

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 _____

PRE CASE DEFINITION SPECIFIC VARIABLES

8. Recorded infant birth weight (earliest at birth)

_____ (in grams)

9. Was infant diagnosed as preterm (< 37 weeks gestation)?

- Yes
- No
- Uncertain/not recorded

10. Elements of the PRETERM BIRTH case definition in clinical or study record (please tick one at each line)

Parameter	Evidence in Medical Record or Study record			Comment
	Yes	No	Uncertain/ not recorded	
a. Newborn 0 to 28 days	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Birth Weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Gestational Age at birth	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Gestational Age assessed using maternal criteria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Gestational Age assessed using infant evaluation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Newborn physical exam by Ballard	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
G .Newborn physical exam by other method	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

*Yes means evidence recorded, No means evidence of absence

QUALITY ASSESSMENT CASE DEFINITION PRE

11. Case abstractor's best assessment of LOC for PRETERM BIRTH 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 _____

12. PI's assessment of LOC for PRETERM BIRTH (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 _____

13. Other comments:

Appendix 1: Preterm Birth (PRE)
Guide for LOC assignment for Preterm Birth (check all that apply)

A term birth has been defined as between 37 and 42 weeks and used to describe the optimal timing for a good outcome for the mother and baby.

Preterm birth defined as less than 37 completed weeks of gestation encompasses a wide gestational age range with rates varying across countries.

The WHO subcategories of ‘extremely preterm’, ‘very preterm’ and ‘moderate or late preterm’ are recommended to improve comparability of preterm birth data in relation to immunisation.

The World Health Organisation (WHO) defines preterm birth as:

Any birth before 37 completed weeks of gestation, or fewer than 259 days since the first day of the woman’s last menstrual period (LMP).

This is further subdivided on the basis of gestational age (GA):

Extremely preterm (<28 weeks)

Very preterm (28–<32 weeks)

Moderate or late preterm (32–<37 completed weeks of gestation)

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.

