

**NVPO Definitions Project
DATA COLLECTION v0.9 (10FEB2018)
SMALL FOR GESTATIONAL AGE (SGA)**

ADMINISTRATIVE INFORMATION

Initials of person performing the review: __ __

Outcome code: SGA

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 SGA ____ ____ ____ ____
 Country Site Origin Number (starting with 01)

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

COMMON VARIABLES

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)

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) (complete)

_____ (in grams)

9. Recorded weight percentile (complete)

_____ (..th percentile)

10. Recorded birth weight/gestational age assessment (tick one):

- SGA (Small for gestational age)**
- AGA (Appropriate for gestational age)**
- LGA (Large for gestational age)**

11. Was subject diagnosed as SGA? (tick one)

- Yes
- No
- Uncertain

12. Enter name of chart used to assess (please tick and complete)

- _____ **Name of reference chart**
- Reference chart not Available** _____

13. Elements of the LBW case definition in clinical or study record (tick one at each line)

Parameter	Evidence in Medical Record or Study MOP/Protocol			Comments
	Yes	No	Uncertain	
a. Newborn 0 to 28 days	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Recorded birth weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Birth weight recorded as below 10 th percentile for age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Weight recorded in the first 24 hr of birth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Weight measured in the first 48 hrs of life (day 1 or 2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Electronic scale used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. Electronic scale graduated to 10 gr	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h. Electronic scale calibrated at least once a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i. Electronic scale placed on a level, hard surface	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
j. Scale tared to zero gr	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
k. 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"/>	
l. Used spring scale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
m. Electronic or spring scale graduated to at least 50 gr	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
n. 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"/>	
o. Electronic or spring scale is tared to zero gr or 0.00 Kg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
p. 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"/>	

q. Used dial or color coded scale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r. Proxy measure of weight used	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
S.Proxy used was: Chest circumference	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
T. Proxy used was: Foot length	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
U . Proxy used was Mid upper arm circumference	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
v. Proxy used was: Difference between adult weight with and without newborn in arms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
w. . Baby noted to be small but no actual Birth Weight recorded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
x. documentation of actual Birth Weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
y.. documentation of Gestational Age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
z.. documentation of BW/GA assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

QUALITY ASSESSMENT CASE DEFINITION

13. Case abstractor's best assessment of LOC for SGA 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 _____

14. PI's assessment of LOC for SGA (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 _____

15. Other comments:

**Appendix 1:
Small for Gestational Age (SGA)
Guide for LOC assignment for SGA (check all that are present)**

SGA (small for gestational age) definition: weight below 10th percentile for gestational age as assessed against a validated global, regional or local standard. These use a gender specific reference population. A recent meta-analysis identified 26 commonly cited reference charts, which include the 10th percentile cut point to define SGA status. The majority of the available reference populations were from North America (n = 12) with some from Europe (n = 6) and Asia (n = 5), and few from Africa (n = 2) and South America (n = 1). The majority of the charts used LMP dates to define gestational age reported to the nearest week, while some used ultrasound or best obstetric estimate.

Levels of Certainty

Level 1

1. Weight below 10th percentile for gestational age

AND

2. The following used in assessment of weight:

- Newborn weighed within 24 hours of birth
- Weight assessed using a calibrated electronic scale with 10 g resolution

AND

3. The following for assessment of gestational age:

- Certain LMP or IUI or embryo transfer date AND confirmatory ultrasound in first trimester

OR

- First trimester ultrasound

Level 2A

1. Weight below 10th percentile for gestational age

AND

2. The following used in assessment of weight

- Newborn weighed within 24 hours of birth on *any* scale with a ≤ 50 g resolution, tared to zero and calibrated

AND

3. The following for assessment of gestational age:

- Certain LMP with first or second trimester ultrasound

OR

- Certain LMP with first trimester physical exam¹

Level 2B

1. Weight below 10th percentile for gestational age

AND

2. The following used in assessment of weight

- Newborn weighed within 24 hours of birth on *any* scale with a ≤ 50 g resolution, tared to zero and calibrated

AND

3. The following assessment of gestational age

- Uncertain LMP with second trimester ultrasound

Level 3A

1. Weight below 10th percentile for gestational age

AND

2. The following used in assessment of weight

- Infant weighed within the first 48 hours of life
- Newborn weighed on *any* scale with a ≤ 50 g resolution, tared to zero and calibrated

AND

3. The following assessment of gestational age

- Certain LMP with third trimester ultrasound
OR
- Certain LMP with confirmatory 2nd trimester fundal height
OR
- Certain LMP with birthweight
OR
- Uncertain LMP with first trimester physical exam

Level 3B

1. Weight below 10th percentile for gestational age

AND

2. The following used in assessment of weight

- Infant weighed within the first 48 hours of life
- Newborn weight assessed by measuring the difference between an adult holding the infant and the adult being weighed alone on *any* scale

AND

3. The following assessment of gestational age

- Uncertain LMP with fundal height
OR
- Uncertain LMP with newborn physical assessment

OR

- Uncertain LMP with birthweight

Level 4

- Baby noted to be small, but no actual weight
- Baby with GA assessed only by infant examination
- Diagnosis extracted from billing codes or chart, with no documentation of actual BW or GA

Level 5

- No evidence of SGA or a confirmed diagnosis other than SGA.

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.

