NPC-QIC DATA COLLECTION FORMS

Provided by NPC-QIC Data Team

VERSION 6.0 DATE 12MARCH2021

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INFORMED CONSENT

NPC-QIC Registry ID: *(Site # - ID#)* *Required |_|_|_|_|-|_|_|_|_|

Verify that your center has current and appropriate IRB approval by checking this box: *Required ☐

1. Date of Informed Consent: *Required |_|_|_|_|-|_|_|-|_|_|
   Y Y Y Y – M M – D D
   ☐ Patient was enrolled via Waiver of Consent[1]

NEURODEVELOPMENTAL INFORMED CONSENT

2. Confirm which components of Phase II Neurodevelopment the patient's parent/caregiver(s) have agreed to participate in: *Required
   (select all that apply)
   ☐ Early Intervention (EI) Outpatient Surveys
   ☐ Brookes Ages & Stages Questionnaires (ASQ)
   ☐ None

If participating in EI Surveys

2a. Provide the email address for the PERSON AT YOUR CENTER who will be responsible for receiving the EI survey links and providing them to the patient's parent/caregiver(s): *Required
_____
(DO NOT enter the patient's parent/caregiver(s) email address here)

2b. What language will the patient's parent/caregiver(s) complete the EI surveys in? *Required
(select only one response)
☐ English
☐ Spanish

RECONSENT INFORMATION

THE RECONSENT INFORMATION FORM IS EXPECTED TO BE COMPLETED ONLY FOR PATIENTS WHO ARE BEING "SHARED" BETWEEN NPC-QIC CENTERS. SHARED PATIENTS ARE DEFINED AS THOSE WHO TRANSFER TO ANOTHER NPC-QIC PARTICIPATING CENTER DURING THEIR FIRST YEAR AND HAVE AGREED TO CONTINUE TO HAVE THEIR DATA COLLECTED FOR NPC-QIC AT THE NEW CENTER. IN ORDER TO SHARE A PATIENT WITH ANOTHER CENTER, THE PATIENT MUST BE CONSENTED AT BOTH CENTERS USING AN INFORMED CONSENT FORM THAT INCLUDES LANGUAGE THAT INFORMS THE PATIENT ABOUT DATA SHARING BETWEEN CENTERS.

IT IS POSSIBLE FOR PATIENTS TO BE SHARED MULTIPLE TIMES ACROSS MULTIPLE CENTERS DURING THE COURSE OF DATA COLLECTION FOR NPC-QIC. A NEW RECONSENT INFORMATION FORM MUST BE COMPLETED FOR EVERY CENTER INVOLVED IN SHARING A PATIENT.

**THE NPC-QIC DATA MANAGEMENT TEAM SHOULD BE NOTIFIED OF EVERY INSTANCE OF PATIENT SHARING. A GUIDE ON THE PATIENT SHARING PROCESS IS AVAILABLE ON THE NPC-QIC SHAREPOINT SITE AND PROVIDES THE LINK FOR NOTIFYING THE DATA MANAGEMENT TEAM.*

NPC-QIC Registry ID: *(Site # - ID#)* **Required* |__|__|__|__|-|__|__|__|__|

1. Is this patient being shared between two NPC-QIC centers[2]?
   (select only one response)
   ☐ Yes
   ☐ No

If Yes

1a. Reconsent Date: |__|__|__|__|-|__|__|-|__|__|
Y Y Y Y – M M – D D

1b. Center Name: _____

PRENATAL INFORMATION

NPC-QIC Registry ID: *(Site # - ID#)* *Required

|_|_|_|_|-|_|_|_|_|

1. Was a fetal cardiac diagnosis made? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

If Yes

2. Was a fetal cardiac intervention performed?
(select all that apply)

- ☐ Yes
- ☐ No

If Yes

2a. Type(s) of fetal cardiac intervention performed:
(select all that apply)

- ☐ Aortic valve dilation
- ☐ Atrial septal dilation/stent
- ☐ Fetal pacemaker
- ☐ Other, specify:
_____

3. Patient's parent/caregiver(s) received the following prenatal support:
*Required
(select all that apply)

- ☐ None
- ☐ Offered connection to parent/caregiver(s) support (e.g. SBH/LBH/local group meeting)
- ☐ Received third trimester (27 weeks or more) echocardiogram and consultation
- ☐ Comprehensive counseling[3] (includes diagnosis, short- and longer-term outcomes, surgical plan, delivery and pre-operative plan, interstage plan, pre- and post-op growth and nutrition, neurodevelopmental issues, long term outlook and QOL)
- ☐ Unknown

4. Surgical center's HLHS palliative surgical outcomes were discussed[4] with patient's parent/caregiver(s) and documented? *Required
(select only one response)

- ☐ Yes
- ☐ No

5. Delivery was coordinated with OB/perinatal team in the following ways:
*Required
(select all that apply)

- ☐ None
- ☐ Interdisciplinary combined case conference prior to delivery
- ☐ Note in medical record documenting closed loop communication between OB and cardiology teams[5]
- ☐ Unknown

POSTNATAL INFORMATION

NPC-QIC Registry ID: *(Site # - ID#)* *Required |__|__|__|-|__|__|__|__|

DEMOGRAPHICS

1. Date of Birth: |__|__|__|__|-|__|__|-|__|__| (YYYY-MM-DD)

If Consented Prenatally

1a. Consent Reaffirmation Date[6]: |__|__|__|__|-|__|__|-|__|__| (YYYY-MM-DD)

☐ Consent Reaffirmation not required by IRB

2. Postal Code for patient's Primary Residence: *Required |__|__|__|__|__|
☐ Zip Code Unknown
☐ Patient's primary residence is outside the U.S.

3. Birth Weight Known?
(select only one response)
☐ Yes
☐ No

If Yes

3a. Birthweight: *Required |__|__|.|__|__|__| (kg)

4. Gestational Age at birth known? *Required
(select only one response)
☐ Yes → |__|__| (weeks) |__|__| / 7 (days) *Required
(enter 40 weeks 0 days if chart only notes 'full term')
☐ No

If Gestational Age at Birth was <39 weeks

4a. Was early delivery due to fetal distress, maternal distress, or early spontaneous labor? *Required
(select only one response)
☐ Yes
☐ No

5. Gender: *Required
(select only one response)
☐ Male
☐ Female
☐ Ambiguous

6. Race: *Required
(select all that apply)
☐ White[7]
☐ Black-African American[8]
☐ Native Hawaiian or Other Pacific Islander[9]
☐ Asian[10]
☐ American Indian or Alaska Native[11]
☐ Other
☐ Unknown

7. Hispanic or Latino Ethnicity: *Required
(select only one response)
☐ Yes
☐ No
☐ Not Documented

8. Type of Health Insurance[12]: *Required
(select only one response)
☐ Government[13]
☐ Commercial
☐ Non-U.S. Insurance
☐ None / Self
☐ Unknown / Not Reported

OTHER POSTNATAL INFORMATION

9. Patient's parent/caregiver(s) received the following postnatal preoperative support:
(select all that apply)
☐ None
☐ Offered connection to parent/caregiver(s) support (e.g. SBH/LBH/local group meeting)
☐ Comprehensive counseling[3] (includes diagnosis, short- and longer-term outcomes, surgical plan, pre-operative plan, interstage plan, pre- and post-op growth and nutrition, neurodevelopmental issues, long term outlook, and QOL)
☐ Unknown

CARDIAC DIAGNOSIS

10. Primary Cardiac Diagnosis at presentation[14]: *Required
(select only one response)

- ☐ Hypoplastic left heart syndrome, HLHS[15]
- ☐ Single ventricle, DILV[16]
- ☐ Single ventricle, DIRV[17]
- ☐ Single ventricle, DORV[18]
- ☐ Single ventricle, Mitral atresia[19]
- ☐ Single ventricle, Tricuspid atresia/transposition[20]
- ☐ Single ventricle, Other[21]
- ☐ Unbalanced AV canal[22]
- ☐ Other, specify:

_____

If HLHS

10a. Subtype: *Required
(select only one response)

- ☐ Aortic Atresia and Mitral Atresia
- ☐ Aortic Atresia and Mitral Stenosis
- ☐ Aortic Stenosis and Mitral Atresia
- ☐ Aortic Stenosis and Mitral Stenosis
- ☐ Other, specify:

_____

11. Secondary Cardiac Diagnosis at presentation:
(select all that apply)

- ☐ None
- ☐ Anomalous pulmonary venous return[23]
- ☐ Ascending Aortic measurement < 2 mm
- ☐ Arrhythmia requiring therapy[24]
- ☐ Endocardial Fibroelastosis (EFE)
- ☐ Intact atrial septum
- ☐ Moderate to severe AV valve regurgitation
- ☐ Moderate to severe ventricular dysfunction
- ☐ Restrictive atrial septum (as determined by your center)
- ☐ Other, specify:

_____

12. Major syndromes: *Required
(select all that apply)

- ☐ None
- ☐ 22q11 Deletion – DiGeorge Syndrome[25]
- ☐ CHARGE Association[26]
- ☐ Down syndrome[27]
- ☐ Heterotaxy Syndrome[28]
- ☐ Jacobsen Syndrome[29]
- ☐ Turner Syndrome[30]
- ☐ VACTERL syndrome (VACTER/VATER/VATERR syndrome)[31]
- ☐ Other, specify:

_____

13. Major congenital anomalies of other organ systems: *Required
(select all that apply)

- ☐ None
- ☐ Major abnormality of brain
- ☐ Major abnormality of gastrointestinal system
- ☐ Major abnormality of kidney, ureter, or bladder
- ☐ Major abnormality of larynx, trachea, or bronchus
- ☐ Major abnormality of lung
- ☐ Major abnormality of spine

NEURODEVELOPMENTAL INFORMATION

14. Did patient's parent/caregiver(s) receive a written, up-to-date, developmental plan at enrollment[32]? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

STAGE 1 PALLIATION SURGICAL INFORMATION AND HOSPITAL COURSE

NPC-QIC Registry ID: *(Site # - ID#)* *Required

|_|_|_|_|-|_|_|_|_|

1. Was patient born at Stage 1 Palliation surgical center? *Required
(select only one response)

☐ Yes
☐ No

(Answer Yes if place of birth is physically connected to surgical center)

If No

1a. Distance from birth hospital to Stage 1 Palliation surgical center:
(select only one response)

☐ Less than 5 miles
☐ 5 – 19 miles
☐ 20 – 100 miles
☐ Over 100 miles

2. Date of hospital admission that included Stage 1 Palliation surgery:
*Required

|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

(Use date of birth if patient was born at surgical center)

3. Center Name where this admission occurred: _____

PREOPERATIVE INFORMATION

4. What type of enteral feedings did the patient receive prior to Stage 1 Palliation surgery (in addition to swab to the mouth)?
(select all that apply)

☐ Breastfeeding
☐ Bottle fed – Formula
☐ Bottle fed – Human Milk
☐ Did not feed – Clinical Reasons
☐ Did not feed – Institutional Practice not to feed prior to Stage 1 Palliation
☐ NG Tube Trophic[33]
☐ NG Tube greater than Trophic[33]

If NG Tube (Trophic or Greater than Trophic)

4a. What is the type of feeding via NG Tube? *Required
(select only one response)

☐ Breastmilk[34]
☐ Formula
☐ Combination of breastmilk and formula

5. Patient had the following checked/performed prior to Stage 1 Palliation surgery:
(select all that apply)

☐ Creatinine
☐ Lactate
☐ Head Ultrasound

6. Did your team perform a daily assessment of physiologic readiness[35] prior to Stage 1 Palliation surgery? *Required
(select only one response)

☐ Yes
☐ No

7. Did the team feel the Stage 1 Palliation surgery was delayed[36]? *Required
(select only one response)

☐ Yes
☐ No

If Yes

7a. Reason Stage 1 Palliation surgery was delayed:
(select only one response)

☐ Surgical scheduling issues
☐ Surgeon availability issues
☐ Emergent surgical case scheduled
☐ Critical care staff/bed space issues
☐ Cardiac anesthesia availability issues
☐ Perfusion concerns
☐ Neurologic concerns
☐ Renal concerns
☐ Infection needing treatment
☐ Other, specify:
_____

8. Patient had the following preoperative factors or adverse events: *Required
(select all that apply)

- ☐ None
- ☐ Arterial pH < 7.2
- ☐ Creatinine > 2
- ☐ Inotrope infusion at time of surgery
- ☐ Lactate > 3
- ☐ Mechanical ventilation to treat cardiorespiratory failure
- ☐ Necrotizing entero-colitis, Treated medically[37]
- ☐ Necrotizing entero-colitis, Treated surgically[38]
- ☐ Preoperative Neurological deficit
- ☐ Preoperative/Preprocedural mechanical circulatory support (IABP, VAD, ECMO, or CPS)
- ☐ Seizure during lifetime
- ☐ Sepsis
- ☐ Shock, Persistent at time of surgery
- ☐ Shock, Resolved at time of surgery
- ☐ Tracheostomy present
- ☐ Other, specify: _____

9. Were PA bands[39] as well as PGE continuation used as early surgical palliation?
(select only one response)

- ☐ Yes
- ☐ No

If Yes

9a. If yes, Date of PA Banding: |_|_|_|_|-|_|_|-|_|_| (YYYY-MM-DD)

10. Was preoperative catheterization done (not including catheterization done as part of Hybrid Stage 1 approach)?
(select only one response)

- ☐ Yes
- ☐ No

If Yes

10a. Type(s) of preoperative catheterization performed:
(select all that apply)

- ☐ Diagnostic study only
- ☐ Aortic valve dilation
- ☐ Atrial septal stent
- ☐ Balloon/blade septostomy
- ☐ Coarctation/arch dilation
- ☐ Coarctation/arch stent
- ☐ Pulmonary vein dilation
- ☐ Pulmonary vein stent
- ☐ Other, specify: _____

11. Patient's parent/caregiver(s) had the following preoperative preparations: *Required
(select all that apply)

- ☐ None
- ☐ Family met surgeon prior to Stage 1 Palliation
- ☐ Prepared for baby's post-op appearance/tech support (prior to Stage 1 Palliation, family shown pictures of expected appearance after Stage 1 Palliation surgery or given tour of ICU)
- ☐ Underwent standardized informed surgical consent process for surgery (prior to Stage 1 Palliation, the surgical team will discuss the goals of the operation, discuss the anticipated surgical approach and potential complications, and share institutional Stage 1 Palliation outcome data on survival and average length of stay)

12. Patient's care was discussed at preoperative multidisciplinary care team planning conference: *Required
(select only one response)

- ☐ Yes
- ☐ No

If No

12a. Reason care was not discussed:
(select all that apply)

- ☐ Urgent/Emergent/Salvage Case
- ☐ Program does not routinely discuss all cases
- ☐ Program does not have regular conferences
- ☐ Surgery occurred between regularly scheduled conferences
- ☐ Other, specify: _____

SURGERY INFORMATION

13. Stage 1 Palliation surgery Date[40]: *Required

|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

☐ Patient Early Exited prior to receiving Stage 1 Palliation surgery *(do not complete remained of this form)*

If patient received Stage 1 Palliation Surgery

14. Type of Stage 1 Palliation surgery performed[41]: *Required
(select only one response)

☐ Norwood with BT shunt
☐ Norwood with Central shunt
☐ Norwood with RV-PA conduit (Sano)
☐ Hybrid Norwood (PA Bands with or without PDA stent)
☐ DKS connection with BT shunt
☐ DKS connection with RV-PA conduit
☐ Other, specify:
_____

If Hybrid Norwood

14a. What was the indication?
(select all that apply)

☐ Standard of care at the institution
☐ Borderline left-sided structures (performed as part of decision tree to decide between 1V or 2V surgical palliation)
☐ Concern for going on cardiopulmonary bypass (i.e. history of head bleed)
☐ Prematurity
☐ Low birth weight
☐ Associated syndrome/multiple other congenital anomalies
☐ Religious (i.e. Jehovah's Witness)
☐ Palliation awaiting transplant

15. What additional cardiac operative procedures were performed at the time of Stage 1 Palliation surgery?
(select all that apply)

☐ None
☐ AV Valve Repair
☐ Pulmonary Vein Repair
☐ Other, specify:
_____

16. Was patient spontaneously breathing at time of being taken to surgery?
(select only one response)

☐ Yes
☐ No

17. Actual Weight at Stage 1 Palliation surgery: *Required

|_|_|_|.|_|_|_|_| (kg)

18. CPB Time:

|_|_|_|_| (minutes) ☐ Not Available

19. Patient had the following during surgery:
(select all that apply)

☐ None
☐ Cerebral Perfusion
☐ Circulatory Arrest
☐ Cross Clamp

If Cerebral Perfusion / Circulatory Arrest / Cross Clamp

19a. Cerebral Perfusion Time: |_|_|_|_| (minutes) ☐ Not Available

19b. Circulatory Arrest Time: |_|_|_|_| (minutes) ☐ Not Available

19c. Cross Clamp Time: |_|_|_|_| (minutes) ☐ Not Available

20. Did patient require an additional cardiopulmonary bypass run or ECMO while in OR for Stage 1 Palliation surgery? *Required
(select all that apply)

☐ None
☐ Cardiopulmonary Bypass
☐ ECMO

If ECMO

20a. Did the patient leave the OR on ECMO?
(select only one response)

☐ Yes
☐ No

21. Patient had the following perioperative communications: *Required
(select all that apply)

- ☐ None
- ☐ Structured preoperative briefing from surgeon to care team[42]
- ☐ Pre-op time out
- ☐ Standardized handoffs using checklist[43]
- ☐ At least hourly communication with parent/caregiver(s) during the procedure

22. Date of initial postoperative extubation[44]: *Required

|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

- ☐ Patient remained intubated at Early Exit or Discharge

If Patient was extubated

22a. Did patient require re-intubation within 48 hours after initial postoperative extubation: *Required
(select only one response)

- ☐ Yes
- ☐ No

If Yes

i. Date of final postoperative extubation[44]: *Required

|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

- ☐ Patient remained intubated at Early Exit or Discharge

POSTOPERATIVE INFORMATION

23. Did patient require ECMO at any time postoperatively?
(select only one response)

- ☐ Yes
- ☐ No

24. Delayed sternal wound closure was used in patient management:
(select only one response)

- ☐ Yes
- ☐ No

25. Postoperative care was managed using a written clinical pathway (written protocol at your institution):
(select only one response)

- ☐ Yes
- ☐ No

26. Postoperative complications: *Required
(select all that apply)

- ☐ None
- ☐ Arrhythmia requiring drug therapy[45]
- ☐ Arrhythmia necessitating pacemaker, Permanent pacemaker[46]
- ☐ Necrotizing entero-colitis, Treated medically[37]
- ☐ Necrotizing entero-colitis, Treated surgically[38]
- ☐ Neurological deficit, Neurological deficit persisting at discharge[47]
- ☐ Paralyzed diaphragm (possible phrenic nerve injury)[48]
- ☐ Pleural effusion, Requiring drainage[49]
- ☐ Pneumonia
- ☐ Pneumothorax, Requiring drainage or evacuation[50]
- ☐ Postoperative/postprocedural respiratory insufficiency requiring reintubation
- ☐ Renal failure – acute renal failure, Acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge
- ☐ Seizure
- ☐ Sepsis
- ☐ Stoke
- ☐ Vocal cord dysfunction (possible recurrent laryngeal nerve injury)[51]
- ☐ Wound Infection
- ☐ Other, specify:

_____
_____
_____

27. Postoperative cardiac arrest? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

28. Significant postoperative rhythm abnormalities that required treatment or medication: *Required
(select all that apply)

- ☐ None
- ☐ Atrial flutter or fibrillation
- ☐ Chaotic atrial rhythm
- ☐ Ectopic atrial tachycardia
- ☐ JET
- ☐ Re-entrant supraventricular tachycardia
- ☐ Second degree AV block
- ☐ Sinus bradycardia
- ☐ Third degree AV block
- ☐ Ventricular Fibrillation
- ☐ Ventricular Tachycardia

29. Were one or more postoperative catheterizations[52] done? *Required
(select only one response)

☐ Yes, specify total done: _____
☐ No

If Yes, complete the Date/Type/Reason for each Catheterization done (use the key below to complete Type & Reason)

Catheterization Types

1	Diagnostic study only	11	PA dilation
2	Aortic valve dilation	12	PA stent
3	AP collateral occlusion	13	PDA stent (to complete PA band + PGE palliation strategy)
4	Atrial septal stent	14	Pulmonary vein dilation
5	Balloon/blade septostomy	15	Pulmonary vein stent
6	BT shunt dilation	16	RV-PA conduit dilation
7	BT shunt stent	17	RV-PA conduit stent
8	Coarctation/arch dilation	18	Other Specify
9	Coarctation/arch stent		
10	Coil veno-venous collaterals		

Catheterization Reasons

1	Cardiac Arrest	6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
2	Chylothorax	7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)	8	Other Specify
4	Echocardiogram findings without clinical signs		
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR		

	Date: *Required	**Type(s):** *Required	**Reason(s):** *Required
29a.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
29b.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
29c.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
29d.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
29e.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
29f.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
29g.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
29h.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____

30. Were one or more cardiac reoperations[53] necessary following the Stage 1 Palliation surgery (other than routine delayed sternal closure)?
*Required
(select only one response)

☐ Yes, specify total done: _____
☐ No

If Yes, complete the Date/Type/Reason for each Cardiac Reoperation done (use the key below to complete Type & Reason)

Reoperation Types

1	Aortic arch repair	11	Pacemaker placement
2	Aortic valve dilation	12	RV-PA conduit revision
3	AP collateral occlusion	13	Sternal or mediastinal debridement
4	Exploration for bleeding or Tamponade	14	Other Specify
6	PA band adjustment		

Reoperation Reasons

1	Cardiac Arrest	6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
2	Chylothorax	7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)	8	Other Specify
4	Echocardiogram findings without clinical signs		
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR		

	Date: *Required	**Type(s):** *Required	**Reason(s):** *Required
30a.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
30b.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____
30c.	|__|__|__|__|-|__|__|-|__|__| Y Y Y Y – M M – D D	_____	_____

30d. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

30e. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

30f. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

30g. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

30h. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

31. Other major postoperative procedures performed:
(select all that apply)

- ☐ None
- ☐ Bedside Laryngoscopy to Assess Vocal Cords
- ☐ Brochoscopy
- ☐ Cardioversion
- ☐ Dialysis
- ☐ Diaphragm Plication
- ☐ Fundoplication
- ☐ G-Tube
- ☐ Pericardiocentesis
- ☐ Thoracic Duct Ligation
- ☐ Tracheostomy
- ☐ Other, specify: _____

32. Patient was weaned off of all inotropes/vasoactive medications[54] within 5 days of Stage 1 Palliation surgery (Day of surgery is considered Day 0): *Required
(select only one response)

- ☐ Yes
- ☐ No

33. Initial postoperative date starting enteral feeds (including trophic feeds): *Required

|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)

- ☐ Patient never began enteral feeds before Early Exit or Discharge

If Patient began enteral feeds before Early Exit or Discharge

33a. Initial postoperative date on 100 kcal/kg/day enteral feeds: |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)

POSTOPERATIVE ECHOCARDIOGRAM INFORMATION

34. Was a transthoracic echocardiogram done within 72 hours after Stage 1 Palliation surgery?
(select only one response)

- ☐ Yes
- ☐ No *(do not complete the remained of this form)*

If Yes

35. Date of transthoracic echocardiogram (closest to 72 hours post Stage 1 Palliation surgery)[55]: *Required

|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)

36. Qualitative assessment of Ventricular Function: *Required
(select only one response)

- ☐ Normal or low normal function
- ☐ Mild dysfunction
- ☐ Moderate dysfunction
- ☐ Severe dysfunction
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

37. Qualitative assessment of Tricuspid/Systemic AV Valve Regurgitation:
*Required
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

Stage 1 NOT Hybrid Norwood

38. Qualitative assessment of neo-Aortic Valve Regurgitation: *Required
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

39. What was the Doppler peak velocity across the distal arch?

|__|__|.|__|__| (m/s) ☐ Not Available

Stage 1 Hybrid Norwood

40. Was the neo-Aortic retrograde arch obstructed (maximum peak instantaneous gradient by Doppler > 10 mmHg) as evaluated by imaging? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Not Evaluated

If Yes

40a. Retrograde aortic arch stenosis:
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

41. PDA stent stenosis:
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

42. PA band gradients:
(select only one response)

- ☐ Adequate (band gradients > 3.5 m/s)
- ☐ Low (band gradients ≤ 3.5 m/s)
- ☐ No information available

43. Was the ASD restrictive (Doppler mean gradient >1 mmHg)?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Not Evaluated

If Yes

43a. ASD Doppler mean gradient: |__|__|__| (mmHg) ☐ Not Available

44. Was there other clinical evidence (blood pressure cuff measurements) demonstrating distal aortic arch obstruction (>10 mmHg)?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ No Information Available

If Yes

44a. Obstruction: |__|__|__| (mmHg) ☐ Not Available

STAGE 1 PALLIATION SURGICAL DISCHARGE INFORMATION

NPC-QIC Registry ID: *(Site # - ID#)* *Required

|_|_|_|_|-|_|_|_|_|

1. Patient's disposition following the Stage 1 Palliation: *Required
(select only one response)

- ☐ Discharged to home from Stage 1 Palliation surgical center
- ☐ Transferred as inpatient to another facility
- ☐ Remained inpatient until Stage 2 Palliation surgery
- ☐ Remained inpatient until first birthday without receiving Stage 2 Palliation
- ☐ Early Exit from study *(do not complete the remained of this form)*

DISCHARGED HOME / TRANSFERRED TO ANOTHER FACILITY INFORMATION

COMPLETE THIS SECTION IF THE PATIENT WAS DISCHARGED TO HOME OR TRANSFERRED TO ANOTHER FACILITY.

2. Date of Discharge from Stage 1 Palliation surgical center: *Required

|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

3. Last Weight recorded prior to discharge: *Required

|_|_|_|.|_|_|_|_| (kg)

4. Was Length collected prior to discharge?
(select only one response)

- ☐ Yes
- ☐ No

If Yes

4a. Last Length recorded prior to discharge: *Required

|_|_|_|_|.|_|_| (cm)

5. Last O2 saturation recorded prior to discharge:

|_|_|_|_| (%)
(enter mean if range is provided)

6. Route of nutrition utilized during hospitalization following Stage 1 Palliation:
(select all that apply)

- ☐ G-Tube/GJ Tube
- ☐ NG/NJ
- ☐ Oral – Breastfed
- ☐ Oral – Bottle fed

7. Type of nutrition utilized during hospitalization following Stage 1 Palliation:
(select only one response)

- ☐ Breastmilk[34]
- ☐ Formula
- ☐ Combination of breastmilk and formula

If Formula

7a. Type(s) of formula recommended in the nutrition plan at discharge:
(select all that apply)

- ☐ Elecare Infant
- ☐ Enfamil Gentlease
- ☐ Enfamil Premium
- ☐ Enfaport
- ☐ Good Start Gentle
- ☐ Neocate Infant
- ☐ Nutramigen
- ☐ "Organic" infant formula
- ☐ Pregestimil
- ☐ Similac Advance
- ☐ Similac Sensitive
- ☐ Similac Alimentum
- ☐ Other, specify: _____

8. Calorie density recommended in the nutrition plan at discharge:

|_|_|_| (kcal/oz)

9. Target kcal/kg/24 hours recommended in the nutrition plan at discharge:

|_|_|_|_| (kcal/kg/24 hours)

10. Postoperative feeding evaluations performed: *Required
(select all that apply)

- ☐ None
- ☐ Clinical Feeding Evaluation by OT/PT or Speech Language Pathologist (SLP)
- ☐ Fiber optic Endoscopic Evaluation of Swallowing
- ☐ Video swallowing study
- ☐ Other, specify: _____

11. Medications prescribed at time of discharge: *Required
(select all that apply)

- ☐ None
- ☐ Amiodarone / Cordarone
- ☐ Amlodipine / Norvasc
- ☐ Antibiotics (any)
- ☐ Antiepileptic medication (any)
- ☐ Aspirin
- ☐ Atenolol / Tenormin
- ☐ Benzodiazepines (e.g. Ativan)
- ☐ Captopril / Capoten
- ☐ Chlorothiazide / Diuril
- ☐ Clonidine / Catapres
- ☐ Clopidogrel / Plavix
- ☐ Digoxin / Lanoxin
- ☐ Enalapril / Vasotec
- ☐ Enoxaparin / Lovenox
- ☐ Famotidine / Pepcid
- ☐ Flecainide / Tambocor
- ☐ Furosemide / Lasix
- ☐ Lansoprazole / Prevacid
- ☐ Lisinopril / Zestril
- ☐ Metoclopramide / Reglan
- ☐ Midazolam / Versed
- ☐ Multivitamin / Vitamin D
- ☐ Omeprazole / Prilosec
- ☐ Opiates (e.g. Methadone)
- ☐ Propranolol / Inderal
- ☐ Ranitidine / Zantac
- ☐ Sildenafil / Viaga / Revatio
- ☐ Sotalol / Betapase / Sotylize / Sorine
- ☐ Spironolactone / Aldactone
- ☐ Supplemental Oxygen
- ☐ Warfarin / Coumadin
- ☐ Other, specify:

_____
_____
_____

If prescribed Digoxin/Lanoxin

11a. Dosage per individual dose: |__|__|.|__|__| (mcg/kg)

11b. Dosage frequency:
(select only one response)

- ☐ One time a day
- ☐ Two times a day
- ☐ Unknown
- ☐ Other, specify:

_____

11c. Reason prescribed: *Required
(select all that apply)

- ☐ Improve Heart Function
- ☐ Treat Arrhythmia
- ☐ Standard Protocol at Center
- ☐ Physician Preference
- ☐ Parent/Caregiver Request
- ☐ Unknown
- ☐ Other, specify:

_____

12. Did patient's parent/caregiver(s) receive a Red Flag Action Plan (list of specific signs, symptoms and/or indications for calling health care professional (HCP), name and phone number of appropriate HCPs) at time of discharge?
(select only one response)

- ☐ Yes
- ☐ No

13. Is patient being discharged with Home Surveillance Strategy (either O2Sat & Weight monitoring or only O2Sat monitoring)?
(select only one response)

- ☐ Yes
- ☐ No

14. Did the patient's parent/caregiver(s) provide 24 hour "room-in" care with the patient prior to discharge?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

15. Where will this patient be followed for outpatient interstage care?
(select only one response)

- ☐ At the same center or satellite clinic of the center where the Stage 1 Palliation surgery was performed
- ☐ At another center (distinct from the center where the Stage 1 Palliation surgery was performed)
- ☐ A combination of both of the above
- ☐ Other, specify:

_____

DISCHARGE ECHOCARDIOGRAM INFORMATION

COMPLETE THIS SECTION IF THE PATIENT WAS DISCHARGED TO HOME OR TRANSFERRED TO ANOTHER FACILITY.

16. Date of transthoracic echocardiogram closest to, but before, discharge: *Required
    |_|_|_|_|-|_|_|-|_|_|
    Y Y Y Y – M M – D D

17. Qualitative assessment of Ventricular Function: *Required
    (select only one response)
    - ☐ Normal or low normal function
    - ☐ Mild dysfunction
    - ☐ Moderate dysfunction
    - ☐ Severe dysfunction
    - ☐ No information available

    (if spanning categories [e.g. mild-moderate], select the more severe category)

18. Qualitative assessment of Tricuspid/Systemic AV Valve Regurgitation:
    *Required
    (select only one response)
    - ☐ None / trivial
    - ☐ Mild
    - ☐ Moderate
    - ☐ Severe
    - ☐ No information available

    (if spanning categories [e.g. mild-moderate], select the more severe category)

Stage 1 NOT Hybrid Norwood

19. Qualitative assessment of neo-Aortic Valve Regurgitation: *Required
    (select only one response)
    - ☐ None / trivial
    - ☐ Mild
    - ☐ Moderate
    - ☐ Severe
    - ☐ No information available

    (if spanning categories [e.g. mild-moderate], select the more severe category)

20. What was the Doppler peak velocity across the distal arch?
    *Required
    |_|_|.|_| (m/s) ☐ Not Available

Stage 1 Hybrid Norwood

21. Was the neo-Aortic retrograde arch obstructed (maximum peak instantaneous gradient by Doppler >10 mmHg) as evaluated by imaging? *Required
    (select only one response)
    - ☐ Yes
    - ☐ No
    - ☐ Not evaluated

If Yes

21a. Retrograde aortic arch stenosis:
(select only one response)
- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

22. PDA stent stenosis:
(select only one response)
- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

23. PA band gradients:
(select only one response)
- ☐ Adequate (band gradients > 3.5 m/s)
- ☐ Low (band gradients ≤ 3.5 m/s)
- ☐ No information available

24. Was the ASD restrictive (Doppler mean gradient >1 mmHg)?
(select only one response)
- ☐ Yes
- ☐ No
- ☐ Not evaluated

If Yes

24a. ASD Doppler mean gradient: |_|_|_| (mmHg) ☐ Not Available

25. Was there other clinical evidence (blood pressure cuff measurements) demonstrating distal aortic arch obstruction (>10 mmHg)?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ No information available

If Yes

25a. Obstruction: |__|__| (mmHg) ☐ Not Available

REMAINED INPATIENT INFORMATION

COMPLETE THIS SECTION IF THE PATIENT REMAINED INPATIENT UNTIL STAGE 2 PALLIATION OR UNTIL FIRST BIRTHDAY.

26. Reason patient remained inpatient: _____
(i.e. social concerns, distance to home, medical concerns, etc.)

27. Route of nutrition utilized during hospitalization following Stage 1 Palliation:
(select all that apply)

- ☐ G-Tube/GJ Tube
- ☐ NG/NJ
- ☐ Oral – Breastfed
- ☐ Oral – Bottle fed

28. Type of nutrition utilized during hospitalization following Stage 1 Palliation:
(select only one response)

- ☐ Breastmilk[34]
- ☐ Formula
- ☐ Combination of breastmilk and formula

29. Postoperative feeding evaluations performed: *Required
(select all that apply)

- ☐ None
- ☐ Clinical Feeding Evaluation by OT/PT or Speech Language Pathologist (SLP)
- ☐ Fiber optic Endoscopic Evaluation of Swallowing
- ☐ Video swallowing study
- ☐ Other, specify: _____

NEURODEVELOPMENTAL INFORMATION

30. Did patient remain inpatient at Stage 1 Palliation surgical center for longer than 28 days post Stage 1 Palliation surgery? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

If Yes

30a. Did patient's parent/caregiver(s) receive a written, up-to-date, developmental plan (or other similar written materials about how to support the patient's development) while inpatient? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

If Discharged Home or Transferred to Another Facility

31. Did patient's parent/caregiver(s) receive a written, up-to-date, developmental plan (or other similar written materials about how to support the patient's development) at discharge? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

INTERSTAGE READMISSION

THIS FORM SHOULD BE COMPLETED FOR EACH READMISSION THE PATIENT HAS BETWEEN THEIR DISCHARGE FROM THE STAGE 1 PALLIATION SURGICAL CENTER AND THEIR ADMISSION FOR STAGE 2 PALLIATION SURGERY. IF COMPLETING THIS FORM ON PAPER, WRITE THE DATE OF READMISSION AT THE TOP OF EACH PAGE TO ENSURE THE ABILITY TO MATCH PAGES TO THE CORRECT READMISSION.

NPC-QIC Registry ID: *(Site # - ID#)* **Required* |__|__|__|-|__|__|__|__|

READMISSION INFORMATION

1. Date of Readmission: **Required* |__|__|__|__|-|__|__|-|__|__| (YYYY – MM – DD)

2. Center Name where this admission occurred: _____

3. Patient admitted from:
(select only one response)
- ☐ Clinic
- ☐ Direct admit from home
- ☐ Emergency room
- ☐ Outside Hospital
- ☐ Pediatrician office
- ☐ Other, specify: _____

4. Unit patient admitted to:
(select only one response)
- ☐ Cardiology Floor/Stepdown
- ☐ CICU
- ☐ General Pediatric Floor
- ☐ NICU
- ☐ PICU
- ☐ Other, specify: _____

5. Was weight recorded during this admission?
(select only one response)
- ☐ Yes
- ☐ No

If Yes

5a. Weight (closest to admission): |__|__|.|__|__|__| (kg)

6. Was this admission for an anticipated pre-Stage 2 Palliation cardiac catheterization? **Required*
(select only one response)
- ☐ Yes
- ☐ No

If Yes

6a. Date of catheterization: |__|__|__|__|-|__|__|-|__|__| (YYYY – MM – DD)

6b. Type(s) of catheterization performed:
(select all that apply)
- ☐ Diagnostic study only
- ☐ Aortic valve dilation
- ☐ AP collateral occlusion
- ☐ Atrial septal stent
- ☐ Balloon/blade septostomy
- ☐ BT shunt dilation
- ☐ BT shunt stent
- ☐ Coarctation/arch dilation
- ☐ Coarctation/arch stent
- ☐ Coil veno-venous collaterals
- ☐ PA dilation
- ☐ PA stent
- ☐ PDA stent (to complete PA band + PGE palliation strategy)
- ☐ Pulmonary vein dilation
- ☐ Pulmonary vein stent
- ☐ RV-PA conduit dilation
- ☐ RV-PA conduit stent
- ☐ Other, specify: _____ _____

6c. Was patient admitted for more than 24 hours after the catheterization for further evaluation and management?
(select only one response)
- ☐ Yes
- ☐ No

If Admission was NOT for an anticipated pre-Stage 2 catheterization

7. Did a 'Red Flag' event prompt this admission?
(select only one response)

☐ Yes
☐ No

If Yes

7a. Which 'Red Flag' event(s) prompted this admission?
(select all that apply)

☐ Breathing problems
☐ Feeding problems
☐ Fever
☐ Fussiness
☐ Increased Cyanosis
☐ Poor Weight gain
☐ Vomiting or diarrhea
☐ Other, specify: _____

8. Did a Major Adverse Event prompt this admission? *Required
(select only one response)

☐ Yes
☐ No

If Yes

8a. Which Major Adverse Event(s) prompted this admission?
(select all that apply)

☐ Aspiration
☐ Cardiac arrest
☐ Infection requiring IV antibiotics
☐ Shunt Occlusion
☐ Life-threatening arrhythmia requiring DC cardioversion
☐ Seizure
☐ Stroke

INTERVENTIONS / PROCEDURES PERFORMED INFORMATION

9. Patient received the following interventions during the first 24 hours following admission: *Required
(select all that apply)

☐ None
☐ Fluid Resuscitation (Given 2 or more fluid boluses (PRBCs included) within 12 hours of admission)
☐ Intubated within 12 hours of admission (not including intubation done during an anticipated cath)
☐ Pericardiocentesis or pleurocentesis within 24 hours of admission
☐ Placed on inotropic support within 12 hours of admission
☐ Unplanned interventional catheterization or an unplanned surgical intervention within 24 hours of admission

10. Were one or more unanticipated catheterizations done as a part of this admission?
(select only one response)

☐ Yes, specify total done: _____
☐ No

If Yes, complete the Date/Type/Reason for each Unanticipated Catheterization done (use the key below to complete Type & Reason)

Catheterization Types

1	Diagnostic study only
2	Aortic valve dilation
3	AP collateral occlusion
4	Atrial septal stent
5	Balloon/blade septostomy
6	BT shunt dilation
7	BT shunt stent
8	Coarctation/arch dilation
9	Coarctation/arch stent
10	Coil veno-venous collaterals
11	PA dilation
12	PA stent
13	PDA stent (to complete PA band + PGE palliation strategy)
14	Pulmonary vein dilation
15	Pulmonary vein stent
16	RV-PA conduit dilation
17	RV-PA conduit stent
18	Other Specify

Catheterization Reasons

1	Cardiac Arrest
2	Chylothorax
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)
4	Echocardiogram findings without clinical signs
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR
6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
8	Other Specify

	Date: *Required	**Type(s):** *Required	**Reason(s):** *Required
10a.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
10b.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
10c.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
10d.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____

10e. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

10f. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

10g. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

10h. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

11. Was cardiac operation necessary during this admission?
(select only one response)

☐ Yes, specify total done: _____
☐ No

If Yes, complete the Date/Type/Reason for each Cardiac Operation done (use the key below to complete Type & Reason)

Reoperation Types

1	Aortic arch repair	11	Pacemaker placement
2	Atrial septectomy	12	RV-PA conduit revision
3	BT shunt revision	13	Sternal or mediastinal debridement
4	Exploration for bleeding or Tamponade	14	Other Specify
6	PA band adjustment		

Reoperation Reasons

1	Cardiac Arrest	6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
2	Chylothorax	7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)	8	Other Specify
4	Echocardiogram findings without clinical signs		
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR		

	Date: **Required*	**Type(s):** **Required*	**Reason(s):** **Required*
11a.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
11b.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
11c.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
11d.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
11e.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
11f.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
11g.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
11h.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____

12. Other major procedures performed during this admission:
(select all that apply)

☐ None
☐ Bronchoscopy
☐ Cardioversion
☐ Dialysis
☐ Diaphragm Plication
☐ Fundoplication
☐ G-Tube
☐ Pericardiocentesis
☐ Peritoneal Drain
☐ Placement on ECMO
☐ Thoracentesis
☐ Thoracic Duct Ligation
☐ Tracheostomy
☐ Other specify: _____

ECHOCARDIOGRAM INFORMATION

13. Was a transthoracic echocardiogram done during this admission?
(select only one response)
- ☐ Yes
- ☐ No *(do not complete the remained of this section)*

If Yes

14. Date of echocardiogram (closest study to admission): |_|_|_|_|-|_|_|-|_|_| (YYYY-MM-DD)

15. Qualitative assessment of Ventricular Function:
(select only one response)
- ☐ Normal or low normal function
- ☐ Mild dysfunction
- ☐ Moderate dysfunction
- ☐ Severe dysfunction
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

16. Qualitative assessment of Tricuspid/Systemic AV Valve Regurgitation:
(select only one response)
- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

Stage 1 NOT Hybrid Norwood

17. Qualitative assessment of neo-Aortic Valve Regurgitation:
(select only one response)
- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

18. What was the Doppler peak velocity across the distal arch? |_|_|.|_| (m/s) ☐ Not Available

Stage 1 Hybrid Norwood

19. Was the neo-Aortic retrograde arch obstructed (maximum peak instantaneous gradient by Doppler >10 mmHg) as evaluated by imaging?
(select only one response)
- ☐ Yes
- ☐ No
- ☐ Not evaluated

If Yes

19a. Retrograde aortic arch stenosis:
(select only one response)
- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

20. PDA stent stenosis:
(select only one response)
- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

21. PA band gradients:
(select only one response)
- ☐ Adequate (band gradients > 3.5 m/s)
- ☐ Low (band gradients ≤ 3.5 m/s)
- ☐ No information available

22. Was the ASD restrictive (Doppler mean gradient >1 mmHg)?
(select only one response)
- ☐ Yes
- ☐ No
- ☐ Not evaluated

If Yes

22a. ASD Doppler mean gradient: |_|_|_| (mmHg) ☐ Not Available

23. Was there other clinical evidence (blood pressure cuff measurements) demonstrating distal aortic arch obstruction (>10 mmHg)?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ No information available

If Yes

23a. Obstruction: |__|__|__| (mmHg) ☐ Not Available

DISCHARGE INFORMATION

24. Patient's disposition at discharge: *Required
(select only one response)

- ☐ Discharged to home
- ☐ Transferred to another facility
- ☐ Remained inpatient until Stage 2 Palliation surgery
- ☐ Remained inpatient until first birthday without receiving Stage 2 Palliation
- ☐ Early Exit from study *(do not complete the remainder of this form)*

If Discharged Home or Transferred to Another Facility

25. Discharge Date: *Required

|__|__|__|__|-|__|__|-|__|__|
Y Y Y Y – M M – D D

26. What was the final diagnosis that resulted in this readmission?
(select all that apply)

- ☐ Altered Mental Status
- ☐ Arrhythmia
- ☐ Bloody Stools
- ☐ Bronchiolitis/Pneumonia
- ☐ Cyanosis/Hypoxia
- ☐ Fussiness, unspecified
- ☐ GERD
- ☐ Inadequate Weight Gain
- ☐ Pleural/Pericardial Effusion
- ☐ Procedure for Residual Lesion
- ☐ Respiratory distress, unspecified
- ☐ Sepsis
- ☐ Stroke
- ☐ Vomiting/Diarrhea
- ☐ Worsening ventricular function
- ☐ Wound infection/Dehiscence
- ☐ Other, specify _____

27. In your opinion, could this readmission have been prevented/avoided?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

If Yes

27a. What could have been done to prevent this readmission?

_____
_____
_____
_____

28. Medications prescribed at time of discharge:
(select all that apply)

- ☐ None
- ☐ Amiodarone / Cordarone
- ☐ Amlodipine / Norvasc
- ☐ Antibiotics (any)
- ☐ Antiepileptic medication (any)
- ☐ Aspirin
- ☐ Atenolol / Tenormin
- ☐ Benzodiazepines (e.g. Ativan)
- ☐ Captopril / Capoten
- ☐ Chlorothiazide / Diuril
- ☐ Clonidine / Catapres
- ☐ Clopidogrel / Plavix
- ☐ Digoxin / Lanoxin
- ☐ Enalapril / Vasotec
- ☐ Enoxaparin / Lovenox
- ☐ Famotidine / Pepcid
- ☐ Flecainide / Tambocor
- ☐ Furosemide / Lasix
- ☐ Lansoprazole / Prevacid
- ☐ Lisinopril / Zestril
- ☐ Metoclopramide / Reglan
- ☐ Midazolam / Versed
- ☐ Multivitamin / Vitamin D
- ☐ Omeprazole / Prilosec
- ☐ Opiates (e.g. Methadone)
- ☐ Propranolol / Inderal
- ☐ Ranitidine / Zantac
- ☐ Sildenafil / Viagra / Revatio
- ☐ Sotalol / Betapase / Sotylize / Sorine
- ☐ Spironolactone / Aldactone
- ☐ Supplemental Oxygen
- ☐ Warfarin / Coumadin
- ☐ Other, specify:

_____
_____
_____

If prescribed Digoxin/Lanoxin

28a. Dosage per individual dose: |__|__|.|__|__| (mcg/kg)

28b. Dosage frequency:
(select only one response)

- ☐ One time a day
- ☐ Two times a day
- ☐ Unknown
- ☐ Other, specify:

_____

28c. Reason prescribed:
(select all that apply)

- ☐ Improve Heart Function
- ☐ Treat Arrhythmia
- ☐ Standard Protocol at Center
- ☐ Physician Preference
- ☐ Parent/Caregiver Request
- ☐ Unknown
- ☐ Other, specify:

_____

STAGE 2 PALLIATION SURGICAL INFORMATION

NPC-QIC Registry ID: *(Site # - ID#)* *Required |__|__|__|-|__|__|__|__|

1. Date of hospital admission that included Stage 2 Palliation surgery: *Required |__|__|__|__|-|__|__|-|__|__| (YYYY–MM–DD)

2. Center Name where this admission occurred: _____

PREOPERATIVE INFORMATION

3. Actual weight at Stage 2 Palliation surgery (weight taken closest, but prior, to surgery): *Required |__|__|__|.|__|__|__| (kg)

4. Was preoperative length collected? *(select only one response)*
   - ☐ Yes
   - ☐ No

If Yes

4a. Length: *Required |__|__|__|__|.|__|__| (cm)

5. O2 Sat at Stage 2 Palliation surgery (preoperative): |__|__|__|__| (%)
(enter mean if range is provided)

6. Route of Nutrition at Stage 2 Palliation surgery (preoperative): *(select all that apply)*
   - ☐ G-Tube/GJ Tube
   - ☐ NG/NJ
   - ☐ Oral – Breastfed
   - ☐ Oral – Bottle fed
   - ☐ TPN (not feeding)

7. Type of nutrition utilized at Stage 2 Palliation surgery (preoperative): *Required *(select only one response)*
   - ☐ Breastmilk[34]
   - ☐ Formula
   - ☐ Combination of breastmilk and formula

8. Has patient been diagnosed with any additional Major Syndromes: *(select all that apply)*
   - ☐ None
   - ☐ 22q11 Deletion – DiGeorge Syndrome[25]
   - ☐ CHARGE Association[26]
   - ☐ Down syndrome[27]
   - ☐ Heterotaxy Syndrome[28]
   - ☐ Jacobsen Syndrome[29]
   - ☐ Turner Syndrome[30]
   - ☐ VACTERL syndrome (VACTER/VATER/VATERR syndrome)[31]
   - ☐ Other, specify: _____

PREOPERATIVE ECHOCARDIOGRAM INFORMATION

9. Date of transthoracic echocardiogram closest to, but before, discharge: *Required |__|__|__|__|-|__|__|-|__|__| (YYYY–MM–DD)

10. Has this echocardiogram been previously recorded for NPC-QIC? *(select only one response)*
    - ☐ Yes *(do not complete the remainder of this section)*
    - ☐ No

If No

11. Qualitative assessment of Ventricular Function: *Required *(select only one response)*
    - ☐ Normal or low normal function
    - ☐ Mild dysfunction
    - ☐ Moderate dysfunction
    - ☐ Severe dysfunction
    - ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

12. Qualitative assessment of Tricuspid/Systemic AV Valve Regurgitation:
*Required
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

Stage 1 NOT Hybrid Norwood

13. Qualitative assessment of neo-Aortic Valve Regurgitation: *Required
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

14. What was the Doppler peak velocity across the distal arch? *Required

|__|__|.|__|__| (m/s) ☐ Not Available

Stage 1 Hybrid Norwood

15. Was the neo-Aortic retrograde arch obstructed (maximum peak instantaneous gradient by Doppler >10 mmHg) as evaluated by imaging? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Not evaluated

If Yes

15a. Retrograde aortic arch stenosis: *Required
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

16. PDA stent stenosis:
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

17. PA band gradients:
(select only one response)

- ☐ Adequate (band gradients > 3.5 m/s)
- ☐ Low (band gradients ≤ 3.5 m/s)
- ☐ No information available

18. Was the ASD restrictive (Doppler mean gradient >1 mmHg)?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Not evaluated

If Yes

18a. ASD Doppler mean gradient: |__|__|__| (mmHg) ☐ Not Available

19. Was there other clinical evidence (blood pressure cuff measurements) demonstrating distal aortic arch obstruction (>10 mmHg)?
(select only one response)

- ☐ Yes
- ☐ No
- ☐ No information available

If Yes

19a. Obstruction: |__|__|__| (mmHg) ☐ Not Available

SURGERY INFORMATION

20. Stage 2 Palliation surgery Date: *Required

|__|__|__|__|-|__|__|-|__|__| (Y Y Y Y – M M – D D)

- ☐ Patient Early Exited prior to receiving Stage 2 Palliation surgery *(do not complete remainder of this section or Postop section)*

21. Type(s) of Stage 2 Palliation surgery performed[56]: *Required
(select all that apply)

- ☐ Unilateral bidirectional Glenn
- ☐ Bilateral bidirectional Glenn
- ☐ Comprehensive Stage 2 (Primary Arch Reconstruction)
- ☐ HemiFontan
- ☐ Kawashima

If Comprehensive Stage 2

21a. Additional cardiac procedures performed at the time of Stage 2 palliation surgery:
(select all that apply)

- ☐ None
- ☐ AV valve repair
- ☐ AV valve replacement
- ☐ Pulmonary vein repair
- ☐ Other, specify: _____

If NOT Comprehensive Stage 2

21b. Additional cardiac procedures performed at the time of Stage 2 palliation surgery:
(select all that apply)

- ☐ None
- ☐ Arch repair
- ☐ Atrial septectomy
- ☐ AV valve repair
- ☐ AV valve replacement
- ☐ Pulmonary vein repair
- ☐ Other, specify: _____

22. CPB Time: |__|__|__| (minutes) ☐ Not Available

23. Patient had the following during surgery:
(select all that apply)

- ☐ None
- ☐ Cerebral Perfusion
- ☐ Circulatory Arrest
- ☐ Cross Clamp

If Cerebral Perfusion / Circulatory Arrest / Cross Clamp

23a. Cerebral Perfusion Time: |__|__|__| (minutes) ☐ Not Available

23b. Circulatory Arrest Time: |__|__|__| (minutes) ☐ Not Available

23c. Cross Clamp Time: |__|__|__| (minutes) ☐ Not Available

24. Date of final extubation: |__|__|__|__|-|__|__|-|__|__| (YYYY–MM–DD)

POSTOPERATIVE INFORMATION

COMPLETE THIS SECTION IF THE PATIENT RECEIVED STAGE 2 PALLIATION

25. Did the patient require ECMO postoperatively?
(select only one response)

- ☐ Yes
- ☐ No

26. Postoperative complications:
(select all that apply)

- ☐ None
- ☐ Arrhythmia requiring drug therapy[45]
- ☐ Arrhythmia necessitating pacemaker, Permanent pacemaker[46]
- ☐ Necrotizing entero-colitis, Treated medically[37]
- ☐ Necrotizing entero-colitis, Treated surgically[38]
- ☐ Neurological deficit, Neurological deficit persisting at discharge[47]
- ☐ Paralyzed diaphragm (possible phrenic nerve injury)[48]
- ☐ Pleural effusion, Requiring drainage[49]
- ☐ Pneumonia
- ☐ Pneumothorax, Requiring drainage or evacuation[50]
- ☐ Postoperative/postprocedural respiratory insufficiency requiring reintubation
- ☐ Renal failure – acute renal failure, Acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge
- ☐ Seizure
- ☐ Sepsis
- ☐ Stoke
- ☐ Vocal cord dysfunction (possible recurrent laryngeal nerve injury)[51]
- ☐ Wound Infection
- ☐ Other, specify: _____ _____ _____

27. Postoperative cardiac arrest? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

28. Were one or more postoperative catheterizations done?
(select only one response)

- ☐ Yes, specify total done: _____
- ☐ No

If Yes, complete the Date/Type/Reason for each Catheterization done (use the key below to complete Type & Reason)

Catheterization Types

1	Diagnostic study only	6	Coarctation/arch stent
2	Aortic valve dilation	7	Coil veno-venous collaterals
3	Atrial septal stent	8	Pulmonary vein dilation
4	Balloon/blade septostomy	9	Pulmonary vein stent
5	Coarctation/arch dilation	10	Other Specify

Catheterization Reasons

1	Cardiac Arrest	6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
2	Chylothorax	7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)	8	Other Specify
4	Echocardiogram findings without clinical signs		
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR		

	Date: *Required	**Type(s):** *Required	**Reason(s):** *Required
28a.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
28b.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
28c.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
28d.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
28e.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
28f.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
28g.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
28h.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		

29. Were one or more reoperations necessary following the Stage 2 Palliation surgery?
(select only one response)

- ☐ Yes, specify total done: _____
- ☐ No

If Yes, complete the Date/Type/Reason for each Reoperation done (use the key below to complete Type & Reason)

Reoperation Types

1	Aortic arch repair	7	PA band adjustment
2	Atrial septectomy	8	Pacemaker placement
3	Diaphragm plication	9	Sternal or mediastinal debridement
4	Exploration for bleeding	10	Thoracic duct ligation
5	Exlploration for suspected Tamponade	11	Other Specify
6	Glenn revision / takedown[57]		

Reoperation Reasons

1	Cardiac Arrest	6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
2	Chylothorax	7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)	8	Other Specify
4	Echocardiogram findings without clinical signs		
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR		

	Date: *Required	**Type(s):** *Required	**Reason(s):** *Required
29a.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		
29b.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)		

29c. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

29d. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

29e. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

29f. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

29g. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

29h. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

29i. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

30. Other major procedures performed:
(select all that apply)

- ☐ None
- ☐ Bronchoscopy
- ☐ Cardioversion
- ☐ Dialysis
- ☐ Diaphragm Plication
- ☐ Fundoplication
- ☐ G-Tube
- ☐ Pericardiocentesis
- ☐ Peritoneal Drain
- ☐ Thoracentesis
- ☐ Thoracic Duct Ligation
- ☐ Tracheostomy
- ☐ Other, specify: _____

POSTOPERATIVE ECHOCARDIOGRAM INFORMATION

COMPLETE THIS SECTION IF THE PATIENT RECEIVED STAGE 2 PALLIATION

31. Was a transthoracic echocardiogram done prior to Stage 2 Palliation discharge?
(select only one response)

- ☐ Yes
- ☐ No *(do not complete the remainder of this section)*

If Yes

32. Date of most recent echocardiogram (closest to discharge): |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)

33. Qualitative assessment of Ventricular Function:
(select only one response)

- ☐ Normal or low normal function
- ☐ Mild dysfunction
- ☐ Moderate dysfunction
- ☐ Severe dysfunction
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

34. Qualitative assessment of Tricuspid/Systemic AV Valve Regurgitation:
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

35. Qualitative assessment of neo-Aortic Valve Regurgitation:
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

36. What was the Doppler peak velocity across the distal arch? |__|.|__| (m/s) ☐ Not Available

37. Were there obstructions at cavopulmonary anastomosis site?
(select only one response)

- ☐ Yes
- ☐ No

If Yes and patient DID NOT have Bilateral Glenn

37a. Mean gradient: |__|__| (mmHg) ☐ Not Available

If Yes and patient had Bilateral Glenn

37b. Mean gradient for right and/or left side:

- ☐ Right: |__|__| (mmHg)
- ☐ Left: |__|__| (mmHg)
- ☐ Not available for either side

DISCHARGE INFORMATION

38. Patient's disposition at Stage 2 Palliation discharge: **Required*
(select only one response)

- ☐ Discharged to home from Stage 2 Palliation surgical center
- ☐ Transferred as inpatient to another facility
- ☐ Remained inpatient until first birthday *(do not complete the remained of this section)*
- ☐ Early Exit from study *(do not complete the remained of this form)*

If Discharged Home or Transferred to Another Facility

39. Date of Discharge from Stage 2 Palliation surgical center: **Required*
|__|__|__|__|-|__|__|-|__|__| (YYYY-MM-DD)

40. Last Weight recorded prior to discharge: |__|__|.|__|__|__| (kg)

41. Was Length collected prior to discharge?
(select only one response)

- ☐ Yes
- ☐ No

If Yes

41a. Last Length recorded prior to discharge: |__|__|__|.|__| (cm)

42. Last O2 Sat recorded prior to discharge: |__|__|__| (%)
(enter mean if range is provided)

43. Medications prescribed at time of discharge:
(select all that apply)

- ☐ None
- ☐ Amiodarone / Cordarone
- ☐ Amlodipine / Norvasc
- ☐ Antibiotics (any)
- ☐ Antiepileptic medication (any)
- ☐ Aspirin
- ☐ Atenolol / Tenormin
- ☐ Benzodiazepines (e.g. Ativan)
- ☐ Captopril / Capoten
- ☐ Chlorothiazide / Diuril
- ☐ Clonidine / Catapres
- ☐ Clopidogrel / Plavix
- ☐ Digoxin / Lanoxin
- ☐ Enalapril / Vasotec
- ☐ Enoxaparin / Lovenox
- ☐ Famotidine / Pepcid
- ☐ Flecainide / Tambocor
- ☐ Furosemide / Lasix
- ☐ Lansoprazole / Prevacid
- ☐ Lisinopril / Zestril
- ☐ Metoclopramide / Reglan
- ☐ Midazolam / Versed
- ☐ Multivitamin / Vitamin D
- ☐ Omeprazole / Prilosec
- ☐ Opiates (e.g. Methadone)
- ☐ Propranolol / Inderal
- ☐ Ranitidine / Zantac
- ☐ Sildenafil / Viagra / Revatio
- ☐ Sotalol / Betapase / Sotylize / Sorine
- ☐ Spironolactone / Aldactone
- ☐ Supplemental Oxygen
- ☐ Warfarin / Coumadin
- ☐ Other, specify:
  _____
  _____
  _____

44. Route of Nutrition recommended in the nutrition plan at discharge:
(select all that apply)

- ☐ G-Tube/GJ Tube
- ☐ NG/NJ
- ☐ Oral – Breastfed
- ☐ Oral – Bottle fed

45. Postoperative feeding evaluations performed: *Required
(select all that apply)

- ☐ None
- ☐ Clinical Feeding Evaluation by OT/PT or Speech Language Pathologist (SLP)
- ☐ Fiber optic Endoscopic Evaluation of Swallowing
- ☐ Video swallowing study
- ☐ Other, specify: _____

NEURODEVELOPMENTAL INFORMATION

46. Did patient remain inpatient at Stage 2 Palliation surgical center for longer than 28 days post Stage 2 Palliation surgery? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

If Yes

46a. Did patient's parent/caregiver(s) receive a written, up-to-date, developmental plan (or other similar written materials about how to support the patient's development) while inpatient? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

If Discharged Home or Transferred to Another Facility

47. Did patient's parent/caregiver(s) receive a written, up-to-date, developmental plan (or other similar written materials about how to support the patient's development) at discharge? *Required
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

PATIENT DISPOSITION

NPC-QIC Registry ID: *(Site # - ID#)* *Required

|_|_|_|_|-|_|_|_|_|

1. Final patient status: *Required
(Check 'Early Exit' for Death, Heart Transplant, Lost to follow-up, Management strategy changed, Not a candidate for Stage 2 Palliation surgery, Withdrawal, or Other reason)
(select only one response)

- ☐ Surviving post Stage 2 Palliation at first birthday (without Heart Transplant and not lost to follow-up)
- ☐ Surviving post Stage 1 Palliation, without Stage 2 Palliation, at first birthday (without Heart Transplant and not lost to follow-up)
- ☐ Early Exit

EARLY EXIT INFORMATION

COMPLETE THIS SECTION IF THE PATIENT EARLY EXITED FROM NPC-QIC.

2. Early Exit Reason[58]: *Required
(select only one response)

- ☐ Fetal Demise (i.e. stillbirth)
- ☐ Referred for Heart Transplant[59]
- ☐ Not a candidate for Stage 1 Palliation surgery and not referred for heart transplant
- ☐ Death (following live birth)[60]
- ☐ Management strategy changed to 2 ventricle repair
- ☐ Not a candidate for Stage 2 Palliation surgery[61], specify: _____
- ☐ Lost to follow-up
- ☐ Withdrawal from NPC-QIC by patient's parent/caregiver(s)
- ☐ Other, specify: _____

3. Date of Early Exit/Death: *Required
(If exact date is not known, use the last date patient was known to meet inclusion criteria or Stage 2 Palliation discharge date, whichever came later)

|_|_|_|_|-|_|_|-|_|_| (YYYY – MM – DD)

DEATH INFORMATION

COMPLETE THIS SECTION IF THE PATIENT EARLY EXITED FROM NPC-QIC WITH REASON OF DEATH.

If Patient did not complete Stage 1 Palliation Surgery

4. Did family choose comfort care following birth (i.e. parent/caregiver(s) and/or clinician decided not to pursue surgery due to new information about patient's condition)?
(select only one response)

- ☐ Yes
- ☐ No

If Yes

4a. Reason Comfort Care was chosen:
(select all that apply)

- ☐ Additional Cardiac Diagnosis
- ☐ Diagnosis of Major Syndrome(s)
- ☐ Diagnosis of Major Congenital Anomaly of Other Organ System(s)
- ☐ Unknown
- ☐ Other, specify: _____

If Patient did not Choose Comfort Care or If Patient completed Stage 1 Palliation

5. Did death occur within 30 days of a cardiac surgical procedure[62]?
(select only one response)

- ☐ Yes
- ☐ No

If Yes

5a. Did death occur within 24 hours of a cardiac surgical procedure?
(select only one response)

- ☐ Yes
- ☐ No

6. Did death occur within 24 hours of a cardiac catheterization procedure?
(select only one response)

- ☐ Yes
- ☐ No

7. Where did death occur?
(select only one response)

- ☐ Catheterization Lab
- ☐ Home
- ☐ Hospital Ward
- ☐ In ER – at Surgical Center
- ☐ In ER – at Outside Center
- ☐ In ICU
- ☐ In OR
- ☐ Other, specify: _____

8. How did death occur?
(select only one response)

- ☐ Arrest with unsuccessful resuscitation
- ☐ Care redirected from surgical pathway due to decompensation in ICU
- ☐ Non-cardiac death
- ☐ Sudden unexpected arrest without resuscitation
- ☐ Other, specify: _____

9. What was the primary cause of death?
(select only one response)

- ☐ Arrhythmia
- ☐ Aspiration
- ☐ Catheterization complication
- ☐ CNS injury
- ☐ ECMO complication
- ☐ Failure to wean from bypass or ECMO
- ☐ Low cardiac output
- ☐ Multi-organ system failure
- ☐ Pneumonia
- ☐ Sepsis
- ☐ Surgery complication
- ☐ Unknown
- ☐ Other, specify: _____

10. Was an autopsy performed?
(select only one response)

- ☐ Yes
- ☐ No

If Yes

10a. What were the autopsy results (e.g. cause of death identified)? _____

11. Were there any new CARDIAC conditions/diagnoses that developed in the interstage period or preceding death that had a significant role in this patient's demise, beyond the immediate cause of death?
(select all that apply)

- ☐ No
- ☐ Arch obstruction
- ☐ Coronary thrombus
- ☐ Discontinuous pulmonary arteries
- ☐ Shunt thrombosis
- ☐ Pulmonary vein stenosis
- ☐ Unknown
- ☐ Other, specify: _____

12. Were there any new NON-CARDIAC conditions/diagnoses that developed in the interstage period or preceding death that had a significant role in this patient's demise, beyond the immediate cause of death?
(select all that apply)

- ☐ No
- ☐ Liver Failure
- ☐ Pulmonary hypertension
- ☐ Renal failure
- ☐ Stroke
- ☐ Systemic venous thrombosis
- ☐ Unknown
- ☐ Other, specify: _____

DECOMPENSATION LEADING TO MORTALITY INFORMATION

13. Date patient experienced acute decompensation leading to mortality: |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)

14. Time of Day (approximately) patient experienced acute decompensation leading to mortality: |_|_|:|_|_| *(24 Hour Clock)* (H H : M M)

15. Describe the last face-to-face encounter (i.e. sick visit, well visit) with a medical care provider (Cardiologist, PCP, or ED) prior to acute decompensation:
_____
_____
_____

16. Is date of last face-to-face encounter (i.e. sick visit, well visit) with a medical care provider (Cardiologist, PCP, or ED) prior to acute decompensation known?
(select only one response)
- ☐ Yes
- ☐ No

If Yes

16a. Date of last encounter: |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)

17. Which signs and symptoms preceded acute decompensation leading to mortality:
(select all that apply)
- ☐ No information available
- ☐ None
- ☐ Breathing problems
- ☐ Feeding problems
- ☐ Fever
- ☐ Fussiness
- ☐ Increased cyanosis
- ☐ Poor weight gain
- ☐ Vomiting or diarrhea
- ☐ Other, specify:
_____

18. What were the circumstances at time of acute decompensation leading to mortality?
(select all that apply)
- ☐ No information available
- ☐ Bathing
- ☐ Feeding
- ☐ In a Car Seat
- ☐ Medication administration
- ☐ Sleeping
- ☐ Sedation or anesthesia for non-cardiac procedure
- ☐ Associated with medical treatment or therapy, specify:
_____
- ☐ Other, specify:
_____

FAMILY-ASSOCIATED BARRIERS INFORMATION

19. Were any barriers to interstage care a factor for the patient's parent/caregiver(s)?
(select only one response)

- ☐ Yes
- ☐ No barriers identified
- ☐ No information available

If Yes

Identify whether each of the barriers to interstage care were a factor for the patient's parent/caregiver(s):
(select only one response for each)

	Yes	No	Unknown
19a. Competency/Compliance with interstage caregiving (feeding, equipment, med admin, etc.):	☐	☐	☐
19b. Distance to surgical center:	☐	☐	☐
19c. Language barriers:	☐	☐	☐
19d. Socio-economic status:	☐	☐	☐
19e. Social service needs:	☐	☐	☐
19f. Other, specify: _____	☐	☐	☐
19g. Other, specify: _____	☐	☐	☐

ADDITIONAL INFORMATION

20. Please provide any additional important or notable information surrounding the patient's death:

_____
_____
_____
_____

1 YEAR BIRTHDAY

THIS FORM IS DESIGNED TO CAPTURE INFORMATION ABOUT THE PATINET AT THEIR FIRST BIRTHDAY; DATA SHOULD BE CAPTURED AND RECORDED AS CLOSE TO THE PATIENT'S FIRST BIRTHDAY AS POSSIBLE. ALL DATE ON THIS FORM MUST BE AFTER THE PATIENT'S LAST PALLIATION SURGERY (RECORDED FOR NPC-QIC) AND NO LATER THAN 1 MONTH AFTER THE PATIENT'S FIRST BIRTHDAY (13 MONTHS OF AGE).

NPC-QIC Registry ID: *(Site # - ID#)* *Required |__|__|__|-|__|__|__|__|

1. Who is the current primary caregiver for this patient (at first birthday)?
(select only one response)
- ☐ Parent(s)
- ☐ Grandparent(s)
- ☐ Foster Care
- ☐ Other, specify: _____

2. What sources were used to obtain patient's information?
(select all that apply)
- ☐ Clinic Visit Notes / Hospital records
- ☐ Direct Patient Calls
- ☐ Home Surveillance(s) Logs
- ☐ Other, specify: _____

3. Most recent weight (after last Palliation and prior to 1 month after first birthday): *Required |__|__|.|__|__|__| (kg) ☐ Not Available

3a. If recorded, Date weight was recorded (after last Palliation and prior to 1 month after first birthday): *Required |__|__|__|__|-|__|__|-|__|__| (YYYY–MM–DD)

4. Most recent length (after last Palliation and prior to 1 month after first birthday): *Required |__|__|__|.|__| (cm) ☐ Not Available

4a. If recorded, Date length was recorded (after last Palliation and prior to 1 month after first birthday): *Required |__|__|__|__|-|__|__|-|__|__| (YYYY–MM–DD)

5. Were one or more catheterizations done between patient's last palliation and first birthday? (not including post-operative catheterizations previously recorded for NPC-QIC)
(select only one response)
- ☐ Yes, specify total done: _____
- ☐ No

If Yes, complete the Date/Type/Reason for each Catheterization done (use the key below to complete Type & Reason)

Catheterization Types

1	Diagnostic study only
2	Aortic valve dilation
3	Atrial septal stent
4	Balloon/blade septostomy
5	Coarctation/arch dilation
6	Coarctation/arch stent
7	Pulmonary vein dilation
8	Pulmonary vein stent
9	Other Specify

Catheterization Reasons

1	Cardiac Arrest
2	Chylothorax
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)
4	Echocardiogram findings without clinical signs
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR
6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
8	Other Specify

	Date: *Required (YYYY–MM–DD)	**Type(s):** *Required	**Reason(s):** *Required
5a.	|__|__|__|__|-|__|__|-|__|__|	_____	_____
5b.	|__|__|__|__|-|__|__|-|__|__|	_____	_____
5c.	|__|__|__|__|-|__|__|-|__|__|	_____	_____
5d.	|__|__|__|__|-|__|__|-|__|__|	_____	_____
5e.	|__|__|__|__|-|__|__|-|__|__|	_____	_____
5f.	|__|__|__|__|-|__|__|-|__|__|	_____	_____

5g. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

5h. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

5i. |_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D) _____ _____

6. Were any cardiac operations necessary between patient's last palliation and first birthday? (not including post-operative additional cardiac operations previously recorded for NPC-QIC)
(select only one response)

☐ Yes, specify total done: _____
☐ No

If Yes, complete the Date/Type/Reason for each Cardiac Operation done (use the key below to complete Type & Reason)

Reoperation Types

1	Aortic arch repair
2	Atrial septectomy
3	AV repair
4	Glenn revision
5	Pacemaker placement
6	Unknown
7	Other Specify

Reoperation Reasons

1	Cardiac Arrest
2	Chylothorax
3	Clinical findings suggestive of anatomic lesion (e.g. Blood pressure discrepancy)
4	Echocardiogram findings without clinical signs
5	Extra-corporeal Membrane Oxygenation (ECMO), including ECPR
6	Inability to extubate or wean respiratory support as expected (e.g. hypoxia)
7	Inability to wean from inotropes as expected / Ongoing hemodynamic instability
8	Other Specify

	Date: **Required*	**Type(s):** **Required*	**Reason(s):** **Required*
6a.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
6b.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
6c.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
6d.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
6e.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
6f.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
6g.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____
6h.	|_|_|_|_|-|_|_|-|_|_| (Y Y Y Y – M M – D D)	_____	_____

7. Were any additional procedures done between patient's last palliation and first birthday? (not including post-operative procedures previously recorded for NPC-QIC)
(select all that apply)

☐ None
☐ Bronchoscopy
☐ Cardioversion
☐ Dialysis
☐ Diaphragm Plication
☐ G-Tube
☐ Nissen Fundoplication
☐ Tracheostomy
☐ Other, specify: _____

8. Check all of the medications the patient is currently taking (at first birthday):
(select all that apply)

- ☐ None
- ☐ Amiodarone / Cordarone
- ☐ Amlodipine / Norvasc
- ☐ Antibiotics (any)
- ☐ Antiepileptic medication (any)
- ☐ Aspirin
- ☐ Atenolol / Tenormin
- ☐ Benzodiazepines (e.g. Ativan)
- ☐ Captopril / Capoten
- ☐ Chlorothiazide / Diuril
- ☐ Clonidine / Catapres
- ☐ Clopidogrel / Plavix
- ☐ Digoxin / Lanoxin
- ☐ Enalapril / Vasotec
- ☐ Enoxaparin / Lovenox
- ☐ Famotidine / Pepcid
- ☐ Flecainide / Tambocor
- ☐ Furosemide / Lasix
- ☐ Lansoprazole / Prevacid
- ☐ Lisinopril / Zestril
- ☐ Metoclopramide / Reglan
- ☐ Midazolam / Versed
- ☐ Multivitamin / Vitamin D
- ☐ Omeprazole / Prilosec
- ☐ Opiates (e.g. Methadone)
- ☐ Propranolol / Inderal
- ☐ Ranitidine / Zantac
- ☐ Sildenafil / Viagra / Revatio
- ☐ Sotalol / Betapase / Sotylize / Sorine
- ☐ Spironolactone / Aldactone
- ☐ Supplemental Oxygen
- ☐ Warfarin / Coumadin
- ☐ Other, specify:

_____
_____
_____

9. Current Nutrition route (at first birthday):
(select all that apply)

- ☐ G-Tube/GJ Tube
- ☐ NG/NJ
- ☐ Oral – Formula/Human Milk
- ☐ Oral – Cereal/Solid Foods

10. Was patient referred for a Neurodevelopmental Evaluation on or prior to their first birthday (i.e. standardized developmental testing [Bayley, Mullen, etc.] in a clinic setting and/or a visit with a psychologist, developmental pediatrician, or neurologist)? **Required*
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

If patient was Discharged Home following Stage 2 Palliation

11. Patient's parent/caregiver(s) were offered connection to support (e.g. SBH/LBH/local group mentoring) following Stage 2 Palliation (after Stage 2 Palliation discharge and prior to patient's first birthday):
(select only one response)

- ☐ Yes
- ☐ No
- ☐ Unknown

ECHOCARDIOGRAM INFORMATION

COMPLETE THIS SECTION ONLY IF PATIENT HAD STAGE 2 PALLIATION

12. Date of most recent transthoracic echocardiogram (after last Palliation and prior to 1 month after first birthday): **Required*

|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

- ☐ Echo Not Done *(do not complete the remainder of this form)*
- ☐ Echo Date Unknown

13. Has this echocardiogram been previously recorded for NPC-QIC? **Required*
(select only one response)

- ☐ Yes *(do not complete the remainder of this form)*
- ☐ No

If No

14. Qualitative assessment of Ventricular Function: **Required*
(select only one response)

- ☐ Normal or low normal function
- ☐ Mild dysfunction
- ☐ Moderate dysfunction
- ☐ Severe dysfunction
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

15. Qualitative assessment of Tricuspid/Systemic AV Valve Regurgitation:
**Required*
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

16. Qualitative assessment of neo-Aortic Valve Regurgitation: *Required
(select only one response)

- ☐ None / trivial
- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ No information available

(if spanning categories [e.g. mild-moderate], select the more severe category)

17. What was the Doppler peak velocity across the distal arch? *Required
|__|__|.|__|__| (m/s) ☐ Not Available

18. Were there obstructions at cavopulmonary anastomosis site?
(select only one response)

- ☐ Yes
- ☐ No

If patient DID NOT have Bilateral Glenn

18a. Mean gradient: |__|__|__| (mmHg) ☐ Not Available

If patient had Bilateral Glenn

18b. Mean gradient for right and/or left side:

- ☐ Right: |__|__|__| (mmHg)
- ☐ Left: |__|__|__| (mmHg)
- ☐ Not available for either side

NEURO SURVEY STATUS PROMPT

NPC-QIC Registry ID: *(Site # - ID#)* *Required |___|___|___|___|-|___|___|___|___|

Survey Time Point:
(select only one response)

☐ 4 months ☐ 6 months ☐ 9 months ☐ 12 months ☐ 15 months

1. Were all Neurodevelopmental (ASQ/EI) surveys assigned to this time point completed?
(select only one response)

☐ Yes
☐ No

If No

1a. Which surveys were not completed?
(select all that apply)

☐ ASQ
☐ Early Intervention (EI)

ASQ SURVEYS

(4 MONTH, 6 MONTH, 9 MONTH, AND 12 MONTH TIME POINTS ONLY)

2. Reason ASQ survey(s) were not completed:
(select only one response)

☐ Patient NOT consented prior to this time point
☐ Parent/caregiver(s) not approached/contacted to complete survey(s)
☐ Parent/caregiver(s) declined to complete survey(s)
☐ Parent/caregiver(s) failed to complete survey(s)
☐ A different standard developmental test was administered (i.e. Bayley)
☐ Other, specify:
_____

If Parent/Caregiver(s) were Not Approached

2a. Reason not approached:
(select all that apply)

☐ Patient was too sick
☐ Parent/caregiver(s) under too much stress
☐ Care center team was uncomfortable approaching parent/caregiver(s)
☐ Parent/caregiver(s) are not English or Spanish speaking
☐ Other, specify:
_____

EARLY INTERVENTION SURVEY

(6 MONTH, 9 MONTH, 12 MONTH, AND 15 MONTH TIME POINTS ONLY)

3. Reason EI survey(s) were not completed:
(select only one response)

☐ Patient NOT consented prior to this time point
☐ Parent/caregiver(s) not approached/contacted to complete survey(s)
☐ Parent/caregiver(s) declined to complete survey(s)
☐ Parent/caregiver(s) failed to complete survey(s)
☐ Patient was inpatient at this time point
☐ Other, specify:
_____

If Parent/Caregiver(s) were Not Approached

3a. Reason not approached:
(select all that apply)

☐ Patient was too sick
☐ Parent/caregiver(s) under too much stress
☐ Care center team was uncomfortable approaching parent/caregiver(s)
☐ Parent/caregiver(s) are not English or Spanish speaking
☐ Other, specify:
_____

EARLY INTERVENTION / OUTPATIENT THERAPIES PARENT SURVEY

NPC-QIC Registry ID: *(Site # - ID#)* *Required |_|_|_|_|-|_|_|_|_|

Survey Time Point: *Required
(select only one response)
☐ 6 months ☐ 9 months ☐ 12 months ☐ 15 months

Date Completed: *Required |_|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

1. Has your baby ever been REFERRED (including self-referral) to your state or county's Early Intervention program (such as Help Me Grow, First Steps, Birth to 3, etc.)? *Required
(select only one response)
☐ Yes
☐ No
☐ I Don't Know

If Yes

1a. Who REFERRED your baby?
(select all that apply)
☐ I referred my baby
☐ Primary Care Doctor
☐ Cardiology Medical Team
☐ Other, specify: _____
☐ I Don't Know

1b. How long ago was your baby REFERRED?
(select only one response)
☐ During the last 3 months
☐ More than 3 months ago
☐ I Don't Know

2. Is your baby currently ENROLLED in your state or county's Early Intervention program (such as Help Me Grow, First Steps, Birth to 3, etc.)?
(select only one response)
☐ Yes
☐ No
☐ I Don't Know

3. For the following questions, please refer to the last 3 months in your baby's care (not including therapies through your state or county's Early Intervention programs):
(select all that apply)

	Referred	Enrolled	Neither Referred nor Enrolled	I Don't Know
3a. Physical Therapy:	☐	☐	☐	☐
3b. Occupational Therapy (OT) – for help feeding:	☐	☐	☐	☐
3c. Occupational Therapy (OT) – for help using hands (fine motor):	☐	☐	☐	☐
3d. Speech/Language Therapy:	☐	☐	☐	☐
3e. Other, specify: _____	☐	☐	☐	☐
3f. Other, specify: _____	☐	☐	☐	☐

15 MONTH TIME POINT ONLY

4. Has your baby had a comprehensive developmental evaluation (i.e. standardized developmental testing [Bayley, Mullen, etc.] in a clinic setting and/or a visit with a psychologist, developmental pediatrician, or neurologist)?
(select only one response)
☐ Yes
☐ No
☐ I Don't Know

ENCUESTA PARA PADRES SOBRE INTERVENCIÓN TEMPRANA/TERAPIAS PARA PACIENTES AMBULATORIOS

Identificación en Registro NPC-QIC: (N.º de sitio - N.º de identificación de 3 dígitos)*Required

|_|_|_|_|-|_|_|_|_|

Fecha en que se completa: *Required

|_|_|_|_|-|_|_|-|_|_|
Y Y Y Y – M M – D D

1. ¿Su bebé fue REFERIDO/A (incluyendo si usted hizo la referencia) al programa de Intervención Temprana de su estado o condado (por ejemplo, Help Me Grow, First Steps, Birth to 3, etc.)? *Required
(Seleccione solo una respuesta)

☐ Sí
☐ No
☐ No sé

1a. Si contestó "Sí", ¿quién REFIRIÓ a su bebé?
(Seleccione todo lo que corresponda)

☐ Yo referí a mi bebé
☐ Médico de atención primaria
☐ Equipo Médico de Cardiología
☐ Otro, especifique:
_____
☐ No sé

1b. Si contestó "Sí", ¿cuánto tiempo hace que se hizo la REFERENCIA para su bebé?
(Seleccione solo una respuesta)

☐ En los últimos 3 meses
☐ Hace más de 3 meses
☐ No sé

2. ¿Su bebé está INSCRITO/A actualmente en el programa de Intervención Temprana de su estado o condado (por ejemplo, Help Me Grow, First Steps, Birth to 3, etc.)?
(Seleccione solo una respuesta)

☐ Sí
☐ No
☐ No sé

3. 3. Para las siguientes preguntas, por favor tenga en cuenta los últimos 3 meses en la atención de su bebé (no se incluyen las terapias proporcionadas a través de los programas de Intervención Temprana de su estado o condado):
(Seleccione todo lo que corresponda para cada terapia)

	Referido/a	Inscrito/a	Ni referido/a ni inscrito/a	No sé
3a. Fisioterapia:	☐	☐	☐	☐
3b. Terapia ocupacional (OT) - para ayudar con la alimentación:	☐	☐	☐	☐
3c. Terapia ocupacional (OT) - para ayudar a usar las manos (motricidad fina):	☐	☐	☐	☐
3d. Terapia del Habla y el Lenguaje:	☐	☐	☐	☐
3e. Otro, especifique: _____	☐	☐	☐	☐
3f. Otro, especifique: _____	☐	☐	☐	☐

SOLO PARA ENCUESTA A LOS 15 MESES

4. ¿Se hizo a su bebé una evaluación del desarrollo integral (prueba del desarrollo estandarizada [Bayley, Mullen, etc.] en un entorno clínico y/o una visita a un sicólogo, pediatra del desarrollo o neurólogo)?
(Seleccione solo una respuesta)

☐ Sí
☐ No
☐ No sé

NEURODEVELOPMENT ASQ-3 (THIS FORM IS READ-ONLY IN THE DATABASE)

NPC-QIC Registry ID: *(Site # - ID#)* |__|__|__|-|__|__|__|__|

Screening Date: |__|__|__|__|-|__|__|-|__|__|
Y Y Y Y – M M – D D

Survey Interval: ☐ 2 ☐ 4 ☐ 6 ☐ 8 ☐ 9 ☐ 10 ☐ 12 ☐ 14

ASQ-3 SCREENING RESULTS

COMMUNICATION DOMAIN

Communication Score: |__|__|.|__|__|

Communication Cutoff: |__|__|.|__|__|

Communication Result: ☐ Above Cutoff ☐ Monitoring Zone ☐ Below Cutoff ☐ Result not available

GROSS MOTOR DOMAIN

Gross Motor Score: |__|__|.|__|__|

Gross Motor Cutoff: |__|__|.|__|__|

Gross Motor Result: ☐ Above Cutoff ☐ Monitoring Zone ☐ Below Cutoff ☐ Result not available

FINE MOTOR DOMAIN

Fine Motor Score: |__|__|.|__|__|

Fine Motor Cutoff: |__|__|.|__|__|

Fine Motor Result: ☐ Above Cutoff ☐ Monitoring Zone ☐ Below Cutoff ☐ Result not available

PROBLEM SOLVING DOMAIN

Problem Solving Score: |__|__|.|__|__|

Problem Solving Cutoff: |__|__|.|__|__|

Problem Solving Result: ☐ Above Cutoff ☐ Monitoring Zone ☐ Below Cutoff ☐ Result not available

PERSONAL-SOCIAL DOMAIN

Personal-Social Score: |__|__|.|__|__|

Personal-Social Cutoff: |__|__|.|__|__|

Personal-Social Result: ☐ Above Cutoff ☐ Monitoring Zone ☐ Below Cutoff ☐ Result not available

OVERALL AREA

Concern: |__|__|

No Concern: |__|__|

NEURODEVELOPMENT ASQ:SE-2 (THIS FORM IS READ-ONLY IN THE DATABASE)

NPC-QIC Registry ID: (Site # - ID#)	|___|___|___|___|-|___|___|___|___|
Screening Date:	|___|___|___|___|-|___|___|-|___|___| (Y Y Y Y – M M – D D)
Survey Interval:	☐ 6 ☐ 12

ASQ:SE SCREENING RESULTS

Score:	|___|___|___|___|.|___|
Cutoff:	|___|___|___|___|.|___|

CAREGIVER CONCERN

Concern:	|___|___|___|
No Concern:	|___|___|___|
Result:	☐ Above Cutoff ☐ Monitoring Zone ☐ Below Cutoff ☐ Result not available

DATA DEFINITIONS

DEFINITIONS SOURCES ARE NOTED FOLLOWING EACH DEFINITOIN BELOW.

[1] Waiver of Consent: Patient must have experienced a live birth and died prior to consent being obtained. Patients who are 1 year of age or older at the time of death, and patients who have been approached for consent and declined, are not eligible for waiver of consent. Final Patient Status must be Early Exit and the Early Exit Reason must be Death on the Patient Disposition form. (NPC-QIC)

[2] Shared Patients: Patients who go to a center that is not participating in NPC-QIC should not be marked as a shared patient and do not need to be reconsented at the non-NPC center. You can enter any data available to your center into the database for these patients. (NPC-QIC)

[3] Comprehensive Counseling: Center must have it documented that they met all criteria listed to select Comprehensive Counseling. (NPC-QIC)

[4] Surgical Center Outcomes were Discussed: NPCQIC does not have a specific definition of how this discussion should be conducted. However, centers are encouraged to work with their surgical teams to add language to their notes that clarifies that they spoke with families specifically about the surgical outcomes at their center. (NPC-QIC)

[5] Note in Medical Record Documenting Closed Loop Communication between OB and Cardiology Teams: Evidence in the medical record that the cardiology team reviewed patient information with the OB team prior to delivery. It should be clear that there was communication between the teams beyond a one-way sending of patient information. (NPC-QIC)

[6] Consent Reaffirmation: Use the checkbox to indicate if Consent Reaffirmation is not required for prenatally enrolled patients. If consent reaffirmation is required by your IRB and you are not able to obtain it, no postnatal data may be collected for this patient, including the Date of Birth. The Patient Disposition form should be completed with reason for Early Exit as Other and Date of Early Exit as the Date of Birth. (NPC-QIC)

[7] Race = White: This includes a person having origins in any of the original peoples of Europe, the Middle East, or North America. (STS)

[8] Race = Black-African American: This includes a person having origins in any of the black racial groups of Africa. Terms such as “Haitian” can be used in addition to “Black or African American”. (STS)

[9] Race = Native Hawaiian or Other Pacific Islander: This includes a person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. (STS)

[10] Race = Asian: This includes a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (STS)

[11] Race = American Indian or Alaskan Native: This includes a person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. (STS)

[12] Type of Health Insurance: This should be the primary insurance payor for this patient at time of birth. (STS)

[13] Government Health Insurance: Includes Medicare, Medicaid, Military Health, Indian Health Service, Correctional Facility, State Specific Plans, and Other Government Insurance Plans. (STS)

[14] Primary Cardiac Diagnosis: This is a diagnosis that is carried with the patient throughout life, through all operations and hospitalizations. The primary diagnosis is the most complex congenital cardiac anomaly or condition of the patient. STS uses the term “single ventricle” as synonymous for the “functionally univentricular heart”. The term "functionally univentricular heart" describes a spectrum of congenital cardiovascular malformations in which the ventricular mass may not readily lend itself to partitioning that commits one ventricular pump to the systemic circulation, and another to the pulmonary circulation. A heart may be functionally univentricular because of its anatomy or because of the lack of feasibility or lack of advisability of surgically partitioning the ventricular mass. (STS)

[15] HLHS: Hypoplastic left heart syndrome (HLHS) is a spectrum of cardiac malformations characterizes by a severe underdevelopment of the left heart-aorta complex, consisting of aortic and/or mitral valve atresia, stenosis, or hypoplasia with marked hypoplasia or absence of the left ventricle, and hypoplasia of the ascending aorta and of the aortic arch with coarctation of the aorta. Hypoplastic left hear complex is a subset of patients at the favorable end of the spectrum of HLHS characterized by hypoplasia of the structures of the left heart-aorta complex, consisting of aortic and mitral valve hypoplasia without valve stenosis or atresia, hypoplasia of the left ventricle, hypoplasia of the ascending aorta and of the aortic arch, with or without coarctation of the aorta. (STS)

[16] DILV: A congenital cardiac malformation in which both atria connect to a single, morphologically left ventricle. (STS)

[17] DIRV: A congenital cardiac malformation in which both atria connect to a single, morphologically right ventricle. (STS)

[18] DORV: Double outlet right ventricle is a type of ventriculoarterial connection in which both great vessels arise entirely or predominantly from the right ventricle. (STS)

[19] Mitral Atresia: A congenital cardiac malformation in which there is no orifice of mitral valve. (STS)

[20] Tricuspid Atresia/Transposition: A congenital cardiac malformation in which there is no orifice of tricuspid valve. (STS)

[21] Single Ventricle, Other: The single ventricle is of primitive or indeterminable type, or if the specific single ventricle diagnosis is not listed as an answer option. Patients with other structural cardiac malformations (e.g., biventricular hearts with straddling atrioventricular valves, pulmonary atresia with intact ventricular septum, some complex forms of double outlet right ventricle), who may at times be best managed in a fashion similar to that which is used to treat univentricular hearts, should not be coded as Single ventricle, Other. These patients should be coded as Other. (STS)

[22] Unbalanced AV Canal: Single ventricle anomalies with a common atrioventricular (AV) valve and only one completely well developed ventricle. If the common AV valve opens predominantly into the morphologic left ventricle, the defect is termed a left ventricle (LV)–type or LV–dominant AV septal defect. If the common AV valve opens predominantly into the morphologic right ventricle, the defect is termed a right ventricular (RV)–type or RV–dominant AV septal defect. (STS)

[23] Anomalous Pulmonary Venous Return: Includes Partial Anomalous Pulmonary Venous Connection (PAPVC), Total Anomalous Pulmonary Venous Connection (TAPVC) Type 1 (supracardiac), Total Anomalous Pulmonary Venous Connection (TAPVC) Type 2 (cardiac), Total Anomalous Pulmonary Venous Connection (TAPVC) Type 3 (infracardiac) and Total Anomalous Pulmonary Venous Connection (TAPVC) Type 4 (mixed). (STS)

[24] Arrhythmia Requiring Therapy: An arrhythmia is defined as atrial tachycardia (automatic or re-entrant), ventricular tachycardia (automatic or re-entrant), junctional tachycardia (automatic or re-entrant), complete heart block, second degree heart block or sinus/junctional bradycardia which requires at least one of the following ICU-level therapies: continuous IV medication (excluding electrolyte repletion with the exception of magnesium for torsades), bolus dosing (excluding bolus digoxin), pacing, defibrillation, cardioversion, or coding. This includes therapies while on ECLS/VAD. This includes arrhythmias clearly documented in the operating room for which therapy was initiated in the OR and was ongoing at the time of CICU admission. Premature ventricular beats of any type and PVCs treated with electrolyte replacement should not be included. (STS)

[25] 22q11 Deletion – DiGeorge Syndrome: DiGeorge syndrome, also known as Shprintzen, Takao, velocardiofacial, or conotruncal anomaly face syndrome, is an autosomal dominant condition [mapped to 22q11.2]. Incidence is 1:4000 births. Cardiovascular anomalies are seen in association with hypoplasia or aplasia of the thymus and parathyroid gland, which are derivatives of pharyngeal pouches III and IV, and which can result in abnormalities of the immune system and calcium metabolism respectively. Cardiovascular abnormalities include conotruncal or outflow tract defects of the heart, such as tetralogy of Fallot, truncus arteriosus, and interrupted aortic arch, particularly type B IAA. Additional defects include VSD, right aortic arch, aberrant right subclavian artery, and PDA. (STS)

[26] CHARGE Association: CHARGE syndrome, or Hall-Hittner syndrome, is an autosomal dominant condition [mapped to 8q12.1 & 7q21.11]; some sporadic cases have been reported. Incidence is 1:8500-10,000 births. CHARGE syndrome is a nonrandom association of congenital anomalies which may include Coloboma, Heart defects, Atresia choanae, Retarded growth and development and/or central nervous system anomalies, Genital anomalies and/or hypogonadism and Ear anomalies and/or deafness. Diagnosis is made if 4/6 major (or 3 major & 3 minor) defects are present. Heart defects are present in 75% to 80% of cases. Of those with heart defects, most have conotruncal anomalies (TOF, DORV, truncus arteriosus) and aortic arch anomalies (vascular ring, aberrant subclavian artery, IAA, coarctation of the aorta, right aortic arch, aortic valve stenosis). Other cardiovascular abnormalities include PDA, AVSD, VSD, and ASD. (STS)

[27] Down Syndrome: Down syndrome, or Trisomy 21, is the most frequent chromosomal abnormality. Incidence is 1:600-1000 live births. Sporadic cases of Down syndrome occur in strong association with advanced maternal age at conception. Affected individuals have an extra (or third) copy of chromosome 21. Cardiovascular abnormalities in 40-50% of cases, in decreasing order of frequency, include AVSD, VSD, TOF and PDA. Left-sided obstructive defects, such as coarctation and aortic valve stenosis, are rare. (STS)

[28] Heterotaxy Syndrome: Heterotaxy is synonymous with 'visceral heterotaxy' and 'heterotaxy syndrome'. Heterotaxy is defined as an abnormality where the internal thoraco-abdominal organs demonstrate abnormal arrangement across the left-right axis of the body. By convention, heterotaxy does not include patients with either the expected usual or normal arrangement of the internal organs along the left-right axis, also known as 'situs solitus', nor patients with complete mirror-imaged arrangement of the internal organs along the left-right axis also known as 'situs inversus'. (STS)

[29] Jacobsen Syndrome: Jacobsen syndrome is a chromosome deletion syndrome [mapped to 11q23]. Incidence is 1:100,000 births. Associated cardiovascular abnormalities include VSD and ASD. (STS)

[30] Turner Syndrome: Turner syndrome (45XO) is a chromosomal deletion abnormality, which occurs in 1:5000 live female births. Although common in first trimester, most 45XO conceptuses are spontaneously aborted. Affected individuals are missing one X chromosome. The major features include short stature, primary amenorrhea due to ovarian dysgenesis, webbed neck, congenital lymphedema, and cubitus valgus. Cardiovascular abnormalities occur in 20-40% of cases, the most common of which is coarctation of the aorta (70%). Additional defects include bicommissural aortic valve, aortic stenosis, a spectrum of left-sided obstructive defects and/or hypoplastic defects, hypoplastic left heart syndrome; aortic dilation, dissection, and rupture. (STS)

[31] VACTERL Syndrome (VACTER/VATER/VATERR Syndrome): VACTERL syndrome is a nonrandom association of defects, including Vertebral anomalies, Anal atresia, Cardiovascular anomalies, Tracheoesophageal fistula, Esophageal atresia, Renal and/or Radial anomalies, and Limb anomalies. Diagnosis is made if 3/7 defects are present. Incidence is 1:6000 births. Cardiovascular malformations include VSD, TOF, TGA and PDA. (STS)

[32] Neurodevelopmental Plan at Enrollment: For patients enrolled after their Stage 1 Palliation surgery the Neurodevelopmental plan given at discharge from Stage 1 hospitalization, or at 28 days still inpatient, should also be counted as the plan given at enrollment. (NPC-QIC)

[33] Trophic: Trophic is defined as small volume feeds, generally designed to stimulate the intestines. NPC-QIC does not define a specific volume for trophic on a collaborative level. Each participating center should use their own institution and clinician's judgement to define trophic volume. (NPC-QIC)

[34] Fortified Breastmilk: Should be categorized as Breastmilk only. (NPC-QIC)

[35] Physiologic Readiness: Each center should determine how a patient's physiologic readiness is defined at their center. The purpose is to determine if there is a daily discussion at the center regarding whether the patient is physiologically ready to go to the OR. (NPC-QIC)

[36] Surgery was Delayed: Each center should determine what qualifies as a delay for their center. (NPC-QIC)

[37] NEC Treated Medically: Necrotizing enterocolitis (NEC) is defined as an acute reduction in the supply of oxygenated blood to the small intestine or large intestine, typically resulting in acidosis, abdominal distention, pneumatosis, and/or intestinal perforation, that prompts initiation of antibiotics or exploratory laparotomy. Select this factor if NEC is present during the same hospitalization as this operation and was managed without surgery to treat the NEC. (STS)

[38] NEC Treated Surgically: Necrotizing enterocolitis (NEC) is defined as an acute reduction in the supply of oxygenated blood to the small intestine or large intestine, typically resulting in acidosis, abdominal distention, pneumatosis, and/or intestinal perforation, that prompts initiation of antibiotics or exploratory laparotomy. Select this factor if NEC is present during the same hospitalization as this operation and was managed with surgery to treat the NEC. (STS)

[39] PA Bands and PDA Stent on Different Dates: Patients who receive PA Bands on one date and PDA Stent on another date should be considered as a Hybrid Norwood procedure. The date of the first procedure where the patient's chest is opened should be used as the date of Stage 1 Palliation surgery. (NPC-QIC)

[40] Hybrid Norwood completed over multiple days/procedures: The date of the first procedure where the patient's chest is opened should be used as the Date of Stage 1 Palliation Surgery. (NPC-QIC)

[41] Multiple Stage 1 Procedures: The procedure that defines the patient's interstage physiology should be recorded as the Stage 1 Palliation surgery. Additional Stage 1 surgeries, regardless if they take place before or after the recorded Stage 1 surgery, should be recorded as postoperative cardiac reoperations under the other option. (NPC-QIC)

[42] Structured Preoperative Briefing from Surgeon to Care Team: A written document, composed by the surgeon, that details the planned approach to anesthesia (potentially including arterial and venous access), cardiopulmonary bypass (potentially including cannulation strategy), surgical details (potentially including shunt type, arch repair, atrial septectomy and other procedures), perioperative imaging and concerns about post-operative care. This document is shared with the surgical team, anesthetic team, cardiologists, and ICU team. (NPC-QIC)

[43] Standardized Handoffs using Checklist: A scripted and reproducible written method used by the surgical, anesthesia, perioperative imaging, and intensive care teams to transfer care details and peri-operative information from the peri-operative team to the intensive care team. Usually, this checklist includes diagnosis, anesthesia events, surgical details, and post-bypass events. The structured handoff will typically include

a routine order of report from various team members and may also include a set of questions to ensure all details/information have been correctly reviewed and confirmed. (NPC-QIC)

[44] Patient Received Tracheotomy: The date of the tracheotomy procedure should be used as the date of extubation. (NPC-QIC)

[45] Arrhythmia Requiring Drug Therapy: Arrhythmia (ROOT Definition) + An arrhythmia requiring drug therapy. (STS)

[46] Arrhythmia Necessitating Permanent Pacemaker: Implantation and utilization of a permanent pacemaker for treatment of any arrhythmia including heart block (atrioventricular [AV] heart block). (STS)

[47] Neurological Deficit Persisting at Discharge: Newly recognized and/or newly acquired deficit of neurologic function leading to inpatient referral, therapy, or intervention not otherwise practiced for a similar unaffected inpatient, With a persisting neurologic deficit present at hospital discharge. In other words, new (onset intraoperatively or postoperatively – or intraprocedurally or postprocedurally) neurological deficit persisting and present at discharge from hospital. (STS)

[48] Paralyzed Diaphragm (possible phrenic nerve injury): Presence of elevated hemi-diaphragm(s) on chest radiograph in conjunction with evidence of weak, immobile, or paradoxical movement assessed by ultrasound or fluoroscopy. (STS)

[49] Pleural Effusion, Requiring Draining: Abnormal accumulation of fluid in the pleural space, Requiring drainage, By any technique. (STS)

[50] Pneumothorax Requiring Draining or Evacuation: A collection of gas in the pleural space resulting in collapse of some or all of the lung on the affected side, requiring intervention. (STS)

[51] Vocal Cord Dysfunction (possible recurrent laryngeal nerve injury): Presence of poor or no vocal cord movement assessed by endoscopy. Patient may or may not have stridor, hoarse voice or poor cry, in conjunction with endoscopic findings. (STS)

[52] Final Hybrid Norwood procedure done in Cath Lab: If the procedure that the patient received in the Cath Lab is considered part of a staged Hybrid Norwood by your center, then this should not be recorded as a postoperative catheterization. Information about this procedure should be included in the Stage 1 Palliation surgery information wherever possible. (NPC-QIC)

[53] Procedures done after Stage 1 Palliation but before Sternal Closure: If the procedure that the patient received is done prior to sternal closure it should not be recorded as a postoperative reoperation. Information about this procedure should be included in the Stage 1 Palliation surgery information wherever possible. (NPC-QIC)

[54] Milrinone: Milrinone is considered a vasoactive medication. Patients still on Milrinone more than 5 days after Stage 1 surgery should not be marked as having weaned off inotropes/vasoactives. (NPC-QIC)

[55] Date of Echo w/in 72 Hours: If multiple transthoracic echocardiograms were done within 72 hours after Stage 1 surgery, record the echocardiogram done closest to 72 hours after surgery. (NPC-QIC)

[56] Stage 2 Palliation followed by Heart Transplant during the same admission: Complete the Stage 2 Palliation form with as much information as possible up to the time that the patient received the transplant/was listed for transplant. The Stage 2 disposition should be Early Exit. The Patient Disposition form should be completed with status of Early Exit, reason of Referred for Transplant, and the Date of Early Exit as the date the patient was listed for transplant or received transplant. (NPC-QIC)

[57] Final Patient Status following Glenn Revision/Takedown: Patients surviving at their first birthday who got Stage 2 surgery, then went on to have a Glenn Revision/Takedown procedure should be categorized as Surviving post Stage1, without Stage 2, at First Birthday. (NPC-QIC)

[58] Death following leaving center AMA: Patients who leave a center AMA and die prior to their first birthday should be recorded as a Death on the Patient Disposition form. There are questions on the Patient Disposition form that allow for further details about the patient's death to be provided. (NPC-QIC)

[59] VAD Placement: Patients who receive VAD placement as a bridge to Heart Transplant should be categorized as an Early Exit with a reason Other "No longer a single ventricle candidate". (NPC-QIC)

[60] Death following discharge home on palliative/hospice care: Data collection can pause for patients who discharge home on palliative/hospice care. Once the patient dies, the Patient Disposition form should be completed with and Early Exit reason of Death (unless the patient was still surviving at their first birthday). (NPC-QIC)

[61] Not a Candidate for Stage 2 Palliation following Glenn Revision/Takedown: Patients who are an Early Exit because they got a Glenn Revision/Takedown and are no longer considered a candidate to receive another Stage 2 surgery should not be categorized as "Not a candidate for Stage 2 Palliation surgery"; this option is meant to capture patients who never get a Stage 2 Palliation surgery. Instead, these patients should be categorized as "Other" with specify text provided. (NPC-QIC)

[62] Death following ECMO: ECMO is not considered a cardiac procedure on its own. (NPC-QIC)

DEFINITION SOURCES

NPC-QIC. (n.d.). Database and Data Entry Guidebook. Retrieved from https://portal.npcqic.org/REDCap/Forms/AllItems.aspx

STS. (n.d.). STS Congenital Heart Surgery Database Data Specifications v3.41. Retrieved from https://www.sts.org/registries-research-center/sts-national-database/congenital-heart-surgery-database/data-collection