

**NVPO Definitions Project  
DATA COLLECTION v0.9 (10FEB2018)  
LOW BIRTH WEIGHT (LBW)**

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**ADMINISTRATIVE INFORMATION**

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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): \_\_\_\_\_

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**COMMON VARIABLES**

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**1. If 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 (years)**

\_\_\_\_\_ (number)

**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)

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**GESTATIONAL AGE ASSESSMENT**

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**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
<b>A. Intrauterine insemination</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>B. Embryo transfer</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>C. Certain LMP (LMP known)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>D. Uncertain LMP (LMP not known)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>E. First trimester US</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>F. Second trimester US</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>G. Third trimester US</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>H. Fundal height (any)</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>i. Fundal height in 2<sup>nd</sup> trimester</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>j. Maternal physical exam in 1<sup>st</sup> trimester</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>k. Birth weight</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
<b>l. Newborn GA by physical exam</b>	<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 \_\_\_\_\_

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**CASE DEFINITION SPECIFIC VARIABLES**

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**8. Recorded infant birth weight (earliest at 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 Manual of procedures /Protocol			Comments
	Yes	No	Uncertain	
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 + 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
P. Used dial or color coded scale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q. Proxy measure of 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"/>

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### QUALITY ASSESSMENT CASE DEFINITION

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**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 U: 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 U: 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 ( $\leq 13\ 6/7$  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  $\leq 14$  weeks; within 14 days at  $\leq 26$  weeks; within 21 days beyond 26 weeks.

**\*Uncertain LMP – first trimester ( $\leq 13\ 6/7$  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 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.