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MESSAGE FROM THE DEPARTMENT OF HEALTH

We are very pleased to provide the information in this booklet for health care providers and for the families of children who need heart surgery. This report summarizes outcomes for pediatric patients undergoing surgery to correct congenital heart defects. Hospital-specific mortality rates that have been adjusted to account for differences in patient severity of illness are included along with the risk factors associated with in-hospital mortality for these procedures. These analyses represent one component of our ongoing efforts to provide comprehensive monitoring and assessment information for both patients and providers. This is the fourth report of risk-adjusted outcomes for pediatric cardiac surgery in New York State (NYS). New York is the only state in the country that we are aware of to evaluate and release this kind of information for all types of pediatric congenital cardiac surgery.

The term congenital heart defect represents a broad range of abnormalities that may be present at birth. According to the National Heart Lung and Blood Institute, about 1 in every 125 newborns is affected by a congenital heart defect. More than 35 different types of congenital heart defects have been identified. Until recent years, the most serious defects were thought to be untreatable. However, as scientific knowledge and technology have increased, more cases have been identified and the range of surgical options to correct them or alleviate their damaging effects has grown.

Evaluating pediatric cardiac surgery data represents special challenges because of the wide range of diagnoses and procedures involved. However, with the guidance of the New York State Cardiac Advisory Committee (CAC), we have been able to develop a statistical model that allows us to monitor and compare outcomes across hospitals. Similar analyses in adult cardiac surgery have been helpful both in documenting the excellent care provided in NYS centers and in continuing to improve care. Improvements have been and will continue to be achieved by sharing these data for pediatric congenital cardiac surgery.

If your child has been diagnosed with a heart defect, it is very important that a specialist in pediatric cardiology evaluate him or her. If surgery is being considered, the pediatric cardiologist and cardiac surgeon will be able to explain the special features of your child’s condition and discuss the various treatment options.

We extend our appreciation to the providers of this state and the CAC for their efforts in developing and refining this remarkable cooperative quality improvement initiative. The New York State Department of Health (DOH) will continue to work in partnership with hospitals and physicians to ensure the continued high quality of pediatric congenital heart surgery available in NYS.
This booklet is intended for health care providers and families of children who have a congenital heart defect. It provides information on risk factors associated with pediatric congenital heart surgery and lists hospital specific mortality rates that have been risk-adjusted to account for differences in patient severity of illness. New York State has taken a leadership role in setting standards for cardiac services, monitoring outcomes, and sharing performance data with patients, hospitals, and physicians. Hospitals and doctors involved in the care of pediatric cardiac patients have worked in cooperation with the DOH and the CAC to compile accurate and meaningful data for use in enhancing quality of care. The data in this report are based on the New York State Pediatric Cardiac Surgery Reporting System. This system is used to gather information on each patient’s diagnoses, the actual procedures performed and other clinical factors that may impact outcomes. As part of the reporting system, hospitals have the ability to track their own data and compare their experience to statewide outcomes. We believe that this process has been instrumental in achieving the excellent outcomes that are experienced in centers across NYS.

**Congenital Heart Defects**

Most congenital heart problems can be successfully treated early in life and beyond. However, these defects remain a leading cause of death in infancy. Congenital heart defects may take many forms and represent a wide range of risk. Some simple defects, such as a small opening between heart chambers, may not negatively affect health and can be associated with a normal life span. However, other defects, such as an under-developed or absent heart chamber, blood vessel or valve may result in shock in the first hours or days of life unless rapid and effective action is taken. Findings of an unusual heart murmur, cyanosis (blueness), or fast breathing may indicate the need for consultation by a pediatric cardiologist (child heart specialist). In some cases, only a physical examination by a pediatric cardiologist is required. If a significant heart problem is suspected, an echocardiogram (ultrasound of the heart) is obtained. If further information is required, a heart catheterization may be performed in which a small catheter or tube is inserted into a blood vessel and threaded into heart chambers and large blood vessels to measure oxygen levels. A special dye may be injected through the catheter making it possible to take internal pictures of certain parts of the heart or major vessels. For some heart defects, special devices may be inserted into the heart through a catheter to open narrowed valves or vessels, or to close simple holes within the heart.

If a patient requires heart surgery to correct a defect, a decision regarding the timing and type of surgery is made jointly between the cardiovascular surgeon and the pediatric cardiologist. During and after surgery, the cardiovascular surgeon leads a team consisting of anesthesiologists, perfusionists, post-operative care specialists, nurses and other relevant care providers to coordinate the needs of the patient and family. Following discharge, the patient is followed jointly by the surgeon, pediatric cardiologist, and primary care provider. Some complex heart defects require a series of operations to allow for growth or to compensate for a significant malformation. Careful joint planning by the entire team of providers is needed for these patients.

Some simple heart defects can be considered “cured” by surgery but in most cases, although good health is restored, lifelong monitoring to prevent or treat later problems is either recommended or required. Because of the extreme variability of congenital heart defects, the timing and type of surgery can vary from patient to patient. The surgical plan may also vary from one surgical center to another when there is no clear advantage of a single approach. When experience has shown one surgical approach superior to another, it is adopted by all centers.

Some patients, particularly neonates with complex defects, who are at very high risk for surgery may be referred to a specific center where a special technique is performed more frequently or is not performed elsewhere. For this reason, it is not possible to determine the level of expertise of a program by looking at the simple mortality rate. It is necessary to compare one center’s experience with the results of others only after adjusting for differences like the nature of the defect, the surgical risk, patient demographics, diagnoses, comorbidities and health conditions.

When heart surgery is recommended for your child, it is important to speak with your pediatric cardiologist and cardiac surgeon. They will be able to explain the special features of your child’s defect and the
experience of a particular center in repairing the type of problem affecting your child and caring for similar patients. The more you understand about your child’s health, the better suited you will be to make critically important decisions about your child’s cardiovascular healthcare.

HEALTH DEPARTMENT PROGRAM

The New York State Department of Health has been studying the effects of patient and treatment characteristics on outcomes for patients undergoing heart surgery for many years. Detailed statistical analyses of the information received from hospitals have been conducted under the guidance of the CAC, a group of independent practicing cardiac surgeons, cardiologists, and other professionals in related fields.

The results have been used to create a cardiac profile system that assesses the performance of hospitals, taking into account the severity of individual patients’ pre-operative conditions. Coronary artery bypass surgery results have been assessed since 1989; percutaneous coronary intervention results were released in 1996 for the first time. The first Pediatric Congenital Cardiac Surgery Report, based on 1997-1999 data, was released in 2004. This report, based on 2014-2017 data, is the fifth report. This report differs slightly from the previous (2010-2013) report in that the methodology has been altered to best capture how all of the important factors related to in-hospital mortality interact with one another to contribute to the overall risk for pediatric patients undergoing cardiac surgery. This methodology is further described under “Assessing Patient Risk” and in Appendix 1.

Designed to improve health in pediatric patients with congenital heart disease, the analyses in this report are aimed at:

Understanding the health risks of patients that adversely affect how they will fare during and after pediatric congenital cardiac surgery;

Assessing and evaluating the results of the surgical treatments for congenital heart disease;

Enabling hospitals, surgeons, operating teams and pediatric cardiologists to improve cardiac care for pediatric patients; and

Providing information to help patients’ families make better decisions about the care of their children.

We encourage doctors to discuss the information in this report with their patients’ families and colleagues as they develop treatment plans. While these statistics are an important tool in making informed health care choices, individual treatment plans must be made by doctors and families together after careful consideration of all pertinent factors. It is important to recognize that many things can influence the outcome of congenital heart surgery. These include the patient’s health before the procedure, the skill of the operating team, and general aftercare. In addition, keep in mind that the information in this booklet does not include data after 2017. Important changes may have taken place in some hospitals since that time.

PATIENT POPULATION

Pediatric patients (age <18 years) undergoing congenital cardiac surgery in New York State hospitals who were discharged between January 1, 2014, and December 31, 2017, are included in these analyses. Observed, expected, and risk-adjusted mortality rates are reported for patients undergoing congenital cardiac surgery in each of the 10 New York State hospitals approved to perform cardiac surgery on pediatric patients between 2014 and 2017. Some patients were excluded from analysis for the following reasons: congenital heart patients with certain non-congenital conditions or with no surgery for a congenital condition; patients with no congenital condition; patients with a heart or lung transplant or tumor removal during the admission, and one patient whose reported congenital conditions could not be accurately placed in a risk group. Of the 5065 total records for the time period, 184 were excluded for one or more of the reasons listed above, resulting in 4881 records in analysis.
Risk-Adjustment for Assessing Provider Performance

Hospital performance is an important factor that directly relates to patient outcomes. Whether patients recover quickly, experience complications or die following a procedure is in part a result of the kind of medical care they receive. It is difficult, however, to compare outcomes among hospitals that treat different types of patients. Hospitals with sicker patients may have higher rates of complications and death than other hospitals in the State. The following describes how the DOH adjusts for patient risk in assessing outcomes of care in different hospitals.

Data Collection, Data Validation and Identifying In-Hospital Deaths

As part of the risk-adjustment process, hospitals in NYS where pediatric cardiac surgery is performed provide information to the DOH for each patient undergoing those procedures. Each hospital’s cardiac surgery department collects data concerning patients’ demographic and clinical characteristics including age, sex, pediatric congenital diagnosis and comorbidities. Approximately 25 of these characteristics (or risk factors) are collected for each patient. These data, along with information about the hospital, physician, procedure performed and the patient’s status at discharge, are entered into a computer and sent to the DOH for analysis. Data are verified through the review of unusual reporting frequencies and cross-matching of pediatric cardiac surgery data with other DOH datasets. These activities are extremely helpful in ensuring consistent interpretation of data elements across hospitals.

The analysis is based on deaths occurring during the same hospital stay in which the patient underwent pediatric congenital cardiac surgery. In this report, an in-hospital death is defined as a patient who died subsequent to cardiac surgery during the same acute care admission or was discharged to hospice.

Assessing Patient Risk

Each person who has a congenital heart defect has a unique history. A cardiac profile system has been developed to evaluate the risk of treatment for each individual patient based on his or her history, weighing the important health factors for that person based on the experiences of patients who have had similar health histories in recent years. All of the important risk factors for each patient are combined to create his or her risk profile.

The method used to assess risk in this report is essentially the same method used in the previous report. Just like in previous reports, certain patient characteristics were found to be important predictors of mortality. These include age at the time of surgery, whether the heart is univentricular or biventricular, the severity of the congenital diagnosis at admission (high, moderate, low) and birthweight for some age groups. A univentricular heart, or “single ventricle,” is a heart that has only one ventricle capable of sustaining a full cardiac output. These important determinants of mortality have been expressed as categories, and then combined with one another into variables that contain combinations of these categories so that patients with similar characteristics are organized into groups. Using the methods described in Appendix 2, 18 patient groups were created.

In addition to these patient groups, the presence of several other pre-existing conditions were also shown to predict mortality.

Appendix 1 presents the risk levels (low, moderate, and high) associated with the pediatric cardiac diagnoses in the registry. Appendix 2 presents prevalence and mortality rates for groups of patients according to age, number of ventricles, risk of diagnoses and birthweight (where applicable). Appendix 3 describes the statistical model used to develop the risk-adjusted mortality rates shown in Table 1, and Appendix 4 provides definitions for those data elements included in the statistical model.
Predicting Patient Mortality Rates for Hospitals

The statistical methods used to predict mortality on the basis of the significant risk factors and diagnoses are tested to determine whether they are sufficiently accurate in predicting mortality for patients who are extremely ill prior to admission as well as for patients who are relatively healthy. These tests have confirmed that the models are reasonably accurate in predicting how patients at all different risk levels will fare when undergoing pediatric congenital cardiac surgery.

The statistical model in Appendix 3 is used to predict the probability of each patient dying in the hospital in the same admission that the surgical procedure was performed. This probability is a function of the patient's age, birthweight, number of ventricles, comorbidities and the overall risk of the patient's diagnoses. For each hospital, these probabilities are averaged across all patients to obtain the predicted, or expected, mortality rate (EMR). The EMR is an estimate of what the hospital's mortality rate would have been if the hospital's performance was identical to the statewide performance. EMR is therefore an indicator of patient severity of illness. A hospital's EMR is then contrasted with its observed mortality rate (OMR), which is the number of pediatric congenital cardiac surgery patients who died in that hospital divided by the total number of pediatric congenital cardiac surgery patients in that hospital.

Computing the Risk-Adjusted Mortality Rate

The risk-adjusted mortality rate (RAMR) represents the best estimate, based on the associated statistical model, of what the hospital's mortality rate would have been if the hospital had a mix of patients identical to the statewide mix. Thus, the RAMR has, to the extent possible, ironed out differences among hospitals in patient severity of illness, since it arrives at a mortality rate for each hospital based on an identical group of patients.

To calculate the RAMR, the OMR is divided by the hospital's EMR. If the resulting ratio is larger than one, the hospital has a higher mortality rate than expected on the basis of the patient mix; if it is smaller than one, the hospital has a lower mortality rate than expected from its patient mix. The ratio is then multiplied by the overall statewide mortality rate (2.81 percent for 2014-2017) to obtain the hospital's risk-adjusted rate.

There is no Statewide EMR or RAMR, because the statewide data is not risk-adjusted. The Statewide OMR (number of total cases divided by number of total deaths) serves as the basis for comparison for each hospital's EMR and RAMR.

Interpreting the Risk-Adjusted Mortality Rate

If the RAMR is significantly lower than the statewide mortality rate, the hospital has a better performance than the state as a whole; if the RAMR is significantly higher than the statewide mortality rate, the hospital's performance is worse than the state as a whole. Significant differences, higher and lower, are identified in Table 1 with one or two asterisks, respectively.

The RAMR is used in this report as a measure of the quality of care provided by hospitals. There are reasons that a provider's risk-adjusted rate may not be indicative of its true quality. However, we have developed mechanisms for limiting the impact of these issues.

For example, extreme outcome rates may occur due to chance alone. This is particularly true for low-volume providers, for whom very high or very low rates are more likely to occur than for high-volume providers. Expected ranges or confidence intervals are included as part of the reported results in an attempt to prevent misinterpretation of differences caused by chance variation.

Differences in hospital coding of risk factors could be an additional reason that a hospital's risk-adjusted mortality rate may not be reflective of their quality of care. Some commentators have suggested that patient severity of illness may not be accurately estimated because some risk factors are not included in the data system, and this could lead to misleading risk-adjusted rates. However, we have attempted to minimize this possibility by having our risk factors reviewed and updated by experts in pediatric cardiac care.
How This Initiative Contributes to Quality Improvement

One goal of the DOH and the CAC is to improve the quality of care related to cardiac surgery in NYS. Providing the hospitals and cardiac surgeons in NYS with data about their own outcomes for these procedures allows them to examine the quality of the care they provide and to identify areas that need improvement.

The data collected and analyzed in this program are reviewed by the CAC. Committee members assist with interpretation and advise the DOH regarding hospitals and surgeons that may need special attention. Committee members have also conducted site visits to particular hospitals and have recommended that some hospitals obtain the expertise of outside consultants to design improvements for their programs.

The overall results of this program of ongoing review show that significant progress is being made. In response to the program’s results for surgery, facilities have refined patient criteria, evaluated patients more closely for pre-operative risks and directed them to the appropriate surgeon. More importantly, many hospitals have identified medical care process problems that have led to less than optimal outcomes, and have altered those processes to achieve improved results.
2014-2017 HOSPITAL OUTCOMES FOR PEDIATRIC CONGENITAL CARDIAC SURGERY

Table 1 presents the 2014-2017 Pediatric Cardiac Surgery results for the 10 hospitals performing congenital heart surgery in pediatric patients in NYS. The table contains, for each hospital, the number of discharges for pediatric congenital cardiac surgery in 2014-2017, the number of in-hospital deaths, the OMR, the EMR based on the statistical model presented in Appendix 3, the RAMR, and the 95% confidence interval for the RAMR.

As indicated in Table 1, the overall mortality for the 4881 pediatric congenital cardiac surgeries discharges was 2.81 percent. In the previous report, the mortality rate was 3.39 percent for patients discharged between January 1, 2010, and December 31, 2013.

In 2014-2017, hospital observed mortality for all pediatric congenital cardiac surgery patients ranged from 0.00 to 5.83 percent. The range in expected mortality, which measures patient severity of illness, was 0.33 to 4.05 percent.

The RAMRs, which are used to measure performance, ranged from 0.00 to 8.26 percent. One hospital (Montefiore Medical Center - Moses Division in the Bronx) had a RAMR that was significantly higher than the statewide rate. One hospital (NYU Hospitals Center) had a RAMR that was significantly lower than the statewide rate.

Definitions of key terms are as follows:

The observed mortality rate (OMR) is the observed number of deaths divided by the total number of pediatric patients who underwent congenital heart surgery.

The expected mortality rate (EMR) is the sum of the predicted probabilities of death for all patients divided by the total number of patients.

The risk-adjusted mortality rate (RAMR) is the best estimate, based on the statistical model, of what the provider’s mortality rate would have been if the provider had a mix of patients identical to the statewide mix. The RAMR is obtained by first dividing the OMR by the EMR, and then multiplying the quotient by the statewide mortality rate (2.81% for all pediatric congenital cardiac surgery patients in 2014-2017).

Confidence intervals are used to identify which hospitals had more or fewer deaths than expected given the risk factors of their patients. The confidence interval identifies the range in which the calculated RAMR may fall. Hospitals with significantly higher rates than expected after adjusting for risk are those where the confidence interval range falls entirely above the statewide mortality rate. Hospitals with significantly lower RAMRs than expected given the severity of illness of their patients before pediatric congenital cardiac surgery have a confidence interval range entirely below the statewide rate.
### Table 1

Hospital Observed, Expected, and Risk-Adjusted Mortality Rates for Pediatric Congenital Cardiac Surgery in New York State, 2014-2017 Discharges

(Listed Alphabetically by Hospital)

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Cases</th>
<th>Deaths</th>
<th>OMR</th>
<th>EMR</th>
<th>RAMR</th>
<th>95% CI for RAMR</th>
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<tbody>
<tr>
<td>Albany Medical Center</td>
<td>275</td>
<td>5</td>
<td>1.82</td>
<td>2.35</td>
<td>2.17</td>
<td>(0.70, 5.08)</td>
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<td>LIJ Medical Center</td>
<td>428</td>
<td>10</td>
<td>2.34</td>
<td>2.18</td>
<td>3.01</td>
<td>(1.44, 5.54)</td>
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<td>Montefiore - Moses</td>
<td>223</td>
<td>13</td>
<td>5.83</td>
<td>1.98</td>
<td>8.26</td>
<td>(4.39, 14.12)</td>
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<td>Mount Sinai</td>
<td>478</td>
<td>14</td>
<td>2.93</td>
<td>1.67</td>
<td>4.92</td>
<td>(2.69, 8.26)</td>
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<tr>
<td>NYP-Columbia Presbyterian</td>
<td>1611</td>
<td>43</td>
<td>2.67</td>
<td>3.27</td>
<td>2.29</td>
<td>(1.66, 3.08)</td>
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<td>NYP-Weill Cornell</td>
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<td>0.38</td>
<td>1.37</td>
<td>0.78</td>
<td>(0.01, 4.32)</td>
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<td>NYU Hospitals Center</td>
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<td>(0.65, 2.71)</td>
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<td>(2.47, 4.79)</td>
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<td>52</td>
<td>0</td>
<td>0.00</td>
<td>0.33</td>
<td>0.00</td>
<td>(0.00, 60.60)</td>
</tr>
<tr>
<td>Westchester Medical Center</td>
<td>179</td>
<td>4</td>
<td>2.23</td>
<td>2.26</td>
<td>2.77</td>
<td>(0.75, 7.10)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>4881</strong></td>
<td><strong>137</strong></td>
<td><strong>2.81</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Risk-adjusted mortality rate significantly higher than the statewide rate based on 95 percent confidence interval.
** Risk-adjusted mortality rate significantly lower than the statewide rate based on 95 percent confidence interval.
APPENDIX 1

Risk level assigned to Pediatric Congenital Diagnoses

In the analysis, a patient's diagnosis severity is represented by one of three categories: high-risk, moderate-risk, and low-risk. To obtain this severity rating, first a risk level was assigned for each possible diagnosis. The Congenital Cardiac Surgery Subcommittee of the CAC made a preliminary assignment based on their clinical expertise and the mortality rate for each diagnosis (when it was the patient's only diagnosis and when it was combined with other diagnoses).

Because patients frequently have more than one cardiac diagnosis, the opinions of the Subcommittee and statistical testing were used to compare ways of assigning risk levels when patients had more than one diagnosis. The final decision was to assign each patient an overall diagnosis risk level that was the highest risk level of any of the patient's individual diagnoses.

Classifying Diagnoses for Univentricular Patients

For univentricular patients there are only high and moderate risk diagnoses – no univentricular patients are considered low risk. The classification of some univentricular diagnoses varied based on the presence of either another diagnosis or a procedure. This additional information helped to appropriately reflect risk for these patients because in the clinical experience of the Subcommittee these diagnoses can represent a wide variation in complexity.

Single ventricle patients with Double Inlet Left Ventricle (DILV) or Double Inlet Right Ventricle (DIRV) without any higher risk diagnoses were classified as moderate risk. Patients with Hypoplastic Left Heart Syndrome (HLHS) or Single Ventricle associated with Mitral Atresia, Unbalanced AV Canal, Heterotaxia Syndrome, or “Other” (not elsewhere classified) single ventricle diagnosis were always classified as high risk. The list below shows the diagnoses where classification was dependent on additional factors.

Univentricular in the Presence of a Single Ventricle Procedure*

Univentricular High Risk

Atrioventricular Canal (AVC, aka Atrioventricular Septal Defect or AVSD), Partial (incomplete)
Ebstein's Anomaly
Double Outlet Right Ventricle (DORV) with AVSD / AVC
Pulmonary Atresia with Intact Ventricular Septum (PA, IVS) with Coronary Anomalies
Single Ventricle with Tricuspid Atresia (univentricular moderate risk without one of the procedures below)

Univentricular Moderate Risk

Pulmonary Atresia with Intact Ventricular Septum (PA, IVS) with no Coronary Anomalies

*Patients with one of the above diagnoses without a single ventricle procedure were classified as biventricular high-risk. For this purpose, single ventricle procedures include any of the following: Norwood procedure; Hybrid Stage 1; Pulmonary Artery reconstruction (plasty), Branch, Central; Modified Blalock-Taussig Shunt (MBTS), systemic to pulmonary shunt; Complete Unifocalization, Bilateral pulmonary unifocalization - all usable MAPCA[s] (Major Aortopulmonary Collateral Arteries) are incorporated; Tetrology of Fallot - Absent pulmonary valve repair.
Classifying Diagnoses for Biventricular Patients

The diagnoses for high-risk and low-risk biventricular groups are listed below. All other biventricular diagnoses were moderate-risk.

**High Risk Diagnoses for Biventricular Patients**

In addition to the 6 diagnoses listed above that are high-risk biventricular in the absence of a single ventricle procedure, the following diagnoses are comprise the High-Risk Biventricular group:

- Total Anomalous Pulmonary Venous Connection (TAPVC), Type 3 (Infracardiac)
- Pulmonary Venous Stenosis
- Tetralogy of Fallot (TOF), Absent Pulmonary Valve
- Pulmonary Atresia (PA):
  - Unspecified Type
  - With VSD (including TOF, PA)
  - VSD-MAPCA (Pseudotruncus)
- Cardiomyopathy:
  - Dilated, Restrictive, Hypertrophic
  - End-Stage Congenital Heart Disease
- Double Outlet Right Ventricle (DORV):
  - TGA Type
  - Remote VSD (Uncommitted VSD)
  - Intact Ventricular Septum (IVS)
- Left Ventricle Aneurysm
  - (Including Pseudoaneurysm)
- Hypoplastic Left Ventricle

**Low Risk Diagnoses for Biventricular Patients**

- Patent Foramen Ovale (PFO)
- Atrial Septal Defect (ASD):
  - Secundum
  - Sinus Venosus
  - Coronary Sinus
  - Common Atrium (Single Atrium)
- Ventricular Septal Defect (VSD):
  - Type 1 (Subarterial / Supracristal / Conal Septal Defect / Infundibular)
  - Type 2 (Perimembranous / Paramembranous / Conoventricular)
  - Type 3 (Inlet / AV Canal Type)
  - Type 4 (Muscular)
  - Gerbode type (LV-RA communication)
  - Multiple
- AVC (AVSD):
  - Complete (CAVSD)
  - Intermediate (Transitional)
  - Partial (Incomplete / PAVSD / ASD, Primum)
- Partial Anomalous Pulmonary Venous Connection (PAPVC) with or without Scimitar
- Systemic Venous Anomaly or Obstruction
- Pulmonary Stenosis, Valvar or Subvalvar
- Double Chamber Right Ventricle (DCRV)
- Aortic Insufficiency
- Coarctation of Aorta
- Vascular Ring
Appendix 2

Patient groups derived from analysis of pediatric congenital cardiac surgery cases in New York State, 2014-2017 discharges.

The following table lists the 18 patient groups derived from the analysis of 2014-2017 pediatric congenital cardiac surgery. The following information is included for each of the 18 groups: the number of cases; the prevalence, or percent of all cases accounted for by that group; the number of deaths within the group; and the observed mortality rate within the group.

The patient groups were created by combining various categories of age, birthweight (where applicable), number of ventricles and risk of diagnosis to classify patients in a meaningful way.

Age was separated into three categories (< 30 days, 1 - 12 months, and > 1 year). Anatomy was expressed as either univentricular or biventricular. A univentricular heart, or “single ventricle”, is a heart that has only one ventricle capable of sustaining a full cardiac output.

A patient’s diagnosis severity was represented by three categories: high-risk, moderate-risk, and low-risk as described in Appendix 1.

Birthweight was categorized as less than 2000 grams (just under four and a half pounds) and 2000 grams or higher. However, for many combinations of age, number of ventricles, and diagnosis risk level, there were too few low birthweight patients to include that variable, so birthweight was added to the patient groups only for biventricular patients between 30 days and one year old.
Risk Groups for Pediatric Cardiac Surgery Patients Based on Combinations of Number of Ventricles, Age, Risk Level of Pediatric Cardiac Diagnoses, and Birth Weight

<table>
<thead>
<tr>
<th>Patient Risk Subgroups</th>
<th>Cases</th>
<th>Prevalence (%)</th>
<th># of Deaths</th>
<th>Mortality rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Univentricle, age &lt; 30 days</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>201</td>
<td>4.12</td>
<td>42</td>
<td>20.90</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>65</td>
<td>1.33</td>
<td>4</td>
<td>6.15</td>
</tr>
<tr>
<td><strong>Univentricle, age 1 – 12 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>173</td>
<td>3.54</td>
<td>14</td>
<td>8.09</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>94</td>
<td>1.93</td>
<td>1</td>
<td>1.06</td>
</tr>
<tr>
<td><strong>Biventricle, age &lt; 30 days</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>139</td>
<td>2.85</td>
<td>11</td>
<td>7.91</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>556</td>
<td>11.39</td>
<td>22</td>
<td>3.96</td>
</tr>
<tr>
<td>Low Risk</td>
<td>81</td>
<td>1.66</td>
<td>2</td>
<td>2.47</td>
</tr>
<tr>
<td><strong>Biventricle, age 1-12 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>32</td>
<td>0.66</td>
<td>3</td>
<td>9.38</td>
</tr>
<tr>
<td>Low birthweight</td>
<td>296</td>
<td>6.06</td>
<td>10</td>
<td>3.38</td>
</tr>
<tr>
<td><strong>Moderate Risk</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low birthweight</td>
<td>154</td>
<td>3.16</td>
<td>8</td>
<td>5.19</td>
</tr>
<tr>
<td>Not low birthweight</td>
<td>652</td>
<td>13.36</td>
<td>7</td>
<td>1.07</td>
</tr>
<tr>
<td><strong>Low Risk</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low birthweight</td>
<td>45</td>
<td>0.92</td>
<td>1</td>
<td>2.22</td>
</tr>
<tr>
<td>Not low birthweight</td>
<td>385</td>
<td>7.89</td>
<td>3</td>
<td>0.78</td>
</tr>
<tr>
<td><strong>Univentricle, Age&gt;=1 year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>149</td>
<td>3.05</td>
<td>2</td>
<td>1.34</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>112</td>
<td>2.29</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Biventricle, Age&gt;=1 year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>227</td>
<td>4.65</td>
<td>4</td>
<td>1.76</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>793</td>
<td>16.25</td>
<td>3</td>
<td>0.38</td>
</tr>
<tr>
<td>Low Risk</td>
<td>727</td>
<td>14.89</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>All Patients</strong></td>
<td>4881</td>
<td>–</td>
<td>137</td>
<td>2.81</td>
</tr>
</tbody>
</table>
APPENDIX 3

2014-2017 Multivariable (Logistic Regression) Model for Pediatric Congenital Cardiac Surgery In-Hospital Mortality

The significant pre-procedural risk factors for in-hospital mortality following pediatric congenital cardiac surgery in 2014-2017 are presented in the table below.

As described in Appendix 1, there was a total of 18 groups in which patients were categorized. For the logistic regression model, some of these groups were combined based on similarities in patient characteristics and outcomes to create the best possible formula for predicting mortality. Specifically, groups for univentricular and biventricular patients ages 1 year and up were combined. Patients who were older than one year who were classified as moderate- or low-risk patients were used as a reference for all other patient characteristic groups. For example, a moderate-risk biventricular patient who is less than 30 days old has odds of dying in the hospital that are 13.13 times as high as patients older than 1 year old who are either moderate- or low-risk, if all of their other significant risk factors are the same.

Additional variables in the statistical model include all pre-existing conditions that proved to be significant when in competition with the patient groups just described. These conditions included arterial pH < 7.25 immediately before the surgery, major extracardiac anomalies, near systemic pulmonary vascular resistance, pre-operative ventricular assist device dependence, and any ventilator dependence during the same admission or within 14 days prior to surgery. Roughly speaking, the odds ratio for each of the pre-existing conditions in the statistical model (the last five variables) represents the number of times more likely to die in the hospital during or after cardiac surgery a patient with the risk factor is than a patient without the risk factor, all other risk factors being the same. For example, a patient with ventilator dependence prior to surgery has an odds of dying in the hospital that is 1.778 times the odds for a patient who does not have ventilator dependence prior to surgery, assuming the patients look identical with regard to all other significant risk factors.
Multivariable risk factor equation for pediatric congenital cardiac surgery in-hospital mortality in New York State, 2014-2017

<table>
<thead>
<tr>
<th>Patient Risk Factor</th>
<th>Prevalence (%)</th>
<th>Logistic Regression</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Coefficient</td>
</tr>
<tr>
<td>Patient Risk Groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Univentricle, age &lt; 30 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>4.12</td>
<td>4.5946</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>1.33</td>
<td>3.3194</td>
</tr>
<tr>
<td>Univentricle, age 1 – 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>3.54</td>
<td>3.6078</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>1.93</td>
<td>1.7504</td>
</tr>
<tr>
<td>Biventricle, age &lt; 30 days</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>2.85</td>
<td>3.3568</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td>11.39</td>
<td>2.5749</td>
</tr>
<tr>
<td>Low Risk</td>
<td>1.66</td>
<td>2.3014</td>
</tr>
<tr>
<td>Biventricle, age 1-12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High-risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low birthweight</td>
<td>0.66</td>
<td>3.5363</td>
</tr>
<tr>
<td>Not low birthweight</td>
<td>6.06</td>
<td>2.7253</td>
</tr>
<tr>
<td>Moderate Risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low birthweight</td>
<td>3.16</td>
<td>2.9764</td>
</tr>
<tr>
<td>Not low birthweight</td>
<td>13.36</td>
<td>1.5413</td>
</tr>
<tr>
<td>Low-risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low birthweight</td>
<td>0.92</td>
<td>2.1463</td>
</tr>
<tr>
<td>Not low birthweight</td>
<td>7.89</td>
<td>1.3848</td>
</tr>
<tr>
<td>Age&gt;=1 year (Univentricle or Biventricle)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Risk</td>
<td>7.70</td>
<td>1.9111</td>
</tr>
<tr>
<td>Low or Moderate Risk</td>
<td>33.43</td>
<td>– Reference –</td>
</tr>
<tr>
<td>Pre-Existing Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arterial pH &lt; 7.25</td>
<td>0.64</td>
<td>1.5426</td>
</tr>
<tr>
<td>Major Extracardiac Anomalies</td>
<td>13.03</td>
<td>0.7364</td>
</tr>
<tr>
<td>Near System Pulmonary Vascular Resistance</td>
<td>3.16</td>
<td>0.8257</td>
</tr>
<tr>
<td>Pre-operative Ventricular Assist Device</td>
<td>0.53</td>
<td>1.7137</td>
</tr>
<tr>
<td>Ventilator Dependence</td>
<td>17.72</td>
<td>0.5755</td>
</tr>
</tbody>
</table>

Intercept = -6.4580
C Statistic = 0.861
Criteria Used in Reporting Significant Risk Factors (2014-2017) Based on Documentation in the Medical Record

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major Extra-cardiac Anomalies</td>
<td>Examples include but are not limited to: Non-Down’s Syndrome chromosomal abnormalities, DiGeorge’s Syndrome, Cystic Fibrosis, Marfan’s Syndrome, Sickle Cell Anemia, Blood Dyscrasia, Omphalocele, Hypoplastic lung, Tracheo-esophageal (TE) fistula, Diaphragmatic hernia</td>
</tr>
<tr>
<td>Arterial pH &lt; 7.25</td>
<td>Arterial pH is &lt; 7.25 within 12 hours prior to surgery but before the first blood gas taken in the operating room</td>
</tr>
<tr>
<td>Ventilator Dependence, same admission or within 14 days</td>
<td>Reported if the patient was ventilator dependent during the same admission or within 14 days prior to surgery.</td>
</tr>
<tr>
<td>Pre-operative Ventricular Assist</td>
<td>One of the following was used prior to the procedure to maintain vital signs: Extracorporeal Membrane Oxygenation (ECMO) Intra-Aortic Balloon Pump (IABP) Left Ventricular Assist Device (LVAD) Right Ventricular Assist Device (RVAD) Bi-Ventricular Assist Device (BIVAD)</td>
</tr>
<tr>
<td>Near Systemic Pulmonary Vascular Resistance (PVR)</td>
<td>In the case of an unrestrictive ventricular or great vessel communication (e.g. ductus or AP window), any of the following would constitute evidence of increased PVR: [ \cdot ] bidirectional shunting (meaning at least some R to L shunting) across the defect [ \cdot ] absence of CHF symptoms in patients at least 2 months of age [ \cdot ] evidence of systemic or suprasystemic RV pressure by tricuspid regurgitant jet velocity in the absence of a moderate or large left to right shunt</td>
</tr>
</tbody>
</table>
NYS PEDIATRIC CARDIAC SURGERY CENTERS

Albany Medical Center Hospital
47 New Scotland Avenue
Albany, New York 12208

Long Island Jewish Medical Center
270-05 76th Avenue
New Hyde Park, New York 11040

Montefiore Medical Center – Henry & Lucy Moses Division
111 East 210th Street
Bronx, New York 10467

Mount Sinai Hospital
One Gustave L. Levy Place
New York, New York 10029

NY Presbyterian Hospital @ Columbia Presbyterian Center
630 West 168th Street
New York, New York 10032

NY Presbyterian Hospital @ Weill Cornell College
525 East 68th Street
New York, New York 10021

NYU Hospitals Center
550 First Avenue
New York, New York 10016

Strong Memorial Hospital
601 Elmwood Avenue
Rochester, New York 14642

Upstate University Hospital – State University of New York
750 East Adams Street
Syracuse, New York 13210

Westchester Medical Center
100 Woods Road
Valhalla, New York 10595

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New York State Department of Health
Albany, New York 12220