

NVPO Definitions Project
DATA COLLECTION FORM v0.9 15 Feb2018
PRETERM LABOR (PTL)

ADMINISTRATIVE INFORMATION

Initials of person performing the review: __ __

Outcome code: PTL

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 PTL _____
Country Site Origin Number (starting with 01)

Which ICD-9/ICD-10/MEDDRA code was used to identify the chart as a case of PTL: (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 record (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 _____ (1X,2X,3X,4,5 or U: unable to assess)

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

Reason _____

CASE DEFINITION SPECIFIC VARIABLES

8. Elements of the PTL case definition in clinical or study record (tick each line):

| Parameter | Evidence in Medical Record or Study MOP/Protocol | | | Comments |
|---|--|--------------------------|--------------------------|----------|
| | Yes | No | Uncertain | |
| a. Patient is determined to be preterm >20, but <37 weeks) with labor | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| b. on presentation, >4 documented uterine contractions per hour as determined by tocodynamometer | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| c. documented change in length or dilation of cervix by physical examination over a two hour period | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| d. documented change in length or dilation of cervix by transvaginal sonogram over a two hour period | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| e. clinical criteria for documenting cervical change by exam include cervical dilation 2 cm or greater at the internal os or cervical length of 1 cm or less or 50% or greater effacement | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |
| f. documented change in length or dilation of cervix transvaginal ultrasound over a two hour period | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | |

QUALITY ASSESSMENT CASE DEFINITION

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

a. Level of certainty _____ (1,2,3 or U: unable to assess)

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

Reason _____

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

a. Level of certainty _____ (1,2,3 or U: unable to assess)

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

Reason _____

11. Other comments:

PreTerm Labor (PTL)
NVPO Data Abstraction and LOC Assignment Tool
Guide for LOC assignment for PTL (check all that are present)

Preterm Labor is characterized by cervical change in the preterm period with gestational age >20 wks but <37 wks.

Case definition of Preterm Labor

For all LEVELS:

- 1. Pregnancy \geq 20 weeks gestation AND
- 2. Pregnancy < 37 weeks gestation

Level 1 of diagnostic certainty

- 1. on presentation, >4 documented uterine contractions per hour as determined by tocodynamometer AND
- 2. documented change in length or dilation of cervix by physical examination over a two hour period OR
- 2. documented change in length or dilation of cervix by transvaginal sonogram over a two hour period AND
- 3. Clinical criteria for cervical change by examination of cervical dilation 2 cm or greater at the internal os by digital examination OR
- 3. Cervical length of 1 cm or less by digital examination OR
- 3. Cervical effacement 50% or greater by digital examination

Level 2 of diagnostic certainty

- 1. on presentation, >4 documented uterine contractions per hour as determined by tocodynamometer AND
- 2. documented change in length or dilation of cervix by physical examination over a two hour period AND
- 3. Clinical criteria for cervical change by examination of cervical dilation 2 cm or greater at the internal os by digital examination OR
- 3. Cervical length of 1 cm or less by digital examination OR
- 3. Cervical effacement 50% or greater by digital examination

Level 3 of diagnostic certainty

- 1. on presentation, >4 documented uterine contractions per hour as determined by clinical assessment AND
- 2. documented change in cervical examination (change in dilation or effacement) over a two hour period

No Level 4,5 for GAIA definition for PTL

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 ($\leq 13 \frac{6}{7}$ weeks).

OR

2. 1st trimester scan ($\leq 13 \frac{6}{7}$ 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.

