

b. Race (tick one)

- Black
- White
- Asian
- Other _____

c. Ethnicity (tick one)

- Hispanic
- Not Hispanic
- Native Population
- Other _____

d. Infant gender (tick one)

- Male
- Female

e. Mode of delivery (tick one)

- Vaginal
- C-section:
- Other: _____

f. Singleton pregnancy (tick one)

- Yes
- No

g. Parity (fill 1-4 each with full number)

1. Prior Term Pregnancies _____ (number)
2. Prior Preterm Pregnancies (<37 wk) _____ (number)
3. Abortions/miscarriage (<20 wk) _____ (number)
4. Born Alive _____ (number)

GESTATIONAL AGE ASSESSMENT

4. Recorded gestational age (from chart)

_____ (Number: weeks/days)

5. How was gestational age assessed:

- 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*). (tick one option on each line for a-l)

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

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 U: 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)

_____ (in grams)

9. Recorded Apgar score

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

11. Infant age at time of diagnosis of RDS

_____ (number of days)

12. Type of Respiratory Distress

_____ (list diagnosis)

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

- 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):

Parameter	Evidence in Medical Record or Study Manual of procedures/Protocol			comments
	Yes	No	Uncertain	
a. Newborn 0 to 28 days	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Recorded abnormal respiratory rate (RR) > 10 min after birth and up to 28 days of life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Recorded Tachypnea (RR ≥ 60 breaths per minute)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Recorded Bradypnea (RR < 30 breaths per minute)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Recorded Apnea (no breaths for ≥ 20 seconds)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. “Rapid breathing” “Slow breathing”, periods of “no breathing” or “ abnormal breathing” reported with no recorded RR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. Recorded clinical symptoms of labored breathing > 10 min after birth and up to 28 days of life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h. Nasal flaring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i. Noisy respirations (grunting, stridor or wheeze)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
j. Retractions or increased chest indrawings on respiration (subcostal, intercostal, sternal, suprasternal)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Central cyanosis (whole body) in room air	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
k. Low Apgar score (< 7 points) at 10 min with respiration score < 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
l. Documented Assessment of respiratory Distress > 10 min after birth and up to 28 days of life	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
m. Examination and documentation by qualified, trained, health care provider appropriate for the clinical setting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

n. Report from non-medical observer (eg. mother, father, community worker), of via standard census mechanisms (eg. Health Surveillance System). Describe.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. Collection of information from records review or billing codes only.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. Not enough information to ascertain case of Respiratory Distress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 U: 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 U: 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.**

For All Levels of Diagnostic Certainty

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 ($\leq 13 \frac{6}{7}$ weeks).
- 2nd trimester scan ($14 \frac{0}{7}$ – $27 \frac{6}{7}$ weeks).
- 3rd trimester ($28 \frac{0}{7}$ + 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 ($\leq 13 \frac{6}{7}$ 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 ($14 \frac{0}{7}$ – $27 \frac{6}{7}$ 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 ($\leq 13\ 6/7$ weeks).

OR

- 2. 1st trimester scan ($\leq 13\ 6/7$ 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.