

NVPO Definitions Project
DATA COLLECTION FORM v1.0 June 29, 2018
DYSFUNCTIONAL LABOR (DYS)

ADMINISTRATIVE INFORMATION

Initials of person performing the review: __ __

Outcome code: DYS

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

Which ICD-9/ICD-10/MEDDRA code was used to identify the chart as a case of **DYS**: (from case identification 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 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).** Gravity 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 maternal 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 _____ (1,2,3,4,5 or UNK: unable to assess)

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

Reason _____

DYS CASE DEFINITION SPECIFIC VARIABLES

8. Elements of the dysfunctional labor case definition in clinical or study record:

Parameter	Evidence in Medical Record or Study record			
	Yes	No	Uncertain	Comment
a. Cervical dilation recorded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b. Contraction frequency recorded	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c. Contractions measured by machine?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d. Contractions measured by palpation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e. Time of cervical exams recorded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f. Documentation of membranes ruptured?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g. Parity of woman recorded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

*yes means recorded evidence, No means evidence of absence

QUALITY ASSESSMENT CASE DEFINITION

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

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

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

Reason _____

10. PI's assessment of LOC for DYS first stage of labor is (Use Case Definition Checklist in appendix 1):

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

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

Reason _____

11. Case abstractor's best assessment of LOC for DYS second stage labor is (Use Case Definition Checklist in appendix 1):

c. Level of certainty _____ (1,2 or UNK: unable to assess)

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

Reason _____

12. PI's assessment of LOC for DYS second stage of labor is (Use Case Definition Checklist in appendix 1):

c. Level of certainty _____ (1,2 or UNK: unable to assess)

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

Reason _____

13. Other comments:

Appendix 1: Dysfunctional Labor (DYS) Guide for LOC assignment for DYS

Dysfunctional labor occurs in a woman who is in established labor once cervical dilation stops in the first stage of labor, or absence of adequate descent of the fetus in second stage of labor. The DYS working group decided that parity is a necessary part of the definition, as is stage of labor.

Case definition of Dysfunctional Labor

For all LEVELS:

- 1. Pregnancy \geq 20 weeks gestation AND
- 2. The woman is in established labor defined by regular contractions and cervical dilation of at least 4 cm.

FIRST STAGE OF LABOR (both nulliparous and multiparous)

Level 1 of diagnostic certainty

- 1. Progress of less than 0.5 cm cervical dilation per hour, for at least 4 hr AND
- 2. Confirmed ruptured membranes.

Level 2 of diagnostic certainty

- 1. Progress of less than 0.5 cm cervical dilation per hour, for at least 4 hr WITHOUT confirmed ruptured membranes.

No Level 3-4 for this definition

5= not a case

SECOND STAGE OF LABOR:

Level 1 of diagnostic certainty in Nulliparous women:

- 1. Full dilation of the cervix AND
 - 2. Onset of active stage (active maternal effort, eg pushing, or visible baby) AND
 - 3. Greater than 2 hr of pushing
- OR
- 3. Use of instrument delivery for the indication of dystocia
- OR
- 3. Cesarean Section for the indication of dystocia

Level 1 of diagnostic certainty in Multiparous women:

- 1. Full dilation of the cervix AND
 - 2. Onset of active stage (active maternal effort, eg pushing, or visible baby) AND
 - 3. Greater than 1 hr of pushing
- OR
- 3. Use of instrument delivery for the indication of dystocia

OR

- 3. Cesarean Section for the indication of dystocia

Level 2 of diagnostic certainty in Nulliparous women:

- 1. Full dilation of the cervix in any phase of the second stage AND
- 2. No delivery within 3 hours of full dilation

OR

- 2. Use of instrument delivery for the indication of dystocia

OR

- 2. Cesarean Section for the indication of dystocia

Level 2 of diagnostic certainty in Multiparous women:

- 1. Full dilation of the cervix in any phase of the second stage AND
- 2. No delivery within 3 hours of full dilation

OR

- 2. Use of instrument delivery for the indication of dystocia

OR

- 2. Cesarean Section for the indication of dystocia

No Level 3,4 for this diagnosis

5= not a case

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

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.

