CONGENITAL DIAPHRAGMATIC HERNIA FORM Version 3

Note: all dates are to be entered as month/day/year (4 digit). May 1, 2006 should be entered as 5/1/2006. All times are to be entered in military time (24-hour clock). 1:30 PM should be entered as 13:30.

1. Year of Birth: (Year baby was born. Birth date of 1/1/2006 would be year 2006)
2. Center #: (Random center number assigned by Pam Lally, between 1 and 100)
3. Patient #: (Number patients consecutively for each year. A patient can then be identified as Year Birth-Center Number- Patient number, e.g. 2006-33-1)
4. Patient Date of Birth: (Date patient was born)
5. Time of Birth: (Time patient was born)
6. 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 thus differentiating outborn babies as those whose initial care is not under the control of the neonatal/surgical team who provides definitive care for CDH.)
7. Admission date: (Date an outborn patient was admitted- leave blank if infant is inborn)
8. Admission time: (Time an outborn patient was admitted- leave blank if infant is inborn)
9. Sex: M (male) / F (female)
10. Race: Black / White / Hispanic / Asian / Native American / Other (specify) (This category is included to help centers collate data for granting agencies)
11. Birthweight: (in kilograms)
12. 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)
13. APGAR (record 1, 5, and 10 minute Apgar on a scale of 0-10, if an Apgar can be assigned; leave blank if there is/are no Apgar scores).
14. CPR in Delivery Room: Was cardio-pulmonary resuscitation (chest compressions and/or medication such as epinephrine, bicarbonate, etc) given in delivery room? Yes or No
15. Method of delivery:
   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). In this case also describe which method of delivery had been planned before emergent C-section was required: Vaginal (Spontaneous), Vaginal (Induced), C-Section (Elective).
16. Prenatal diagnosis of CDH: Was CDH was diagnosed before delivery? Yes or No. 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.)
17. Prenatal steroids given: Were steroids were given at any time before delivery? Yes or No. Enter unknown if you are unsure from the records or if the infant is part of a study and use cannot be determined. If steroids were given, provide the weeks gestation at which each dose was given.
18. Chromosomal anomalies: check if infant has a chromosomal anomaly (such as Trisomy 18, 21, or 13) or a syndrome (such as Fryns)— describe the anomaly (e.g. Trisomy 21, Fryns syndrome)
19. Other anomalies: check if any anomalies are noted on exam or evaluation (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.
20. Cardiac anomalies: check all cardiac anomalies noted (if the anomaly is not listed, describe it in the blank space after “Other:”)

21. Surfactant: Was surfactant given? Yes or No. If yes, note the date and time of initial dose, and the total number of doses administered during the neonatal hospitalization.

22. Pulmonary hypertension - first echocardiogram:
   a. Enter date of first post-natal echocardiogram
   b. 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
   c. Note if ductus is Open or Closed
   d. If ductus is open, note if flow through ductus is from right-to-left (as with suprasystemic pulmonary hypertension), left-to-right (as with no pulmonary hypertension, or pulmonary hypertension that is less than systemic BP), or bidirectional (as with pulmonary hypertension that approximates systemic levels).
   e. Was an atrial shunt (through patent foramen ovale) present? Yes or No
   f. Was tricuspid regurgitation present? Yes or No

23. Pulmonary hypertension - last echocardiogram performed (ideally pre-discharge):
   a. Enter date of last post-natal echocardiogram
   b. 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
   c. Note if ductus is Open or Closed
   d. If ductus is open, note if flow through ductus is from right-to-left (as with suprasystemic pulmonary hypertension), left-to-right (as with no pulmonary hypertension, or pulmonary hypertension that is less than systemic BP), or bidirectional (as with pulmonary hypertension that approximates systemic levels).
   e. Was an atrial shunt (through patent foramen ovale) present? Yes or No
   f. Was tricuspid regurgitation present? Yes or No

24. Treatment of pulmonary hypertension: check all medications used during the neonatal hospitalization to treat the pulmonary hypertension. Record date medication started and date medication stopped (if multiple courses are required, record date of first dose for first course as “date started” and date of last dose for last course as “date ended”). 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 (check box if infant was never extubated- this will include infants who are transferred to another center while still intubated and infants who have complications that require a tracheostomy and continued ventilation at home or in a long-term care facility)

27. Enter values for O₂ and CO₂:
   a. Highest pre-ductal PaO₂ in mm Hg and/or O₂ sat (check box if not available)
   b. Highest post-ductal PaO₂ in mm Hg and/or O₂ sat (check box if not available)
   c. Highest PaCO₂ in mm Hg (check box if not available)
   d. Lowest PaCO₂ in mm Hg (check box if not available)
   e. Highest Lactate in mmol/L in the first 24 hours
   f. Highest Lactate in mmol/L in the first 72 hours

28. Side of Diaphragmatic Hernia: Check Left, Right, or Bilateral/Central

29. If no repair was done:
   a. Check the one category that best describes the infant who was not repaired:
      i. Unable to stabilize
      ii. Felt to be non-survivable
iii. Felt to be survivable, deteriorating condition indicates need for ECMO, but infant not deemed a candidate for ECMO
iv. Felt to be survivable and placed on ECMO, but not repaired
v. Felt to be survivable, placed on ECMO, came off ECMO, but not repaired

b. Within each category, check the one box that best describes the reason the infant was not repaired. If none of the reasons “fits” your infant, describe the reason for non-repair in your own words.

30. If repair was done:

a. Enter date and time operative repair of CDH was begun
b. Using the attached sheet of 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 (or draw defect using “D” if defect description not shown)
c. Select type of repair: primary closure (closing defect requires sutures alone) or patch (closing defect requires use of sutures and a patch)
d. If a patch was used to close the defect, select type: PTFE (GoreTex), Surgisis, mesh plug, Alloderm, or other
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
h. Check how abdomen was closed: primary (sutures closed abdomen with fascia), ventral hernia (abdomen closed with skin only), or use of silo or patch (or other)
i. Was a chest tube placed? Yes or No

31. ECMO data:

a. Record date and time infant was first placed on ECMO
b. Record date and time infant was finally taken off ECMO
c. Select ECMO mode: VA, VA (+V), VV (DL), VV to VA
d. Select the one main reason for starting ECMO: poor oxygenation, poor ventilation, or hemodynamic instability
e. Ventilatory status- (enter all data that is available: for example, some infants may have PaO2 and O2 sat, some may have only O2 sat, etc. Ideally enter data at the time decision is made to put infant on ECMO; if this timing cannot easily be determined from the chart, use data that is available just before infant is placed on ECMO.)
   i. FiO2 (oxygen concentration as %, ranging from 21 to 100)
   ii. PaO2 (in mm Hg), check if value is pre-ductal or post-ductal
   iii. O2 sat (in %), check if value is pre-ductal or post-ductal
   iv. PaCO2 (in mm Hg)
   v. MAP (mean arterial pressure in cm H2O)
   vi. PIP (peak inspiratory pressure in cm H2O)
f. Was a second run was required? If so, check Yes and enter start date and time, end date and time, and ECMO mode

32. Chylothorax:

a. Was a chylothorax diagnosed? If so, check Yes
b. Enter date chylothorax was first diagnosed
c. Check method by which chylothorax was diagnosed (check all that apply): chest x-ray, chest ultrasound, examination of pleural fluid, or other
d. Check feeding intervention (check all that apply):
   i. special feeds (enter date started and describe special feeds)
   ii. TPN (parenteral nutrition: enter date TPN started)
   iii. CT (placement of chest tube: enter date chest tube placed)
   iv. ligation of thoracic duct (enter date surgical ligation was performed)
   v. pleurodesis (enter date)
e. Enter dates where treatment of chylothorax ended:
   i. Enter date where chest x-ray confirmed resolution of chylothorax
   ii. Enter date chest tube (placed for treatment of chylothorax) was removed
   iii. Enter date TPN stopped
33. Check all other surgeries performed during the neonatal hospitalization and enter the dates for each procedure. If the surgical procedure is not listed (or if multiple procedures were performed), please provide details of the procedure(s) and dates in the comments section at the end of the data collection sheet.

34. Outcome if infant expires:
   a. Enter date and time of death.
   b. Select cause(s) of death (check all that apply)

35. Outcome if infant survives:
   a. Enter date at which infant is discharged home or is transferred to another hospital or is transferred to long-term care (within same institution)
   b. Document pulmonary status at 30 days of age
   c. Document pulmonary status at time of discharge or transfer
   d. Document results of other pre-discharge evaluations:
      i. Eye exam: normal, abnormal, or not done
      ii. Cranial exam (head ultrasound, head CT, or cranial MRI): normal, abnormal, or not done
      iii. Hearing evaluation (BAER or other): normal, abnormal, or not done
   e. Discharge weight (in kilograms)
   f. Document feeding at time of discharge: select method by which infant is receiving more than 50% of calories: po, ng (naso-gastric 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. If so, what was the most invasive/sophisticated method of diagnosis, ranging from clinical, to UGI (upper gastro-intestinal series), pH probe, nuclear medicine scan
      ii. If so, how was the GER treated: none (includes modifications such as thickened feeds or elevating head of bed but no specific medications), medical (medications such as prokinetics and antacids), or surgical (fundoplication)
   i. Check all discharge medications: a list of these can usually be found in the discharge note in the chart, on the discharge form given to parents, or in the dictated discharge summary in the chart.

36. Additional comments: include any relevant or clarifying information about this infant. Past comments have included: details of the pregnancy, summaries of findings at port-mortem, explanations of complications of ECMO or surgical repair, or other aspects that made this infant’s course unique.

Completing the forms:
1. The web site is now up-to-date and has the most current version of all the forms (including alternate date formats and kilopascal formats).
2. CDH Data Form V2 Paper and CDH Data Form V3 Paper should be completed by hand and mailed to Kevin Lally at:
   Kevin P. Lally, MD
   Suite 5.258
   6431 Fannin Street
   Houston, TX 77030
3. CDH Data Form V2 Electronic and CDH Data Form V3 Electronic should be completed on a computer and emailed to cdhsg@mindspring.com To complete the electronic form:
   a. Open CDH Data Form V3 Electronic from the web site and click Save As …, give the file a name, and save it as a word document (on your computer).
   b. Enter the information, using drop-down lists where available.
   c. After you are done entering the information, save the document again.
   d. 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 a 3 digit number using the center number (center 9 will use password 009, center 43 will use password 043, etc.). You may also use any password you would like (just be sure to let me know so I can open the files). There is no way to recover a password-protected file if you forget the password, so make sure you make a note of the password.
   e. Email the document to cdhsg@mindspring.com
   f. You may also store the template (which is a .dot file) on your computer and open it as a Word document, then follow steps a-e. If you wish to have the template on your computer send an email request to me at cdhsg@mindspring.com and I will email you the .dot file).
4. A note about “number" formats (if you are using the electronic template):
   a. The template allows 2 number formats: integer (e.g. 1, 55, 99) and real number with 2 decimal places (e.g. 1.00, 99.70, .05).
   b. The following entries are in integer format (and will not allow a decimal entry, so round to the nearest whole number): gestational ages (at birth, for prenatal diagnosis, and for prenatal steroid doses), Apgar scores, number of surfactant doses, all PaO₂ and PaCO₂ values (in mm Hg), O₂ sats and FiO₂ (ranging from 21 to 100), and ventilator measurements (MAP, PIP, PEEP, and CPAP).
   c. Entries that are in real number (decimal) formats include: birth weight (kgs) and discharge weight (kgs), iNO dose (ppm), lactate (mmol/L), and nasal cannula O₂ (liters).
   d. The template also validates dates (in month/day/year format) and times (in military time using 24 hour clock, requiring a colon as in 14:45).