NVPO Definitions Project
DATA COLLECTION v1.0 (June 28, 2018)
RESPIRATORY DISTRES (RDS)

ADMINISTRATIVE INFORMATION

Initials of person performing the review: __ __

Outcome code: **RDS**

Country code: **US, AU, UK:** __ __

Site code: **BC, CC, EM, UW, MO, SG, SU:** __ __

Origin code **CT=clinical trial** **MR= medical record:** __ __

Subject ID number **RDS** _____ _____ _____ _____
Country **Site** **Origin** **Number (starting with 01)**

Which ICD-9/ICD-10/MEDDRA code was used to identify the chart as a case of RDS:
(obtain this information from the case identification log): _____

COMMON VARIABLES

1. **If case from clinical trial (tick and list study drug/vaccine):**
   - ☐ **Vaccine ____**
   - ☐ **Drug _____**
   - ☐ **Epidemiologic _____**
   - ☐ **Other _____**

2. **Year of event:** _____ (full year)

3. General pregnancy variables

a. Maternal Age (whole years) at time of delivery

_____ (number if uknown fill UNK)

b. **Race (**tick one, please tick other and state UNK, if unknown/uncertain)

- ☐ Black
- ☐ White
- ☐ Asian
- ☐ Other ____

c. **Ethnicity (**tick one, please tick other and state UNK if unknown/uncertain)

d.
- ☐ Hispanic
- ☐ Not Hispanic
- ☐ Native Population
- ☐ Other _____

e. **Infant gender (**tick one, please tick other and state UNK if unknown/uncertain)

- ☐ Male
- ☐ Female
- ☐ Other _____

f. Mode of delivery (tick one, please tick other and state UNK if unknown/uncertain)

- ☐ Vaginal
- ☐ C-section:
- ☐ Other: _____

g. Singleton pregnancy (tick one, please tick other and state UNK, if unknown/uncertain)

- ☐ Yes
- ☐ No
- ☐ Other: _____

h. **Parity (fill 1-4 each with full number based on the status at start of this pregnancy). Gravidity is defined as the number of times that a woman has been pregnant and parity is defined as the number of times that she has given birth to a fetus, regardless of whether the child was born alive or was stillborn**

(fill what you see in chart, if absent state UNK)

Gravidity/Parity reported G…. P…..

1. **Prior** Term Pregnancies_____ (number or fill UNK if unknown)
2. **Prior** Preterm Pregnancies (<37 wk) _____ (number or fill UNK if unknown)
3. Abortions/miscarriage (<20 wk)_____ (number or fill UNK if unknown)
4. Born Alive _____ (number or fill UNK if unknown)

GESTATIONAL AGE ASSESSMENT

4. Recorded gestational age (from chart)

_____ (Number: weeks/days, if absent or unknow state UNK)

5. **How was reported gestational age above assessed (**tick one, and if unknown tick other and state UNK)

- ☐ Antenatal Maternal US
- ☐ LMP
- ☐ Infant Exam,
- ☐ Other (describe) _____

6. **Elements of GA available in the neonatal record (**including copy of maternal/delivery record in the neonatal chart: *only if available in neonatal chart, it is not the intention to find the maternal chart*)**. (**tick one option on each line for a-l)

	Recorded	NOT recorded	Incomplete/ uncertain	Comments/Issues
a. **Intrauterine insemination**	☐	☐	☐	_____
b. **Embryo transfer**	☐	☐	☐	_____
c. **Certain LMP (LMP known)**	☐	☐	☐	_____
d. **Uncertain LMP (LMP not known)**	☐	☐	☐	_____
e. **First trimester US**	☐	☐	☐	_____
f. **Second trimester US**	☐	☐	☐	_____
g. **Third trimester US**	☐	☐	☐	_____
h. **Fundal height (any)**	☐	☐	☐	_____
i. **Fundal height in 2nd trimester**	☐	☐	☐	_____
j. **Maternal physical exam in 1st trimester**	☐	☐	☐	_____
k. **Birth weight**	☐	☐	☐	_____
l. **Newborn GA by physical exam**	☐	☐	☐	_____

7. Assessment of Gestational Age LOC based on GAIA Definition (Use Case Definition Checklist:see appendix 2):

a. Level of certainty ____ (1,2,3,4,5 or UNK: unable to assess)

b. If unable to assign GA LOC, describe the reason(s):

Reason _____

CASE DEFINITION SPECIFIC VARIABLES

8. Recorded infant birth weight (earliest at birth, if unknown fill UNK**)**

_____ (in grams)

9. Recorded Apgar score (if unknown leave empty**)**

a. At 1 min _____ (number 0-10)

b. At 5 min_____ (number 0-10)

c. At 10 min_____ (number 0-10)

10. Was respiratory distress diagnosed within > 10 min to 28 days after birth? (tick one)

- ☐ Yes
- ☐ No
- ☐ **Uncertain/unknown**

11. Infant age at time of first diagnosis of RDS

_____ (number of days, fill UNK if unknown)

12. Type of Respiratory Distress

_____ (list diagnosis, fill UNK if unknown)

13. Intervention to manage Respiratory distress (Eg. blow by oxygen, nasal cannula, face mask, mechanical ventilation, ECMO, other, if unknown fill UNK):

a. Intervention 1 _____

b. Intervention 2 _____

14. Elements of the RESPIRATORY DISTRESS case definition in clinical or study record (please tick one at each line, if unknown or not recorded tick uncertain):

	Parameter	Evidence in Medical Record or Study Manual of procedures/Protocol			
		Yes	No	Uncertain	comments
a.	Newborn 0 to 28 days	☐	☐	☐	
b.	Recorded abnormal respiratory rate (RR) > 10 min after birth and up to 28 days of life	☐	☐	☐	
c.	Recorded Tachypnea (RR ≥ 60 breaths per minute)	☐	☐	☐	
d.	Recorded Bradypnea (RR < 30 breaths per minute)	☐	☐	☐	
e.	Recorded Apnea (no breaths for ≥ 20 seconds)	☐	☐	☐	
f.	"Rapid breathing" "Slow breathing", periods of "no breathing" or " abnormal breathing" reported with no recorded RR	☐	☐	☐	
g.	Recorded clinical symptoms of labored breathing > 10 min after birth and up to 28 days of life	☐	☐	☐	
h.	Nasal flaring	☐	☐	☐	
i.	Noisy respirations (grunting, stridor or wheeze)	☐	☐	☐	
j.	Retractions or increased chest indrawings on respiration (subcostal, intercostal, sternal, suprasternal)	☐	☐	☐	
k.	Central cyanosis (whole body) in room air	☐	☐	☐	
l.	Low Apgar score (< 7 points) at 10 min with respiration score < 2	☐	☐	☐	
m.	Documented Assessment of respiratory Distress > 10 min after birth and up to 28 days of life	☐	☐	☐	
n.	Examination and documentation by qualified, trained, health care provider appropriate for the clinical setting	☐	☐	☐	
o.	Report from non-medical observer (eg. mother, father, community worker), of via standard census mechanisms (eg. Health Surveillance System). Describe.	☐	☐	☐	
p.	Collection of information from records review or billing codes only.	☐	☐	☐	
q.	Not enough information to ascertain case of Respiratory Distress	☐	☐	☐	

QUALITY ASSESSMENT CASE DEFINITION

15. Case abstractor's best assessment of LOC for RESPIRATORY DISTRESS is (Use Case Definition Checklist in appendix 1):

a. Level of certainty ____ (1,2,3,4,5 or UNK: unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason _____

16. PI's assessment of LOC for RESPIRATORY DISTRESS (Use Case Definition Checklist in appendix 1):

a. Level of certainty ____ (1,2,3,4,5 or UNK: unable to assess)

b. If unable to assign LOC, describe the reason(s):

Reason _____

17. Other comments:

_____

Appendix 1: Respiratory Distress
Guide for LOC assignment of RESPIRATORY DISTRESS (Check all that are present)

The term Respiratory Distress in the Neonate refers to a **constellation of clinical findings that support the presence of breathing difficulty in the neonate (0 to 28 days of life**), independent from etiology or severity, and independent from the infant's gestational age or circumstances at the time of delivery. Respiratory distress is distinct from the clinical findings observed during normal transition from intra- to extra- uterine life in all newborns. Different terminology exists in the literature in relation to respiratory distress in the neonate, from a very broad characterization as ''increased work of breathing" or ''dyspnea", to various measurable findings (e.g. respiratory rate), to observing for the presence of clinical findings consistent with difficulty breathing (e.g. expiratory grunting, chest retractions) or with the consequences of poor oxygenation (e.g. central cyanosis), to, in some cases, laboratory findings (e.g. arterial blood gas analysis).

Different terminologies in the literature that refer to the clinical syndrome of Respiratory Distress in the Neonate were identified, including: respiratory distress, difficulty breathing, labored breathing, shortness of breath, increased work of breathing, labored respirations, respiratory insufficiency, respiratory failure, respiratory arrest, respiratory acidosis, respiratory complications, respiratory disease, respiratory illness, and respiratory disorder. The term Respiratory Distress Syndrome is utilized specifically to designate hyaline membrane disease, and it is distinct from the term Respiratory Distress in the Neonate selected for this case definition.

The Brighton Collaboration case definition of respiratory distress in the neonate is based on **clinical observation only**, utilizing auscultation with stethoscope when available. The case definition identifies cases of respiratory distress in the neonate, independently from the cause or the severity of the clinical findings of respiratory distress. **Clinical findings should be persistent beyond the first 10 min of life** (when Apgar scores are collected), **or occur at any time after this transition period and before day of life 28.**

<u>For All Levels of Diagnostic Certainty</u>

Respiratory Distress in the Neonate is a clinical syndrome occurring in Newborns 0 to 28 days of life, characterized by the presence of:

1. Abnormal respiratory rate

□ Measurement of number of breaths per minute consistent with:

□ Tachypnea = respiratory rate of 60 or more breaths per minute

OR

□ Bradypnea = respiratory rate of less than 30 breaths per minute

OR

□ Apnea = cessation of respiratory effort (no breaths) for at least 20 s

AND

□ **2. Clinical symptoms consistent with labored breathing**

Clinical observation of:

□ Nasal flaring (dilatation of alae nasi)

OR

□ Noisy respirations in the form of expiratory grunting, stridor, or wheeze

OR

□ Retractions or increased chest indrawings on respiration (subcostal, intercostal, sternal, suprasternal notch)

OR

□ Central cyanosis (whole body, including lips and tongue) on room air

OR

□ Low Apgar Score (<7 points) at 10 min, with respiration score <2

Diagnostic levels of certainty

Level 1

□ 1. Newborn 0 to 28 days of life

AND

□ 2. Abnormal respiratory rate: Measurement of number of breaths per minute consistent with:

□ Tachypnea = respiratory rate of 60 or more breaths per minute

OR

□ Bradypnea = respiratory rate of less than 30 breaths per minute

OR

□ Apnea = cessation of respiratory effort (no breaths) for at least 20 s

AND

□ 3.Clinical symptoms consistent with labored breathing:

□ Nasal flaring (dilatation of alae nasi)

OR

□ Noisy respirations in the form of expiratory grunting, stridor, or wheeze

OR

□ Retractions or increased chest indrawings on respiration (subcostal, intercostal, sternal, suprasternal notch)

OR

□ Central cyanosis (whole body, including lips and tongue) on room air

OR

□ Low Apgar Score (< 7 points) at 10 min, with respiration score < 2

AND

□ 4. Examination and documentation by qualified, trained, health care provider appropriate for the clinical setting.

Level 2

□ 1. Newborn 0 to 28 days of life

AND

□ 2. Abnormal respiratory rate NOT measured, but reported as

- □ ‘‘rapid breathing”

OR

- □ ‘‘slow breathing”

OR

- □ “having periods of not breathing”

OR

- □ ‘‘abnormal breathing”

AND

□ 3. Clinical symptoms consistent with labored breathing

- □ Nasal flaring (dilatation of alae nasi)

OR

- □ Noisy respirations in the form of expiratory grunting, stridor, or wheeze

OR

- □ Retractions or increased chest indrawings on respiration (subcostal, intercostal, sternal, suprasternal notch) or seesaw respirations

OR

- □ Central cyanosis (whole body, including lips and tongue) on room air

OR

- □ Low Apgar Score (<7 points) at 10 min, with respiration score <2

AND

□ 4. No medical record documentation, but reporting through either a non-medical observer (e.g. mother, father, community worker) or via standard census mechanisms (e.g. Demographic and Health Surveillance System)

OR

□ 4.Collection of information from medical record review or billing codes.

Level 3

No need for a level 3 per working group.

Level 4

□ Not enough information to ascertain case of respiratory distress.

Level 5

□ Not a case of respiratory distress in the neonate.

Appendix 2: Gestational Age Assessment Guide

Definitions of terms used:

Intrauterine insemination (IUI) – A procedure in which a fine catheter is inserted through the cervix into the uterus to deposit a sperm sample directly into the uterus, to achieve fertilization and pregnancy.

Embryo transfer – The procedure in which one or more embryos are placed in the uterus or fallopian tube.

Ultrasound (U/S):

- 1st trimester (≤ 13 6/7 weeks).

- 2nd trimester scan (14 0/7–27 6/7 weeks).

- 3rd trimester (28 0/7 + weeks).

LMP (last menstrual period) – GA is calculated from the first day of the mother's LMP. If LMP and U/S do not correlate, default to U/S GA assessment.

***Certain LMP**: (LMP date + 280 days): Use LMP if within 7 days at ≤ 14 weeks; within 14 days at ≤26 weeks; within 21 days beyond 26 weeks.

***Uncertain LMP – first trimester** (≤13 6/7 weeks by LMP): Use the approximate date of the last menstrual period (LMP) if corroborated by physical exam, or a first trimester ultrasound. If there is a discrepancy of >7 days between the LMP and the first trimester ultrasound, the ultrasound-established dates will take preference over LMP for gestational age dating.

***Uncertain LMP – second trimester** (14 0/7–27 6/7 weeks by LMP): Use the approximate date of the LMP if corroborated by physical exam including fundal height, or a second trimester ultrasound. If there is a discrepancy of >10 days between the LMP and the second trimester ultrasound, the ultrasound-established dates will take preference over LMP for GA dating.

***Uncertain LMP – third trimester** >28 weeks – third trimester ultrasound.

***No LMP date:** If menstrual dates are unknown, the ultrasound established dates will be used for gestational age dating or 2nd trimester fundal height and/or newborn physical examination.

Pregnancy symptoms– nausea, fatigue, tender swollen breasts, frequent urination.

Antenatal Physical Examination– pelvic bimanual examination confirming enlarged uterus.

Newborn Physical Examination– New Ballard Score – physical and neurological assessment.

Fundal Height (FH) in cms

Birth Weight (BW) in grams

GA Levels of Certainty (Check all that are present)

Level 1

□ 1. Certain LMP* or intrauterine insemination (IUI) date or embryo transfer (ET) date with confirmatory 1st trimester scan (< 13 6/7 weeks).

OR

□ 2. 1st trimester scan (< 13 6/7 weeks).

Level 2A

□ 1. Certain LMP* with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks). If LMP and U/S do not correlate, default to U/S GA assessment.

OR

□ 2. Certain LMP* with 1st trimester physical examination.

Level 2B

□ Uncertain LMP with 2nd trimester scan (14 0/7 weeks to 27 6/7 weeks).

Level 3A

□ 1. Certain LMP with 3rd trimester scan – 28 0/7 weeks +.

OR

□ 2. Certain LMP with confirmatory 2nd trimester FH.

OR

□ 3. Certain LMP with birth weight.

OR

□ 4. Uncertain LMP with 1st trimester physical examination.

Level 3B

□ 1. Uncertain LMP with FH.

OR

□ 2. Uncertain LMP with newborn physical assessment.

OR

□ 3. Uncertain LMP with Birth weight.