

## CDHSG DATA DICTIONARY Version 5

### Completing the Forms:

1. The website is up-to-date and has the most current version of all forms, data dictionary, and contacts for the CDH Study Group. <https://med.uth.edu/pediatricsurgery/research/research-centers-and-programs/cdhsg/>
2. To complete the electronic form:
  - a. Open the form CDH\_Data\_Form\_V5 in Word.
  - b. Click Save As and save the file as Center Number-Birth Year-Patient number for year; example 00-2021-01.
  - c. Enter the information using the check boxes and text fields. Make sure to include dates when indicated. Please be as complete as possible and feel free to add as much or as little information in the comment section at the end of the main form.
  - d. Make sure to save the document and keep a copy in your records. The CDHSG does not keep copies of data collection forms after entering into the database.
  - e. You may password protect the document by selecting Tools-Options-Security, enter a password (you'll be asked to enter it again), then save the document one last time. The default password for each center will be an 8 digit password CDHSG + 0 + center number. Centers 1-9 will use CDHSG + 00 + center number. Make note of the password used as there is no way to recover a password-protected file.
  - f. Email the document to [cdhsg@uth.tmc.edu](mailto:cdhsg@uth.tmc.edu). This is the preferred method. If this does not work for you, and you'd prefer to mail a hard copy, please reach out via email to discuss.
3. All emails are deleted and forms are shredded after data entry.

### CDHSG Data Collection Sheet:

#### Note:

**\*\*\*Enter the dates in the format which you commonly use in your country.**

**\*\*\*Enter times as military time (24-hour clock) such that 1:30 PM is 13:30.**

**\*\*\*Enter values in PO<sub>2</sub> and PCO<sub>2</sub> in mm Hg or kilopascal-whichever unit you commonly use in your country.**

1. Center #: Random center number assigned by CDHSG Coordinator, usually between 1 and 100
2. Patient #: Number patients consecutively for each year. A patient can then be identified as Year Birth and Patient number, e.g. 2015-01
3. Patient Date of Birth: Date patient was born
4. Time of Birth: Time patient was born
5. Inborn/Outborn: An inborn baby is born in the institution where definitive care for CDH will be provided. An outborn baby is delivered in a separate institution and a transport team is required to bring the baby to the center where definitive care for CDH will be provided. If the infant is born in a separate institution but is managed from birth by the same neonatal/surgical team, and requires only a brief transport to a separate institution, the infant should be considered inborn. We are this differentiating outborn babies as those who initial care is not under the control of the neonatal/surgical team who provides definitive care for CDH.

6. Admission date: Date an outborn patient was admitted-leave blank if infant is inborn
7. Admission time: Time as outborn patient was admitted-leave blank if infant is inborn
8. Sex: M (male)/ F (female)
9. Race: Asian/ Black/ Hispanic/ Native American/ White/ Other (specify). This category is included to help center collate data for granting agencies
10. EGA (at birth): Gestational age at birth in weeks. Ignore “days” such that a baby born at 35 weeks and 6 days is 35 weeks EGA
11. Birthweight (in kilograms)
12. APGAR: record 1 and 5 minute Apgar on a scale of 0-10, if an Apgar can be assigned; leave blank if there is/are no Apgar scores
13. Method of deliver:
  - a. Vaginal (Spontaneous)
  - b. Vaginal (Induced-labor requires Pitocin or other agents for initiation)
  - c. C-Section (Elective-planned C-section)
  - d. C-Section (Urgent or Non-Elective-other delivery such as spontaneous or induced vaginal delivery was attempted, or mother/baby presented in distress and required emergent delivery).
14. Prenatal diagnosis of CDH: Was CDH diagnosed before delivery? Yes or No.
  - a. If Yes, provide the gestational age in weeks when the diagnosis was made. (Ignore “days” such that a baby diagnosed at 30 weeks and 6 days is diagnosed at 30 weeks).
15. Were prenatal steroids given? Yes, No, Unknown
16. Was surfactant given (after delivery)? Yes, No, Unknown
17. Was a chromosomal analysis (Karyotype) sent? Yes or No; Result: normal, abnormal, pending, or unknown. Place any comments/results in the “diagnosis made/comment” free text field in the genetic studies section below.
18. Was a chromosomal microarray analysis (CMA) sent? Yes or No; Result: normal, abnormal, pending, or unknown. Place any comments/results in the “diagnosis made/comment” free text field in the genetic studies section below.
19. Were any of the following sequencing tests sent: single gene/panel, whole exome (WES), or whole genome (WGS)? Result: normal, abnormal, variant of uncertain significance (VUS), pending, unknown. Place any comments/results in the “diagnosis made/comment” free text field in the genetic studies section below.
20. Use free text field to comment on diagnosis made (or strongly suspected) or abnormal/VUS results.
21. Other anomalies: Check if any anomalies are noted on exam or evaluations (especially significant would be any anomalies that might complicate the infant’s care such as Omphalocele or other GI anomalies such as TEF, neural tube anomalies, vertebral anomalies, or pulmonary anomalies such as sequestrations). Any anomalies noted here will be included in the database and may help future identification of syndromes, etc that are associated with CDH.
22. Cardiac anomalies: Check all cardiac anomalies noted (if the anomaly is not listed, describe it in the free text field after “Other”
23. Pulmonary hypertension/Cardiac dysfunction (CDH-PH/CD): Record 3 echocardiograms if possible. First echo: earliest echo, ideally after birth/diagnosis/admission. Second echo: ideally closes to pre-op or repair. Last echo: ideally before discharge.

- a. Enter date and time of echocardiogram
  - b. PH: Check the box that most closely describes the presence or absence of pulmonary hypertension noted:
    - i. None
    - ii. Elevated and  $< 2/3$  systemic BP
    - iii. Elevated and between  $2/3$  systemic BP and systemic BP
    - iv.  $>$  systemic BP
    - v. Present but cannot qualify
  - c. PDA:
    - i. L to R: predominantly left to right
    - ii. Bidirectional
    - iii. R to L: predominantly right to left
    - iv. No shunt
  - d. Atrial shunt:
    - i. L to R: predominantly left to right
    - ii. Bidirectional
    - iii. R to L: predominantly right to left
    - iv. No shunt
  - e. Tricuspid regurgitation: peak velocity in m/sec
  - f. Systemic BP at time of exam
  - g. Septal position: Check the box that describes the position of the septal position; normal, flattened, further left deviation (this is subjective and should be determined at the discretion of your cardiologist)
  - h. RV size: normal or dilated (this is subjective and should be determined at the discretion of your cardiologist)
  - i. RV function: normal or impaired (this is subjective and should be determined at the discretion of your cardiologist)
  - j. LV size: below normal, normal, or dilated (this is subjective and should be determined at the discretion of your cardiologist)
  - k. LV function: normal or impaired (this is subjective and should be determined at the discretion of your cardiologist)
  - l. Plasma pro-BNP level in pg/ml and date it was collected (ideal if close to the time of echocardiography)
24. Treatment of pulmonary hypertension: Check all the medications used during the neonatal hospitalizations to treat the pulmonary hypertension. Record date medication started and date medication stopped (if multiple course are required, provide the name of medication and dates using "other" entries or provide details in comments section at end of neonatal form. Leave "date ended" blank if infant is discharged home (or transferred to another center) on that medication.
25. Ventilation: Record date and time of initial intubation
26. Ventilation: Record date of final extubation or check box if infant was never extubated (this will include infants who expire while still intubated as well as infants who are transferred to another center while still intubated or infants who have complications that require a tracheostomy and continued ventilation at home or in a long-term care facility)

27. Enter values for O<sub>2</sub> and CO<sub>2</sub> in the first 24 hours of life:
  - a. Highest pre-ductal PaO<sub>2</sub> in mm HG and /or O<sub>2</sub> sat
  - b. Highest post-ductal PaO<sub>2</sub> in mm Hg and/ or O<sub>2</sub> sat
  - c. Highest PaCO<sub>2</sub> in mm Hg
  - d. Lowest PaCO<sub>2</sub> in mm Hg
28. Extracorporeal Life Support (ECLS), previously known as ECMO data:
  - a. Record date and time infant was first placed on ECLS
  - b. Record date and time infant was taken off ECLS
  - c. Select ECLS mode: VA, VA (+V), VV (DL), VV to VA
  - d. Last ABG (blood gas) prior to initiating ECLS:
    - i. PaO<sub>2</sub> (in mm Hg), check if value is pre-ductal or post-ductal
    - ii. O<sub>2</sub> sat (in %), check if value is pre-ductal or post-ductal
    - iii. PaCO<sub>2</sub> (in mm Hg)
  - e. Was a second run required? If so, check Yes and enter start date and time, end date and time, and ECLS mode
29. Side of Diaphragmatic Hernia: Check left, right, bilateral, or central
30. Repair: if not repaired, check box for not repaired. If repair was done:
  - a. Enter date and time of operative repair of CDH
  - b. Using the diagrams of CDH defects, have the operating surgeon select the diagram that best approximates the size of the defect encountered during surgery: A, B, C, or D. This field is critical (important for staging patients). Please see detailed defect description form on the website or request it by emailing [cdhsg@uth.tmc.edu](mailto:cdhsg@uth.tmc.edu). If you cannot determine the defect (and cannot contact the surgeon for his/her determination), excerpt the portion of the operative note detailing the description of the diaphragmatic defect and paste into the comments section at the end of the neonatal form and the CDHSG will then try and determine the defect description.
  - c. Select type of repair: primary closure (closing defect requires sutures alone) or patch (closing defect requires use of sutures and a patch to close defect) or primary repair with patch overlay (closing defect with sutures alone and adding a patch to overlay the sutured repair for reinforcement)
  - d. If a patch was used to close the defect, select type: PTFE (GoreTex), PTFE/combination patch (GoreTex AND another material such as Alloderm, Dacron, mesh plug, Surgisis), muscle flap, or other (provide details in free text field)
  - e. Was a hernia sac present? Yes or No
  - f. Check if, at surgery, liver was found initially to be in the chest or abdomen
  - g. Check the approach used to repair the diaphragmatic defect: subcostal, thoracic, both (subcostal and thoracic), thoracoscopic, laparoscopic, or other (provide details in free text field)
  - h. Enter the amount of estimated blood loss (EBL) at the time of operation that is listed on the operative note
31. Complication/Other Surgical Procedures: Check all complications that occurred and other surgeries performed during the neonatal hospitalization and enter the dates for each complication or procedure. These are important to capture in the database. If the surgical procedure is not listed (or if multiple procedures were performed), please provide details of the

procedure(s) and dates under “other surgery” or in the comments section at the end of the neonatal sheet.

- a. Bleed requiring reoperation for hemorrhage control: Indicate date surgery occurred and the organ/site of hemorrhage. This could occur on or off ECLS.
32. Outcome if infant expires: Enter date and time of death
33. Outcome if infant survives:
- a. Enter the date at which infant is discharged home or is transferred and provide disposition:
    - i. Discharged home
    - ii. Transferred to another hospital
    - iii. Transferred to long-term care (within same institution)
  - b. Document pulmonary status at 30 days of age (if discharged prior to 30 days, leave blank and fill in status at discharge only)
  - c. Document pulmonary status at time of discharge or transfer
  - d. Document results of other pre-discharge evaluations:
    - i. Cranial exam (head ultrasound, head CT, cranial MRI): normal, abnormal, or not done
  - e. Weight at time of discharge (in kilograms)
  - f. Document feeding at time of discharge: select method by which infant is receiving more than 50% of calories: PO, NG (nasogastric tube), or GT (gastrostomy tube)
  - g. Note date at which infant was on full enteral (no IV) feeds
  - h. Was GER (gastro-esophageal reflux) diagnosed? Yes or No
  - i. Check all discharge medications: a list of these can usually be found in the discharge note in the chart, on the discharge forms given to parents, or in the dictated discharge summary in chart.
34. Additional comments: include any relevant or clarifying information about this infant. Past comments include: details of the pregnancy, summaries of findings at post-mortem, explanations of complications of ECLS or surgical repair, or other aspects that made infant's course unique.

**CDHSG Prenatal Data Collection Section: Ultrasound and/or MRI**

**To be completed only for patients where CDH is diagnosed pre-natally. This form is optional but highly encouraged.**

Maternal Age: Age of mother at time of diagnosis

Gravida: number of total pregnancies

Parity: Number of births to a fetus with a gestational age of 24 weeks or more, regardless of whether the child was born alive or was stillborn

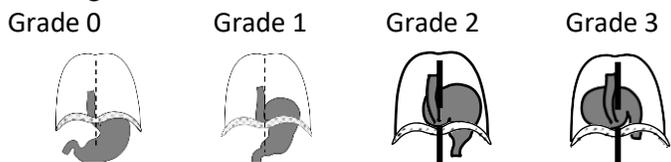
**Prenatal Ultrasound**

**The first ultrasound should be done ideally between 20-24 weeks gestation (and as close to 24 weeks as possible). The second ultrasound (done at 30 weeks gestation, ideally last ultrasound before delivery) can be recorded if done.**

1. Date of ultrasound

2. Gestational age at time of exam in weeks
3. Side of hernia: Left, right, bilateral, central
4. Sign of hydrops (check all that apply): none, skin edema, pleural effusion, pericardial effusion, ascites
5. Liver herniation: Yes or No, if yes estimate:  $<1/3$  thoracic cavity height or  $\geq 1/3$  thoracic cavity height
6. LHR: range 0.5-2.5, and check method used:
  - a. Method A: Lung AP diameter at MCL X perpendicular diameter at midpoint of AP diameter method  $((\text{Length 1} \times \text{Length 2}) / \text{Head circumference})$
  - b. Method B: Lung longest diameter X widest perpendicular diameter method  $((\text{Length 1} \times \text{Length 2}) / \text{Head circumference})$
  - c. Method C: Lung tracing method (Lung area/Head circumference) note: all measurement are on the contralateral lung
7. Observed/ Expected LHR (O/E LHR): range 0-150% (record in percent %). LHR expected may be obtained from a published chart ( *Peralta et al, Ultrasound Obstet Gynecol 2005; 26: 718-724*) or by using [www.perinatology.com/calculators/LHR.htm](http://www.perinatology.com/calculators/LHR.htm)
8. Lung/Thorax Ratio (L/T ratio): range 0-0.5 Lung area/Thorax area. For reference, see *Usui et al, Pediatr Surg Int 2007; 23:971-97*.

9. Grading of Stomach Herniation – Kitano

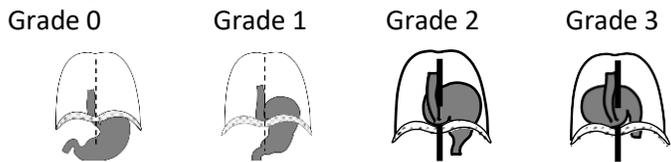


- a. Grade 0: abdominal
  - b. Grade 1: ipsilateral thoracic
  - c. Grade 2: less than half of the stomach herniated into the contralateral chest
  - d. Grade 3: more than half of the stomach herniated into the contralateral chest
10. Stomach Herniation-Cordier Method
- a. Grade 1: stomach not visualized
  - b. Grade 2: stomach visualized anteriorly next to the apex of the heart, with no structures in between stomach and the sternum
  - c. Grade 3: stomach showing abdominal structures anteriorly
  - d. Grade 4: stomach showing abdominal structures anteriorly and stomach has its larger part posterior to the level of the atrial-ventricular heart valves
11. Was fetoscopic endoluminal tracheal occlusion (FETO) performed? If yes, fill in table below.
- a. For each column, balloon in and balloon out, fill in the following:
    - i. Date
    - ii. EGA
    - iii. O/E LHR (0-150%)
    - iv. LHR (0.5-2.5)
    - v. O/E Total fetal lung volume (%)
    - vi. Total fetal lung volume (ml)

- b. The values for each should be the closest date imaging was performed at time of balloon insertion and time of balloon removal. Please list all information available at those time periods.
12. Were any other malformations noted? Yes or No, if yes, provide details in the free text field

**Prenatal MRI**

1. Date performed
2. Gestational age at time of exam in weeks
3. Side of hernia: Left, right, central, bilateral
4. Lung volumes: left lung (in ml), right lung (in ml), total lung volume (left + right in ml)
5. Thoracic volume (in ml)
6. Mediastinal Volume (in ml)
7. Percent Predicted Lung Volume (PPLV) as  $\% = \text{Total Lung Volume} \times 100 / (\text{Thoracic volume} - \text{Mediastinal volume})$
8. O/E lung volume as  $\% = \text{Observed (total lung volume)} \times 100 / \text{Expected lung volume (for gestational age)}$
9. Liver: Estimated percent of liver in chest with 0= all liver in abdomen and 100= all liver in chest
10. Were any other malformation noted? Yes or Not, If yes provide details in free text field
11. Grading of Stomach Herniation – Kitano



- a. Grade 0: abdominal
- b. Grade 1: ipsilateral thoracic
- c. Grade 2: less than half of the stomach herniated into the contralateral chest
- d. Grade 3: more than half of the stomach herniated into the contralateral chest