NVPO Definitions Project DATA COLLECTION v1.0 June 29, 2018 SMALL FOR GESTATIONAL AGE (SGA)

ADMINISTRATIVE INFORMATION

| Initials of person per | rforming the review: | _ | |
|------------------------|----------------------|----------------|-----------------------------|
| Outcome code: | SGA | | |
| Country code: | US, AU, UK: | | |
| Site code: | BC, CC, EM, UW, MO, | SG, SU: _ | |
| Origin code | CT=clinical trial MI | R= medical re | cord: |
| Subject ID number | SGA Site | Origin | Number (starting with 01) |
| Which ICD-9/ICD-1 | 0/MEDDRA code was us | ed to identify | the chart as a case of SGA: |
| (from case identificat | ion 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

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

G.... P.....

4. Born Alive _____ (number or fill UNK if unknown)

GESTATIONAL AGE ASSESSMENT

4. Recorded gestational age (from chart)

_____ (Number: weeks/days, if absent or unknown 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 2 nd trimester | | | | |
| j. | Maternal physical exam | | | | |
| | in 1 st trimester | | | | |
| k. | Birth weight | | | | |
| ١. | 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 ______

SGA CASE DEFINITION SPECIFIC VARIABLES

8. Recorded infant birth weight (earliest at birth) (complete, if not recorded state UNK)
_____ (in grams)

9. Recorded weight percentile (complete if absent or unknown state UNK)

_____ (..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)

Not recorded/unknown

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

Yes

No

Uncertain/not recorded

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

_____ Name of reference chart

Reference chart not available /unknown

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

| | Parameter | | Evidence in Medical Record or Study Record | | | | |
|----|----------------------------------------------------------------------------------------|------|--------------------------------------------|-------------------------------|----------|--|--|
| | | Yes* | No* | Uncertain/ not recorded | Comments | | |
| a. | Newborn 0 to 28 days | | | | | | |
| b. | Recorded birth weight | | | | | | |
| c. | Birth weight recorded as below 10 th percentile for age | | | | | | |
| d. | Weight recorded in the first 24 hr of birth | | | | | | |
| e. | Weight measured in the first 48 hrs of life (day 1 or 2) | | | | | | |
| f. | Electronic scale used* | | | | | | |
| g. | Electronic scale graduated to 10 gr* | | | | | | |
| h. | Electronic scale calibrated at least once a year* | | | | | | |
| i. | Electronic scale placed on a level, hard surface* | | | | | | |
| j. | Scale tared to zero gr* | | | | | | |
| 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.* | | | | | | |
| Ι. | Used spring scale * | | | | | | |
| m. | Electronic or spring scale graduated to at least 50 gr* | | | | | | |
| n. | Electronic or spring scale is calibrated at least once a year, or more often if moved* | | | | | | |
| 0. | Electronic or spring scale is tared to zero gr or 0.00 Kg* | | | | | | |
| n | BW assessed as per health care facilities SOP | | | | | | |
| р. | 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* | | | | | | |
| | Used dial or color coded scale* | | | | | | |

r. Proxy measure of weight used

s. Proxy used was: Chest circumference

t. Proxy used was: Foot length

u. Proxy used was Mid upper arm circumference

v. Proxy used was: Difference between adult weight

with and without newborn in arms

w. Baby noted to be small but no actual Birth Weight

recorded

x. Documentation of actual Birth Weight

y. Documentation of Gestational Age

z. Documentation of BW/GA assessment

*yes means recorded evidence in chart or because of hospital procedures protocol (for calibration of scales/taring or type of scale), No means evidence of absence.

QUALITY ASSESSMENT CASE DEFINITION

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

a. Level of certainty _____ (1,2A/B,3A/B,4,5 or UNK: unable to assess)

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

Reason _____

15. PI's assessment of LOC for SGA (Use Case Definition Checklist in appendix 1):

- a. Level of certainty _____ (1,2A/B,3A/B,4,5 or UNK: unable to assess)
- b. If unable to assign LOC, describe the reason(s):

Reason _____

16. 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 10^{th} 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

<u>1. Weight below 10th percentile for gestational age</u>

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:

o 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

<u>1. Weight below 10th percentile for gestational age</u>

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

<u>3. The following assessment of gestational age</u>

- 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 (< 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 (<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

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

OR

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

Level 2A

 $\hfill\square$ 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

 \Box 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.