asphyxia

Answer "Yes" if infant was diagnosed with perinatal asphyxia.

Answer “No” if infant was not diagnosed with perinatal asphyxia.

Answer “Unknown” if the diagnosis of perinatal asphyxia is unknown in this infant.

NOTES:

The World Health Organization defines birth asphyxia (perinatal asphyxia) as failure to initiate or sustain breathing at birth.


Severe birth asphyxia is defined as pulse < 100 per minute and falling or steady, respiration absent or gasping, color poor, tone absent; 1-minute Apgar score 0-3.

Mild and moderate birth asphyxia is defined as normal respiration not established within 1-minute, but heart rate 100 or above, some muscle tone present, some response to stimulation; 1-minute Apgar 4-7.

“This category is not to be used for low Apgar score without mention of asphyxia or other respiratory problems.”


ITEM 26e: Seizure

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

Answer “No” if infant was not diagnosed with seizure.

Answer “Unknown” if the diagnosis of seizure is unknown in this infant.
ITEM 26f: Intraventricular Hemorrhage
Answer “Yes” if infant was diagnosed with a periventricular or intraventricular hemorrhage by cranial ultrasound, CT or MRI based on any study using the criteria below:

- 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 “No” if infant had cranial imaging with cranial ultrasound, CT or MRI, and did not have subependymal, intraventricular or intraparenchymal hemorrhage.

Answer “Unknown” if infant did not have cranial imaging, and diagnosis of intraventricular hemorrhage is unknown in this infant.
ITEM 26 g-h: Suspected and Proven Sepsis

NOTES:
Signs and symptoms of neonatal sepsis are often nonspecific, and may include temperature instability, cardiovascular instability or poor perfusion, respiratory distress, cyanosis, apnea, feeding difficulties, lethargy or irritability, hypotonia, seizures, bulging fontanelle, bleeding problems, abdominal distention, hepatomegaly, unexplained jaundice.

ITEM 26g: Suspected Sepsis (Clinical or Culture-Negative Sepsis)
Answer “Yes” if an infant has clinical signs and/or symptoms of neonatal sepsis along with ANY ONE (1) of the following criteria:

1. At least one sepsis risk factor, including: prematurity (<37 weeks gestation), maternal fever (>38 °C) before delivery or during labor, prolonged rupture of membranes (≥18 hours) before delivery, or amniotic fluid was foul smelling or purulent.
2. Positive sepsis laboratory screen including white blood cell count <5000/mm³, absolute neutrophil count <2000/mm³, immature to total ratio of neutrophils ≥ 0.2, or C-reactive protein > 1mg/dL
3. Radiologic evidence of pneumonia

And

Specimens of blood, urine, CSF or other tissues do not have any evidence of pathogenic growth in culture, or are unable to be obtained.

Answer “No” if the infant does not meet the above criteria for suspected sepsis.

Answer “Unknown” if the diagnosis of suspected sepsis is unknown in this infant.

ITEM 26h: Proven Sepsis
Answer "Yes" if an infant has clinical signs and/or symptoms of neonatal sepsis and there is evidence of pathogenic growth in culture from blood, urine, CSF or other tissue sample.

Answer "Yes" if an infant has clinical signs and/or symptoms of neonatal sepsis and there is pathological evidence of sepsis on autopsy.

Answer "No" if the infant does not meet the above criteria for proven sepsis.

Answer “Unknown” if the diagnosis of proven sepsis is unknown in this infant.
ITEM 26i: 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 in this infant.

ITEM 26j: Congenital Malformation

Answer "Yes" if the infant had one or more major congenital malformations 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 an infant was not diagnosed with a major congenital malformation that is considered lethal or life threatening.

Answer “Unknown” if the diagnosis of major congenital malformation is unknown in this infant.

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.

ITEM 26k: Congenital Infection
Answer "Yes" if infant was diagnosed with an infection on the Congenital Infection List acquired in utero or during birth (see below).
Answer “No” if infant was not diagnosed with an infection on the Congenital Infection list acquired in utero or during birth.
Answer “Unknown” if the diagnosis of congenital infection is unknown in this infant.

Congenital Infection, Organism(s)
If Congenital Infection is answered “Yes”, select all the organisms from the Congenital Infections List that apply to this infant. This data item is not applicable if Congenital Infection is answered “No”.

<table>
<thead>
<tr>
<th>Congenital Infection List:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Toxoplasmosis</td>
</tr>
<tr>
<td>• Rubella</td>
</tr>
<tr>
<td>• Syphilis <em>(Treponema pallidum)</em></td>
</tr>
<tr>
<td>• Cytomegalovirus (CMV)</td>
</tr>
<tr>
<td>• Human Immunodeficiency Virus (HIV)</td>
</tr>
<tr>
<td>• Zika virus</td>
</tr>
<tr>
<td>• Malaria <em>(Plasmodium falciparum and vivax)</em></td>
</tr>
<tr>
<td>• Parvovirus B19 (fifth disease)</td>
</tr>
<tr>
<td>• Herpes simplex virus (HSV)</td>
</tr>
<tr>
<td>• Varicella zoster virus (chicken pox)</td>
</tr>
</tbody>
</table>

ITEM 27: Interventions

ITEM 27a: Vitamin K
Answer “Yes” if infant received vitamin K IM after birth.
Answer “No” if infant did not receive vitamin K IM after birth.
Answer “Unknown” if treatment with vitamin K after birth is unknown and unable to be ascertained from medical record.
ITEM 27b: Eye Prophylaxis
Answer “Yes” if infant received eye prophylaxis (drops or ointment) after birth.
Answer “No” if infant did not receive eye prophylaxis after birth.
Answer “Unknown” if eye prophylaxis after birth is unknown and unable to be ascertained from medical record.

ITEM 27c: BCG Vaccine
Answer “Yes” if infant received BCG vaccine after birth.
Answer “No” if infant did not receive BCG vaccine after birth.
Answer “Unknown” if BCG vaccination status is unknown and unable to be ascertained from medical record.

ITEM 27d: Oral Polio Vaccine (OPV)
Answer “Yes” if infant received oral polio vaccine after birth.
Answer “No” if infant did not receive oral polio vaccine after birth.
Answer “Unknown” if oral polio vaccination status is unknown and unable to be ascertained from medical record.

ITEM 27e: Kangaroo Care or Kangaroo Mother Care (KMC)
Answer "Yes" if infant was treated with kangaroo care (intermittent or continuous) during NICU admission.
Answer "No" if infant was not treated with kangaroo care (intermittent or continuous) during NICU admission.
Answer “Unknown” if treatment with kangaroo care is unknown in this infant.

ITEM 27f: Blood Transfusion
Answer “Yes” if infant received a transfusion with red blood cells.
Answer “No” if infant did not receive a transfusion with red blood cells.
Answer “No” if infant did not receive a transfusion with red blood cells, 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 is unknown and unable to be ascertained from medical record.
ITEM 27g: Exchange Transfusion
Answer “Yes” if infant received an exchange transfusion with red blood cells.
Answer “No” if infant did not receive an exchange transfusion with red blood cells.
Answer “Unknown” if exchange transfusion status is unknown and unable to be ascertained from medical record.

ITEM 27h: Phototherapy
Answer “Yes” if infant was treated with phototherapy.
Answer “No” if infant was not treated with phototherapy.
Answer “Unknown” if treatment with phototherapy is unknown and unable to be ascertained from medical record.

ITEM 27i: IV or IM Antibiotics
Answer “Yes” if infant received treatment with IV or IM antibiotics.
Answer “No” if infant did not receive treatment with IV or IM antibiotics.
Answer “No” if infant received antibiotics, but all doses were administered via oral route.
Answer “Unknown” if treatment with IV or IM antibiotics is unknown and unable to be ascertained from medical record.

ITEM 27j: Oxygen
Answer "Yes" if the infant received any supplemental oxygen in the delivery room during the initial resuscitation or at any time during the neonatal unit admission.
Answer "No" if the infant did not receive supplemental oxygen in the delivery room or during the neonatal unit admission.
Answer “Unknown” if treatment with oxygen is unknown, and is unable to be ascertained from the medical record.

NOTES:
• 21% oxygen is room air. This is not considered supplemental oxygen, no matter how administered.
ITEM 27k: Nasal CPAP
Answer "Yes" if the infant was given continuous positive airway pressure (CPAP) applied through the nose in the delivery room during the initial resuscitation or at any time during the neonatal unit admission.
Answer "No" if the infant was never given continuous positive airway pressure applied through the nose.
Answer “Unknown” if treatment with Nasal CPAP is unknown, and unable to be ascertained from the medical record.

NOTES:
- CPAP administered through a face mask covering the nose without the administration of intermittent breaths is considered nasal CPAP for the purpose of this definition.
- Nasal IMV (intermittent mandatory ventilation) and nasal SIMV (synchronized intermittent mandatory ventilation) are both considered forms of nasal CPAP for the purpose of this definition.
- Nasal cannula and high flow nasal cannula oxygen are not considered nasal CPAP for the purpose of this definition.

ITEM 27l: 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.
Answer "No" if the infant was never mechanically ventilated through an endotracheal tube after leaving the delivery room/initial resuscitation area.
Answer “Unknown” if the treatment with mechanical ventilation through an endotracheal tube is unknown, and unable to be ascertained from the medical record.

NOTES:
- Intermittent positive pressure ventilation (Nasal IMV) via nasal prongs is not considered conventional mechanical ventilation.
- Synchronized intermittent positive pressure ventilation (SIMV) via nasal prongs is not considered conventional mechanical ventilation.
ITEM 27m: Surgery
Answer "Yes" if infant was treated with surgery.
Answer "No" if the infant was not treated with surgery.
Answer “Unknown” if treatment with surgery is unknown and unable to be ascertained from medical record.

ITEM 27n: Anticonvulsants
Answer “Yes” if infant was treated with anticonvulsants.
Answer “No” if infant was not treated with anticonvulsants.
Answer “Unknown” if treatment with anticonvulsants is unknown and unable to be ascertained from medical record.

ITEM 28a: Discharge
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 "Home" if the infant was discharged home from your hospital without ever transferring to another hospital.
Answer "Died" if the infant died at your hospital prior to being discharged home or transferred.
Answer "Transported" if the infant was transferred to another hospital or chronic care facility before going home.

ITEM 28b: If Transported, to What Facility
If the infant is transported to another health facility, enter the name of the facility to which the infant was transported. This item is not applicable if the infant dies or is discharged to home.
ITEM 28c: If Died, Cause of Death

Record the primary cause of death. Only one answer is allowed.

Answer "Prematurity" if the infant was born preterm (< 37 weeks gestation) and the primary cause of death was due to complications related to prematurity.

Answer "Infection" if the primary cause of death was overwhelming infection.

Answer "Intrapartum-related/Asphyxia" if the primary cause of death was an intrapartum-related cause (perinatal asphyxia or birth trauma).

Answer "Congenital Malformation" if the infant had a lethal or life-threatening congenital malformation, and the primary cause of death was the congenital malformation.

Answer "Other" if the primary cause of death was not complications of prematurity, infection, intrapartum-related/asphyxia, or congenital malformation.

- Enter the primary cause of death for this infant.

ITEM 29a: Date of Discharge or Death

Record the date on which the infant died, was discharged to home, or was transferred to another health facility. The date is recorded in the Gregorian (Western) calendar in the format day-month-year (DD-MM-YYYY).

ITEM 29b: Time of Death

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

ITEM 30: Discharge Weight

Enter the weight in grams as recorded in the chart or clinical flow sheets on the date of discharge to home, 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 31: Feeding at Discharge

Complete this item based on enteral feedings received during the 24 hour period prior to discharge, transfer, or death.

Answer "Human Milk" 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).

Answer "Fortified Human Milk" if the infant was discharged receiving fortified human milk as the only enteral feeding, either by being breastfed and supplemented with bottles of fortified human milk, or by receiving expressed human milk with fortifier.

Answer "Formula" 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.

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 enteral 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.
CHAPTER 3

Data Collection Form

The Global Neonatal Database has a customized one-page data collection form. This tool may be used in paper format to record and verify data prior to electronic entry.

For infants that die within 24 hours of admission to the NICU, data entry is limited to the items highlighted. These indicators are aligned with the World Health Organization’s recommended minimum set of perinatal indicators to collect for all births and perinatal deaths.


When the record is entered electronically into REDCap, a unique Record ID is assigned. It is important to document this REDCap Record ID at the bottom of the one-page paper data collection form.
Vermont Oxford Network (VON) Global Neonatal Database

**Name:**

**Medical Record/Card Number:**

1. **Date of Birth:** __/__/____  
   **2. Date of Admission:** __/__/____ (DD/MM/YYYY)

3. **Did infant die within 24 hours of admission:** Yes ☐ No ☐ Unk ☐  
   *If yes, complete highlighted sections only*

4a. **Place of Delivery:** Inborn L&D ☐ Inborn OPD ☐ Other Hospital ☐ Health Center ☐ Home ☐ Unk

4b. **If transported, from what facility:**

5. **Mode of Delivery:** Spontaneous Vaginal ☐ Assisted Vaginal ☐ Cesarean Section ☐

6. **Antenatal Care:** 2-4 visits ☐ 1-2 visits ☐ None ☐ Unk

7. **Maternal Age:** __years ☐ Unk

8. **Maternal Gravida:** __  
   **Maternal Parity:** Previous live births ☐ Previous stillbirths/abortion(s) ☐

10. **Maternal History (current pregnancy):**  
11. **Maternal Treatment (during pregnancy/labor):**

   a) **HIV** ☐ Yes ☐ No ☐ Unk
   b) **Hepatitis B** ☐ Yes ☐ No ☐ Unk
   c) **Syphilis** ☐ Yes ☐ No ☐ Unk
   d) **Malaria** ☐ Yes ☐ No ☐ Unk
   e) **Hypertension** ☐ Yes ☐ No ☐ Unk
   f) **Chorioamnionitis** ☐ Yes ☐ No ☐ Unk
   g) **Preterm labor** ☐ Yes ☐ No ☐ Unk
   h) **Blood type Rh negative** ☐ Yes ☐ No ☐ Unk
   i) **If 10a is yes, HAART** ☐ Yes ☐ No ☐ Unk
   j) **If 10b is yes, Hepatitis B anti-viral** ☐ Yes ☐ No ☐ Unk
   k) **If 10c is yes, Penicillin G for syphilis** ☐ Yes ☐ No ☐ Unk
   l) **If 10d is yes, Anti-malarial** ☐ Yes ☐ No ☐ Unk
   m) **If 10e is yes, Anti-hypertensive** ☐ Yes ☐ No ☐ Unk
   n) **If 10f is yes, Antibiotics during labor** ☐ Yes ☐ No ☐ Unk
   o) **If 10g is yes, Antenatal Corticosteroids** ☐ Yes ☐ No ☐ Unk

12. **If maternal HIV status is positive, did infant receive prophylaxis for HIV?** Yes ☐ No ☐ Unk

13. **Gestational Age:** ___ weeks ___ days

14. **Method of Determination:** Sure LMP ☐ Unsure LMP ☐ Early Ultrasound ☐ Late Ultrasound ☐ Postnatal Exam

15. **Birth weight:** __ grams

16. **Head Circumference:** __ cm

17. **Sex:** Male ☐ Female ☐ Unk

18. **Multiple Gestations:** Yes ☐ No ☐ Unk

19. **Delivery attended by provider trained in HBB/antenatal resuscitation?** Yes ☐ No ☐ Unk

20. **Received bag-mask ventilation in delivery room?** Yes ☐ No ☐ Unk

21. **Dried immediately at birth:** Yes ☐ No ☐ Unk

22. **Placed skin-to-skin at birth:** Yes ☐ No ☐ Unk

23. **Received delayed cord clamping:** Yes ☐ No ☐ Unk

24. **Initiation of breastfeeding within 1-hr of birth:** Yes ☐ No ☐ Unk

25a. **Temperature measured within 1-hr of admission:** Yes ☐ No ☐ Unk

25b. **If measured, ___ °Celsius

26. **Major clinical diagnoses during admission to neonatal unit:**

   a) **Respiratory Distress** ☐ Yes ☐ No ☐ Unk
   b) **Meconium Aspiration** ☐ Yes ☐ No ☐ Unk
   c) **Birth Trauma** ☐ Yes ☐ No ☐ Unk
   d) **Perinatal Asphyxia** ☐ Yes ☐ No ☐ Unk
   e) **Seizure** ☐ Yes ☐ No ☐ Unk
   f) **Intraventricular Hemorrhage** ☐ Yes ☐ No ☐ Unk
   g) **Suspected Sepsis** ☐ Yes ☐ No ☐ Unk
   h) **Proven Sepsis** ☐ Yes ☐ No ☐ Unk
   i) **Hyperbilirubinemia** ☐ Yes ☐ No ☐ Unk
   j) **Congenital Malformation** ☐ Yes ☐ No ☐ Unk
   k) **Congenital Infection** ☐ Yes ☐ No ☐ Unk
   l) **Toxoplasmosis** ☐ Yes ☐ No ☐ Unk
   m) **Rubella** ☐ Yes ☐ No ☐ Unk
   n) **Syphilis** ☐ Yes ☐ No ☐ Unk
   o) **HIV, Zika** ☐ Yes ☐ No ☐ Unk
   p) **Malaria** ☐ Yes ☐ No ☐ Unk
   q) **Parvovirus B19** ☐ Yes ☐ No ☐ Unk
   r) **Herpes Simplex** ☐ Yes ☐ No ☐ Unk
   s) **Varicella Zoster** ☐ Yes ☐ No ☐ Unk

27. **Interventions:**

   a) **Vitamin K** ☐ Yes ☐ No ☐ Unk
   b) **Eye prophylaxis** ☐ Yes ☐ No ☐ Unk
   c) **BCG vaccine** ☐ Yes ☐ No ☐ Unk
   d) **Polio Vaccine** ☐ Yes ☐ No ☐ Unk
   e) **Kangaroo Care** ☐ Yes ☐ No ☐ Unk
   f) **Blood transfusion** ☐ Yes ☐ No ☐ Unk
   g) **Exchange transfusion** ☐ Yes ☐ No ☐ Unk
   h) **Phototherapy** ☐ Yes ☐ No ☐ Unk
   i) **IV or IM antibiotics** ☐ Yes ☐ No ☐ Unk
   j) **Oxygen** ☐ Yes ☐ No ☐ Unk
   k) **Ventilation** ☐ Yes ☐ No ☐ Unk
   l) **Mechanical ventilation** ☐ Yes ☐ No ☐ Unk
   m) **Surgery** ☐ Yes ☐ No ☐ Unk
   n) **Anticonvulsants** ☐ Yes ☐ No ☐ Unk

28a. **Discharge:** Home ☐ Died ☐ Transferred

28b. **If transported, to what facility:**

28c. **If died, cause of death (check only one):**

   a) **Prematurity** ☐ Infection ☐ Intrapartum-related/Asphyxia ☐ Congenital Malformation ☐ Other
   b) **Date of Discharge or Death:** __/__/____ (DD/MM/YYYY)

29a. **If died, time of death:** __:__ (HH:MM 24hr clock)

30. **Diaphragm weights:** __ grams

31. **Feeding at Discharge:** Human Milk ☐ Fortified Human Milk ☐ Formula ☐ Combination

☐ Completed form entered electronically  
**REDCap ID:**

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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 REDCap 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 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

A Team Leader should be identified to coordinate 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 REDCap mobile application, if applicable, for data entry.

• Maintaining an up-to-date list of team members' names and email addresses to ensure the appropriate staff have access to the REDCap database for your center

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 actually 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 at your center receives published Network reports. This person should be a member of your center’s peer review committee and be active in quality improvement activities. S/he will be 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 REDCap statistics and reporting tool to monitor real-time data between the annual reporting schedule.

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 in order 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, and 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 REDCap web-based application at https://redcap.vtoxford.org or via the REDCap mobile application. See Chapters 5 and 6 for specific instructions on data submission.

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 REDCap and submit the corrected records to Vermont Oxford Network. Data submissions may include both new and updated records. Corrections will be accepted for records in the current 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
CHAPTER 5

Introduction to REDCap (Research Electronic Data Capture)

REDCap is the web-based platform utilized by the VON Global Neonatal Database for data entry and submission. The REDCap database is maintained and secured on the Vermont Oxford Network server.

Each member center will appoint a team leader. The email address of the team leader will be provided to VON. The team leader is responsible for supplying VON with the names and email addresses of their team members, including data contacts and report contacts. VON will create REDCap usernames for all team members provided by the team leader that require access to REDCap. All team members will then be granted access to REDCap for data entry and editing, data submission, and reporting/statistics for their center.

Gaining Access
The team member names and email addresses supplied to Vermont Oxford Network by the team leader will be assigned unique REDCap usernames.

Each team member will then receive two personal emails from DEhret@vtoxford.org.

The first email is to notify that access has been granted to REDCap. The subject line will be “REDCap access granted”. The body of the email will read: “A REDCap account has been created for you in which your REDCap username is ‘______’. Click the link below to set your new password and log in.”

The second email is to notify that access to the project has been granted. The subject line will be “REDCap project access granted”. This body of this email will read: “You have been given access to the REDCap project named ‘VON Global Neonatal Database’. Using your username ‘______’, you may log in to the project using the link below. https://redcap.vtoxford.org/”
Logging On

Users may access the VON Global Neonatal database by entering their username and password at:  https://redcap.vtoxford.org/

NOTE:
The first time users log in, they will be prompted to set up a password recovery question.  This step is very important in the event that a password is forgotten in the future.  By successfully answering this question, a link will be sent to the email listed for the account to reset the password.
Accessing Database

Once a user is logged on to REDCap, there will be a number of tabs visible at the top of the screen. Click the tab for “My Projects”. The project “VON Global Neonatal Database” will be listed. Click here.

Once you enter the project, you should see either the Project Home or Project Setup page. The left-hand column has numerous options.
Entering Data

On the left-hand column, click “Add/Edit Records” under the Data Collection heading. The screen below with the VON Global Neonatal Database will be shown. Click on “Add new record”.

An electronic format of the one-page paper data collection form is then shown. REDCap automatically assigns each new record a “Record ID”. This is available at the top of the electronic data collection form.

NOTE:

It is important to document the REDCap Record ID at the bottom of the one-page paper data collection form.

• This Record ID is the key to link the electronic record to the infant’s name and card number, which is not stored in the REDCap database.

• The Record ID may be needed in the future to complete, edit or verify information, or for quality improvement activities at your center.
Scroll down as you enter all data items on the corresponding one-page paper data collection form.

If the data for the record is complete and does not need further verification, answer the final question as “Complete” and click “Save Record”. This record is now saved under “Complete Records” for your center. There is not a separate step for data submission as each record is entered in real-time to the REDCap database for your center with continuous internet access. To verify that your record has been saved, click on “Add/Edit Records” on the left-hand column, and then “Select Record” next to “Complete Records” to verify that your Record ID is listed.

It is ideal to enter completed and verified data collection forms, and save them as complete. However, if additional information is needed, or information needs verification, answer the final question with “Incomplete” and click “Save Record”. This record is now saved accordingly, under “Incomplete Records”. To edit and complete these records at a later date, see below.
Editing Records

To edit a previously entered record, again click on the “Add/Edit Records” on the left hand column. Click on the dropdown tab “Select Record” to locate the record of interest. Select the Record ID to edit, located under one of three categories, incomplete, unverified or complete records. Any record entered is able to be edited, whether originally saved as complete, or incomplete.

The Record ID must be known to make edits. Following creation of an electronic record, REDCap automatically assigns a Record ID. This should be documented at the bottom of the corresponding one-page paper data collection form.
After the record has been edited and is complete, answer the final question as “Complete” and click “Save Record”. This record is now saved under “Complete Records” for your center.
Reports and Stats

To view real-time reports and stats for all records entered for your center in the current year, click on “Data Exports, Reports, and Stats” on the left-hand column, under Applications.

This application allows users to easily view reports of data, and inspect plots and descriptive statistics of the center’s data. To view the center’s real-time report, click “View Report”. To view the center’s real-time stats and charts, click “Stats & Charts”.

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Reports will list all of the center’s records entered for that year, in a table format.
Stats & Charts will display the aggregated data that has been entered for each variable or data item at your center for the current year. Viewing options for this data include plots (bar chart) and/or stats (table) for each data item. The table will list the total count (N) and percentage of records that have this data item missing. “Unique” refers to the number of different responses that have been selected for this data item. An example is shown below for the data item “Place of Delivery.”
DISPLAY OPTIONS
Optional: Select a record to overlay onto the plots below
This option will highlight the answers for each data item for an individual record, by displaying the answer in yellow-orange, with the remainder of the records for the center represented in blue.
NOTE:
In addition to the real-time reports and statistics available in REDCap for your center, the report contact will receive an Annual Report from Vermont Oxford Network. The Annual Report will display a summary of all infants discharged from your center in that year. For more information on Reporting, refer to Chapter 8.
CHAPTER 6

REDCap Mobile Application

Introduction

The REDCap mobile app is an app that can be installed on a tablet or mobile device so that data may then be collected in an offline fashion on that device, after which it may then be synced back to the project on the server. The app is useful when there is limited or intermittent internet access. Once the mobile project is set up on the device, the user can collect data (which is stored locally on the device), and then sync that data to the REDCap server when there is internet access.

In order to enter data on the REDCap mobile app, a user must first have a REDCap username and REDCap mobile app privileges. All members of the VON Global Neonatal Database will be granted privileges for installing the REDCap mobile app and access to the project’s mobile data collection form for the purpose of offline data collection.

Setting up REDCap Mobile App

Step 1: Download the app on your device
You must first download the REDCap mobile app on your iOS or Android device. You can search the App Store or Google Play Store for ‘REDCap’ on your mobile device to find the app there to download. The app is available for the following platforms: iOS 6.0 or later (iPhone 4 and up, iPad 2 and up) and Android 4.3 or later (phones and tablets).

Once the app is downloaded, you will be prompted to click Agree to the End-User License Terms for the “REDCap Mobile App”.

Step 2: Create Admin and Data Collector
These two roles are specific to your device, and must be created simultaneously. The admin role is linked to a specific REDCap username. An admin cannot enter data, however can add multiple data collectors. For an admin to enter data, a data collector role must be created. It is suggested that the admin create the first data collector role for themselves.

The Admin for the selected device must create a 6-digit PIN. The Admin must also create the first data collector account at this time. A username and 6-digit PIN must be entered.
Step 3: Set Up Mobile Project
This step requires simultaneous use of a mobile device or tablet, and to be logged in to an existing REDCap account on the computer. All REDCap usernames created by VON have REDCap Mobile App privileges.

To set up this project in the REDCap app, log in to your account at https://redcap.vtoxford.org. On the left-hand column, click “REDCap Mobile App”. Then open the app on your mobile device or tablet, and click the “Set Up Mobile Project” button.

There are two ways to set up the project: “Scan QR code” or “Alternative Method”, which utilizes an initialization code.

You will be prompted to select this choice from your mobile device or tablet.
To use the QR code, click “Scan QR code” and then hold your mobile device in front of the code displayed on your computer screen. The camera on your device will automatically scan this code. To use the alternative method to set up the project, click “Can’t get the QR code to work?” under the QR code on the computer screen. A new box will pop up with the title “Alternative method to set up project” with a 10-digit initialization code. Type this code into your mobile device or tablet.

After the QR scan or initialization code is successful, you may log-off the computer. The remainder of the set-up steps are directed solely from the mobile device or tablet. Next, you will be prompted to “Initialize a Project”.
On your mobile device or tablet, click on “VON Global Neonatal Database”. The screen will then display the title “Setting Up Project”, with four options listed below:

- Download All 11 Records
- Download by Form Status
- Get a Partial Set of Data
- Do NOT Download Records

Recommended

For the purpose of solely entering new records without downloading previously entered records from your center, select “Do NOT download Records”.

To have a complete set of records saved to the mobile app, select “Download All __ Records”. This is recommended as the numerical Record IDs automatically assigned by REDCap will start at one on the mobile app if no other records are saved locally.

For more information on editing records on the mobile app, refer to the section on editing data.
Entering Data

To enter new records on the mobile app, select “Collect Data”.

You will be prompted to select an instrument. The only option listed will be “VON Global Neonatal Database”. Select this option.

You will then view the following page:

Select “Create New Record”.

The VON Global Neonatal Database Data Collection Form will then appear on your device. The fields on this form match the online form, as well as the one-page paper data collection form. Scroll down as all fields are entered. Then click “Save Record”.

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If the data is complete and does not need further verification, answer the final question as “Complete” and click “Save Record”. This record is now saved under “Complete Records” for your center.

It is ideal to enter completed and verified data collection forms, and save them as complete. However, if additional information is needed, or information needs verification, answer the final question with “Incomplete” and click “Save Record”. This record is now saved accordingly, under “Incomplete Records”. To edit and complete these records at a later date, see below.

NOTES:

- If the option under “Setting Up Project” is selected as “Do NOT download Records”, the first Record ID will automatically be labeled as “1”, and count numerically upward during data collection as there are no other records stored on the device.
- At the time of data submission, the Record IDs on the mobile device will be compared to Record IDs already saved in the REDCap database for your center. If there is a conflict in duplicate Record IDs, they will be reassigned following data submission.
- The screen shown below will be seen with the number of records affected, and their corrected name.

For more information, see section on Record Reassignment.
In this example, Record 1 is “affected” as this number already exists in the REDCap database for the center. The record submitted from this mobile device has been renamed to Record 12. Record 12 should be the ID recorded on the bottom of the paper data collection form.

**NOTE:**

It is important to document the REDCap Record ID at the bottom of the one-page paper data collection form.

- This record ID is the key to link the electronic record to the infant’s name and card number, which is not stored in the REDCap database.
- The Record ID may be needed in the future to complete or verify information, or for quality improvement activities at your center.

**It is important to verify if the Record ID has changed following data submission with the mobile app, and record the final Record ID on the paper form.**
Editing Data

To edit a previously entered record, again select “Collect Data”, and then select the instrument “VON Global Neonatal Database”.

Below the option to “Create New Record”, you will see a list of all the previously entered records. Each record has the Record ID visible, along with a color scheme. Green dots are for complete records, yellow dots for unverified records, and red dots for incomplete records. Select the Record ID to edit. Any record entered in the current year is able to be edited, whether originally saved as complete, incomplete, or unverified. If the record of interest is not listed, see the section below on re-syncing the device.

The Record ID must be known to make edits. Following creation of an electronic record, REDCap automatically assigns a Record ID. This should be documented at the bottom of the corresponding one-page paper data collection form.

After the record has been edited and is complete, answer the final question as “Complete” and click “Save Record”. This record is now saved under “Complete Records” for your center.

Re-syncing device under “Setting Up Project”
If the Record ID of interest to be edited is not listed, it is not currently saved locally on the mobile device or tablet. To re-sync the device with all existing records for your center, select “Check for Other Records on the Server”. This option will check if there are records on the server that aren’t on the mobile device.
A second option is to “Refresh Setup & Data” on your mobile device or tablet. Choosing this option will not affect any data on the server or database. This option will delete the current local copy of the project data and configurations in the app, and then install a new current version. To choose this option, select “Refresh Setup & Data”, then “Proceed”.

*Note- Do not proceed with this option if you have new records saved on your device that are not uploaded to the database yet. They will be deleted. Please see section on Emergency Data Dump under submitting data.

This option will return the user to the choices of downloading existing records for the center to the local device to allow for editing and viewing.

The top option “Download All ___ Records” will download all the previously submitted center’s records to the device. The second option “Download by Form Status” allows to sort by complete, incomplete, and unverified prior to download. The third option “Get a Partial Set of Data” allows to choose by Record ID.

### Submitting Data

Data collection on the mobile device or tablet does not require internet access. Prior to data submission, all records are only saved locally to that specific device. To submit records to the REDCap database for your center, internet access is required. The type of internet required (WIFI, Ethernet/cable, phone/modem, etc.) depends on the capabilities of your device.

When internet access has been established, and you are ready to submit data, select “Send Data to Server”.
After selecting “Send Data to Server”, there will be two options for sending data:

“Begin Send of All Data” will submit all data saved to your mobile device or tablet to the REDCap database for your center.

“Select a Partial Set of Records” will only submit new and modified records saved to your mobile device or tablet to the REDCap database for your center.

Following successful submission of your records, you will see a confirmation screen with “Done! Data and files sent to server successfully” in green.
Record Reassignment

If there are additional records on the REDCap database for your center that are not saved locally to your device, Record IDs that are autonumbered may need to be reassigned following data submission.

For example, if there are no existing records saved to the mobile device, data collection will begin autonumbering with the first Record ID automatically labeled as “1”. The app will then count numerically upward during data collection as there are no previous or existing records stored on the device.

At the time of data submission, the Record IDs on the mobile device will be compared to Record IDs already saved in the REDCap database for your center. If there is a conflict in duplicate Record IDs, they will be reassigned following data submission.

The screens shown below will be seen with the number of records affected, and their corrected name or Record ID. In this example, Record 1 is renamed to Record 12.

To continue data collection without refreshing, select “Back to Project”.

If you would like to update locally saved data to resync with all existing records for your center saved on the database, or edit existing records that are not currently saved locally to your device, select “Refresh Setup & Data”. This will return you to the original setup options. See “Resyncing Device” on page 60 of this manual.
Emergency Data Dump

If your team has had difficulties with uploading files through the normal process in the app as described previously, tech support or your Network Account Manager may advise that you send an **Emergency Data Dump**. An emergency data dump will not delete any records already existing on your device. However, the file is sent in a different manner.

Sending one’s data to the server might rarely fail due to software or internet limitations. Because the data is so important, this alternate mechanism sends data to the server as a CSV file that VON can review manually. It should only be used in emergencies, and it requires the internet to function properly. The CSV files will show up under the REDCap Mobile App icon on the toolbar and under the Mobile App File Archive tab on the web-version of REDCap.

If directed to send an **Emergency Data Dump** through the mobile app, this option is found on the main menu page of the mobile app once you have entered the **VON Global Neonatal Database** instrument.
Once you click, “Send Emergency Data Dump”, the three options for sending records will be:

- All Records
- New/Modified Only
- Select records manually

Recommended

Your Account Manager or Tech Support will advise you on the file to send. If you select “All Records”, REDCap will compare the file you send to records already uploaded to your database. Only new/modified records will be uploaded. This is the easiest and safest option to ensuring that all records saved to the device are incorporated to your center’s database.

Once your record selection for uploading has been made, Click “Proceed with Emergency Send”

Following successful upload, a confirmation message will appear: “File upload. The document has been successfully uploaded to REDCap.” Your Account Manager or Tech Support will have further instructions for you to incorporate this file into your center’s database.
CHAPTER 7

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 Database in that year. Annual Reports are based on the year infants are discharged. Each January 1st 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.

<table>
<thead>
<tr>
<th>The Annual Cycle for Data Submission and Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Complete the annual Membership Survey at the beginning of the calendar year, before submitting data for the new year.</td>
</tr>
<tr>
<td>2. Submit data for all infants over the course of the year.</td>
</tr>
<tr>
<td>3. Correct data as necessary as the year progresses.</td>
</tr>
<tr>
<td>4. Finalize data for the Annual Report after confirming that data for all infants discharged from your unit in the calendar year was submitted.</td>
</tr>
<tr>
<td>5. Use REDCap regularly to review up-to-date information on patient demographics, outcomes, and interventions to support your quality improvement activities throughout the year.</td>
</tr>
</tbody>
</table>
1. Complete the Annual Membership Survey

At the beginning of each year, the Membership Survey must be completed based on your center characteristics for the current year. The Membership Survey is available for completion in REDCap at https://redcap.vtoxford.org

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 start of each calendar year, before data is submitted on infants for that year.

2. Submit Data for All Infants

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

3. 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. Chapters 5 and 6 describes the process for data correction in REDCap. Follow the guidelines in Chapters 5 and 6 to make corrections and ensure that all data are complete and correct.

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 the Network Reports for Quality Improvement

The Network reports provide a wealth of information that can be used by your center to improve the quality of care. The REDCap reporting and statistics features provide up-to-date information on patient demographics, outcomes, and interventions. See Chapter 8 for more details about reports.
CHAPTER 8
Using Center and Network Reports for Quality Improvement

Introduction

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 Database as a whole.

To effectively use the center and VON Global Neonatal 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 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.