



Patent Ductus Arteriosus (PDA) Observational Study

Manual of Definitions for Infants Born in 2011

Version 1.5

June 15, 2011

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REVISIONS

This 2011 PDA Observational Study Manual of Definitions reflects information gathered from collaboration and an on-going dialogue between our membership and committees. The Data Center would like to thank the PQIP Research Committee, Health Information Solutions, Vermont Oxford Network, Data Center Advisory Group, Data Contacts, doctors, nurses and others who have given us feedback.

We are committed to developing and maintaining the CPQCC Network Database as a perinatal tool for quality improvement. Additionally, we strive to implement systems upgrades that will ease the data collection burden for our Data Contacts.

Updates were released as follows: Version 1.0 (2/1/11)¹, Version 1.1 (2/8/11)², Version 1.2 (2/10/11)³, Version 1.2.1 (2/23/11)⁴, Version 1.3 (3/28/11)⁵, Version 1.4 (6/7/11)⁶, Version 1.5 (6/15/11)⁷.

Study Procedures Clarification:

Section III. ELIGIBILITY⁵, a **VLBW (≤ 1500 gram)** infant that meets **one** of the following six criteria is eligible for the PDA Supplemental Form:

- meets the VON 2011 revised definition of PDA, OR
- was treated with Indomethacin for PDA, OR
- was treated with Ibuprofen for PDA, OR
- underwent a PDA ligation, OR
- had a PDA ascertained via an echocardiographic or clinical diagnosis.
- is an outborn infant that had PDA diagnosed elsewhere⁵

Section IV. PROCEDURES FOR COMPLETING FORMS, 2011 PDA Observational Study Supplemental On-line Form⁵, if an infant is transferred from your NICU to another hospital for treatment and then readmitted back to your hospital, you are **NOT** required to update this form. Centers participating in the PDA Observational Study are only required to document the **initial episode of care at YOUR hospital**.

Section V. PROCEDURES FOR SUBMITTING DATA, www.cpqccdata.org Logic Checks^{4, 5}, we have implemented the following:

- An error check for **Item 39d. PDA Ligation**.⁴ The updated A/D form no longer includes a Not Applicable option for PDA ligation in Item 39d. Under the revised PDA criteria, it is possible for an infant to undergo a PDA ligation without having a PDA diagnosis as defined by the revised 2011 VON PDA criteria.

Any submitted forms for which PDA ligation was submitted as Not Applicable will have to have Item 39d updated. The most efficient way to find all records that need to be updated is to perform an error check for your 2011 data. **As the Not Applicable option is no longer allowed for Item 39d, all records that have currently Not Applicable coded for Item 39d are listed in the Error and Warning Report.**

- We have implemented an updated error checking for the new skip patterns and a consistency check with the A/D form with respect to:⁵

- **A/D Item 39a. Patent Ductus Arteriosus.** A Warning message is displayed if PDA is checked on the A/D form, but the PDA form does not have the necessary checks in Item 6. Diagnosis and Treatment of PDA.
- **A/D Item 39d. PDA Ligation.** A Warning message is displayed if PDA ligation is NOT checked on the A/D form AND the PDA form (PDA Item 14a. PDA Ligation) or vice versa.
- **A/D Item 54. Initial Disposition = Transferred OR Died.** A Warning message is displayed if the baby went home according to the A/D form (fdisp=1) and the user is using the skips in the PDA form for Transferred OR Died.

Note that all of these are **Warnings** so that the submission of the form is still allowed. We cannot assume that the error is on the PDA form since the error might be on the A/D form.

New Data Items:

We have revised the heading for **Item 6. Diagnosis and Treatment of PDA** since we have added a new item on PDA Treatment.²

- Item 6 has been renumbered to **Item 6a) Diagnosis of PDA** (Check all the conditions that are present):²
- A new item has been added as **Item 6b) Treatment of PDA.**²

Definition Clarifications:

Item 4^{3,5}, we have added a new checkbox for **PDA diagnosed elsewhere (if the infant is Outborn and the Diagnosis of PDA cannot be confirmed)**. Check **PDA Diagnosed Elsewhere** if the infant is Outborn and the Date of PDA Diagnosis cannot be confirmed. This option is grayed out for Inborn infants.

Item 6b⁵, we have clarified the definition of **Yes, the infant was evaluated for or received medical and/or treatment**. We have also added a new checkbox for **No, the infant was transferred out for treatment or died prior to initiation of treatment**. We have clarified the answer choices as follows:

- Yes, the infant was evaluated for or received medical and/or surgical treatment⁵
- No, the infant was only observed for PDA
- No, the infant was transferred out for treatment or died prior to initiation of treatment⁵
- Unknown

We have added a **Not Applicable** answer choice to the following items:

- **PDA Diagnosis and Therapy (Items 7-13)**⁵
- **PDA Ligation (Items 14-19)**⁵
- **Discharge (Item 21)**⁵

Item 7³, we have clarified the definition by adding the following:

Note: This item applies to the **last value** obtained in the **24-hour period before treatment** was started.

Item 7⁷, we have clarified the question stem by including surgical treatment as follows:
Clinical status at the initiation of Medical **and/or Surgical** Treatment.

Items 7c⁵, 15c⁵, 16c⁵, 17c⁵, we have reformatted the option **Intubated High Frequency Ventilation (Intubated HIFI Vent)** to **Intubated HIFI Ventilation**.

Item 11⁵, we have clarified the question stem as follows:

Did the baby receive more than 3 therapeutic courses of Indomethacin/Ibuprofen solely for PDA at your center?

Item 14⁵, we have deleted the Yes, elsewhere option. We have clarified the definition as follows:

Check **Yes, here** if surgical ligation of the ductus arteriosus was performed either in the operating room or NICU at **YOUR** hospital prior to initial disposition.

Check **No** if surgical ligation of the ductus arteriosus was not performed and the infant was not transferred to another location for possibly additional PDA treatment.

Check **Transferred out or died** if surgical ligation of the ductus arteriosus was not performed at your center since the infant was transferred to another hospital or expired.

Check **Unknown** if this information cannot be obtained.

Item 15³, we have clarified the definition by adding the following:

Note: This item applies to the **last value** obtained during the **24-hour period before surgery**.

Item 16³, we have clarified the definition by adding the following:

Note: This item applies to the **first value** obtained during the **24-30 hours after surgery started**.

Item 17³, we have clarified the definition by adding the following:

Note: This item applies to the **first value** obtained during the **72-78 hours after surgery started**.

Item 19⁵, we have added an option Check **Other**. If checked, **enter description**. We have also added the following:

Note: **Check Not Applicable** was transferred out or died prior to the start of post-op enteral nutrition. No ligation is always checked for infants who did not undergo a ligation.

Item 20^{3,5}, we have clarified the definition by adding the following:

Note: This item applies to the **last Echo** performed between the time after surgery or after the last medical treatment and discharge.³ If the infant did not receive any medical or surgical treatment at your center, use the last echo performed prior to discharge.⁵

Item 21⁵, we have clarified the definition by combining Items 21a and 21b. The options have been revised as follows:

Check **Infant did not receive parenteral** nutrition if infant did not receive any parenteral nutrition at your center.

Check **Infant was discharged or died on parenteral nutrition** if infant did receive parenteral nutrition **at your center and died or was discharged on parenteral nutrition**.

Check **Infant received and stopped parenteral nutrition at this center** if infant did receive parenteral nutrition from all other situations. Indicate the **date on which the infant last received parenteral nutrition**.

Check **Unknown** if this information cannot be obtained.

Typographical Error Corrections:

A/D Item 39a, A/D Item 39e, Item 6a⁴, we corrected the typo in the definition for Item 6a to reflect the new VON definition for PDA in A/D Items 39a and 39e wherein the Diagnostic Criteria Set 2 requires that at least **two** conditions are present. The previous version incorrectly stated one.

Item 6a) Diagnosis of PDA (Check all the conditions that are present):

Check all the conditions that are present in diagnosing PDA:

VON 2011 Criteria:

Diagnostic criteria set 1 (At least one of the following is present):

- Left to right or bidirectional ductal shunt on Doppler echo
- Systolic or continuous murmur

Diagnostic criteria set 2 (At least two of the following are present):⁴

- Hyperdynamic precordium
- Bounding pulses
- Wide pulse pressure
- Pulmonary vascular congestion, cardiomegaly, or both

Additional Criteria other than VON 2011:

If the patient does not have at least one item from the diagnostic criteria set 1 AND at least two items from the diagnostic criteria set 2, then check the following two criteria if they were used for diagnosing PDA.⁴

- Echocardiographic
- Clinical
- PDA diagnosed elsewhere (if the infant is Outborn and the Diagnosis of PDA cannot be confirmed)

Items 8b¹, 9b¹, 10b¹, 14c¹, and 20¹, we have corrected a typo affecting the unit of measurement for the PDA status. The unit of measure should be in **millimeters** instead of centimeters. We have corrected the on-line PDA form, the on-line Help Windows, and the hard copy form.

Item 21⁶, we have corrected a typo for the item description. We have corrected the hard copy form. Item 21 was titled as "Parenteral Nutrition" and has been revised to "**PDA Status on Echo after all Treatments or at Discharge**" to match the on-line PDA form.

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I. STUDY PURPOSE

The diagnosis and treatment of Patent Ductus Arteriosus is being scrutinized in the neonatology literature and at scientific forums in the past few years. With the paucity of evidence guiding clinical management there are widely divergent approaches that are thought to be practiced by neonatologists in CPQCC centers. Using the CPQCC database and partnering with the community of neonatologists committed to improving the quality of care in California we have a unique opportunity to collect data about the variations in practice and important associations with outcome of VLBW patients with PDA. In addition to the standard variables that are submitted to the CPQCC data center, we are asking for your help in collecting a limited number of additional supplemental items related to PDA management for the year 2011.

The supplemental data sheet will consist of 18 items describing the presentation, management and outcome of VLBW infants treated for PDA during the upcoming year. The results will be analyzed by CPQCC and will be published in the same manner as the recent observational study on the use of postnatal steroids, which made important and previously unreported observations that contributed to our understanding of the use of these agents.

II. TECHNICAL SUPPORT

The CPQCC Data Center Staff provides technical support for data collection and for interpreting our reports. Please direct all of your questions and comments regarding data submission and reports to our staff at support@cpqcc.org. Email is our preferred method of communication for non-urgent data issues.

All research questions related to this study will be referred to **Richard Powers, MD**, Chair PQIP Research Committee, and PDA Study Director.

All membership participation questions will be referred to **Courtney Nisbet, RN, MS**, CPQCC Quality Improvement Program Manager.

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III. ELIGIBILITY

A **VLBW (≤ 1500 gram)** infant that meets **one** of the following six criteria is eligible for the PDA Supplemental Form:

- meets the VON 2011 revised definition of PDA, OR
- was treated with Indomethacin for PDA, OR
- was treated with Ibuprofen for PDA, OR
- underwent a PDA ligation, OR
- had a PDA ascertained via an echocardiographic or clinical diagnosis,
- is an outborn infant that had PDA diagnosed elsewhere

IV. PROCEDURES FOR COMPLETING FORMS

On our website www.cpqcc.org, you will find updates to this Manual, a list of participating hospitals, a list of Data Contacts with contact information, OSHPD codes, and electronic versions of the data collection forms.

2011 CPQCC Admission / Discharge On-line Form

Please refer to the 2011 CPQCC Manual of Definitions for complete instructions.

- **Item 39e. Expanded PDA Criteria** has been added to the 2011 CPQCC Hard Copy Admission/Discharge, Transport Form as follows:
Item 39e. If your center is participating in the PDA Supplemental study, please also check this additional item to verify eligibility for this study AND fill out a Supplemental PDA Report. Go to http://www.cpqcc.org/data/cpqcc_downloads to retrieve the hard copy.

39e). Did this infant meet the [expanded PDA criteria](#) including an echocardiographic or clinical diagnosis of PDA? Yes/No/Unknown

2011 PDA Observational Study Supplemental On-line Form

For an infant who is admitted to your NICU, or is under the care of the neonatology service in any inpatient unit, and is not a delivery room death, complete all items on the 2011 PDA Supplemental Form.

If an infant is transferred from your NICU to another unit within your Center (Step-Down unit, Well Baby Nursery, Pediatrics Ward, Intermediate Care Nursery, PICU, etc.), continue collecting data until discharge to home, transfer to another hospital, or death.

If an infant is transferred from your NICU to another hospital for treatment and then readmitted back to your hospital, you are **NOT** required to update this form. Centers participating in the PDA Observational Study are only required to document the **initial episode of care at YOUR hospital**.

V. PROCEDURES FOR SUBMITTING DATA

On our website www.cpqccdata.org, you can access a secure and comprehensive data management tool. You can download the *2011 On-line Web-based Data Entry System (OWDES) Instructions* from www.cpqcc.org/data/electronic_data_submission.

CPQCC is not creating an electronic data submission (EDS) module for the PDA Observational study at this time. Thus, to generate a PDA Supplemental form, **EDS submitters MUST answer Item 39e on-line**, and then **must submit the PDA Supplemental data on-line**.

Reminder for www.cpqccdata.org users:

The PDA section of the A/D on-line form now includes the additional expanded PDA screener question (Item 39e). Once you check 'Yes' for expanded PDA eligibility (Item 39e), the PDA on-line form will be available as a link on your Edit ID screen.

To preview the online PDA Supplemental form, follow these instructions:

- 1) Logon to www.cpqccdata.org as a test Center (CPQCC Center Number=0000, Password=test),
- 2) Click on Edit Data – 2011, then
- 3) Click on A/D to preview Item 39e in the Admission/Discharge Form, and then
- 4) Click on PDA to preview the PDA Supplemental Form.

www.cpqccdata.org Logic Checks:

We have implemented the following:

- An error check for **Item 39d. PDA Ligation**.⁴ The updated A/D form no longer includes a Not Application option for PDA ligation in Item 39d. Under the revised PDA criteria, it is possible for an infant to undergo a PDA ligation without having a PDA diagnosis as defined by the revised 2011 VON PDA criteria.

Any submitted forms for which PDA ligation was submitted as Not Applicable will have to have Item 39d updated. The most efficient way to find all records that need to be updated is to perform an error check for your 2011 data. **As the Not Applicable option is no longer allowed for Item 39d, all records that have currently Not Applicable coded for Item 39d are listed in the Error and Warning Report.**

- We have implemented an updated error checking for the new skip patterns and a consistency check with the A/D form with respect to:⁵
 - **A/D Item 39a. Patent Ductus Arteriosus.** A Warning message is displayed if PDA is checked on the A/D form, but the PDA form does not have the necessary checks in Item 6. Diagnosis and Treatment of PDA.
 - **A/D Item 39d. PDA Ligation.** A Warning message is displayed if PDA ligation is NOT checked on the A/D form AND the PDA form (PDA Item 14a. PDA Ligation) or vice versa.
 - **A/D Item 54. Initial Disposition = Transferred OR Died.** A warning is displayed if the baby went home according to the A/D form (fdisp=1) and the user is using the skips in the PDA form for Transferred OR Died.

Note that all of these are **Warnings** so that the submission of the form is still allowed. We cannot assume that the error is on the PDA form since the error might be on the A/D form.

VI. DEFINITIONS OF DATA ITEMS

Admission/Discharge Form

Post-Delivery Room Diagnoses and Interventions - Other Diagnoses, Surgeries and Surgical Complications (Items 39-44)

Item 39e. Patent Ductus Arteriosus - Expanded Criteria for PDA Supplemental Form Eligibility for Infants \leq 1,500 grams Only

Participating NICUs will notice an additional item in their Admission/Discharge form. **Item 39e MUST be answered Yes in order to generate an on-line PDA Supplemental form** for the eligible VLBW infant.

Item 39e. Your center is participating in the PDA Supplemental study, please also check this additional item to verify eligibility for this study. Did this infant meet the [expanded PDA criteria](#) including an echocardiographic or clinical diagnosis of PDA?

Patent Ductus Arteriosus - Expanded Criteria for PDA Supplemental Form Eligibility for Infants \leq 1,500 grams Only

If a VLBW (\leq 1500 gram) infant meets the expanded PDA criteria, the infant is eligible for the PDA supplemental form:

In addition to the VON 2011 PDA criteria, treatment with Ibuprofen for PDA, treatment with Indomethacin for PDA, or use of a PDA ligation, an infant meets the expanded PDA criteria if the PDA was ascertained based on an echocardiographic or clinical diagnosis, or an outborn infant that had PDA diagnosed elsewhere.

Check **Yes** if PDA was ascertained based on an echocardiographic or clinical diagnosis.

The checkbox **Yes** is auto-selected if the infant meets the VON 2011 revised PDA criteria, in other words, if at least one of the following is present:

1. Left to right or bidirectional ductal shunt on Doppler echo;
2. Systolic or continuous murmur

AND at least two of the following findings are present:

1. Hyperdynamic precordium
2. Bounding pulses
3. Wide pulse pressure
4. Pulmonary vascular congestion, cardiomegaly, or both

The checkbox **Yes** is auto-selected if the infant was treated with Ibuprofen for PDA or Indomethacin for PDA or underwent a PDA ligation.

Check **No** if the infant does not satisfy any the above conditions. The checkbox **No** is auto-selected if the infant's birth weight exceeds 1,500 grams.

Check **Unknown** if this information cannot be obtained.

PDA Supplemental Form

Birth Stats (Items 1-3, automatically pulled from database)

Reminder for www.cpqccdata.org users:

Changes to Items 1-3 MUST be initiated in the Admission/Discharge Form.

Item 1. Birth Weight (grams)

Record the birth weight in grams.

Since many weights may be obtained on an infant shortly after birth, enter the weight from the Labor and Delivery record if available and judged to be accurate.

If unavailable or judged to be inaccurate, use the weight on admission to the neonatal unit or lastly, the weight obtained on autopsy (if the infant expired within 24 hours of birth).

Do **not** use a comma separator as in 1,224. Use only numbers as in 1224.

Item 2. Birth Date

Enter the date of birth. Note that the birth year is already selected as it should correspond to the previously submitted birth year. Once the month of birth is selected, the appropriate selection of days for the month will appear. The date of birth is used in subsequent portions of the form as it helps to determine the date of Day 3, date of Day 28, and Week 36 of adjusted gestational age.

Item 3. Gestational Age (weeks, days)

Record the best estimate of gestational age in weeks and days.

Where sources disagree, use the following hierarchy:

- 1) Obstetrical measures based on last menstrual period, obstetrical parameters, or prenatal ultrasound as recorded in the maternal chart.
- 2) Neonatologist's estimate based on physical criteria, neurologic examination, combined physical and gestational age exam (Ballard or Dubowitz), or examination of the lens.

Record gestational age in weeks and days. In cases when the best estimate of gestational age is an exact number of weeks, enter the number of weeks in the space provided for weeks and enter "0" in the space provided for days. *Do not leave the number of days blank.*

Check **Unknown** if this information cannot be obtained.

PDA Diagnosis and Therapy (Items 4-13)

Item 4. Date of PDA Diagnosis

Enter the date of the PDA diagnosis.

PDA is defined according to the expanded definition. Details of the expanded definition are shown under the help entry for item 6a.

Check **PDA diagnosed elsewhere and date cannot be confirmed** if the infant is Outborn and the Date of PDA Diagnosis cannot be confirmed. This option is grayed out for Inborn infants.

Item 5. Prophylaxis

Note: Indomethacin or Ibuprofen given only for prophylaxis, not for a diagnosis of PDA or for any reason other than prophylaxis of IVH or PDA

Check **None** if Indomethacin or Ibuprofen was NOT administered for prophylaxis, but for a diagnosis of PDA or for any reason other than prophylaxis of IVH or PDA.

Check **Indomethacin** if Indomethacin was administered after birth for prophylaxis, not for a diagnosis of PDA or for any reason other than prophylaxis of IVH or PDA. The answer to this question may be Yes even if the infant did not meet the definition of PDA given in Item 6.

Enter the **number of doses** administered.

Enter the **date on which administration of Indomethacin was started**.

Check **Ibuprofen** if Ibuprofen was administered after birth for prophylaxis, not for a diagnosis of PDA or for any reason other than prophylaxis of IVH or PDA. The answer to this question may be Yes even if the infant did not meet the definition of PDA given in Item 6.

Enter the **number of doses** administered.

Enter the **date on which administration of Ibuprofen was started**.

Check **Unknown** if this information cannot be obtained.

Item 6. Diagnosis and Treatment of PDA

6a) Diagnosis of PDA (Check all the conditions that are present):

Check all the conditions that are present in diagnosing PDA:

VON 2011 Criteria:

Diagnostic criteria set 1 (At least one of the following is present):

- Left to right or bidirectional ductal shunt on Doppler echo
- Systolic or continuous murmur

Diagnostic criteria set 2 (At least two of the following are present):

- Hyperdynamic precordium
- Bounding pulses
- Wide pulse pressure
- Pulmonary vascular congestion, cardiomegaly, or both

Additional Criteria other than VON 2011:

If the patient does not have at least one item from the diagnostic criteria set 1 AND at least two items from the diagnostic criteria set 2, then check the following two criteria if they were used for diagnosing PDA.

- Echocardiographic
- Clinical
- PDA diagnosed elsewhere (if the infant is Outborn and the Diagnosis of PDA cannot be confirmed)

6b) Treatment of PDA

Check **Yes, the infant was evaluated for or received medical and/or surgical treatment**, if the infant underwent initial evaluation for PDA treatment or received any medical treatment for PDA (Indomethacin or Ibuprofen) or any surgical treatment (catheter-based procedures or ligation).

Check **No, the infant was only observed for PDA** if the infant was only observed for PDA, and did not receive any medical treatment for PDA (Indomethacin or Ibuprofen) or any surgical treatment (catheter-based procedures or ligation).

Check **No, the infant was transferred out for treatment or died prior to the initiation of treatment** if the infant was transferred out or died prior to the initiation of any medical treatment.

Check **Unknown** if this information cannot be obtained.

Item 7. Clinical status at the initiation of Medical and/or Surgical Treatment

Note: This item applies to the **last value** obtained in the **24-hour period before treatment** was started.

The **Not Applicable** options for all items under clinical status at the initiation of medical treatment is automatically checked in the situations that the infant was observed for PDA only, or that the treatment for this infant was not initiated at this location, or that the infant expired prior to treatment start, or if PDA treatment is unknown.

7a) Hematocrit (0 - 100 %)

Enter **Hematocrit** value as a percentage (0 – 100%): [x] millimeters of red blood cells in 100 millimeters of blood.

Check **Unknown** if this information cannot be obtained.

7b) Platelet count (5 – 1,000 platelets (in thousands) per microliter)

Enter platelet count in 1000 platelets per microliter. The platelet count should range from 5,000 to 1,000,000 (entered as 5 to 1,000 platelets (in 1000s) per microliter).

Check **Unknown** if this information cannot be obtained.

7c) Respiratory support (Choose only one):

Enter the type of respiratory support administered at the Initiation of Medical Treatment.
Choose only one.

Check **Intubated HIFI Ventilation** if the infant received intubated high frequency ventilation (IMV rate >240/minute) immediately prior to receiving medical treatment.

Note: High Frequency ventilation via nasal prongs is NOT considered intubated high frequency ventilation.

Check **Intubated Conventional Ventilation** if the infant was given intermittent positive pressure ventilation through an endotracheal tube with a conventional ventilator (IMV rate <240/minute) immediately prior to receiving medical treatment.

Note: Intermittent positive pressure ventilation (IPPV) via nasal prongs is NOT considered conventional ventilation. Synchronized intermittent positive pressure ventilation (SIMV) via nasal prongs is NOT considered conventional ventilation.

Check **Non-invasive ventilation** if the infant received intermittent positive pressure ventilation (intermittent mandatory ventilation or synchronized intermittent mandatory ventilation) via nasal prongs or other nasal device at any time after leaving the delivery room or the Initial Resuscitation Area.

Note: Non-intubated assisted ventilation is defined as a mechanically-produced breath. CPAP alone DOES NOT qualify as non-intubated assisted ventilation.

Check **Nasal CPAP** if the infant was given continuous positive airway pressure applied through the nose immediately prior to receiving medical treatment.

Check **High Flow Nasal Cannula** if the infant received air or oxygen (any FiO_2) at a flow rate of one liter per minute or more via nasal cannula immediately prior to receiving medical treatment.

Check **Room Air** if the infant received room air or 21% oxygen immediately prior to receiving medical treatment.

Check **Unknown** if this information cannot be obtained.

7d) Inspired Oxygen Concentration (FiO_2)(21 to 100%)

Indicate **Inspired Oxygen Concentration (FiO_2) (21 to 100%)** measured immediately prior to receiving medical treatment. This item is grayed out (not applicable) for infants on Room Air or if the type of respiratory support is Unknown.

Check **Unknown** if this information cannot be obtained.

7e) Dopamine

Check **Yes** if Dopamine was administered immediately prior to receiving medical treatment for

PDA.

Check **No** if Dopamine was not administered immediately prior to receiving medical treatment for PDA.

Check **Unknown** if this information cannot be obtained.

7f) Dobutamine

Check **Yes** if Dobutamine was administered immediately prior to receiving medical treatment for PDA.

Check **No** if Dobutamine was not administered immediately prior to receiving medical treatment for PDA.

Check **Unknown** if this information cannot be obtained.

7g) Epinephrine

Check **Yes** if Epinephrine was administered immediately prior to receiving medical treatment for PDA.

Check **No** if Epinephrine was not administered immediately prior to receiving medical treatment for PDA.

Check **Unknown** if this information cannot be obtained.

7h) Dexamethasone

Check **Yes** if Dexamethasone was administered immediately prior to receiving medical treatment.

Check **No** if Dexamethasone was not administered immediately prior to receiving medical treatment.

Check **Unknown** if this information cannot be obtained.

7i) Hydrocortisone

Check **Yes** if Hydrocortisone was administered immediately prior to receiving medical treatment.

Check **No** if Hydrocortisone was not administered immediately prior to receiving medical treatment.

Check **Unknown** if this information cannot be obtained.

Item 8. First Therapeutic Course

- Check here if infant was transferred out or died prior to any therapeutic courses and without undergoing a ligation.

8a) First course - Indomethacin or Ibuprofen given solely for a diagnosis of PDA, not for any other reason.

Check **None** if Indomethacin or Ibuprofen was NOT administered for a diagnosis of PDA.

Check **Indomethacin** if Indomethacin was administered after birth, for a diagnosis of PDA.

Enter the **number of doses** administered.

Enter the **date on which administration of Indomethacin was started**.

Check **Ibuprofen** if Ibuprofen was administered after birth, for a diagnosis of PDA.

Enter the **number of doses** administered.

Enter the **date on which administration of Ibuprofen was started**.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, or if PDA treatment is unknown.

Check **Unknown** if this information cannot be obtained.

8b) Enter PDA status on echo prior to treatment.

Check **Echo not done** if echo was not done prior to treatment.

Check **Small (< 1.5 mm)** if the PDA status on echo prior to treatment was < 1.5 mm.

Check **Moderate (1.5 to 2.5 mm)** if the PDA status on echo prior to treatment was 1.5 to 2.5 mm.

Check **Large (> 2.5 mm)** if the PDA status on echo prior to treatment was > 2.5 mm.

Check **Size not specified** if the PDA status on echo prior to treatment was not specified.

Check **Closed** if the PDA status on echo prior to treatment was Closed.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, or if PDA treatment is unknown.

Check **Unknown** if the PDA status on echo prior to treatment was Unknown.

Item 9. Second Therapeutic Course

- Check here if the infant was transferred out or died after the first therapeutic course without undergoing a ligation.

9a) Second course - Indomethacin or Ibuprofen given solely for a diagnosis of PDA, not for any other reason

Check **None** if Indomethacin or Ibuprofen was NOT administered for a diagnosis of PDA.

Check **Indomethacin** if Indomethacin was administered after birth, for a diagnosis of PDA.

Enter the **number of doses** administered.

Enter the **date on which administration of Indomethacin was started**.

Check **Ibuprofen** if Ibuprofen was administered after birth, for a diagnosis of PDA.

Enter the **number of doses** administered.

Enter the **date on which administration of Ibuprofen was started**.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant did not undergo a first therapeutic course.

Check **Unknown** if this information cannot be obtained.

9b) Enter PDA status on echo prior to treatment.

Check **Echo not done** if echo was not done prior to treatment.

Check **Small (< 1.5 mm)** if the PDA status on echo prior to treatment was < 1.5 mm.

Check **Moderate (1.5 to 2.5 mm)** if the PDA status on echo prior to treatment was 1.5 to 2.5 mm.

Check **Large (> 2.5 mm)** if the PDA status on echo prior to treatment was > 2.5 mm.

Check **Size not specified** if the PDA status on echo prior to treatment was not specified.

Check **Closed** if the PDA status on echo prior to treatment was Closed.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, if the infant did not undergo a first therapeutic course, if a second therapeutic course with indomethacin or ibuprofen was not started, or if it is unknown that a second therapeutic course with indomethacin or ibuprofen was started.

Check **Unknown** if the PDA status on echo prior to treatment was Unknown.

Item 10. Third Therapeutic Course

- Check here if the infant was transferred out or died after the second therapeutic course without undergoing a ligation.

10a) Third course - Indomethacin or Ibuprofen given solely for a diagnosis of PDA, not for any other reason

Check **None** if Indomethacin or Ibuprofen was NOT administered for a diagnosis of PDA.

Check **Indomethacin** if Indomethacin was administered after birth, for a diagnosis of PDA.

Enter the **number of doses** administered.

Enter the **date on which administration of Indomethacin was started**.

Check **Ibuprofen** if Ibuprofen was administered after birth, for a diagnosis of PDA.

Enter the **number of doses** administered.

Enter the **date on which administration of Ibuprofen was started**.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant did not undergo a first and second therapeutic course.

Check **Unknown** if this information cannot be obtained.

10b) Enter PDA status on echo prior to treatment.

Check **Echo not done** if echo was not done prior to treatment.

Check **Small (< 1.5 mm)** if the PDA status on echo prior to treatment was < 1.5 mm.

Check **Moderate (1.5 to 2.5 mm)** if the PDA status on echo prior to treatment was 1.5 to 2.5 mm.

Check **Large (> 2.5 mm)** if the PDA status on echo prior to treatment was > 2.5 mm.

Check **Size not specified** if the PDA status on echo prior to treatment was not specified.

Check **Closed** if the PDA status on echo prior to treatment was Closed.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, if the infant did not undergo a first and second therapeutic course, if a third therapeutic course with indomethacin or ibuprofen was not started, or if it is unknown that a third therapeutic course with indomethacin or ibuprofen was started.

Check **Unknown** if the PDA status on echo prior to treatment was Unknown.

Item 11. Did the baby receive more than 3 therapeutic courses of Indomethacin/Ibuprofen solely for PDA at your center?

Check **Yes** if the baby receive more than 3 therapeutic courses of Indomethacin or Ibuprofen solely for a diagnosis of PDA, and not for any other reason.

Check **No** if the baby did not receive more than 3 therapeutic courses of Indomethacin or Ibuprofen solely for a diagnosis of PDA, and not for any other reason.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, if the infant did not undergo a first, second and third therapeutic course.

Check **Unknown** if this information cannot be obtained.

Item 12. If prophylactic treatment with Ibuprofen or Indomethacin, did the infant receive enteral nutrition during part or all of the prophylactic course?

Check **Yes** if the baby did receive enteral nutrition during part or all of the prophylactic course.

Check **No** if the baby did not receive any enteral nutrition during part or all of the prophylactic course.

The **Not Applicable** option is automatically checked if the infant did not receive prophylactic treatment with Ibuprofen or Indomethacin.

Check **Unknown** if this information cannot be obtained.

Item 13. If therapeutic treatment with Ibuprofen or Indomethacin, did the infant receive enteral nutrition during part or all of the therapeutic course?

Check **Yes** if the baby received enteral nutrition during part or all of the therapeutic course.

Check **No** if the baby did not receive enteral nutrition during part or all of the therapeutic course.

The **Not Applicable** option is automatically checked if the infant did not receive any therapeutic treatments with Ibuprofen or Indomethacin.

Check **Unknown** if this information cannot be obtained.

PDA Ligation (Items 14-19)

Item 14. PDA Ligation

14a) Was ligation used?

Check **Yes, here** if surgical ligation of the ductus arteriosus was performed either in the operating room or NICU at **YOUR** hospital prior to initial disposition.

Check **No** if surgical ligation of the ductus arteriosus was not performed and the infant was not transferred to another location for possibly additional PDA treatment.

Check **Transferred out or died** if surgical ligation of the ductus arteriosus was not performed at your center since the infant was transferred to another hospital or expired.

Check **Unknown** if this information cannot be obtained.

14b) If PDA ligation was performed, enter the **date of ligation.**

14c) Enter **PDA status on echo prior to ligation.**

Check **Echo not done** if echo was not done prior to treatment.

Check **Small (< 1.5 mm)** if the PDA status on echo prior to treatment was < 1.5 mm.

Check **Moderate (1.5 to 2.5 mm)** if the PDA status on echo prior to treatment was 1.5 to 2.5 mm.

Check **Large (> 2.5 mm)** if the PDA status on echo prior to treatment was > 2.5 mm.

Check **Size not specified** if the PDA status on echo prior to treatment was not specified.

Check **Closed** if the PDA status on echo prior to treatment was Closed.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if the PDA status on echo prior to treatment was Unknown.

Item 15. If Ligated, Status Immediately Prior to Surgery

Note: This item applies to the **last value** obtained during the **24-hour period before surgery**.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

15a) Hematocrit (0 – 100 %)

Enter **Hematocrit** value as a percentage where [x] millimeters of red blood cells in 100 millimeters of blood.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15b) Platelet count (5 – 1,000 platelets (in thousands) per microliter)

Enter platelet count in 1000 platelets per microliter. The platelet count should range from 5,000 to 1,000,000 (entered as 5 to 1,000 platelets (in 1000s) per microliter).

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15c) Respiratory support (Choose only one)

Enter the type of respiratory support administered immediately prior to surgery. Choose only one.

Check **Intubated HIFI Ventilation** if the infant received intubated high frequency ventilation (IMV rate >240/minute) immediately prior to surgery.

Note: High Frequency ventilation via nasal prongs is NOT considered intubated high frequency ventilation.

Check **Intubated Conventional Ventilation** if the infant was given intermittent positive pressure ventilation through an endotracheal tube with a conventional ventilator (IMV rate <240/minute) immediately prior to surgery.

Note: Intermittent positive pressure ventilation (IPPV) via nasal prongs is NOT considered conventional ventilation. Synchronized intermittent positive pressure ventilation (SIMV) via nasal prongs is NOT considered conventional ventilation.

Check **Non-invasive ventilation** if the infant received intermittent positive pressure ventilation (intermittent mandatory ventilation or synchronized intermittent mandatory ventilation) via nasal prongs or other nasal device at any time after leaving the delivery room or the Initial Resuscitation Area.

Note: Non-intubated assisted ventilation is defined as a mechanically-produced breath. CPAP alone DOES NOT qualify as non-intubated assisted ventilation.

Check **Nasal CPAP** if the infant was given continuous positive airway pressure applied through

the nose immediately prior to surgery.

Check **High Flow Nasal Cannula** if the infant received air or oxygen (any FiO₂) at a flow rate of one liter per minute or more via nasal cannula immediately prior to surgery.

Check **Room Air** if the infant received room air or 21% oxygen immediately prior to surgery.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15d) Inspired Oxygen Concentration (FiO₂) (21 to 100)

Indicate **Inspired Oxygen Concentration (FiO₂)** (21 to 100%) measured immediately prior to surgery. This item is grayed out (not applicable) for infants on Room Air or if the type of respiratory support is Unknown.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15e) Dopamine

Check **Yes** if Dopamine was administered immediately prior to surgery.

Check **No** if Dopamine was not administered immediately prior to surgery.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15f) Dobutamine

Check **Yes** if Dobutamine was administered immediately prior to surgery.

Check **No** if Dobutamine was not administered immediately prior to surgery.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15g) Epinephrine

Check **Yes** if Epinephrine was administered immediately prior to surgery.

Check **No** if Epinephrine was not administered immediately prior to surgery.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15h) Dexamethasone

Check **Yes** if Dexamethasone was administered immediately prior to surgery.

Check **No** if Dexamethasone was not administered immediately prior to surgery.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

15i) Hydrocortisone

Check **Yes** if Hydrocortisone was administered immediately prior to surgery.

Check **No** if Hydrocortisone was not administered immediately prior to surgery.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery.

Check **Unknown** if this information cannot be obtained.

Item 16. If Ligated, Status 24 hours Post-Op

Note: This item applies to the **first value** obtained during the **24-30 hours after surgery started**.

Check here if infant was transferred out or died within the 24 hours following the start of the ligation.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery.

Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

16a) Hematocrit (0 – 100 %)

Enter **Hematocrit** value at 24-hours post-op as a percentage where [x] millimeters of red blood cells in 100 millimeters of blood.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16b) Platelet count (5 – 1,000 platelets (in thousands) per microliter)

Enter platelet count in 1000 platelets per microliter at 24-hours post-op. The platelet count should range from 5,000 to 1,000,0000 (entered as 5 to 1,000 platelets (in 1000s) per microliter).

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16c) Respiratory support (Choose only one)

Enter the type of respiratory support administered 24-hours post-op. Choose only one.

Check **Intubated HIFI Ventilation** if the infant received intubated high frequency ventilation (IMV rate >240/minute).

Note: High Frequency ventilation via nasal prongs is NOT considered intubated high frequency ventilation.

Check **Intubated Conventional Ventilation** if the infant was given intermittent positive pressure ventilation through an endotracheal tube with a conventional ventilator (IMV rate <240/minute).

Note: Intermittent positive pressure ventilation (IPPV) via nasal prongs is NOT considered conventional ventilation. Synchronized intermittent positive pressure ventilation (SIMV) via nasal prongs is NOT considered conventional ventilation.

Check **Non-invasive ventilation** if the infant received intermittent positive pressure ventilation (intermittent mandatory ventilation or synchronized intermittent mandatory ventilation) via nasal prongs or other nasal device at any time after leaving the delivery room or the Initial Resuscitation Area.

Note: Non-intubated assisted ventilation is defined as a mechanically-produced breath. CPAP alone DOES NOT qualify as non-intubated assisted ventilation.

Check **Nasal CPAP** if the infant was given continuous positive airway pressure applied through the nose.

Check **High Flow Nasal Cannula** if the infant received air or oxygen (any FiO₂) at a flow rate of one liter per minute or more via nasal cannula.

Check **Room Air** if the infant received room air or 21% oxygen.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16d) Inspired Oxygen Concentration (FiO₂)(21 to 100%)

Indicate **Inspired Oxygen Concentration (FiO₂)** (21 to 100%) measured. This item is grayed out (not applicable) for infants on Room Air or if the type of respiratory support is Unknown.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16e) Dopamine

Check **Yes** if Dopamine was administered at 24-hours post-op.

Check **No** if Dopamine was not administered at 24-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery,

or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16f) Dobutamine

Check **Yes** if Dobutamine was administered at 24-hours post-op.

Check **No** if Dobutamine was not administered at 24-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16g) Epinephrine

Check **Yes** if Epinephrine was administered at 24-hours post-op.

Check **No** if Epinephrine was not administered at 24-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16h) Dexamethasone

Check **Yes** if Dexamethasone was administered at 24-hours post-op.

Check **No** if Dexamethasone was not administered at 24-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

16i) Hydrocortisone

Check **Yes** if Hydrocortisone was administered at 24-hours post-op.

Check **No** if Hydrocortisone was not administered at 24-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 24 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 24 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

Item 17. If Ligated, Status 72 hours Post-Op

Note: This item applies to the **first value** obtained during the **72-78 hours after surgery started**.

- Check here if infant was transferred out or died within 72 hours following the start of the ligation.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

17a) Hematocrit (0 – 100 %)

Enter **Hematocrit** value at 72-hours post-op as a percentage where [x] millimeters of red blood cells in 100 millimeters of blood.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17b) Platelet count (5 – 1,000 platelets (in thousands) per microliter)

Enter platelet count in 1000 platelets per microliter at 72-hours post-op. The platelet count should range from 5,000 to 1,000,000 (entered as 5 to 1,000 platelets (in 1000s) per microliter).

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17c) Respiratory support (Choose only one)

Enter the type of respiratory support administered 72-hours post-op. Choose only one.

Check **Intubated HIFI Ventilation** if the infant received intubated high frequency ventilation (IMV rate >240/minute).

Note: High frequency ventilation via nasal prongs is NOT considered intubated high frequency ventilation.

Check **Intubated Conventional Ventilation** if the infant was given intermittent positive pressure ventilation through an endotracheal tube with a conventional ventilator (IMV rate <240/minute).

Note: Intermittent positive pressure ventilation (IPPV) via nasal prongs is NOT considered conventional ventilation. Synchronized intermittent positive pressure ventilation (SIMV) via nasal prongs is NOT considered conventional ventilation.

Check **Non-invasive ventilation** if the infant received intermittent positive pressure ventilation (intermittent mandatory ventilation or synchronized intermittent mandatory ventilation) via nasal prongs or other nasal device at any time after leaving the delivery room or the Initial Resuscitation Area.

Note: Non-intubated assisted ventilation is defined as a mechanically-produced breath. CPAP alone DOES NOT qualify as non-intubated assisted ventilation.

Check **Nasal CPAP** if the infant was given continuous positive airway pressure applied through the nose.

Check **High Flow Nasal Cannula** if the infant received air or oxygen (any FiO₂) at a flow rate of one liter per minute or more via nasal cannula.

Check **Room Air** if the infant received room air or 21% oxygen.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery.

Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17d) Inspired Oxygen Concentration (FiO₂) (21 to 100%)

Indicate **Inspired Oxygen Concentration (FiO₂)** (21 to 100%) measured. This item is grayed out (not applicable) for infants on Room Air or if the type of respiratory support is Unknown.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17e) Dopamine

Check **Yes** if Dopamine was administered at 72-hours post-op.

Check **No** if Dopamine was not administered at 72-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17f) Dobutamine

Check **Yes** if Dobutamine was administered at 72-hours post-op.

Check **No** if Dobutamine was not administered at 72-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17g) Epinephrine

Check **Yes** if Epinephrine was administered at 72-hours post-op.

Check **No** if Epinephrine was not administered at 72-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17h) Dexamethasone

Check **Yes** if Dexamethasone was administered at 72-hours post-op.

Check **No** if Dexamethasone was not administered at 72-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

17i) Hydrocortisone

Check **Yes** if Hydrocortisone was administered at 72-hours post-op.

Check **No** if Hydrocortisone was not administered at 72-hours post-op.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery, or if the infant was transferred or died within the 72 hours following the start of the surgery. Please use the checkbox at the start of the section to indicate that the infant was transferred or died within 72 hours following the start of the surgery.

Check **Unknown** if this information cannot be obtained.

Item 18. If Ligated, Post-Op Complications (Check all that apply)

This question focuses on post-operative complications that may affect the infant after PDA Ligation.

Check all of the post-operative complications related to PDA ligation.

Check **None** if there were no post-operative complications related to PDA ligation.

Check **Diaphragm paralysis / paresis** if there is a "flaccid diaphragm due to accidental section of phrenic nerve during procedure" (ICD-9-CM: 519.4 or 998.2).

Check **Vocal cord paralysis/paresis** if they occur post-op (ICD-9-CM: 478.30-478.34).

Check **Chylothorax / Pleural effusion** if they occur post-op (ICD-9-CM 457.8 or 511.9).

Check **Other**. If checked, **enter description**.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery .

Check **Unknown** if this information cannot be obtained.

Item 19. Post-Op Enteral Nutrition

Note: Check Not Applicable if infant was transferred out or died prior to the start of post-op enteral nutrition. No ligation is always checked for infants who did not undergo a ligation.

If the infant was ligated, indicate the **date on which the infant was started on feedings of any kind by any enteral route**.

The **Not Applicable** option is automatically checked if the infant was observed for PDA only, if treatment for this infant was not initiated at this location, if the infant expired prior to treatment start, if PDA treatment is unknown, or if the infant was transferred prior to surgery . Check Not Applicable if the infant was transferred out or died prior to the start of post-op enteral nutrition.

Check **Unknown** if this information cannot be obtained.

Discharge (Items 20-21)

Item 20. PDA Status on Echo After All Treatments or at Discharge

Note: This item applies to the **last Echo** performed between the time after surgery or after the last medical treatment and discharge. If the infant did not receive any medical or surgical treatment at your center, use the last echo performed prior to discharge.

Check **Echo not done** if echo was not done after all treatments or at discharge.

Check **Small (< 1.5 mm)** if the PDA status on echo after all treatments or at discharge was < 1.5 mm.

Check **Moderate (1.5 to 2.5 mm)** if the PDA status on echo after all treatments or at discharge was 1.5 to 2.5 mm.

Check **Large (> 2.5 mm)** if the PDA status on echo after all treatments or at discharge was > 2.5 mm.

Check **Size not specified** if the PDA status on echo after all treatments or at discharge was not specified.

Check **Closed** if the PDA status on echo after all treatments or at discharge was Closed.

Check **Unknown** if the PDA status on echo after all treatments or at discharge was Unknown.

Item 21. Parenteral Nutrition

Check **Infant did not receive parenteral** nutrition if infant did not receive any parenteral nutrition at your center.

Check **Infant was discharged or died on parenteral nutrition** if infant did receive parenteral nutrition **at your center and died or was discharged on parenteral nutrition.**

Check **Infant received and stopped parenteral nutrition at this center** if infant did receive parenteral nutrition from all other situations. Indicate the **date on which the infant last received parenteral nutrition.**

Check **Unknown** if this information cannot be obtained.

User Comment Box

At the end of the online PDA Supplemental Form, we have added a text box for user comments.



California Perinatal Quality Care Collaborative (CPQCC)

Patent Ductus Arteriosus (PDA) Observation Study

Supplemental PDA Report for Infants Born in 2011

Version 1.5

Network ID

Hospital ID

Infant's Name (NOTE: DO NOT submit to the CPQCC Data Center)

Reminder for www.cpqccdata.org users:

The PDA section of the A/D on-line form now includes the additional expanded PDA screener question (Item 39e). Once you check 'Yes' for expanded PDA eligibility (Item 39e), the PDA on-line form will be available as a link on your Edit ID screen.

Eligibility Criteria. A VLBW (≤ 1500 gram) infant that meets one of the following six criteria is eligible for the PDA supplemental form:

- meets the VON 2011 revised definition of PDA, OR
- was treated with Indomethacin for PDA, OR
- was treated with Ibuprofen for PDA, OR
- underwent a PDA ligation, OR
- had a PDA ascertained via an echocardiographic or a clinical diagnosis
- is an Outborn infant that had PDA diagnosed elsewhere

Birth Stats (Items 1-3, will automatically be pulled from database online www.cpqccdata.org)

1. Birth Weight (grams)
2. Birth Date / /
3. Gestational Age weeks days

PDA Diagnosis and Therapy (Items 4-13)

4. Date of PDA Diagnosis / /

PDA diagnosed elsewhere and date cannot be confirmed.

5. Prophylaxis

Note: *Indomethacin or Ibuprofen given only for prophylaxis, not for a diagnosis of PDA or for any reason other than prophylaxis of IVH or PDA.*

None (If checked, mark Item 12 as Not Applicable)

Indomethacin Number of Doses (0 -10) Date Started / /

Ibuprofen Number of Doses (0 -10) Date Started / /

Unknown (If checked, mark Item 12 as Not Applicable)

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Supplemental PDA Report for Infants born in 2011

Network ID

Hospital ID

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6. Diagnosis and Treatment of PDA

a) Diagnosis of PDA (Check all the conditions that are present):

VON 2011 Criteria:

Diagnostic criteria set 1 (At least one of the following is present):

Left to right or bidirectional shunt on Doppler Echo

Systolic or continuous murmur

Diagnostic criteria set 2 (At least two of the following are present):

Hyperdynamic precordium

Bounding pulses

Wide pulse pressure

Pulmonary vascular congestion and/or cardiomegaly, or both

Additional Criteria other than VON 2011:

If a patient does not have at least one item from the diagnostic criteria set 1 AND at least two items from diagnostic criteria set 2, then check the following criteria if they are used for diagnosing PDA.

Echocardiographic

Clinical

PDA Diagnosed Elsewhere (If the infant is Outborn and the Diagnosis of PDA cannot be confirmed)

b) Treatment of PDA

Note: If "No" or "Unknown" is checked then **items 7 - 11 and items 13 -19** should be marked as "Not Applicable".

Yes, the infant was evaluated for or received medical and/or surgical treatment

No, the infant was only observed for PDA

No, the infant was transferred out for treatment or died prior to initiation of treatment

Unknown

7. Clinical Status at the Initiation of Medical and/or Surgical Treatment

Note: This item applies to the last value obtained in the 24-hour period before treatment was started.

a) Hematocrit (0 - 100%) N/A Unknown

b) Platelet count (5 - 1,000 platelets (in 1000s) per microliter) N/A Unknown

c) Respiratory support (Choose only one):

Intubated HIFI Ventilation

Nasal CPAP

N/A

Intubated Conventional Ventilation

Nasal Cannula

Unknown

Non-invasive Ventilation

Room Air



Supplemental PDA Report for Infants born in 2011

Network ID Hospital ID

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7. Clinical status at the initiation of Medical and/or Surgical Treatment (Cont'd)

Note: This item applies to the last value obtained in the 24-hour period before treatment was started.

- d) Inspired Oxygen Concentration (FiO₂)(21 to 100%) N/A Unknown
- e) Dopamine Yes No N/A Unknown
- f) Dobutamine Yes No N/A Unknown
- g) Epinephrine Yes No N/A Unknown
- h) Dexamethasone Yes No N/A Unknown
- i) Hydrocortisone Yes No N/A Unknown

8. First Therapeutic Course

Check here if infant was transferred out or died prior to any therapeutic courses and without undergoing a ligation.

Note: If this box is checked, then items 8 - 11 and items 13 - 19 should be marked as "Not Applicable".

If None OR Unknown is selected, then Items 8b - 11 and Item 13 are "Not Applicable".

a) First course - Indomethacin or Ibuprofen given solely for a diagnosis of PDA, not for any other reason.

- None
- Indomethacin Number of Doses (0 -10) Date Started / /
- Ibuprofen Number of Doses (0 -10) Date Started / /
- N/A
- Unknown

b) PDA status on echo prior to treatment

- Echo not done Size not specified
- Small (< 1.5 mm) Closed
- Moderate (1.5 to 2.5 mm) N/A
- Large (> 2.5 mm) Unknown

9. Second Therapeutic Course

Check here if infant was transferred out or died prior to any therapeutic courses and without undergoing a ligation.

Note: If this box is checked, then items 9 - 11 and items 14 - 19 should be marked as "Not Applicable".

If None OR Unknown is selected, then Items 9b - 11 are "Not Applicable".

a) Second course - Indomethacin or Ibuprofen given solely for a diagnosis of PDA, not for any other reason.

- None
- Indomethacin Number of Doses (0 -10) Date Started / /
- Ibuprofen Number of Doses (0 -10) Date Started / /
- N/A
- Unknown

b) PDA status on echo prior to treatment

- Echo not done
- Small (< 1.5 mm)



Supplemental PDA Report for Infants born in 2011

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9b. Second Therapeutic Course (cont'd)

- Moderate (1.5 to 2.5 mm)
- Large (> 2.5 mm)
- Size not specified
- Closed
- N/A
- Unknown

10. Third Therapeutic Course

Check here if infant was transferred out or died prior to any therapeutic courses and without undergoing a ligation.

Note: If this box is checked, then **items 10, 11 and items 14 - 19** should be marked as **"Not Applicable"**.

If **None OR Unknown** is selected, then **Item 10b and Item 11** are **"Not Applicable"**.

a) Third course - Indomethacin or Ibuprofen given solely for a diagnosis of PDA, not for any other reason.

- None
- Indomethacin Number of Doses (0 -10) Date Started / /
- Ibuprofen Number of Doses (0 -10) Date Started / /
- N/A
- Unknown

b) PDA status on echo prior to treatment

- Echo not done
- Small (< 1.5 mm)
- Moderate (1.5 to 2.5 mm)
- Large (> 2.5 mm)
- Size not specified
- Closed
- N/A
- Unknown

11. Did the baby receive more than 3 therapeutic courses of Indomethacin/Ibuprofen solely for PDA at your center? Yes No N/A Unknown

12. If prophylactic treatment with Ibuprofen or Indomethacin, did the infant receive enteral nutrition during part or all of the prophylactic course? Yes No N/A Unknown

13. If therapeutic treatment with Ibuprofen or Indomethacin, did the infant receive enteral nutrition during part or all of the therapeutic course? Yes No N/A Unknown

PDA Ligation (Items 14 - 19)

14. PDA Ligation

Note: If **ANY** other option besides **"Yes"** is selected, then **items 14 - 18** should be marked as **"Not Applicable"**.

Item 19 should be marked as **"No Ligation"**.

a) Was ligation used? Yes Transferred out or died
 No (no transfer/no death) Unknown

b) If Yes, date ligated? / / N/A Unknown

c) PDA status on echo prior to ligation

- Echo not done
- Small (< 1.5 mm)
- Moderate (1.5 to 2.5 mm)
- Large (> 2.5 mm)
- Size not specified
- Closed
- N/A
- Unknown



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15. If Ligated, Status Immediately Prior to Surgery

Note: This item applies to the last value obtained during the 24-hour period prior to surgery.

- a) Hematocrit (0 - 100%) N/A Unknown
- b) Platelet count (5 – 1,000 platelets (in 1000s) per microliter) N/A Unknown
- c) Respiratory support (Choose only one):
 - Intubated HIFI Ventilation Nasal CPAP N/A
 - Intubated Conventional Ventilation Nasal Cannula Unknown
 - Non-invasive Ventilation Room Air
- d) Inspired Oxygen Concentration (FiO₂)(21 to 100%) N/A Unknown
- e) Dopamine Yes No N/A Unknown
- f) Dobutamine Yes No N/A Unknown
- g) Epinephrine Yes No N/A Unknown
- h) Dexamethasone Yes No N/A Unknown
- i) Hydrocortisone Yes No N/A Unknown

16. If Ligated, Status 24 hours Post-Op

Note: This item applies to the first value obtained during the 24 to 30 - hour after surgery was started.

- Check here if infant was transferred out or died **within the 24 hours** following the start of the ligation.
 Note: If this box is checked, then **items 16 a - i and 17 a-i** should be marked as **"Not Applicable"**.

- a) Hematocrit (0 - 100%) N/A Unknown
- b) Platelet count (5 – 1,000 platelets (in 1000s) per microliter) N/A Unknown
- c) Respiratory support (Choose only one):
 - Intubated HIFI Ventilation Nasal CPAP N/A
 - Intubated Conventional Ventilation Nasal Cannula Unknown
 - Non-invasive Ventilation Room Air
- d) Inspired Oxygen Concentration (FiO₂)(21 to 100%) N/A Unknown
- e) Dopamine Yes No N/A Unknown
- f) Dobutamine Yes No N/A Unknown
- g) Epinephrine Yes No N/A Unknown
- h) Dexamethasone Yes No N/A Unknown
- i) Hydrocortisone Yes No N/A Unknown



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17. If Ligated, Status 72 hours Post-Op

Note: This item applies to the first value obtained during the 72 to 78 - hours after surgery started.

Check here if infant was transferred out or died **within the 72 hour** following the start of the ligation.
Note: If this box is checked, then **items 17 a - i** should be marked as "Not Applicable".

- a) Hematocrit (0 - 100%) N/A Unknown
- b) Platelet count (5 – 1,000 platelets (in thousands) per microliter) N/A Unknown
- c) Respiratory support (Choose only one):
 - Intubated HIFI Ventilation Nasal CPAP N/A
 - Intubated Conventional Ventilation Nasal Cannula Unknown
 - Non-invasive Ventilation Room Air
- d) Inspired Oxygen Concentration (FiO₂)(21 to 100%) N/A Unknown
- e) Dopamine Yes No N/A Unknown
- f) Dobutamine Yes No N/A Unknown
- g) Epinephrine Yes No N/A Unknown
- h) Dexamethasone Yes No N/A Unknown
- i) Hydrocortisone Yes No N/A Unknown

18. If Ligated, Post-Op Complications (Check all that apply)

- None
- Diaphragm paralysis/paresis
- Vocal cord paralysis/paresis
- Chylothorax/Pleural Effusion
- Other, If checked, enter description:
- N/A
- Unknown

19. Post-Op Enteral Nutrition

If Ligated, Date on Which Post-Op Enteral Nutrition Started

/ / N/A No, Ligation Unknown

Note: Check Not Applicable if infant was transferred out or died prior to the start of post-op enteral nutrition.
No Ligation is always checked for infants who did not undergo a ligation.



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Discharge (Items 20-21)

20. PDA Status on Echo after all Treatments or at Discharge

Note: This item applies to the last echo performed between the time after surgery or after the last medical treatment and discharge. If the infant did not receive any medical or surgical treatment at your center, use the last echo performed prior to discharge.

- Echo not done
- Small (< 1.5 mm)
- Moderate (1.5 to 2.5 mm)
- Large (> 2.5 mm)
- Size not specified
- Closed
- Unknown

21. Parenteral Nutrition

- Infant did not receive parenteral nutrition
- Infant was discharged or died on parenteral nutrition
- Infant received and stopped parenteral nutrition at this center

Please enter last day on which the infant received Parenteral Nutrition:

/ / Unknown

Comment Box:

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