Hearts for Life across the World

WORLD DATABASE FOR PEDIATRIC AND CONGENITAL HEART SURGERY

Manual of Operations and Protocol

Data Entry Manual

To be used for all surgeries on or after January 1, 2017

Version 1.0.7
Released March 9, 2020

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I. Introduction

Mission Statement

As part of the mission of the World Society for Pediatric and Congenital Heart Surgery, the World Database for Pediatric and Congenital Heart Surgery will be developed and maintained for the purposes of furthering knowledge concerning the global practice and outcomes of pediatric and congenital heart surgery; fostering an environment of quality improvement in participating hospitals, without geographic constraints regarding eligibility for participation; and promoting scientific investigation and publication based on analyses of this world database, with collaboration among a wide array of international colleagues.

Definitions

- **Cardiac Surgery:** Any surgery of the heart that is not also a congenital surgery
- **Congenital Surgery:** A surgery on the heart that is correcting a cardiac abnormality the patient was born with.
- **DCC:** Data Collection and Analysis Center
- **Discharge:** Discharge is defined as the date the patient is discharged from the hospital OR 90 days' post-surgery if the patient is still in the hospital at this time.
- **Operation/Surgery:** Surgical procedure for palliation or repair of congenital heart disease.
- **Readmission:** Hospital admission that requires another operation (planned or unplanned) for congenital heart disease.
- **Reintervention:** A Non-surgical procedure.
- **Reoperation:** Subsequent (planned or unplanned) operation
- **Tier 1 Surgery:** A major operation for congenital heart disease that is not resulting from a complication of a prior operation. This is also known as an index surgery.
- **Surgery vs Procedure:** The patient can have multiple procedures during one surgery as long as the procedures are in the same operating room visit. Separate operating room visits should be reported as separate surgeries.
- **WDPCHS:** World Society for Pediatric and Congenital Heart Database
- **WSPCHS:** World Society for Pediatric and Congenital Heart Surgery

II. Institution Enrollment

1) An Institution can enroll by accepting all standards and regulations described by the WDPCHS and signing a Data Use Agreement with the WSPCHS. These agreements will be provided by the WSPCHS and maintained at the DCC.

2) The Institution must designate one staff member as an institutional representative to the WDPCH. The individual must be a member, in good standing, of the WSPCHS. All communications will be between the WDPCHS and DCC with the Institution will proceed via this individual. The individual does NOT have to be a pediatric cardiac surgeon. It is suggested, but not required, that the institution assign a data manager. This individual is responsible for the timely entry of center specific information as well as addressing issues and concerns of the data center.

   Suggested Member Roles:

   - Principal Investigator (PI)
   - Co-Investigator
   - Site Administrator
   - Coordinator

3) Designated staff members and data coordinators will be expected to participate in semi-annual conference calls organized by the WDPCHS and DCC.

4) As the mechanism of data submission will be digital, the center must have adequate and secure internet access. The system is only supported by Internet Explorer 11.0 and higher, Google Chrome, and Mozilla Firefox. *Data encryption for information being sent over the internet is SSL. This is the same type used by banks and meets the highest standard. You should see 'https:' in the URL when entering patient data. The database where the data is stored is also encrypted, the encryption method exceeds federal FISMA standards.*

Quality Assurance

Site performance as it pertains to the data entry process into WDPCHS will be regularly monitored for compliance, completeness, and accuracy by the DCC. Forms are due within 30 days of when the event occurs. The focus of monitoring is on:

- completeness of the data entered into the WDPCHS application
- identification of impossible or improbable combinations of variables using data integrity checks

Surgery counts: Each quarter the DCC will send a certification letter to the site PI with a copy to the data coordinator. This letter will include the total surgery

counts (Tier 1 and Tier 2) for the closing quarter. The site will be responsible for confirming the surgery counts and confirming all surgeries performed at their hospital have been entered. In reviewing these surgery counts, if any surgeries are missing, the site is responsible for entering the missing surgeries within 30 days of the closing quarter. The signed certification letter should be scanned and returned to the DCC.

Enrollment

1) At the time of enrollment into the registry, hospitals will complete an *Institutional Practice Details* F*orm*. This form gathers information on the variation of practice among hospitals. Each hospital will then complete an updated form each January.

2) Patients are entered into the database at the time of surgery with the completion of an *Add Surgery Form*. After completion of the *Add Surgery Form,* the system will automatically generate additional forms for patients that have had a Tier 1 surgery. Once the Tier 1 patient has been discharged from the hospital, the *Post-Operative Events Form* will be completed. If a patient remains in the hospital for more than 90 days post-surgery, the *Post-Operative Events Form* should be completed at that time. Additional data collected pertains to one-year follow-up, readmission, and death. All Tier 1 surgeries are followed for one year post surgery. For Tier 2 surgeries, no forms in addition to the *Add Surgery* and *Tier 2 Surgery and Discharge Form* are required.

General Information

This manual provides information on patient eligibility, form completion and form submission. The forms included in this manual are updated with each database revision. In addition to the manual, WSPCHS maintains separate bylaws describing the organizational structure and functionality of the society and registry.

While we have tried to address all major concerns regarding form completion in the current version of the manual. 'Frequently asked questions' are noted in blue to provide additional examples and clarification, these will be updated with each database revision. You are highly encouraged to consult your hospital surgeon, the DCC, and/or the WDPCHS representative with any questions.

For questions directed to the DCC regarding enrollment, please contact:
Claire Covington, Project Manager
University of Alabama at Birmingham
Office: (205) 934-3991
Email: wdpchs@uabmc.edu

For questions directed to the DCC regarding patient data entry or training, please contact:

Janella Miller, Nurse Monitor
University of Alabama at Birmingham
Email: wdpchs@uabmc.edu

III. Patient Enrollment

Member Hospitals and Institutional Date of Database Entry

Member hospitals must maintain a Data Use Agreement (DUA) with the World Society for Pediatric and Congenital Heart Surgery. Hospitals are responsible for keeping a current Institutional Review Board (IRB) approval or Ethics Committee approval at the local hospital.

Each member hospital has an initial date of database entry. For the original institutions, this date is January 1, 2017. For new institutions, this is the date the institution completes the enrollment process.

Patient Enrollment

Patients should be enrolled into the database at the time the surgery is completed. Patients that die in the operating room following surgery must be included. When the patient is enrolled, the *Add Surgery Form* should be completed.

Multiple Surgeries

If a patient receives a subsequent surgery after they have been enrolled in the registry, the patient will maintain the same patient number. The additional surgeries should be entered by adding another *Add Surgery Form*.

Inclusion Criteria

All pediatric patients (18 years of age or less) that have surgery for heart disease (regardless of whether congenital or not) and any adult patient (19 years of age and up) that has surgery for congenital heart disease on or after the hospital enrolls in the WDPCHS are eligible for inclusion in the database. This includes patients with rheumatic heart disease or endocarditis.

Exclusion Criteria

Adults (19 years of age and up) who do not have surgery for congenital heart disease are not eligible. A complete list of congenital surgeries can be found in **Appendix** A.

Patient Follow-up and Censoring

Circumstances that stop follow-up are:

1. Patient death.
2. Patient one-year follow-up completed.

There are no other reasons for patient removal or censoring. A patient who subsequently receives another surgery is not removed from the database and his/her follow-up is not terminated.

Patient Identification Number

The web based data entry system will automatically generate each patient number. The number generation will be shared among all participating hospitals so no two patients in the database will have the same patient number. This number cannot be changed once a patient is enrolled.

Local Hospital Identifier

This field is an option field on the "Add Surgery" form. When a patient is initially enrolled into the database, the data entry personnel will have the option to add a local hospital I such as a patient name or medical record number. This field is strictly for use of the local data entry personnel to identify the patients. Any information entered into this field WILL be stored on the same servers as the other data entered in the United States. Before any PHI (Protected Health Information) is entered into this field, check with your local hospital regulatory representatives to be sure it is okay to enter this information.

IV. Data Collection and Submission

Overview

When a patient is enrolled and assigned a unique patient ID, the coordinator completes the *Add Surgery Form*. The coordinator is then responsible for the timely and accurate submission of the appropriate forms on an ongoing basis. Any additional surgeries will be added by completing another *Add Surgery Form*.

Surgeries will be classified automatically as Tier 1 or Tier 2 each time an *Add Surgery Form* is completed. Tier 1 surgeries will have expanded data collection. Minimal information will be collected for Tier 2 surgeries.

Local Patient Log

The WDPCHS does not collect patient names, only the first three letters of the patient's last name. Data entry personnel are encouraged to keep a local log of the patient name, and patient number to help track the patients at your center. This log is strictly to be used internally and should never be sent to the DCC. An example patient log can be found in **Appendix** I.

Data Collection Schedule

Coordinators are encouraged to complete and submit relevant forms as events occur (surgery, post-operative events, and one-year follow-up). It is important that the data submission be timely. Forms are due based on the date the event occurred. Coordinators will have 30 days after each event to submit the forms associated with each event.

Data Extraction
Source documents needed for data entry may come from a number of places. Listed below are some of the places you can find the data:

- History and Physical
- Pre-Operative Notes
- Operative Notes
- Admission Notes
- Perfusion/Anesthesia Record
- Discharge Summaries

Form Overview
The table below lists all of the WDPCHS forms in order of their form number. It lists the name of the form and the time at which the form should be completed.

Form	To Be Completed
Institutional Practice Details	At time of hospital enrollment into WDPCHS and each January.
Add Surgery Form	At time of surgery
Additional forms required for Tier 1 surgeries:	
Demographics Form	At time of surgery
Tier 1 Surgery Form	At time of surgery
Postoperative Events Form	At time of discharge or 90 days post-surgery if patient is still in the hospital
Annual Follow-up Form	At time of one-year follow-up
Death Form	At time of death
Additional forms required for Tier 2 surgeries:	
Tier 2 Surgery Form	At time of surgery
Tier 2 Discharge Form	At time of discharge or 90 days post-surgery if patient is still in the hospital

FAQ's will be added to the document in blue to provide additional examples and clarification.

Use the Ctrl + F function to search for a number or term of interest.

For all questions where the choices include "not done" and "unknown": When a history and physical or a consultation exists in the medical record and the values are not specifically addressed in the documentation, enter "not done". "Unknown" should only be used when no clinical documentation exists and the patient cannot give history and supportive documentation.

Annual Reports and Research
At the time of annual reports, centers will be individually reviewed for data completeness.

- Centers with less than six months of data will not have their data included in the annual reports and will not receive a hospital specific report, but will receive an aggregate report.
- Centers that have not entered any cases in the past six months prior to the report date will not have their data included in the annual reports and will not receive a hospital specific report, but will receive an aggregate report.
- Centers excluded from reports will be eligible for the next report if they meet the above criteria.

V. Form Specific Instructions

Institutional Practice Details

This form should be completed at the time a hospital enrolls in the registry. An updated form should be completed each January.

1. **Date of completion:** Indicate the day, month, and year the form is completed.
2. **Previous year's hospital case volume of congenital cardiac surgeries:** Indicate the case volume of Tier 1 AND Tier 2 surgeries for the previous calendar year. (This is the total number of surgeries, not the number of patients).
    - ○ Less than or equal to 100 per year
    - ○ 101-250 per year
    - ○ 251-500 per year
    - ○ Greater than 500 per year
3. **Active congenital heart surgeons:** Indicate the number of active congenital heart surgeons currently practicing at your hospital.
    a. **How is a congenital heart surgeon certified in your country?** Indicate how a congenital heart surgeon is certified. *(Question added March 9, 2020)*
4. **Cardioplegia type:** Check all cardioplegia types that your hospital uses. If there are multiple cardioplegia types that your hospital uses that are not options in the list provided, enter all of them in the "other, specify" box separating them by commas (,).
5. **Geographic region served:** *(Modified Answer Options added March 9,2020)*
    - ○ Local: one city or metro area
    - ○ Regional: geographically larger than a metro area
    - ○ National: one country
    - ○ International: multiple countries
6. **Estimated population served:** Based on answer to the previous question. *(Answer Options added March 9, 2020)*
    - ○ Less than 10 million
    - ○ 10-30 million
    - ○ 31-50 million
    - ○ Greater than 51 million
    - ○ Unknown
7. **Total number of institutions providing pediatric cardiac services in the region:** Based on answer to question 5. Specify the total number including your

institution. If your institution is the only institution providing pediatric cardiac services in the region, specify one.

8. **Does your institution have an established pediatric cardiology practice:** specify yes or no.
9. **Number of pediatric cardiac operating rooms:** Specify the total number. *(Revised January 25, 2018 to specify pediatric cardiac operating rooms.)*
10. **Does your institution have an exclusive pediatric cardiac intensive care unit:** Indicate yes or no.
11. **Does your institution have a pediatric cardiac intensivist:** Indicate yes or no.
12. **Does your institution have an ECMO (Extra Corporeal Membrane Oxygenation) program:** Indicate yes or no.
    a. **Does your hospital provide extracorporeal cardiopulmonary resuscitation (ECPR)?** Indicate yes or no. *(Question added March 9, 2020)*
13. **Does your institution have a pediatric cardiac catheterization laboratory:** Indicate yes or no.
14. **Does your institution have an electrophysiology service:** Indicate yes or no.
15. **Does your hospital have an Electronic Medical Records system (EMR)?** Indicate yes or no. If yes is selected, enter software vendor. *(Question added March 9, 2020)*
16. **Does your hospital participate in a National Congenital Heart Surgery Database?** Indicate yes or no. If yes is selected enter name of database. *(Question added March 9, 2020)*
17. **Does your hospital have a routine preoperative planning conference?** Indicate yes or no. *(Question added March 9, 2020)*
18. **Does your hospital have intraoperative Trans esophageal ECHO?** Indicate yes or no. *(Question added March 9, 2020)*
19. **Does your hospital have intraoperative Epicardial ECHO?** Indicate yes or no. *(Question added March 9, 2020)*
20. **Who performs the Pre-operative Trans Thoracic ECHO?** *(Question added March 9, 2020)*
    - ○ Cardiologist
    - ○ Cardiac Surgeon
    - ○ Trained ECHO Technologist
21. **Usual Patient follow up post discharge.** *(Question added March 9, 2020)*
    - ○ Cardiologist
    - ○ Surgeon
    - ○ Referring Physician
    - ○ Other, Specify

Add Surgery Form

This form should be completed at the time of each surgery.

Tier 1 Case submission (this is also known as an index procedure): The complete list of Tier 1 surgeries is:

- Ventricular Septal Defect (All types, excluding Gerbode type and Multiple Type)

- Atrioventricular Septal Defect (Including complete, balanced, excluding unbalanced)
- Tetralogy of Fallot (Include pulmonary stenosis, exclude Absent Pulmonary Valve Syndrome, CAVSD, and Pulmonary Atresia)
- Transposition of the Great Arteries with intact Ventricular septum (Excluding Ventricular Septal Defect, Corrected TGA, LVOTO)
- Coarctation of the Aorta
- Superior Caval to Pulmonary Artery Anastomosis (Including Bi-Directional Glenn Procedure, Hemi-Fontan Procedure)
- Compete Caval to Pulmonary Artery Anastomosis (Fontan including extra-cardiac, Lateral Tunnel, Internal Conduit, and Extra/Intra conduit type)
- Truncus Arteriosus (Excluding Interrupted Aortic Arch)
- Hypoplastic Left Heart Syndrome (Include those undergoing Norwood Procedure. Exclude those undergoing a hybrid Stage I)
- Ebstein Malformation
- Total Anomalous Pulmonary Venous Connection
- Partial Anomalous Pulmonary Venous Connection (Including Scimitar Syndrome and association with sinus venous atrial septal defect)
- Interrupted Aortic Arch

Tier 2 Case submission (Surgical Procedures)
This applies to all surgical procedures listed in the procedure list in Appendix A and not a Tier 1 case. Limited data will be collected on these cases. These variables include patient partial last name, date of birth, cardiac diagnosis, cardiac procedure, and survival status (alive vs dead).

1. **First Three Letters of Patient Last Name:** Indicate the first three letters of the patient's last name. If this information cannot be provided, select a unique patient identifier.
2. **Gender:** Indicate male, female or unknown.
3. **Date of birth:** Indicate the day, month, and year of patient's birth.
4. **Local Hospital Patient ID:** This field is an option field on the "Add Surgery" form. When a patient is initially enrolled into the database, the data entry personnel will have the option to add a local hospital id such as a patient name or medical record number. This field is strictly for use of the local data entry personnel to identify the patients. Any information entered into this field WILL be stored on the same servers as the other data entered in the United States. There is no character limit on this field and it is not a required field. The data entry personnel may enter as much or as little information as they would like to here to help identify the patients for which they are entering data.
5. **Date of Surgery:** Indicate the day, month, and year of patient surgery. This is the date the patient enters the operating room.
6. **Primary Cardiac Procedure:** Select the patient's primary surgical procedure. If the patient has multiple operating room visits, these should be reported on additional "Add Surgery Forms." A complete list of procedures can be found in Appendix A.

Q: How do I enter “Aortic Advancement”?
A: Enter as “Aortic Arch Repair”.

Q: How do I enter “Pulmonary Valve Replacement with Contegra”?
A: Enter as “Pulmonary Valve Replacement, Bioprosthetic”.

Q: How do I enter mediastinal exploration and delayed sternal wound closure?
A: For Tier 1 surgery patients, enter on either the Post-Operative Events or Follow-Up form**. For Tier 2 surgery patients**, add as a Tier 2 surgery – “other, specify” and indicate the name of the procedure.

Q: How do I enter pacemaker procedures such as: battery/lead replacement, PM upgrade or pacemaker explant?
A: For Tier 1 surgery patients, enter on either the Post-Operative Events or Follow-Up form. **For Tier 2 surgery patients**, add as a Tier 2 surgery – “other, specify” and indicate the name of the procedure.

Q: How do I enter surgery for Chylothorax that required a pleural drain?
A: If the surgery is after a Tier 1 surgery, please enter on the Post-Operative Events form as a complication (Chylothorax or pleural effusion, requiring drainage) or on the one year Follow-Up form as a re-operation (select the type of non-cardiac re-operation such as “ligation of thoracic duct” or “unplanned non-cardiac reoperation, other, specify: _____”). **If the surgery is not after a Tier 1 procedure**, enter this as a new surgery “Procedure for Chylothorax”.

Q: How do I enter a surgery that is not listed?
A: Enter “other, specify” and indicate the name of the surgery. These will be classified as Tier 2 procedures.

Q: For primary cardiac surgery, do you select the biggest/most important procedure or the procedure that is most significant to the diagnosis? For example: Patient diagnosis: Tricuspid atresia type IIB + Hypoplasia of Aortic Arch + Coarctation of the aorta, Single ventricle. Patient procedure: Pulmonary artery banding, coarctation repair end to end, VSD creation, ASD creation. Would the primary procedure be the coarctation repair (biggest impact) or pulmonary banding (important for next stage surgery)?
A: In general, please enter the biggest/most important procedure (Tier 1 procedure) as the patient’s primary cardiac procedure and the other procedure can be entered as additional cardiac procedures done during the same OR visit. In the example above, enter the coarctation repair, end to end (Tier 1 procedure) as the primary cardiac procedure and the (Tier 2 procedures) pulmonary artery banding, VSD creation, and ASD creation as additional procedures done during the same OR visit.

Q: How do I enter a shunt re-operation for a shunt revision?

A: If the patient has had a prior Tier 1 surgery, please enter shunt revision on the postoperative events form or on the one year Follow-Up form as a non-cardiac operation (requirement for shunt revision). **If the surgery is not after a Tier 1 procedure**, enter this as a new surgery (several options include: shunt, ligation and takedown or procedures for chylothorax (for pleuroperitoneal shunt), or "Other, specify: and type in the procedure name".

Q: How do I enter a Starnes procedure with central shunt, open atrial septectomy, tricuspid valve closure with fenestration and open pulmonary valvotomy with ligation of patent ductus arteriosus?
A: Enter "other, specify" and indicate Starnes procedure. This will be classified as a Tier 2 procedure.

**For Tier 1 patients, the system will automatically generate the required forms as indicated below.*
**For Tier 2 patients, the completion of the Tier 2 Surgery Form is the end of data entry unless the patient has an additional surgery.*

Tier 2 Surgery Form

Patient identifier questions will be auto populated from the Add Surgery Form.

Date of Surgery: Indicate the day, month, and year of patient surgery.

1. **Primary Cardiac Procedure:** Select the patient's primary surgical procedure. If the patient has multiple surgeries during separate operating room visits, additional surgeries should be reported on additional Add Surgery Forms. A complete list of procedures can be found in Appendix A.
2. **Were there any additional Cardiac Procedures during the same OR visit?** Indicate yes, no, or unknown.
   a. **Additional Procedures during the same OR visit:** Select additional procedures during the same operating room visit. See Appendix A for a complete list including definitions.

Q: Explain: "Other cardiac procedures in the same OR visit?" For example, does a VSD and ASD closure count as 2 procedures? Does Tetralogy of Fallot correction and ASD closure counts as 2 corrections?
A: For "other cardiac procedures in the same OR visit", we are interested in any additional procedures that were done during the same operation. Several procedures may be done in the same surgery, but all would count as 1 surgery.

For example, if the VSD closure is a routine part of the operation, it does not need to be entered as a separate procedure, as in Tetralogy of Fallot repair, Ventriculotomy (Tier 1): This procedure assumes VSD closure and relief of pulmonary stenosis at one or more levels. The repair utilizes a ventriculotomy incision, but without placement of a transpulmonary annulus patch.

Please refer to the Appendices, Appendix A contains the Surgical Procedure Terms and Definitions. The surgical definitions explain what is considered routine

for that procedure so if it is listed in the definition, it does not need to be entered as a separate procedure.

In the example above, a Tetralogy of Fallot correction and ASD closure would be entered as 2 procedures done in the same surgery (the Tetralogy of Fallot correction would be the primary procedure, and the ASD closure would be the other cardiac procedure in the same OR visit).

Q: How would I enter a sub pulmonary VSD with patch tunnel type from LV to Aorta (intraventricular tunnel), closure of the pulmonary valve, RV to PA conduit, and ASD closure with patch that was done last week and then 24 hours later the patient needed ECMO?
A: Add a surgery for this patient, select DORV intraventricular tunnel repair as the procedure. This will direct you to the Tier 2 surgery form. Select DORV, TGA type as the diagnosis. After you select "Validate and Save", you will be taken to the patient summary. At the top left of the patient summary, select "Add surgery to this patient". Enter the date of ECMO as the date of surgery. Then add "ECMO cannulation" as the procedure name. Another Tier 2 surgery form will need to be completed about the ECMO procedure. When this form is complete, you should see both procedures, the DORV repair and the ECMO on the patient summary.

3. **Primary Cardiac Diagnosis:** Related to this surgery (Check only one). Select the structural heart disease (such as aortic stenosis, valvar) as the primary diagnosis. Other diagnoses (such as rheumatic heart disease) will be listed as additional diagnoses. See Appendix B for a complete list of options and the International Paediatric and Congenital Cardiac Code (IPCCC) definition of each option.
    a. If Hypoplastic Left Heart Syndrome is selected indicate yes, no, or unknown for the following.
        i. **Aortic Arch Coarctation?** *(Option added March 22, 2017)*
        ii. **Aortic Arch Hypoplasia?** *(Option added March 22, 2017)*
        iii. **Aortic Valve Atresia?**
        iv. **Aortic Valve Stenosis?**
        v. **Aortic Valve Hypoplasia?**
        vi. **Mitral Valve Atresia?**
        vii. **Mitral Valve Stenosis?**
        viii. **Mitral Valve Hypoplasia?**
        ix. **Ventricular Septal Defect?**
        x. **Left Ventricle Size?** Indicate normal, small, or unknown
4. **Are there any additional Cardiac Diagnoses:** Indicate yes, no, or unknown. See Appendix B for a complete list including definitions.
    a. **Additional Cardiac Diagnoses:** Check all that apply. List the structural heart disease (such as aortic stenosis, valvar) as the primary diagnosis and other diagnoses (such as rheumatic heart disease) here. If Hypoplastic Left Heart Syndrome is selected indicate yes, no, or unknown for the following.

i. **Aortic Arch Coarctation?** *(Option added March 22, 2017)*
ii. **Aortic Arch Hypoplasia?** *(Option added March 22, 2017)*
iii. **Aortic Valve Atresia?**
iv. **Aortic Valve Stenosis?**
v. **Aortic Valve Hypoplasia?**
vi. **Mitral Valve Atresia?**
vii. **Mitral Valve Stenosis?**
viii. **Mitral Valve Hypoplasia?**
ix. **Ventricular Septal Defect?**
x. **Left Ventricle Size?** Indicate normal, small, or unknown

5. **Intraoperative Mortality:** Did the patient die intraoperatively? Indicate yes or no.

Tier 2 Discharge Form (Tier 2 Surgery)

This form is to be completed post operatively for all Tier 2 surgeries reported. Each Tier 2 Surgery Form entered for a patient should have a corresponding Tier 2 Discharge Form. If the patient is still in the hospital at 90 days post-surgery, this form should be completed on day 91 .

1. **At the time of patient discharge (or at 90 days postop if patient is still in the hospital), is patient still alive?:** Indicate yes or no.
   Date of patient discharge: Enter day/month/year of patient discharge.
   Date of patient death: Enter day/month/year of patient death.

Demographics Form (Tier 1 Surgery)

This form will be automatically generated at the time a patient has their first Tier 1 surgery. Each Tier 1 patient should only have one demographics form.

1. **Birth country:** Indicate the country in which the patient was born. If the country of birth is not an option in the list provided, select “other, specify” and specify the correct country. If birth country is not known, select “unknown”.
   See Appendix C for a complete list of birth country options.

   Q: Is there any time limit for the arrival of the mother in the country of birth in cases of large immigration?
   A: No, enter the birth country at the time of birth

2. **Premature birth:** Indicate whether the patient was born prematurely as defined by a gestational period of less than or equal to 37 weeks.
3. **Race:** Specify patient race.
   - ☐ African-American (Black): racial origins in any of the black racial groups of Africa
   - ☐ Alaska Indian: racial origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition
   - ☐ American Indian: racial origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition

- ☐ Asian: racial origins in any of the original peoples of the Far East and Southeast Asia (examples include China, Japan, and Korea)
- ☐ Caribbean *(Option added July 2, 2019)*
- ☐ Eskimo
- ☐ Hispanic/Latino: Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture of origin
- ☐ Mixed Race *(Option added July 2, 2019)*
- ☐ Pacific Islander: racial origins in any of the peoples of the Pacific Islands (examples include the Philippine Islands, Samoa, Guam and the Hawaiian Islands)
- ☐ White: racial origins in any of the original peoples of Europe
- ☐ Other, specify
- ☐ Unknown

4. **Did patient have any non-cardiac congenital anatomic abnormalities:** Indicate yes, no, or unknown.
   a. **Non-cardiac congenital anatomic abnormalities:** If patient had a non-cardiac congenital anatomic abnormality, check all that apply in the pull down list.
   A complete list of non-congenital cardiac anatomic abnormities with definitions can be found in Appendix D.
5. **Was patient diagnosed with a chromosomal abnormality:** Indicate yes, no, or unknown.
   a. **Chromosomal abnormality:** If patient had a chromosomal abnormality, check all that apply in the pull down list. See Appendix E
6. **Was patient diagnosed with a syndrome:** Indicate yes, no, or unknown.
   a. **Syndromes:** If patient was diagnosed with a syndrome, select all that apply in the pull down menu. See Appendix F for a complete list of syndromes and definitions.

Q: For chromosomal abnormalities/syndromes, do we enter only confirmed diagnosis or phenotypes (facial characteristics) also?
A: Chromosomal abnormalities and syndromes should be entered if there is a clinical diagnosis documented in the medical record.

7. **Is this the patient's first congenital surgery:** Indicate yes, no, or unknown. *(Question moved from Tier 1 Surgery form on March 9, 2020)*

a. **Specify previous congenital cardiac operations:** For each previous operation, indicate how many times the patient had the operation. *(Question moved & modified from Tier 1 Surgery form on March 9, 2020)*

Tier 1 Surgery Form (Tier 1 Surgery)

This form is to be completed at the time of each Tier 1 surgery. This form will be automatically generated once a Tier 1 surgery has been entered on the *Add Surgery Form*.

Date of surgery: This will be auto generated based on the date entered on the *Add Surgery Form*.

1. **Primary Cardiac Procedure:** This will be auto generated based on the procedure entered on the *Add Surgery Form*.
2. **Were there additional cardiac procedures done in the same OR visit?** Indicate yes, no, or unknown. See Appendix A for a complete list including definitions.
   a. **Additional Cardiac Procedures:** Select additional procedures during the same operating room visit. See Appendix A for a complete list including definitions.

   Q: Explain: "Other cardiac procedures in the same OR visit?" For example, does a VSD and ASD closure count as 2 procedures? Does Tetralogy of Fallot correction and ASD closure counts as 2 corrections?
   A: For "other cardiac procedures in the same OR visit", we are interested in any additional procedures that were done during the same operation. Several procedures may be done in the same surgery, but all would count as 1 surgery.

   For example, if the VSD closure is a routine part of the operation, it does not need to be entered as a separate procedure, as in Tetralogy of Fallot repair, Ventriculotomy (Tier 1): This procedure assumes VSD closure and relief of pulmonary stenosis at one or more levels. The repair utilizes a ventriculotomy incision, but without placement of a transpulmonary annulus patch.

   Please refer to the Appendices, Appendix A contains the Surgical Procedure Terms and Definitions. The surgical definitions explain what is considered routine for that procedure so if it is listed in the definition, it does not need to be entered as a separate procedure.

   In the example above, a Tetralogy of Fallot correction and ASD closure would be entered as 2 procedures done in the same surgery (the Tetralogy of Fallot correction would be the primary procedure, and the ASD closure would be the other cardiac procedure in the same OR visit).

3. **Primary Cardiac Diagnosis:** Select the <u>one</u> cardiac diagnosis related to this surgery. List the structural heart disease. See Appendix B for a complete list of options and the International Paediatric and Congenital Cardiac Code (IPCCC) definition of each option. If Hypoplastic Left Heart Syndrome is selected indicate yes, no, or unknown for the following.
   a. **Aortic Arch Coarctation?** *(Option added March 22, 2017)*
   b. **Aortic Arch Hypoplasia?** *(Option added March 22, 2017)*
   c. **Aortic Valve Atresia?**
   d. **Aortic Valve Stenosis?**
   e. **Aortic Valve Hypoplasia?**
   f. **Mitral Valve Atresia?**
   g. **Mitral Valve Stenosis?**
   h. **Mitral Valve Hypoplasia?**

i. **Ventricular Septal Defect?**
j. **Left Ventricle Size?** Indicate normal, small, or unknown

4. **Are there any additional Cardiac Diagnoses:** Indicate yes, no, or unknown. See Appendix B for a complete list including definitions.
   a. **Additional Cardiac Diagnoses:** Check all that apply. List the structural heart disease (such as aortic stenosis, valvar) as the primary diagnoses (such as rheumatic heart disease) here. If Hypoplastic Left Heart Syndrome is selected indicate yes, no, or unknown for the following.
      i. **Aortic Arch Coarctation?** *(Option added March 22, 2017)*
      ii. **Aortic Arch Hypoplasia?** *(Option added March 22, 2017)*
      iii. **Aortic Valve Atresia?**
      iv. **Aortic Valve Stenosis?**
      v. **Aortic Valve Hypoplasia?**
      vi. **Mitral Valve Atresia?**
      vii. **Mitral Valve Stenosis?**
      viii. **Mitral Valve Hypoplasia?**
      ix. **Ventricular Septal Defect?**
      x. **Left Ventricle Size?** Indicate normal, small, or unknown
5. **Preoperative risk factors:** If the patient had preoperative risk factors, select all that apply. This can often times be done by memory if completed by healthcare worker. If not, a chart review might be required. Please see Appendix F for a complete list of Items with definitions.
6. **Weight at time of surgery:** Indicate the weight in kilograms at time of surgery. If weight is not known, indicate so by selecting "unknown" as a Missing Reason. *(Question switched from number 8 to 7 November 11th, 2019)*
7. **Height at time of surgery:** Indicate the height in centimeters at time of surgery. If height is not known, indicate so by selecting "unknown" as a Missing Reason. *(Question switched from number 7 to 8 November 11th, 2019)*

8. **Status at operation:** Indicate the status of the operation. Check only one.
   - Elective: The patient's cardiovascular status has been stable in the days or weeks prior to the operation. The procedure could be deferred without increased risk of compromised outcome.
   - Urgent: Procedure required during same hospitalization in order to minimize chance of further clinical deterioration. Generally, should undergo the operative procedure within 24 hours of indication.
   - Emergent: Patients requiring emergency operations will have ongoing severe cardiovascular compromise, not responsive to any form of therapy except cardiac surgery. An emergency operation is one in which there should be no delay in providing operative intervention.
   - Salvage: The patient is undergoing CPR en route to the operating room or prior to anesthesia induction or has ongoing ECMO support to maintain life.

Q: Should Norwoods/ASO/Truncus repairs that are stable in ICU be entered as "elective" or "urgent"?
A: These should be classified as "urgent".

9. **Was patient on cardiopulmonary bypass during operation:** Indicate yes, no, or unknown. If more than one period of cardiopulmonary bypass (CPB) is required during surgery add the minutes of all CPB together during surgery and enter the total CPB time.
    a. **Duration of cardiopulmonary bypass:** Indicate the total number of minutes the patient was on cardiopulmonary bypass. If unknown, select "unknown" as a Missing Reason.
10. **Cross clamp time:** Indicate the total cross clamp time in minutes. This is the duration of cardiac ischemia. If more than one period of cross clamp time is required during surgery add the minutes of all cross clamp time together during surgery and enter the total cross clamp time. If not used, select "not done". If unknown, select "unknown" as a Missing Reason.
11. **Circulatory arrest time:** Indicate the total number of minutes the patient was under circulatory arrest. If more than one period of circulatory arrest is required during surgery add the minutes of all circulatory arrest together during surgery and enter the total circulatory arrest time. If not used, select "not done". If unknown, select "unknown" as a Missing Reason.
12. **Selective cerebral perfusion time:** Indicate the total number of minutes the patient had selective cerebral perfusion. Duration of time in which perfusion was maintained selectively to the brain while the remainder of the body was under circulatory arrest. If not used, select "not done". If unknown, select "unknown" as a Missing Reason.
13. **Cardioplegia type:** Select the cardioplegia type used. Check only one type.
    - ○ Buckberg
    - ○ Custodiol/Bretschneider (HTK)
    - ○ Del Nido
    - ○ Microplegia with Adenocaine
    - ○ Microplegia with Potassium
    - ○ Plegisol/St. Thomas
    - ○ Roe's Solution
    - ○ University of Wisconsin
    - ○ Other, specify
    - ○ None
14. **Was Transesophageal ECHO (TEE) used in this operation:** Indicate yes, no, or unknown to report if TEE was used during operation.
15. **Was an epicardial echo done in this operation?** Indicate yes, no, or unknown. *(Question added January 18, 2018)*
16. **Was sternum left open at the end of operation:** Indicate yes, no, or unknown to report if the sternum was left open at the end of operation. *(Question added October 11, 2017)*
17. **Were there any complications during this operation:** If patient experienced complications diagnosed during the operation, specify the complications. All neurological complications including those diagnosed in the operating room will be reported on the Post Operative Events Form.
    a. **Complications:** Check all that apply.
        - ☐ Arrhythmia requiring drug therapy

- ☐ Arrhythmia requiring electrical cardioversion or defibrillation
- ☐ Arrhythmia requiring permanent pacemaker
- ☐ Bleeding
- ☐ Cardiac dysfunction resulting in low cardiac output
- ☐ Cardiac failure (severe cardiac dysfunction)
- ☐ Mechanical circulatory support (IABP, VAD, ECMO, or CPS)
- ☐ Multi-System Organ Failure (MSOF) = Multi-Organ Dysfunction Syndrome (MODS)
- ☐ Seizure
- ☐ Unknown
- ☐ Other, specify

18. **Intraoperative Mortality:** Did the patient die intraoperatively? Indicate yes or no.

Post-Operative Events Form (Tier 1 Surgery)

This form is to be completed post operatively for all Tier 1 surgeries reported. Each Tier 1 Surgery Form entered for a patient should have a corresponding Post-Operative Events Form. If the patient is still in the hospital at 90 days post-surgery, this form should be completed on day 91. All questions on this form are pertaining to events that happened post surgery and pre discharge. Any events that happen after discharge should be reported on the annual follow-up form.

This form should <u>not</u> be completed if the patient dies intraoperatively.

Date of surgery: This will be auto generated based on the date entered on the *Add Surgery Form*.
Primary Cardiac Procedure: This will be auto generated based on the procedure entered on the *Add Surgery Form*.

1. **Did the patient have a post-operative complication associated with this Tier 1 surgery:** Indicate yes, no, or unknown.
   a. **Specify complication(s):** Check all that
   b. apply. Please see Appendix H for a complete list of Items with definitions
      - ☐ Arrhythmia requiring drug therapy
      - ☐ Arrhythmia requiring electrical cardioversion or defibrillation
      - ☐ Arrhythmia requiring Permanent pacemaker
      - ☐ Bleeding, requiring reoperation
      - ☐ Cardiac dysfunction resulting in low cardiac output
      - ☐ Cardiac failure (severe cardiac dysfunction)
      - ☐ Chylothorax or pleural effusion, requiring drainage
      - ☐ Endocarditis-post procedural infective endocarditis
      - ☐ Intraventricular hemorrhage (IVH) > grade 2
      - ☐ Mechanical circulatory support (IABP, VAD, ECMO, or CPS)
      - ☐ Multi-System Organ Failure (MSOF) = Multi-Organ Dysfunction Syndrome (MODS)
      - ☐ Neurological deficit diagnosed in the operating room, persisting at discharge or 91 days if patient is still in hospital.

- ☐ Neurological deficit diagnosed in the operating room, not present at discharge
- ☐ Neurological deficit that occurred after the operating room visit, persisting at discharge
- ☐ Neurological deficit that occurred after the operating room visit, not present at discharge
- ☐ Paralyzed diaphragm (possible phrenic nerve injury), requiring surgical plication
- ☐ Pericardial Effusion, requiring drainage
- ☐ Peripheral nerve injury persisting at discharge or 91 days if patient is still in hospital
- ☐ Peripheral nerve injury not present at discharge or 91 days if patient is still in hospital
- ☐ Postoperative/Post procedural respiratory insufficiency requiring mechanical ventilatory support > 7 days
- ☐ Postoperative/Post procedural respiratory insufficiency requiring reintubation
- ☐ Pneumonia – a respiratory disease characterized by inflammation of the lung parenchyma (including alveolar spaces and interstitial tissue), most commonly caused by infection". Pneumonia is diagnosed by appropriate clinical findings (such as fever, leukopenia or leukocytosis, and new onset of purulent sputum) and one or more of the following: positive cultures (of sputum or pulmonary secretions) and / or pulmonary infiltrate on chest x-ray. An endotracheal tube culture may or may not be positive. Patients commonly demonstrate an evolving area of focal lung consolidation accompanied by fever (>38.5). Pneumonia (pneumonitis) may affect an entire lobe (lobar pneumonia), a segment of a lobe (segmental or lobular pneumonia), alveoli contiguous to bronchi (bronchopneumonia), or interstitial tissue (interstitial pneumonia). These distinctions are generally based on xray observations.
  (Option added April 24, 2018)
- ☐ Pulmonary vein obstruction
- ☐ Renal failure - acute renal failure, Acute renal failure requiring dialysis at the time of hospital discharge or 91 days if patient is still in hospital
- ☐ Renal failure - acute renal failure, Acute renal failure requiring temporary dialysis with the need for dialysis not present at hospital discharge or 91 days if patient is still in hospital
- ☐ Renal failure - acute renal failure, Acute renal failure requiring temporary hemofiltration with the need for dialysis not present at hospital discharge or 91 days if patient is still in hospital
- ☐ Respiratory failure, requiring tracheostomy
- ☐ Seizure
- ☐ Sepsis
- ☐ Spinal cord injury, Neurological deficit persisting at discharge
  (Option added October 11, 2017)
- ☐ Stroke: Ischemic

- ☐ Subdural Bleed
- ☐ Systemic vein obstruction
- ☐ Unplanned cardiac reoperation during the postoperative or post procedural time period, exclusive of reoperation for bleeding
- ☐ Vocal cord dysfunction (possible recurrent laryngeal nerve injury)
- ☐ Wound dehiscence-Median Sternotomy *(Option added October 11, 2017)*
- ☐ Wound infection-Mediastinitis
- ☐ Wound infection-Superficial wound infection
- ☐ Unknown
- ☐ Other, specify

Q: How should I enter surgery for infective endocarditis on the Postoperative Events form?
A: Select "endocarditis-post procedural infective endocarditis" for this question. Then, for question #2, enter as "Unplanned Non-cardiac Reoperation, other, specify" and specify the operation.

Q: If the sternum is left open as a planned part of the procedure, should it be recorded as a complication?
A: No, record as a complication if it is unplanned for the sternum to be left open.

Q: What is considered mechanical ventilation in this database? (invasive and non-invasive? Or only invasive?)
A: Only invasive, patient would either be intubated and on ventilator or have a tracheostomy connected to a ventilator.

2. **Did the patient have a non-cardiac operation within this admission:** Indicate yes, no, or unknown. If more than one operation within this admission, enter each operation with its associated date.
   a. **Date of operation:** If patient had a reoperation, indicate the day, month, and year of the reoperation.
   b. **Specify non-cardiac operation:** If patient had a reoperation, indicate the operation.
      - ○ Mediastinal Exploration (Bleeding)
      - ○ Pacemaker Placement
      - ~~○ Pulmonary Embolectomy~~ *(Option removed March 9, 2020)*
      - ○ Ligation of Thoracic Duct
      - ○ Diaphragm Plication
      - ○ Tracheostomy
      - ○ Mediastinal Drainage
      - ○ Wound debridement/ exploration *(Option modified March 9, 2020)*
      - ○ Post-operative mechanical circulatory support: (IABP, ECMO, VAD, CPS Cardiopulmonary Support)
      - ~~○ Requirement for Shunt Revision~~ *(Option removed March 9, 2020)*
      - ○ Unplanned Non-cardiac Reoperation, other, specify
      - ○ Gastrostomy tube placement *(Option added March 9, 2020)*

- ○ Pericardial drainage tube/catheter *(Option added March 9, 2020)*
- ○ Pleural drainage tube/catheter *(Option added March 9, 2020)*
- ○ Mediastinal Drainage/Exploration for blood or fluid *(Option added March 9, 2020)*
- ○ Mediastinal Drainage/Exploration for infection *(Option added March 9, 2020)*

i. Specify post-operative mechanical circulatory support

- ☐ CPS (Cardiopulmonary Support)
- ☐ ECMO (Extracorporeal Membrane Oxygenation)
- ☐ IABP (Intra-Aortic Balloon Pump)
- ☐ VAD (Ventricular Assist Device)

3. **Did the patient have a catheter based-intervention within this admission**? Indicate yes, no, or unknown. If more than one intervention within this admission, enter each intervention with its associated date.
   a. **Date of Reintervention:** If the patient had a reintervention, indicate the day, month, and year of reintervention.
   b. **Specify catheter-based intervention:** Indicate the intervention performed. *(Modified list on March 9, 2020)*
      - ☐ Aortic arch: Balloon /Stent Placement
      - ☐ Aortic Valve: Balloon Valvuloplasty
      - ☐ Arrhythmia ablation
      - ☐ Arterial-Pulmonary (AP) collaterals: Occluding Device, placement
      - ☐ Atrial Septal Defect: Occluding Device, placement
      - ~~☐ Coronary arteries~~ *(Option removed March 9,2020)*
      - ☐ Descending Aorta / Isthmus: Balloon /Stent Placement
      - ~~☐ Descending thoracic aorta/coarctation~~ *(Option removed March 9, 2020)*
      - ☐ Drainage of Seroma
      - ~~☐ Intra-cardiac-atrial~~ *(Option removed March 9, 2020)*
      - ~~☐ Intra-cardiac-ventricular~~ *(Option removed March 9, 2020)*
      - ☐ Mitral Valve: Balloon Valvuloplasty
      - ☐ Patent Ductus Arteriosus: Balloon/Stent placement
      - ☐ Patent Ductus Arteriosus: Occluding Device, placement
      - ~~☐ Pulmonary arteries~~ *(Option removed March 9, 2020)*
      - ☐ Pulmonary veins: Balloon/Stent placement
      - ☐ Pulmonary Valve: Balloon Valvuloplasty
      - ☐ RVOT: Balloon/Stent placement
      - ☐ Shunt closure
      - ☐ Shunt Thrombolysis
      - ☐ Systemic veins: Balloon/Stent placement
      - ☐ Systemic to Pulmonary Stunt: Balloon/Stent placement
      - ~~☐ Valvar~~ *(Option removed March 9, 2020)*
      - ☐ Veno-venous collaterals: Occluding Device, placement
      - ☐ Other, specify
4. **Did the patient have another cardiac surgery within this admission:** Indicate yes, no, or unknown. If yes, an *Add Surgery Form* should be completed. A complete list of procedures can be found in Appendix A.

5. **Date of Patient Discharge:** Indicate the day, month, and year of patient discharge. If patient has not been discharged at day 91 post operation, select "still in hospital". If patient died in hospital, date of death should be entered as the discharge date.

   Q: What is the discharge date for a patient that transfers to another hospital?
   A: Use the date the patient transfers from the hospital where the surgery took place as the discharge date.

6. **Status at discharge or at 90 days post-op if still in hospital:** Indicate the status of the patient at discharge. If patient is dead, complete death form.
   - ○ Alive
   - ○ Dead *(complete death form)*

Follow-up Form (Tier 1 Surgery) *Changed name from One Year Follow Up on March 9, 2020*

All questions on this form are pertaining to events that occurred post discharge and prior to the date of this follow-up. Any events that occurred prior to discharge should be reported on the Post Operative Events Form. This form is to be completed at time of one-year follow-up from Tier 1 surgery. The follow-up should fall within a window of one year after the surgery date + 60 days.

Date of surgery: This will be auto generated based on the date entered on the *Add Surgery Form*.
Primary Cardiac Procedure: This will be auto generated based on the procedure entered on the *Add Surgery Form*.

1. **Do you have any follow up information since the most recent form (discharge/90 days or follow up) was completed?** *(Question modified March 9, 2020)*
   - ○ Yes (complete the rest of this form)
   - ○ No (no further questions)
   - **a. How was the follow up information obtained?** *(Question added March 9, 2020)*
   - ○ Phone
   - ○ Clinic
   - ○ Hospital
   - ○ Relative
   - ○ Other, specify
   - **b. Is the patient alive?** Indicate yes, no or unknown. If no is selected, death form should be completed. *(Question added March 9, 2020)*
   - **c. Has the ongoing care of the patient been transferred to another facility?** Indicate yes or no. If yes is selected, indicate date: month/year. *(Question added March 9, 2020)*

2. **Was the patient readmitted for a non-cardiac operation since completion of the last Post-Operative Events Form:** Indicate yes, no, or unknown. If more

than one operation within this admission, enter each operation with its associated date.

a. **Date of reoperation:** Indicate day, month, and year of reoperation.
b. **Specify non-cardiac reoperation:** Specify the type of reoperation. Check only one. If patient had multiple reoperations, indicate so by selecting Add Surgery to this patient from the Patient Summary.
   - ○ Mediastinal Exploration (Bleeding)
   - ○ Pacemaker Placement
   - ~~○ Pulmonary Embolectomy~~ *(Option removed March 9, 2020)*
   - ○ Ligation of Thoracic Duct
   - ○ Diaphragm Plication
   - ○ Tracheostomy
   - ○ Mediastinal Drainage
   - ○ Wound debridement/ exploration *(Option modified March 9, 2020)*
   - ○ Post-operative mechanical circulatory support: (IABP, ECMO, VAD, CPS Cardiopulmonary Support)
   - ~~○ Requirement for Shunt Revision~~ *(Option removed March 9, 2020)*
   - ○ Unplanned Non-cardiac Reoperation, other, specify
     Gastrostomy tube placement *(Option added March 9, 2020)*
   - ○ Pericardial drainage tube/catheter *(Option added March 9, 2020)*
   - ○ Pleural drainage tube/catheter *(Option added March 9, 2020)*
   - ○ Mediastinal Drainage/Exploration for blood or fluid *(Option added March 9, 2020)*
   - ○ Mediastinal Drainage/Exploration for infection *(Option added March 9, 2020)*

     Q: How should I enter surgery for infective endocarditis on 1 Year Follow-up Form?
     A: Enter as “Unplanned Non-cardiac Reoperation, other, specify” and specify the operation.

i. Specify post-operative mechanical circulatory support

- ☐ CPS (Cardiopulmonary Support
- ☐ ECMO (Extracorporeal Membrane Oxygenation)
- ☐ IABP (Intra-Aortic Balloon Pump)
- ☐ VAD (Ventricular Assist Device)

3. **Did the patient have a catheter-based intervention since the completion of last Post-Operative Events Form?** Indicate yes, no, or unknown. If more than one intervention within this admission, enter each intervention with its associated date.

a. **Date of intervention:** Indicate month and year of intervention.
b. **Catheter-based intervention:** check all catheter based interventions that the patient had.*(Modified list on March 9, 2020)*
   - ☐ Aortic arch: Balloon /Stent Placement

- ☐ Aortic Valve: Balloon Valvuloplasty
- ☐ Arrhythmia ablation
- ☐ Arterial-Pulmonary (AP) collaterals: Occluding Device, placement
- ☐ Atrial Septal Defect: Occluding Device, placement
- ~~☐ Coronary arteries~~ *(Option removed March 9,2020)*
- ☐ Descending Aorta / Isthmus: Balloon /Stent Placement
- ~~☐ Descending thoracic aorta/coarctation~~ *(Option removed March 9, 2020)*
- ☐ Drainage of Seroma
- ~~☐ Intra-cardiac-atrial~~ *(Option removed March 9, 2020)*
- ~~☐ Intra-cardiac-ventricular~~ *(Option removed March 9, 2020)*
- ☐ Mitral Valve: Balloon Valvuloplasty
- ☐ Patent Ductus Arteriosus: Balloon/Stent placement
- ☐ Patent Ductus Arteriosus: Occluding Device, placement
- ~~☐ Pulmonary arteries~~ *(Option removed March 9, 2020)*
- ☐ Pulmonary veins: Balloon/Stent placement
- ☐ Pulmonary Valve: Balloon Valvuloplasty
- ☐ RVOT: Balloon/Stent placement
- ☐ Shunt closure
- ☐ Shunt Thrombolysis
- ☐ Systemic veins: Balloon/Stent placement
- ☐ Systemic to Pulmonary Stunt: Balloon/Stent placement
- ~~☐ Valvar~~ *(Option removed March 9, 2020)*
- ☐ Veno-venous collaterals: Occluding Device, placement
- ☐ Other, specify

4. **Readmission for any pediatric or congenital heart surgery since completion of last Post-Operative Events Form:** Indicate yes or no. If yes, an *Add Surgery Form* should be completed. Additionally, a new one-year follow-up form should be completed at one-year post surgery date.
5. ~~**NYHA Functional Class:** indicate the NYHA class at time of this report~~ *(Question removed March 9,2020)*

Death Form (Tier 1 Surgery)

This form should be completed at the time of death if the patient died within one year (+ 60 days) of the index surgery.

1. **Date of death:** Provide day, month, and year of patient death.
2. **Primary cause of death:** Enter only ONE primary cause of death. If unsure of the primary, check with your local surgeon.
   - ○ Accident (example: trauma, drowning, poisoning)
   - ○ Acute or chronic cardiac failure
   - ○ Anoxic event
   - ○ Bleeding
   - ○ Non-cardiac bleeding
   - ○ Surgical bleeding (intra op or post op)
   - ○ Coronary artery event
   - ○ Gastrointestinal complications
   - ○ Inoperable Defect

- Liver failure
- Malignancy
- Mechanical circulatory support failure
- Neurologic event
- Pulmonary embolism
- Rejection
- Renal failure
- Respiratory failure
- Rhythm disturbance
- Suicide
- Surgical site infection
- Sepsis
- Other major infection
- Systemic embolism
- Other, specify

3. **Autopsy:** Was an autopsy performed? Indicate yes, no, or unknown.
   a. **Autopsy findings:** If an autopsy was performed, specify the autopsy findings. If the findings are not known, select “unknown” from the Missing Reason options.
4. **Special circumstances:** Report any special circumstances in the text field. If there were no special circumstances, select “No special circumstances” from the Missing Reason options. If it is not known if there were special circumstances, select “Unknown” from the Missing Reason options.