

NVPO Definitions Project
DATA COLLECTION v1.0 (June 28, 2018)
LOW BIRTH WEIGHT (LBW)

ADMINISTRATIVE INFORMATION

Initials of person performing the review: ___

Outcome code: LBW

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 LBW _____
Country Site Origin Number (starting with 01)

Which ICD-9/ICD-10/MEDDRA code was used to identify the chart as a case of LBW:
(from 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 unknown 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	<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 UNK: unable to assess)

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

Reason _____

LBW CASE DEFINITION SPECIFIC VARIABLES

8. Recorded infant birth weight (first reported weight after birth)

_____ (in grams)

9. Elements of the LBW case definition in clinical or study record (please tick each line):

Parameter	Evidence in Medical Record or Study Record			Comments
	Yes*	No	Uncertain /not recorded and not in hospital procedures	
a. Newborn 0 to 28 days	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Birth weight recorded as < 2500 g	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Weight recorded in the first 24 hr of birth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Weight measured in the first 48 hr of life (day 1 or 2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Electronic scale used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Electronic scale graduated to 10 gr	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. Electronic scale calibrated at least once a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h. Electronic scale placed on a level, hard surface	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i. Scale tared to zero gr	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
j. BW assessed as per health care facilities SOP which fulfills: NB weight within 24 hrs of birth + use of electronic scale which is graduated to 10 g + scale is calibrated at least once a year + scale is placed on a level, hard surface + scale tared to 0 grams.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
k. Used spring scale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
l. Electronic or spring scale graduated to at least 50 gr	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
m. Electronic or spring scale is calibrated at least once a year, or more often if moved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
n. Electronic or spring scale is tared to zero gr or 0.00 Kg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
o. BW assessed as per health care facilities SOP which fulfills: NB weight within 24 hrs of birth +	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

use of electronic or spring scale graduated to at least 50 g + scale is calibrated at least once a year + scale tared to 0 gr or 0.00 Kg

P. Used dial or color coded scale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q. Proxy measure of birth weight used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
R. Proxy used was: Chest circumference	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
S. Proxy used was: Foot length	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
T. Proxy used was Mid upper arm circumference	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
U. Proxy used was: Difference between adult weight with and without newborn in arms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*NB if hospital has standard calibration protocol for scales, please assume it was done as per protocol

QUALITY ASSESSMENT CASE DEFINITION

10. Case abstractor's best assessment of LOC for LBW 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 _____

11. PI's assessment of LOC for LBW (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 _____

12. Other comments:

Appendix 1: Low Birth Weight (LBW) Case definition
Guide for LOC assignment for LBW (check all that are present)

‘Low birth weight’ (LBW) has been defined as first weight recorded within hours of birth of <2500 g. Very low birth weight (VLBW) is accepted as <1500 g and extremely low birth weight (ELBW) is <1000 g.

The LBW working group decided to restrict ‘birth weight’ to a weight measured in the first 48 h of life. In the absence of a weight measured within the first 48 h of life, a weight measured during the first week of life, could be classified as an ‘early neonatal weight’ but not ‘birth weight’.

Case definition of low birth weight

Level 1 of diagnostic certainty

- 1. Newborn infant weighed within 24 h of birth AND
- 2. Use electronic scale which is graduated to 10 g AND
- 3. Scale is calibrated at least once a year AND
- 4. Scale placed on level, hard surface AND
- 5. Scale tared to zero grams AND
- 6. Weight recorded as <2500 g

OR

- 6. Birth weight recorded as <2500 g AND
- Birth weight assessed as per health care facility’s standard operating procedure, which fulfills criteria 1 to 5 of LOC1

Level 2 of diagnostic certainty

- 1. Newborn infant weighed within 24 h of birth AND
- 2. Scale (electronic/spring) is graduated to at least 50 g AND
- 3. Scale is calibrated at least once a year, or more often if moved AND
- 4. Scale tared to zero grams or 0.00 kg AND
- 5. Weight recorded as <2500 g

OR

- 5. Birth weight recorded as <2500 g AND
- Birth weight assessed as per health care facility’s standard operating procedure, which fulfills criteria 1 to 4 of LOC2

*Scale used: could be electronic or spring scale, including color coded scale.

Level 3 of diagnostic certainty

- 1. Newborn infant weighed on day 1 or 2 of life (first 48 h of life) AND
- 2. Weight measured using dial/spring/color-coded scale AND
- 3. Weight assessed as <2500 g

Level 4 of diagnostic certainty

- 1. Newborn infant 'weight' assessed on day 1 or 2 of life (first 48 h of life) AND
- 2. Proxy measure of birth weight used AND
- 3. Weight CATEGORY assessed as <2500 g

Proxy measures:

- Newborn foot length
- Chest circumference
- Mid upper arm circumference
- Difference between adult weight with and without newborn in arms

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 cm

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.