

NVPO Definitions Project  
DATA COLLECTION FORM v0.9 Feb152018  
**DYSFUNCTIONAL LABOR (DYS)**

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**ADMINISTRATIVE INFORMATION**

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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): \_\_\_\_\_

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**COMMON VARIABLES**

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**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)

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**GESTATIONAL AGE ASSESSMENT**

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**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 <sup>nd</sup> trimester	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____
j. Maternal physical exam in 1 <sup>st</sup> 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 DYS case definition in clinical or study record:**

Parameter	Evidence in Medical Record or Study			Comment
	MOP/Protocol			
	Yes	No	Uncertain	
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"/>	

**QUALITY ASSESSMENT CASE DEFINITION**

**8. 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 U: unable to assess)

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

Reason \_\_\_\_\_

**9. 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 U: unable to assess)

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

Reason \_\_\_\_\_

**10. 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 U: unable to assess)

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

Reason \_\_\_\_\_

**11. 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 U: unable to assess)

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

Reason \_\_\_\_\_

**12. 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  $\leq 14$  weeks; within 14 days at  $\leq 26$  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.

