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9-714-507
REV: MARCH 6, 2018

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Texas Children's Hospital: Congenital Heart Disease Care

In 2014, Dr. Charles D. Fraser Jr., Surgeon-in-Chief of Texas Children's Hospital in Houston, was contemplating the future direction of the congenital heart disease program. The nation's largest pediatric hospital, Texas Children's was ranked by U.S. News & World Report as #4 in the nation in 2014-2015.[1] It was ranked #2 in pediatric heart care and heart surgery, behind Boston Children's and ahead of Children's Hospital of Philadelphia (CHOP).[2] Texas Children's had the third highest pediatric cardiac admissions in the nation, seeing more than 25,000 congenital heart disease patients and performing over 800 cardiac surgeries annually.

Fraser had led the reorganization of Texas Children's care for congenital heart disease conditions beginning in 1995. The challenge in 2014 was to continue to improve care in a complicated patient population, and take outcome measurement to the next level. Also, Texas Children's had recently formed partnerships with pediatric hospitals in Lubbock, San Antonio and Mexico City, and how to best structure these partnerships was under active discussion.

Texas Children's Hospital

Texas Children's was founded in 1954 with 106 beds to serve the large pediatric population in Houston, Texas. Boston Children's Hospital and Children's Hospital of Philadelphia were far older, dating back to the 1850s and 1860s. A non-profit, Texas Children's had a teaching affiliation with the Baylor College of Medicine from its inception, and was located in the Texas Medical Center complex including 21 separate hospitals.

Over the years, Texas Children's had expanded its services and capacity, funded by numerous philanthropic gifts from the Houston community. By 2013, Texas Children's had 639 beds with more than 1,500 board-certified physicians, surgeons and dentists (see **Exhibit 1**) and $1.4 billion in total revenue (see **Exhibit 2**, Selected Financial and Operational Information for Texas Children's Hospital, 2010-2013). The CEO was Mark Wallace, appointed in 1989.

The majority of physicians at Texas Children's had academic appointments and were employed by Baylor College of Medicine. For example, Dr. Mark Kline, the Physician-in-Chief, was also the Chairman of the Department of Pediatrics at Baylor. Physicians were also members of the Texas Children's Hospital Physician Services Organization that paid their salaries, which were set based on

HBS Professor Michael E. Porter, independent researcher Justin M. Bachmann, and Senior Researcher Zachary C. Landman prepared this case. It was reviewed and approved before publication by a company designate. Funding for the development of this case was provided by Harvard Business School and not by the company. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

comparable market compensation by specialty, seniority, and clinical volume. Department heads had annual performance appraisals with compensation incentives tied to performance. As part of these appraisals, each department chose quality metrics that affected individual provider compensation. In Pediatric Cardiac Surgery, for example, the metric was the proportion of patients who needed to return to the operating room to address defects that were not corrected in the initial operation.

The clinical leadership team, which reported to the CEO, consisted of Dr. Mark Kline, Dr. Michael Belfort, Obstetrician/Gynecologist-in-Chief, and Dr. Charles Fraser, Surgeon-in-Chief. Each clinical department had a chief that reported to one of these three leaders. For example, gynecologic oncology and maternal fetal medicine reported to the Obstetrician/Gynecologist-in-Chief, neurosurgery and orthopedic surgery reported to the Surgeon-in-Chief, and pediatric endocrinology and cardiology reported to the Physician-in-Chief.

While physicians reported up through a traditional departmental structure, there were several major care centers that co-located subspecialists to provide multidisciplinary care to patients. These included the Cancer Center, the Fetal Center, and the Heart Center. Of these, The Heart Center involved the most extensive co-location of physicians and support staff. As of June 2014, cleft lip and palate and spine care were also moving to a more integrated structure, and Texas Children's was expanding the number of conditions with formal outcome measurement. In all of the centers, however physician compensation continued to flow through the department structure.

Major regional competitors to Texas Children's were Children's Medical Center at Dallas, a 414-bed facility with three pediatric cardiac surgeons performing approximately 350 cardiac surgeries annually,[3] and Children's Memorial Hermann Hospital in Houston, a 110-bed pediatric hospital with two pediatric cardiac surgeons and four pediatric cardiologists **(**the number of cardiac surgeries was not disclosed). A wide variety of other hospitals performed pediatric cardiac surgery in Texas, as shown in **Exhibit 3**. Texas Children's also competed for complex patients with Boston Children's and CHOP on a national basis.

Like many other academic medical centers, including CHOP and Children's Medical Center of Dallas, Texas Children's utilized Epic Systems (Epic) as its comprehensive electronic health record system. Epic covered all inpatient and outpatient services, with clinical decision support available for some conditions in the form of order sets. Physicians could access the Epic system remotely through a web portal. Epic MyChart served as a personal health record for patients, allowing parents to access their children's clinical documentation and laboratory data.

Congenital Heart Disease Care

Congenital heart defects were the most common type of birth defect in the United States, with an incidence of 1 percent of births or 40,000 cases per year.[4] Congenital heart disease included a heterogeneous set of hundreds of different specific conditions, ranging from relatively simple ventricular septal defects to syndromes involving multiple defects such as hypoplastic left heart syndrome. Congenital defects tended to occur in various combinations, and thus overall treatment could be highly individualized (see **Exhibit 4**, Incidence of Congenital Heart Disease per Million Live Births). Of all babies born with congenital heart defects, about one third required early surgical or other intervention to prevent death in the first year of life.

Congenital heart disease had traditionally been diagnosed by pediatricians, who detected cardiac murmurs with a stethoscope during routine clinic visits or at the time of birth. An echocardiogram, or ultrasound of the heart, was performed to further define the problem. Increasingly, congenital heart

defects were detected prior to birth through the use of fetal ultrasound. In 2014 approximately 50% of congenital heart disease was diagnosed prenatally.[5]

If a congenital heart defect was identified prenatally, the mother would be referred to a Maternal-Fetal Medicine specialist, a subspecialty of obstetrics that treated women with high-risk pregnancies. These physicians frequently collaborated with pediatric cardiologists. Women with fetuses who were known to have significant congenital heart defects would generally give birth at a tertiary or quaternary care center where the baby could quickly be transported to an intensive care unit if necessary. Often a pediatric cardiologist would be at the bedside during delivery.

Congenital heart defects identified after birth resulted in referral to a pediatric cardiologist, who might perform further diagnostic testing such as a cardiac catheterization. The simplest congenital heart defects, such as small atrial septal defects, could be managed conservatively and monitored with echocardiograms to ensure they were not having deleterious effects on the child's body. If surgery was necessary, the child would be referred to a pediatric cardiac surgeon. Until the decision to have surgery was made, patients were managed medically by their pediatric cardiologist.

Pediatric heart surgery was technically demanding due to the tiny size and delicate tissue of infant hearts, making it one of the most highly specialized of all surgical subspecialties. In 2013, there were approximately 200 active pediatric cardiac surgeons in the United States, and few centers had the volume necessary to train new surgeons.[6] The repair of congenital heart defects accounted for over 90% of pediatric cardiac surgery, with heart transplants comprising the remainder of cases. Heart transplants were undertaken for children that had congenital heart defects that were not amenable to surgical repair, who had failed surgeries, or for children who developed life-threatening heart failure due to a viral infection (viral cardiomyopathy).

Pediatric cardiac surgery, like adult cardiac surgery, usually required the use of cardiopulmonary bypass (CPB), in which deoxygenated blood was diverted from the heart, passed through an oxygenator, and returned to circulation. After CPB was initiated, the heart was infused with a cold electrolyte solution that stopped the heartbeat and allowed surgeons to operate in a bloodless, motionless field. Cardiac perfusionists, specialized technicians who operated CPB machines, worked closely with cardiac surgeons in the operating room along with anesthesiologists. Anesthesiology in open heart surgery was complex because of the need to work in tandem with surgeons and perfusionists to monitor vital signs, tissue perfusion, and neurologic function.

Awareness of the relationship between surgery and neurodevelopmental outcomes was growing. In 2002, pediatric cardiac surgeons at Boston Children's Hospital had demonstrated a possible inverse association between intensive care unit length of stay and cardiopulmonary bypass time with IQ scores later in life.[7] Postoperative magnetic resonance imaging (MRI) studies were routinely performed in the field starting in the mid-2000s to monitor for postoperative brain injury, though imaging findings did not correlate exactly with functional outcomes such as cognition and motor skills. The International Cardiac Collaborative on Neurodevelopment (ICCON) had recently pooled testing data from Texas Children's and 24 other Centers in 7 countries to assess neurodevelopmental outcomes for 2,450 survivors of infant surgery for congenital heart disease between 1989-2009, and found that 1,770 children had neurodevelopmental outcomes below population norms.

After one or more surgeries, patients with congenital heart disease generally required long-term follow-up. Surgery could not always entirely correct structural abnormalities of the heart, and children with congenital heart disease had higher rates of heart failure later in life than the general population. Additionally, scar tissue from surgery could disrupt the development of the heart's electrical conduction system, predisposing patients to abnormal heart rhythms such as atrial fibrillation and

atrial flutter. Children with congenital heart disease often needed chronic disease management, ongoing cardiac catheterizations to evaluate heart function, and reoperations to replace outgrown implants. Patients with congenital heart defects also experienced other problems such as brain injury which impacted speech, cognitive, and motor ability as well as behavior, both independent of or related to the heart defects themselves**.** Children with congenital heart disease could also have chromosomal anomalies such as Marfan's or Turner's syndromes that affected long term outcomes, and non-cardiac defects like tracheoesophageal fistula that affected swallowing or hydronephrosis that affected kidney function. Such children required frequent care from other specialists including gastroenterologists, endocrinologists, pulmonologists, speech and swallow therapists, developmental pediatricians, and orthopedists.

Children with simpler defects like ventricular septal defects, and who were otherwise healthy, were followed-up on an annual basis by a pediatric cardiologist. Children with more complex heart defects, like hypoplastic left heart syndrome, required more frequent surveillance by cardiac, neurologic, and developmental specialists. Organization of ongoing care varied widely among providers. Some patients returned to management by their primary care physician, whereas others were followed by providers where the surgery occurred. There were no well-defined national standards for frequency or type of continuing care. In 2012, the American Heart Association released a statement recommending regular developmental follow-up to optimize outcomes in patients with congenital heart disease.

Once patients became adults, the care process varied even more widely. Some patients were followed by adult congenital heart disease specialists, who were adult cardiologists with subspecialty training in congenital heart disease, while others were managed by adult cardiologists or primary care physicians with no formal training in the management of congenital heart disease. By 2013 some academic medical centers, such as Boston Children's Hospital, had established adult congenital heart disease programs. This specialty was growing as more children with congenital heart disease survived to adulthood.

Types of Congenital Heart Defects

There were hundreds of variations of congenital heart disease, which could be loosely organized into a number of categories: defects associated with increased blood flow to the lungs (patent ductus arteriosus, atrial septal defects, ventricular septal defects, atrioventricular canal defects, etc.); defects associated with decreased blood flow to the lungs (tetralogy of Fallot, pulmonary stenosis, etc.); defects associated with the great vessels (transposition of the great arteries, etc.); defects obstructing blood flow to the body (aortic valve stenosis, subaortic valve stenosis, etc.); defects associated with the arch **o**f the aorta (coarctation of the aorta, interrupted aortic arch, etc.); defects leading to only one functioning ventricle (tricuspid atresia, hypoplastic left heart syndrome, etc.); coronary artery anomalies (anomalous left coronary artery to the pulmonary artery, anomalous aortic origin of the coronary artery, etc.); valve anomalies and miscellaneous other problems, (vascular rings, pulmonary slings, etc.). Each of these congenital heart defects could occur individually or in association with each other.

About 85 to 90 percent of CHD had no known cause, while 10 percent were due to genetic or environmental factors. Of this 10 percent, five percent were related to major chromosomal anomalies such as Down or Turner Syndromes. These typically resulted in defects involving multiple systems including physical features, speech, swallowing, and neurodevelopment. Three to 5 percent were the result of a single gene defect. DiGeorge syndrome, now called 22q11.2 deletion syndrome, for example, led to congenital heart defects, defects in the palate, learning disabilities, differences in facial features, and increased susceptibility to infections. Other genetic mutations, such as MYH7 (hypertrophic

cardiomyopathy), exclusively involved the heart. Finally, the remaining 2 percent of defects were due to environmental factors such as maternal illnesses, medications affecting the fetus, or substances taken during pregnancy.

Three of the most common defects and described below, Ventricular Septal Defects, Transposition of the Great Arteries, and Hypoplastic Left Heart Syndrome, which were representative of the spectrum of cardiac defects:

Ventricular Septal Defects The most common congenital heart defect was a ventricular septal defect (VSD), a hole in the wall that divided the left and right ventricles. VSDs accounted for approximately 50% of all congenital heart defects, or 35.7 per 10,000 births. VSDs allowed blood from the left ventricle to leak into the right ventricle, and if untreated caused the right ventricle to fail due to progressive volume overload or damage to the lungs. Some small VSDs closed spontaneously, and others occasionally could be treated in the cardiac catheterization laboratory. However, medium-sized to large VSDs required surgery to patch the hole (see **Appendix**, Ventricular Septal Defect Repair).

Transposition of the Great Arteries Transposition of the Great Arteries (TGA) was a more complex congenital heart defect in which the right ventricle, which normally pumped blood through the lungs, was connected to the aorta (which normally pumped blood through the rest of the body). The left ventricle, normally connected to the aorta, instead pumped blood through the lungs. The right ventricle was not capable of sustaining the high pressures necessary to pump blood through the rest of the body, leading to progressive right ventricular failure. Ninety percent of untreated patients died within the first year of life. TGA had an incidence of 4.7 per 10,000 births in the United States.[4] Surgery for TGA involved disconnecting the pulmonary artery and aorta and then reattaching them properly (see **Appendix**, Arterial Switch Operation). The average survival rate for the Arterial Switch Operation was 96% across all cases.

Hypoplastic Left Heart Syndrome One of the most complex congenital heart defects was hypoplastic left heart syndrome (HLHS), accounting for 2-3% of all congenital heart disease or 2.2 of 10,000 live births annually in the United States.[4] The left side of the heart, including the left ventricle, left atrium, and associated valves, did not fully develop. Without treatment, death invariably occurred within the first weeks of life.

In 1981, Dr. William Norwood developed the Norwood procedure, in which the main pulmonary artery was attached to the aorta and the innominate artery was connected to the right pulmonary artery, effectively allowing the right ventricle to pump blood to the entire body (see **Appendix**, Norwood Operation). The Norwood procedure was palliative, since the right ventricle progressively deteriorated within 3-4 months, so two additional surgeries were necessary. The Glenn shunt, a connection between the pulmonary artery and the superior vena cava, was typically performed at 4-6 months of age. The Fontan procedure, during which the pulmonary artery was connected with the inferior vena cava, was performed from 18 months to four years of age. This allowed the child to develop into an adult, though such children still needed long term follow up and sometimes a heart transplant.

With the advent of the Norwood procedure, the survival rate for HLHS had increased from 0% in the 1970s to three to five-year survival rates of 80% in 2013,[8] although survival rates varied widely between hospitals. The Norwood procedure was one of the most technically demanding operations in pediatric cardiac surgery. Surgeons were unable to use bypass, and deep hypothermic circulatory arrest (DHCA) was employed to cool the infant to 17-22 degrees Centigrade to minimize cerebral metabolism. The procedure required precision and speed as well as diligent post-surgical intensive care.[9]

HLHS patients, both before and after undergoing a Norwood procedure, were notorious for their propensity to become critically ill. Small fluctuations in oxygen saturations and blood pressure would often lead to cardiogenic shock and death. A crying spell, generally innocuous for normal infants, could lead to a rise in pulmonary artery pressure and cardiac arrest. This meant that HLHS patients required close monitoring by experienced nursing staff.

Outcomes

Prior to the 1990s there had been no national system of outcomes measurement for congenital heart disease. A few institutions had tracked mortality rates for various surgeries internally, while others had formed consortiums that shared data. Among the early leaders were Boston Children's Hospital, Children's Hospital of Philadelphia, University of Michigan, Great Ormand Street Hospital in the United Kingdom, and the Royal Children's Hospital of Melbourne Australia.

In 2002, the Society for Thoracic Surgeons (STS) formed the Congenital Heart Surgery Database, which collected pediatric cardiac surgery 1 year inpatient mortality data. This effort was an extension of the STS Adult Cardiac Surgery Database that was formed in 1989 as one of the first large scale efforts in the U.S. to collect outcomes data, on adult cardiac surgery. The Congenital Heart Surgery Database began with 16 participating centers, including Texas Children's. By 2013, 108 of the 125 hospitals that performed congenital heart surgery in the United States reported in the Congenital Heart Surgery Database.[6]

In 2002, 82 pediatric cardiac surgical procedures were grouped into six different risk categories based on the work of a panel of pediatric cardiologists and pediatric cardiac surgeons. These groupings and expected mortality rates were validated and published in 2002 as the Risk Adjustment for Congenital Heart Surgery 1 (RACHS-1) classification (see **Exhibit 5**).[10] The STS Congenital Heart Surgery Database stratified mortality data by these categories, allowing the first national benchmarks. In 2012, VSD repair was RACHS-1 category two with a 1.1% mortality benchmark, TGA was in RACHS-1 category four with a 6.7% benchmark, and the Norwood procedure was RACHS-1 category six with a 15.8% benchmark (see **Exhibit 6**). More recently, an empirically-derived risk-adjustment methodology developed by the Society of Thoracic Surgeons (STS) and the European Association of Cardiothoracic Surgery (EACTS), termed STAT Mortality Categories, would be utilized in future reporting.

History of the Heart Center at Texas Children's

In 1962, Texas Children's had collaborated with Dr. Denton Cooley to form the Texas Heart Institute at St. Luke's Episcopal Hospital, located nearby in the Texas Medical Center. Dr. Cooley, a Professor of Surgery at Baylor College of Medicine, was a pioneer in cardiac surgery in the United States along with Dr. Michael DeBakey. As Surgeon-in-Chief of the Texas Heart Institute, Cooley performed one of the first human heart transplants in the United States in 1968. Cooley was also cardiovascular consultant to Texas Children's.

Texas Children's began seeing increasing numbers of children with congenital heart defects in the 1980s. Until 1994, pediatric cardiac surgery patients were operated on at the Texas Heart Institute (THI), which was connected by a passageway to Texas Children's. Pediatric patients underwent surgery in the same operating rooms that served adults, and a section of the adult intensive care unit at St. Luke's was reserved for pediatric patients. Three cardiac surgeons from THI performed some pediatric cardiac surgery, representing about 10% of their cases. Anesthesiologists also split their cases between adult and pediatric, as did operating room personnel, perfusionists, and intensive care nurses.

Although individual surgeons at Texas Children's Hospital had intermittently tracked mortality starting in the 1950s when VSD repairs were first attempted, there had been no systematic measurement and reporting of pediatric cardiac surgery mortality across institutions nationwide.

In 1991, Texas Children's first began developing its own pediatric cardiac surgery facilities. THI surgeons retained privileges at Texas Children's and began operating there. Initially, pediatric cardiac surgery was performed using the same operating rooms and personnel used for other pediatric surgical specialties, such as general surgery and neurosurgery.

In 1995, Dr. Charles D. Fraser, Jr. was recruited from the Cleveland Clinic. He had trained at Johns Hopkins in general surgery, cardiothoracic surgery, and thoracic transplant surgery and completed a fellowship in pediatric cardiac surgery at the Royal Children's Hospital in Melbourne, Australia. At the Cleveland Clinic, he was mentored by Dr. Roger Mee, a world-renowned pediatric cardiac surgeon who was an early proponent of the importance of postoperative care. Mee had said in 1991:

> *Outcomes in congenital heart surgery are optimized by surrounding the patient with the greatest expertise possible during all times of the surgical and postoperative period.*

When Fraser arrived, the only way to compare mortality rates at Texas Children's with those of other hospitals was through the research literature. He described the situation:

> *As a young surgeon, you question whether or not you are qualified to take care of someone's child. In 1995, however, it was hard to know. If you did ten arterial switches, how many patients should die? And how did you compare with other institutions? There was no clinical database. So we looked at the best available literature and tried to figure out who was doing the best with each defect.*

From 1989-1993, a consortium of 40 academic medical centers which did not include Texas Children's had measured and reported an average in-hospital Norwood mortality rate of 43%, with centers having dedicated congenital programs somewhat lower. Norwood mortality at Texas Children's in the early 1990's was 100%.[11] A Boston Children's study reported a 5 year arterial switch mortality of 9% from 1983-1992 versus 14% at Texas Children's.[12] A study from the National Yang-Ming Medical College in Taiwan demonstrated 3% mortality in infants undergoing VSD repair, versus 6% at Texas Children's Hospital.[13]

Dr. Fraser concluded that patient outcomes at Texas Children's lagged behind national leaders. Upon joining, his team began recording mortality, as well as intraoperative process measures such as cardiopulmonary bypass times, estimated blood loss and hemodynamic data.

Fraser set out to create a dedicated organization to treat congenital heart conditions, including not only the surgery but pre- and postoperative care. Traditionally, congenital heart surgery was requested by a Texas Children's pediatric cardiologist, who would often specify the type of procedure to be performed. Cardiac surgeons performed the procedures, splitting their time between children and adults.

In the new approach, the surgeons and pediatric cardiologists would consult prior to scheduling a patient for surgery. Weekly conferences were established in which pediatric cardiologists presented cases they felt required surgery for discussion of the risks and benefits. Fraser, initially Texas Childrens' only pediatric cardiac surgeon, was an active participant at these conferences.

Between 1995 and 2000, operating room space and personnel specifically designated for pediatric cardiac surgery was put in place. Dedicated staff included scrub technicians, who prepared tools and other equipment for the surgeon's use, circulators who were registered nurses that prepared the

operating room for surgery and monitored the procedure intraoperatively, and dedicated perfusionists. The Heart Center was formalized in 2001 when the physical space was completed to co-locate the team.

The emerging team worked to revise protocols around best practices elsewhere. Efforts were also undertaken to improve postoperative care. Mary Claire McGarry, who was one of the first cardiac perfusionists to join, recalled:

> *For the first year, Dr. Fraser would fax our pump records to perfusionists at the Royal Children's Hospital in Melbourne, who would critique them and then send them back. We would meet in his office and learn how we could do better.*

Typically cardiac perfusionists were not able to observe the surgical field while operating the large cardiopulmonary bypass pump. Closed-circuit cameras were installed in the operating room so that perfusionists and other personnel could see the surgical field at all times (see **Exhibit 7**, Pediatric Cardiac Surgery Operating Room).

Prior to 1996, surgery patients were assigned to a specific section of the pediatric intensive care unit but cared for by nurses who cared for all medical and surgical conditions. In 1996, cardiac surgery patients were cared for in a designated part of the ICU (Pod 3) that had largely dedicated nurses. In 2001 with the addition of new space, a Cardiovascular Intensive Care Unit (CVICU) designated for the postoperative care of congenital heart disease patients was established with a dedicated nursing staff. Located on the same floor as the operating rooms, this facilitated a smooth transition to the CVICU and expeditious transfer back to the operating room if necessary.

Formal protocols for post-operative care drawn from Royal Children's Hospital in Melbourne were instituted. The number of doctors caring for postoperative patients was reduced to fewer full time staff who attended daily rounds together.

Traditionally, the intensive care unit had specified visiting hours for parents. This was changed to 24 hours a day, except during rounds and emergencies. Reclining chairs were made available for parents so they could stay with their children overnight if they wished.

Nurse liaisons were named that would function as the "eyes and ears" of surgeons while they were in the operating room, helping surgeons to monitor patients on the inpatient wards. Nurse liaisons would also provide hourly updates to families while their children were in surgery. Carmen Watrin, a pediatric cardiac intensive care unit nurse who had been at Texas Children's since 1989, was one of the first nurse liaisons. She recalled:

> *Dr. Fraser would call you into the operating room during a case and ask about the pressures, saturations, and labs of patients whom he had operated on earlier in the week. We had to know our patients well.*

Pediatric cardiac anesthesiologists were also recruited. Dr. Dean Andropolous joined the Heart Center as the Director of Pediatric Cardiac Anesthesiology in 2002, devoting his time solely to pediatric cardiac surgery cases.

In 2005, the congenital heart surgery program established an outcomes center, joining the STS Congenital Heart Surgery Database in 2007. In 2011, a broader Surgical Outcomes Center (which was later renamed the Outcomes & Impact Service) was formed in order to expand and refine outcomes measurement programs across the institution. Led by Kathleen Carberry, RN, MPH, an experienced

CVICU nurse, the Center initially focused on pediatric cardiac surgery but began to track outcomes in other fields such as pediatric general surgery and pediatric plastic surgery.

The volume of congenital heart patients seen by the Heart Center steadily increased. By 2010, the wait time to see a pediatric cardiologist was 2-3 weeks due to the heavy volume of patients. Some community pediatricians were beginning to send patients to other institutions with shorter wait times (such as Children's Memorial Hermann Hospital). The Heart Center responded by recruiting additional pediatric cardiology faculty, reducing the average wait time to 1-2 days.

The Texas Children's Heart Center in 2014

In 2014 the Texas Children's Heart Center occupied the 15th, 17th, 18th, 19th and 20th floors of the main hospital building. It co-located the Division of Pediatric Cardiology, the Division of Pediatric Cardiac Surgery, and the Division of Pediatric Cardiac Anesthesiology, and hospital staff including the perfusion team, dedicated nursing, nurse practitioners, physician assistants, social workers, nutritionists, translators, childlife specialists, care managers, and the research and outcomes team. All echocardiograms and cardiac catheterizations were performed in The Heart Center while CTs and MRIs were shared across the hospital and were performed in the Pavilion for Women and the first floor of the West Tower, depending on the type and urgency of the study. Other non-cardiac physician specialists such as gastroenterologists, pulmonologists, hematologists, infectious disease specialists, developmental pediatricians, child psychologists and radiologists also provided care to patients, but saw patients primarily in their own clinics or during hospital rounds.

There were five pediatric cardiac surgeons, including Fraser, and 54 pediatric cardiologists, chaired by Daniel Penny. The pediatric cardiology faculty included subspecialists in interventional cardiology, cardiac electrophysiology, cardiac imaging and heart failure. The Division of Pediatric Cardiac Anesthesiology consisted of ten anesthesiologists, led by Dr. Emad Mossad. The pediatric cardiac intensivists were led by Dr. Lara Shekerdemian, chief of critical care medicine. In 2012, the Heart Center performed 742 cardiac surgeries, 14 pediatric heart transplants, and 948 cardiac catheterizations and was the highest volume center in Texas.[14]

The Heart Center employed thirteen cardiovascular operating room nurses and seventy-three CVICU nurses who typically spent at least six-months in an orientation period during which they were paired with more experienced staff. CVICU nurses would be initially be assigned to patients with relatively simple defects such as VSDs, and advance to more complex syndromes over time. Dr. Paul Checchia, pediatric cardiac intensivist, and Medical Director of the CVICU, explained:

> *Inexperienced staff cannot take care of these patients. The circulation in these patients is tenuous, and they have zero reserve. You get away with nothing on a Norwood. It exposes an institution's deficiencies. Everything a unit learns from taking care of a Norwood patient is directly applicable to other forms of congenital heart disease. If you do Norwoods well, your other outcomes are probably good.*

Patients arrived at the Heart Center via three major methods: Referral from community pediatricians, self-referral, or referral from the Texas Children's Fetal Center. Community pediatricians or parents of patients contacted the Heart Center through a centralized scheduling line that was designated specifically for congenital heart disease patients. Referrals from the Fetal Center took place internally through the TCH scheduling system. However, there were also exceptions to how patients accessed the Center; some parents from other states or countries called the Division of Congenital Heart Surgery directly when their child was diagnosed with a congenital heart defect that might require

surgery. Surgeons at other institutions also contacted Fraser or his colleagues directly to discuss referrals or transfers as well.

Most patients and their families visiting the Heart Center first saw a pediatric cardiologist and underwent preliminary diagnostic testing. The initial evaluation included a physical examination, pulse oximetry (a device that measures blood oxygenation levels), a chest x-ray, an electrocardiogram, and an echocardiogram. Some patients underwent more advanced testing such as cardiac MRI or invasive studies such as cardiac catheterization. Patients referred from outside would often need to have some tests repeated to produce the images needed by surgeons. Complex patients would often require consultation with other specialties. For example, children with genetic disorders saw cardiac geneticists, while those with arrhythmias would see pediatric cardiologists with subspecialty training in electrophysiology.

If surgery was recommended, the patient's pediatric cardiologist presented the case at the weekly Congenital Heart Disease Case Management Conference, held every Monday morning at 7:30 am. The conference included cardiologists, surgeons, anesthesiologists, nurses, perfusionists, social workers and care managers. Cardiologists would present their patients' clinical histories and associated data. The group discussed whether the patient was appropriate for surgery and, if so, the expected procedure and postoperative course. A decision regarding surgery was occasionally deferred until additional information was obtained such as a cardiac catheterization. In some cases, however, cardiologists proceeded with catheterization procedures for simpler defects without conference evaluation for surgery. Such cases sometimes failed to adequately address the defect and required follow-up surgery in a separate admission.

If surgery was recommended, the pediatric cardiologist who initially presented the patient, as well as a pediatric cardiac surgeon would serve as co-team captains for the remainder of the care process, although this was not always the case. The surgeon was selected according to the patient's particular condition, the family's preference, and the surgeon's area of interest. For example, Dr. Fraser was highly experienced with Norwood procedures and the treatment of HLHS.

The surgery scheduling coordinator reserved time on the schedule and ensured that all preoperative testing, including an appointment with the pediatric cardiac anesthesiologist, was arranged. The Heart Center had a dedicated Child Life specialist who provided age and developmentally appropriate emotional support to children undergoing medical treatment.

A financial counselor conducted financial prescreening and clearance with out-of-network insurance. As a non-profit institution, however, Texas Children's Hospital tried not to turn any children away and provided millions of dollars in free care every year.

Social workers within the Heart Center assisted parents in obtaining local support and lodging for the duration of the patient's stay. Care managers, who were generally nurses or social workers, were assigned to each patient upon admission to the hospital and would follow the patient throughout their hospitalization. They also coordinated services associated with discharge and post-discharge follow-up.

On the day of surgery parents waited in the Ronald McDonald Family Waiting Room, which provided food and entertainment options for patients' siblings such as books and video games. There were individual conference rooms attached to the lounge where surgeons could meet privately with parents. Families were updated on the progress of the surgery by the nursing staff several times throughout the operation.

At the conclusion of surgery, the OR team including the surgeon transported the patient to an intensive care bed. A handoff was conducted between the anesthesiologist, the CVICU attending physician and the patient's CVICU nurse. The CVICU had 21 beds dedicated to the care of congenital heart disease patients. Patients were rounded on daily by a multidisciplinary team including the surgeon, the CVICU intensivists (a cardiologist or critical care trained physician), and nurses. The daily census of the CVICU was regularly at 100% capacity.

The length of time in intensive care varied with the severity of the defect and the complexity of the surgery. Less complex patients, such as those undergoing a VSD repair, stayed one to three days and then moved to an acute care floor with a 1:5 nurse to patient ratio. Norwood patients stayed in the CVICU at least one week and then moved to a monitored unit with a 1:2 nurse to patient ratio.

Upon discharge, patients were followed carefully by a care manager within the Heart Center, who checked in once per week during the first month after discharge. Beyond that, patients with simpler procedures such as VSD repairs were seen on a yearly basis while complex patients, such as those with HLHS, had monthly follow-up visits with comprehensive exams for at least the first year. Care pathways detailing the frequency and type of follow-up from birth through full recovery were in the process of being established, but had not yet been formalized or adopted across the institution. However, all patients underwent follow up echocardiograms and electrocardiograms on at least a yearly basis, to monitor for structural changes in the heart and the heart function as well as to check for abnormal heart rhythms which were frequently seen in congenital heart patients later in life.

For patients with severe multi-system issues or who needed frequent care from numerous specialties, Texas Children's had established a Special Needs Service in November 2007. Sometimes, patients' medical needs would change over time from primarily cardiac initially to later non-cardiac issues, such as speech, swallowing, development, or function. For these patients, the Heart Center would serve as the primary team initially, and shift to a supporting role as the patient's Heart Center needs changed, often over decades.

Until the mid-2000s, patients who turned eighteen were transitioned to adult physicians for further care. In 2004, the Heart Center established an adult congenital heart program which grew by 2014 to four physicians who had training and expertise in both adult and pediatric heart disease.

Every Thursday morning, a pediatric cardiac surgery teaching conference, called the "Fraser rounds," was held during which Dr. Fraser used recent cases to teach pediatric cardiac surgery fellows. Pediatric cardiologists and other members of the clinical team were often in attendance at these meetings and provided further context to the case discussions.

Outcomes Measurement

The Heart Center reported risk adjusted inpatient mortality for all congenital heart disease surgery patients to the STS database (see **Exhibit 8**). Outcomes for patients who did not undergo surgery or cardiac catheterization were not yet systemically measured. Intraoperative process measures such as cardiopulmonary bypass times, estimated blood loss and hemodynamic data were also tracked in order to create a foundation for a robust outcomes improvement program.

Surgeons had initially completed a comprehensive questionnaire after each case recording multiple data points, which required a significant time in order to obtain all the necessary data. The data had to be inputed into a database by the Outcomes Center staff.

In 2008 the Outcomes Center engaged Perficient, an IT consulting firm, to develop a web-based application that would minimize surgeon time for data entry. A data mart solution was completed in 2008 called Operative Data Web Application (ODWA), which included web-browser based data collection tools. ODWA was integrated with the hospital-wide Epic system, which prepopulated data into ODWA when the surgeon completed the operative note. On average, surgeons required eight minutes to fill out ODWA's prepopulated online questionnaire as opposed to twenty minutes to fill out the questionnaire manually.

In the late 2000s, the Heart Center began measuring the long-term quality of life and neurodevelopmental status of children after congenital heart surgery. A Neurodevelopmental Clinic was formed in the Heart Center in 2013, where patients with congenital heart disease and other disease conditions could be followed and their neurodevelopmental outcomes measured using functional tests on a longitudinal basis.

The Neurodevelopmental Clinic used the Bayley Scales of Infant Development-II (BSID-II), a functional test designed to measure the neurodevelopmental status of infants and toddlers 0-3 years of age.[15] Originally developed by the psychologist Nancy Bayley in the 1960s, the BSID-II took approximately one hour to administer. A Psychomotor Development Index (PDI) measured fine and gross motor skills by evaluating rolling, crawling, grasp and use of utensils, and a Mental Development Index (MDI) assessed receptive and expressive language and cognitive development by evaluating speech and comprehension of various pictures and objects. Raw scores on each scale were converted to composite scores which allowed comparison with age norms.

The CardioAccess International Clinical Outcomes Database was implemented in 2009, which was an industry standard database interfacing with the various clinical registries including the Congenital Cardiovascular and the STS Thoracic Surgical Database, the Congenital Anesthesia Database, the American College of Cardiology's IMPACT Registry (for patients undergoing diagnostic catheterization and catheter-based interventions), and the Cardiac Intensive Care Pediatric Cardiac Critical Care Consortium (PC4) Registry.[16] These registries provided benchmarking data.

Beginning in 2009, the Heart Center publicly reported outcomes for individual procedures on its website and in a yearly booklet.[14] The booklet included surgical volumes for specific congenital heart defects, cardiac catheterizations and heart transplants. Surgical mortality rates for individual congenital heart defects were reported, as were complication rates from anesthesia as well as neurodevelopmental outcomes. Parents were increasingly obtaining outcomes data from the website, comparing them to other hospitals, and bringing the booklet to clinic visits for discussions with their providers.

In 2010, the Heart Center CVICU had joined the Virtual Pediatric Intensive Care Unit System (VPS), a national pediatric critical care data registry. Formed in 2003, the VPS reported a predicted one year mortality score called PIM2 (Pediatric Index of Mortality Version 2) that had been developed and validated in twelve pediatric intensive care units in Australia, New Zealand and the United Kingdom.[17] A PIM2 score was calculated for every critical care admission based on the diagnosis and comorbidities, allowing intensive care units to compare predicted and actual mortality.

By 2014, inpatient mortality, readmission rates, surgical complication rates, and a comprehensive suite of intraoperative process measures were compiled for each patient by the Outcomes and Impact Service and reported to the STS National Congenital Heart Surgery database. Pilot projects were underway to better measure other outcomes such as quality of life and emotional wellbeing.

As of 2014, the Heart Center had an inpatient mortality rate of less than 1% for 609 risk-adjusted pediatric cardiac surgeries, compared to an STS national benchmark of 3.2%. Mortality rates were well below STS national benchmarks in RACHS-1 risk categories 1 through 4. The mortality rate for RACHS-1 categories 5 and 6 was 18.2% versus a STS national benchmark of 15.0%. This higher mortality was attributed to the highly complex cases seen by the Heart Center, and the fact that some surgeries were revisions of failed operations from other institutions. The CVICU had an actual inpatient motality mortality rate of 1.83% in 2013, versus the 3.51% predicted score derived from the Virtual Pediatric Intensive Care Unit registry.[14]

Neurodevelopmental outcomes were tracked using a separate system for patients being seen in the Neurodevelopmental Clinic, though not all Heart Center patients were tracked. Based on one and three-year follow-up neurodevelopmental data, children who underwent cardiac surgery at Texas Children's had cognitive and motor function skills as measured by the BSID-II comparable to children who had not undergone surgery.[14] Neurodevelopmental outcome measurement was being extended to five years.

A Heart Center Quality Conference was held every Wednesday morning with the focus rotating among the different Heart Center specialties. On the fourth Wednesday morning of every month, a multidisciplinary Morbidity and Mortality conference was held in which the entire Heart Center team discussed surgical complications such as bleeding and infection, and refined their procedures accordingly. During the conference the Heart Center's outcomes would be compared to other institutions and discussed.

Next Steps

The outcome measurement efforts initially developed at the Heart Center were being expanded to other specialties, including pediatric general surgery, pediatric urology, pediatric orthopedic surgery, pediatric plastic surgery, pediatric transplant surgery, and pediatric endocrinology.

At the Heart Center, outcome measurement for medically managed conditions was being developed. For instance, patients with an anomalous coronary artery were being followed longitudinally with validated measurement tools such as the PedsQL, a measure covering physical, emotional, social, and school wellbeing. As of 2014, outcome measurement for other conditions such as arrhythmias was being considered.

The Operative Data Web Application had worked well and was beginning to attract attention from surgery programs elsewhere. Texas Children's had begun to work on how to utilize its Epic electronic health record system to collect outcomes during the care delivery process itself.

Led by Carberry, the Outcomes & Impact Service was working to incorporate outcome measurement into the Epic workflow and customize it to the preferences of each department. In orthopedics, an Epic "document flow sheet" was created to help track outcomes for pediatric supracondylar fractures. In urology, check-box based "smart forms" were implemented which automatically populated notes with validated measurement surveys. In plastic surgery, structured templates were created which required providers to record specific, structured data before the system allowed the note to be signed and finalized.

Texas Children's was also exploring relationships in other regions of Texas and elsewhere. In 2012, after a national provider announced a plan to build a new children's hospital in San Antonio, Texas Children's established an administrative and management relationship with the Children's Hospital of San Antonio (CHofSA) to help further develop its subspecialty services, including care for congenital

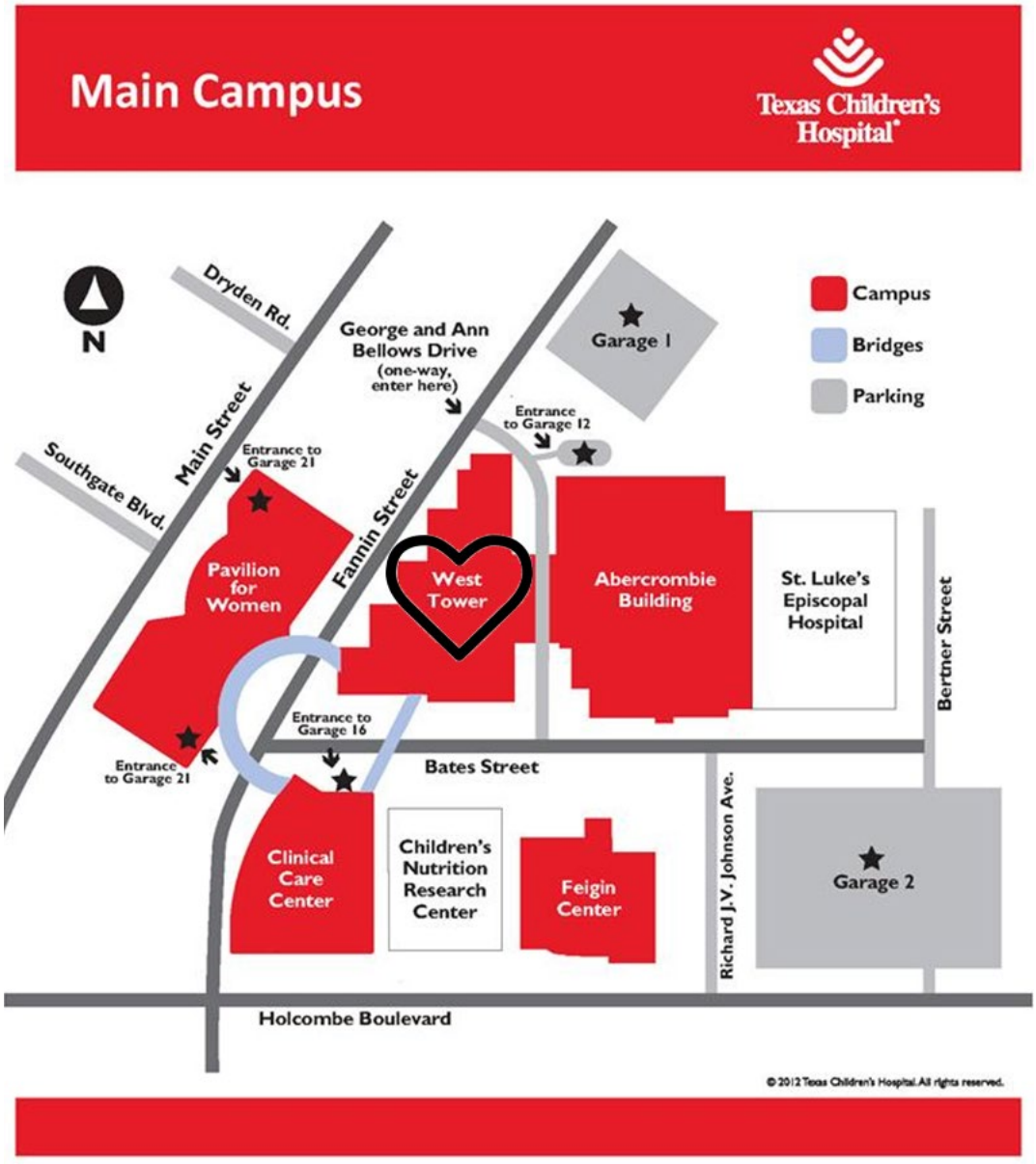
heart disease. San Antonio was the seventh most populous city in the United States with a very high birth rate,[18] While CHofSA hoped to grow into a quaternary pediatric hospital serving the San Antonio region, it had recently lost all three of its pediatric cardiac surgeons to other institutions in the area. As part of the partnership between CHofSA and Texas Children's, the Heart Center helped CHofSA construct a new cardiovascular intensive care unit, recruit new surgeons, and establish a formal outcome measurement program, which initially consisted of reporting mortality data to the STS Congenital Heart Surgery Database. Several Texas Children's pediatric subspecialists, including cardiologists, were temporarily providing coverage in San Antonio to enhance CHofSA's clinical services and to help transfer the Heart Center mentality and culture to CHofSA. As of 2014, however, cultural differences remained a challenge to the adoption of the Heart Center care model. In 2014, Texas Children's helped recruit two congenital heart surgeons to CHofSA who had academic teaching appointments at Baylor Medical School.

Fraser's first congenital heart surgery fellow at Texas Children's, Dr. Alexis Palacios-Macedo had returned to practice in Mexico City in 1998. Dr. Fraser had been providing advice to Dr. Palacios, who wanted to build a high quality practice rooted in outcome measurement. Though he was Director of Surgical Services at The Instituto Nacional de Pediatria (INP), one of the country's 12 specialty public hospitals, it was challenging to drive quality improvement efforts. Texas Children's began exploring ways it could formally interact with Dr. Palacios and his team.

In March 2012, a multidisciplinary team of surgeons, cardiologists, cardiac intensivists, nurses, operating room staff, and perfusionists from Texas Children's went to Mexico City to evaluate the hospitals and assist in improving perioperative care. The following year, Texas Children's established a relationship with Centro Médico Centro ABC, a large non-profit hospital that provided care to privately insured patients. The extensive backlog of patients needing congenital heart surgery, prompted the federal government to pay for care to be done at private hospitals, such as Centro Medico, where Dr. Palacio also had surgical privileges. Texas Children's established a 3-year formal consulting partnership with Centro Médico to assist in education (i.e. weekly telemedicine rounds to review surgical cases, observerships at Texas Children's for surgeons and other providers on the care team), management infrastructure, and outcome measurement. Dr. Palacios had worked to develop an outcome measurement program that had yielded positive results. The spring 2015 site visit confirmed inpatient mortality to be under 2%, a number similar to that of Texas Children's in 2012.

In 2013, Covenant Children's Hospital (CCH), located in the West Texas city of Lubbock, had a single pediatric cardiac surgeon performing congenital heart procedures. For certain procedures, inpatient mortality was four to five times higher than procedures reported by Texas Children's. Epidemiologic data suggested that there were an estimated 200 live births with congenital heart disease per year in the region, and that the number was growing. When the surgeon left the practice in September 2013, the community sought a high quality health care provider to address this problem and turned to Texas Children's. The Heart Center began transporting an entire team, including surgeons, anesthesiologists, perfusionists, OR nurses, intensivists, nurse practitioners, CVICU nurses, and the outcome measurement team, to Lubbock to work side by side with local staff. With an initial focus on RACHS level 1 and 2 cases, Heart Center staff were paired 1:1 with Lubbock staff and remained through patient discharge to help streamline communication, workflow, supplies, and equipment. Texas Children's and CCH also built relationships with pediatric cardiologists in West Texas (including Amarillo and Midland) to better integrate care (see **Exhibit 9**, Texas Children's Pediatric Cardiac Surgery Network). The Heart Center began offering annual educational seminars to primary care physicians on congenital heart disease topics and developed a relationship with the local patient support group. A 2-year contract to provide surgical services in Lubbock commenced in 2014.

Exhibit 1 Texas Children's Hospital



Texas Children's Hospital
Main Campus in the Texas Medical Center

The Heart Center

20th Floor – Clinic, Echocardiography Lab, Clinical Research Core

19th Floor – Administrative Offices

18th Floor – Cardiovascular Intensive Care Unit (21-bed), Cardiovascular Operating Rooms (3), Cardiac Catheterization Laboratories (3), Holding Area, Post-Anesthesia Recovery Unit, Heart Center Pharmacy

17th Floor – Ronald McDonald Family Waiting Room, CV anesthesiology offices, Social Work, Child Life

15th Floor – Inpatient Acute Care Unit (35-bed), Cardiovascular Intensive Care Unit Step-Down Unit

Source: Casewriter, based on company documents.

Exhibit 2 Selected Financial and Operational Information for Texas Children's Hospital, Fiscal Year 2010-2013

Dollars in thousands

Revenue	FY 2013	FY 2012	FY 2011	FY 2010	FY 2009
Net patient revenue	1,229,687	1,057,319	925,995	829,658	812,224
DSH and other government revenue*	76,296	64,622	31,441	42,604	57,724
Charitable Contributions	31,903	25,491	20,204	21,568	33,219
Grants	12,739	10,473	10,488	9,809	8,630
Other operating revenue	63,142	43,364	47,202	51,897	48,456
Total	**1,413,767**	**1,201,269**	**1,035,328**	**955,536**	**960,253**
Expenses					
Salaries and Benefits	628,879	592,500	505,406	469,975	458,940
Professional Fees-Baylor College of Medicine	166,017	151,354	122,401	127,075	120,045
Supplies	141,343	131,808	116,747	107,672	101,956
Enhanced Mission Support**	41,952	21,993	-	-	-
Other non-personnel expense	225,580	192,904	165,796	147,725	154,413
Depreciation and interest	139,826	120,481	92,892	78,213	76,003
Total	**1,343,597**	**1,211,041**	**1,003,242**	**930,661**	**911,356**
Operating Margin	**70,169**	**(9,772)**	**32,086**	**24,875**	**48,896**
Percent Operating Margin	5.0%	(0.8%)	3.1%	2.6%	5.1%

*DSH: Disproportionate Share Revenue provided by the state to account for high burden of low income and uninsured patients

**Enhanced Mission Support refers to funds used for uncompensated care.

Source: Casewriter, based on company documents.

Exhibit 3 Geographic Distribution of Pediatric Cardiac Surgery in Texas, 2012

Hospital	Cases	Number of Deaths	Risk-Adjusted Inpatient Mortality
Texas Children's Hospital	449	7	2.2% *
Children's Medical Center-Dallas	328	7	2.5% *
Cook Children's Medical Center	252	13	7.2%
Medical City Dallas Hospital	211	9	4.6%
Memorial Hermann Hospital	178	12	5.5%
Methodist Hospital San Antonio	172	7	4.2%
Driscoll Children's Hospital	154	12	10.7% **
Children's Hospital of San Antonio	139	7	6.9%
Dell Children's Medical Center	101	0	0.0%
Covenant Children's Hospital	39	5	17.1% **
Rio Grande Regional Hospital	15	Not Reported	
Baylor University Medical Center	10	Not Reported	
Women's Hospital-Texas	10	Not Reported	
CHRISTUS Spohn Hospital Corpus	6	Not Reported	
St. Joseph Medical Center	6	Not Reported	
Providence Medical Center	5	Not Reported	
El Paso Children's Hospital	Less than 5	Not Reported	
McLane Children's Hospital	Less than 5	Not Reported	
Baptist St. Anthony's Hospital	Less than 5	Not Reported	
North Austin Medical Center	Less than 5	Not Reported	
Seton Medical Center	Less than 5	Not Reported	
St. David's Hospital	Less than 5	Not Reported	
University Medical	Less than 5	Not Reported	
Medical Center-Plano	Less than 5	Not Reported	
Texas Health Harris Methodist	Less than 5	Not Reported	
Texas Health Presbyterian Hospital	Less than 5	Not Reported	
UT-Southwestern University	Less than 5	Not Reported	
Les Palmas Medical Center	Less than 5	Not Reported	
University Medical Center of El Paso	Less than 5	Not Reported	
Lyndon B Johnson General Hospital	Less than 5	Not Reported	
UT Medical Branch Hospital	Less than 5	Not Reported	
Scott & White Memorial Hospital	Less than 5	Not Reported	
Doctors Hospital-Renaissance	Less than 5	Not Reported	
McAllen Medical Center	Less than 5	Not Reported	
Odessa Regional Medical Center	Less than 5	Not Reported	
North Central Baptist Hospital	Less than 5	Not Reported	
St. Luke's Baptist Hospital	Less than 5	Not Reported	
University Hospital	Less than 5	Not Reported	

* Risk-adjusted hospital mortality rate is significantly lower than state average
** Risk-adjusted hospital mortality rate is significantly higher than state average

Source: Texas Department of State Health Services, 2012.

Exhibit 4 Incidence of Types of Congenital Heart Disease per Million Live Births

Type of Defect	Incidence per Million Live Births	Percent of all CHD
Ventricular Septal Defect	**3,570**	**10-15%**
Atrial Septal Defect	941	5-10%
Patent Ductus Arteriosus	799	5-10%
Pulmonary Stenosis	729	5-10%
Tetralogy of Fallot	421	9-14%
Coarctation of the Aorta	409	6-8%
Aortic Stenosis	401	4-5%
Atrioventricular Septal Defect	348	4-5%
Transposition of the Great Arteries	**315**	**5-7%**
Hypoplastic Left Heart Syndrome	**266**	**2-3%**
Hypoplastic Right Heart Syndrome	222	1-2%
Pulmonary Atresia	132	3-6%
Ebstein's Anomaly	114	<1%
Truncus Arteriosus	107	<1%
Tricuspid Atresia	79	<1%

Source: Hoffman et al., 2002. "The Incidence of Congenital Heart Disease," Journal of the American College of Cardiology; 39(12):1890-900.

Note: Bolded conditions discussed in the text.

Exhibit 5 Classification of Risk Adjustment for Congenital Heart Surgery Procedures (RACHS-1)

Risk category 1

Atrial septal defect surgery (including atrial septal defect secundum,sinus venosus atrial septal defect, patent foramen ovale closure)

Aortopexy

Patent ductus arteriosus surgery at age >30 days

Coarctation repair at age >30 d

Partially anomalous pulmonary venous connection surgery

Risk category 2

Aortic valvotomy or valvuloplasty at age >30 days

Subaortic stenosis resection

Pulmonary valvotomy or valvuloplasty

Pulmonary valve replacement

Right ventricular infundibulectomy

Pulmonary outflow tract augmentation

Repair of coronary artery fistula

Atrial septal defect and ventricular septal defect repair

Atrial septal defect primum repair

Ventricular septal defect repair

Ventricular septal defect closure and pulmonary valvotomy or infundibular resection

Ventricular septal defect closure and pulmonary artery band removal

Repair of unspecified septal defect

Total repair of tetralogy of Fallot

Repair of total anomalous pulmonary veins at age >30 days

Glenn shunt

Vascular ring surgery

Repair of aorta-pulmonary window

Coarctation repair at age <30 days

Repair of pulmonary artery stenosis

Transection of pulmonary artery

Common atrium closure

Left ventricular to right atrial shunt repair

Risk category 3

Aortic valve replacement

Ross procedure

Left ventricular outflow tract patch

Ventriculomyotomy

Aortoplasty

Mitral valvotomy or valvuloplasty

Mitral valve replacement

Valvectomy of tricuspid valve

Tricuspid valvotomy or valvuloplasty

Tricuspid valve replacement

Tricuspid valve repositioning for Ebstein anomaly at age >30 days

Repair of anomalous coronary artery without intrapulmonary tunnel

Repair of anomalous coronary artery with intrapulmonary tunnel (Takeuchi)

Closure of semilunar valve, aortic or pulmonary

Right ventricular to pulmonary artery conduit

Left ventricular to pulmonary artery conduit

Repair of double-outlet right ventricle with or without repair of right ventricular obstruction

Fontan procedure

Repair of transitional or complete atrioventricular canal with or without valve replacement

Pulmonary artery banding

Repair of tetralogy of Fallot with pulmonary atresia

Repair of cor triatriatum

Systemic to pulmonary artery shunt

Arterial switch operation with ventricular septal defect

Risk category 3 (continued)

Atrial switch operation

Arterial switch operation

Reimplantation of anomalous pulmonary artery

Annuloplasty

Repair of coarctation and ventricular septal defect closure

Excision of intracardiac tumor

Risk category 4

Aortic valvotomy or valvuloplasty at age <30 days

Konno procedure

Repair of complex anomaly (single ventricle) by ventricular septal defect enlargement

Repair of total anomalous pulmonary veins at age <30 days

Atrial septectomy

Repair of transposition, ventricular septal defect, and subpulmonary stenosis (Rastelli)

Atrial switch operation with ventricular septal defect closure

Atrial switch operation with repair of subpulmonary stenosis

Arterial switch operation with pulmonary artery band removal closure

Arterial switch operation with repair of subpulmonary stenosis

Repair of truncus arteriosus

Repair of hypoplastic or interrupted arch without ventricular septal defect closure

Repair of hypoplastic or interrupted aortic arch with ventricular septal defect closure

Transverse arch graft

Unifocalization for tetralogy of Fallot and pulmonary atresia

Double switch

Risk category 5

Tricuspid valve repositioning for neonatal Ebstein anomaly at age <30 days

Repair of truncus arteriosus and interrupted arch

Risk category 6

Stage 1 **repair of hypoplastic left heart syndrome** (Norwood operation)

Stage 1 repair of nonhypoplastic left heart syndrome conditions

Damus-Kaye-Stansel procedure

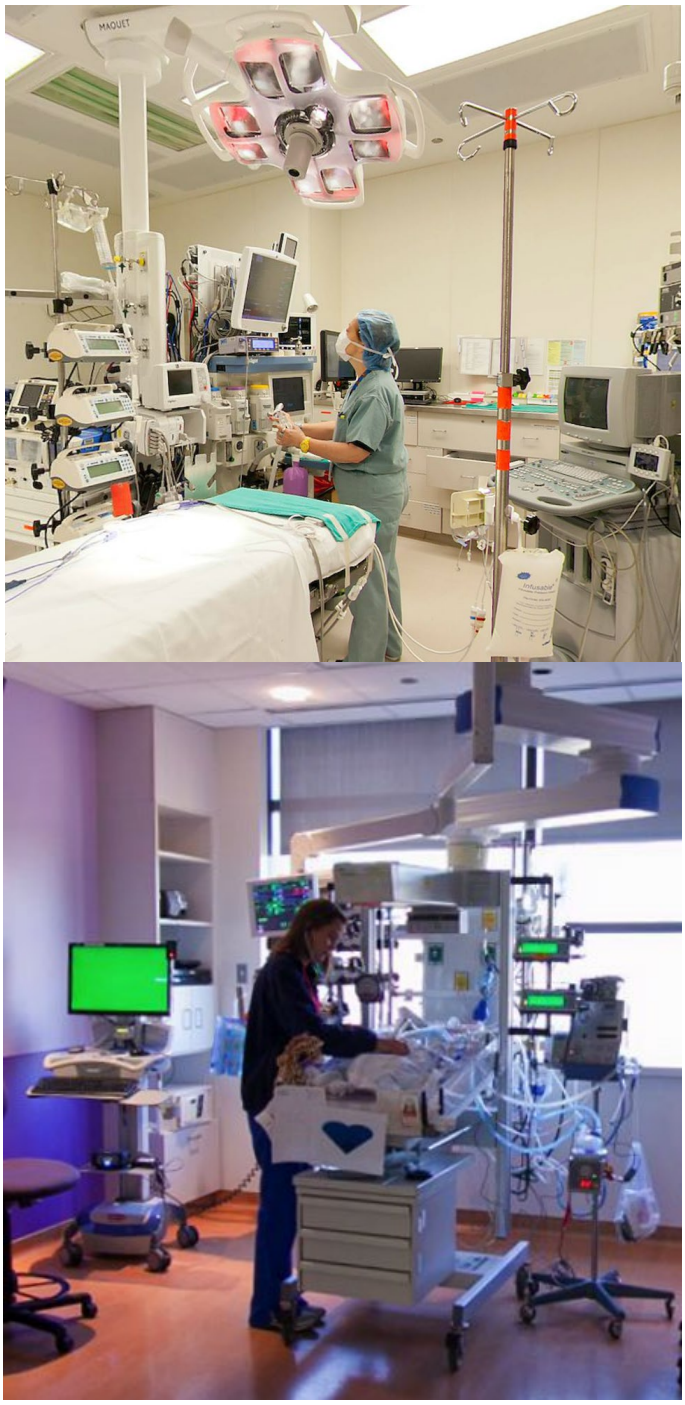
Source: Jenkins et al., 2012. "Consensus-based method for risk adjustment for surgery for congenital heart disease," *The Journal of Thoracic and Cardiovascular Surgery*.

Exhibit 6 Inpatient Mortality by RACHS-1 Classification, Texas Children's Hospital, 2014

Primary Procedure	Number of Procedures	TCH Inpatient Mortality	STS National Benchmark
Total for Risk Category 1	99	0.0 %	0.3 %
Total for Risk Category 2	223	0.0 %	0.9 %
Total for Risk Category 3	206	0.0 %	3.6 %
Total for Risk Category 4	59	3.4 %	6.3 %
Total for Risk Category 5 & 6	22	18.2 %	15.0 %
Grand Total	**609**	**<1.0 %**	**3.2 %**

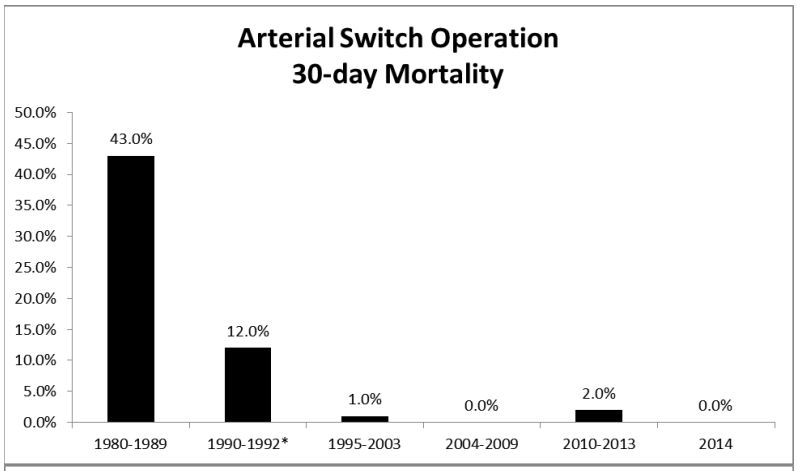
Source: Casewriter, based on 2014 "Texas Children's Hospital – Heart Center Outcomes" report.

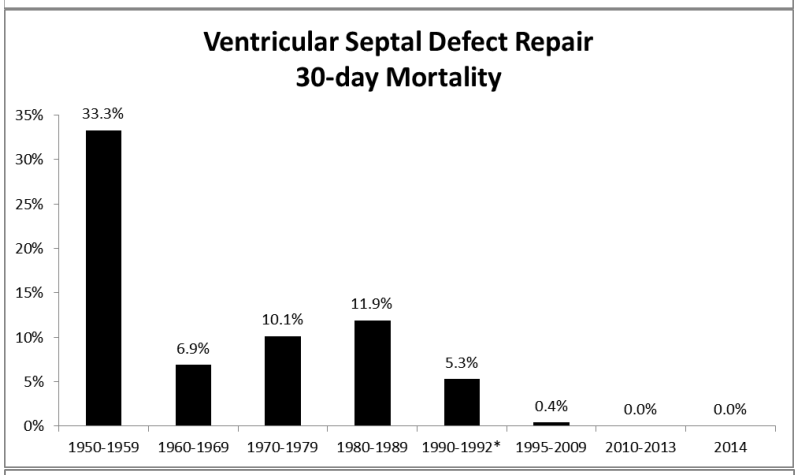
Exhibit 7 Pediatric Cardiac Surgery Operating Room and Cardiovascular Intensive Care Unit Room

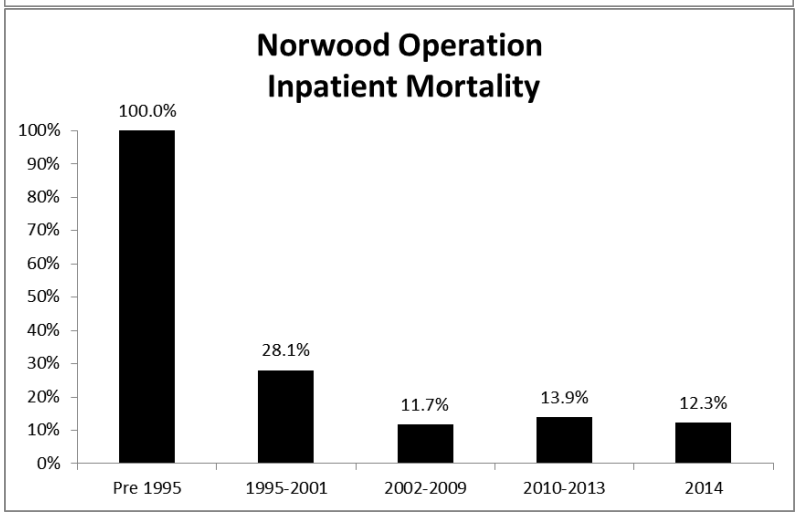


Source: Casewriter, based on company documents.

Exhibit 8 Mortality rates for selected conditions at Texas Children's Hospital, 1950-2014







Source: Casewriter, based on company documents, specifically the internal Texas Children's Heart Center mortality records.

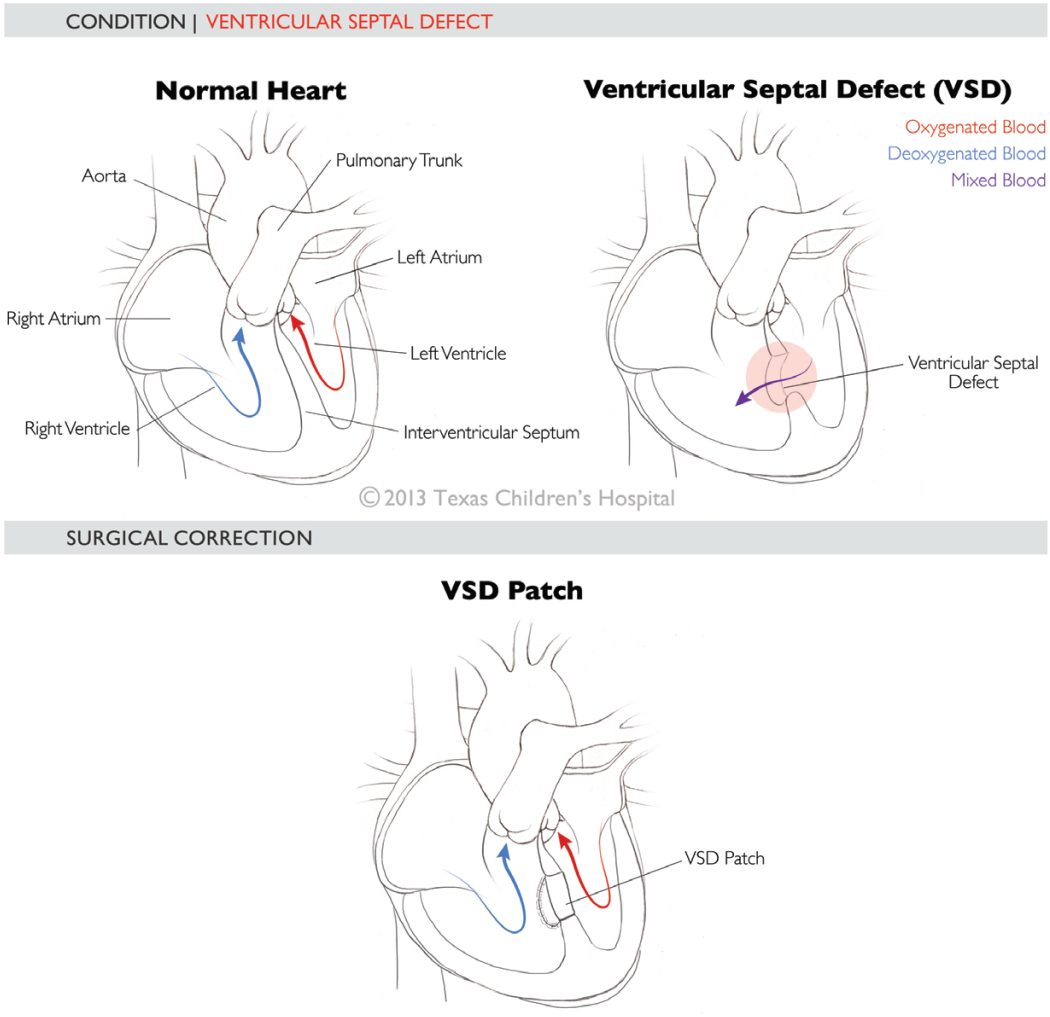
* Data missing from 1993-1995.

Exhibit 9 Texas Children's Pediatric Cardiac Surgery Network

Source: Casewriter, based on company documents.

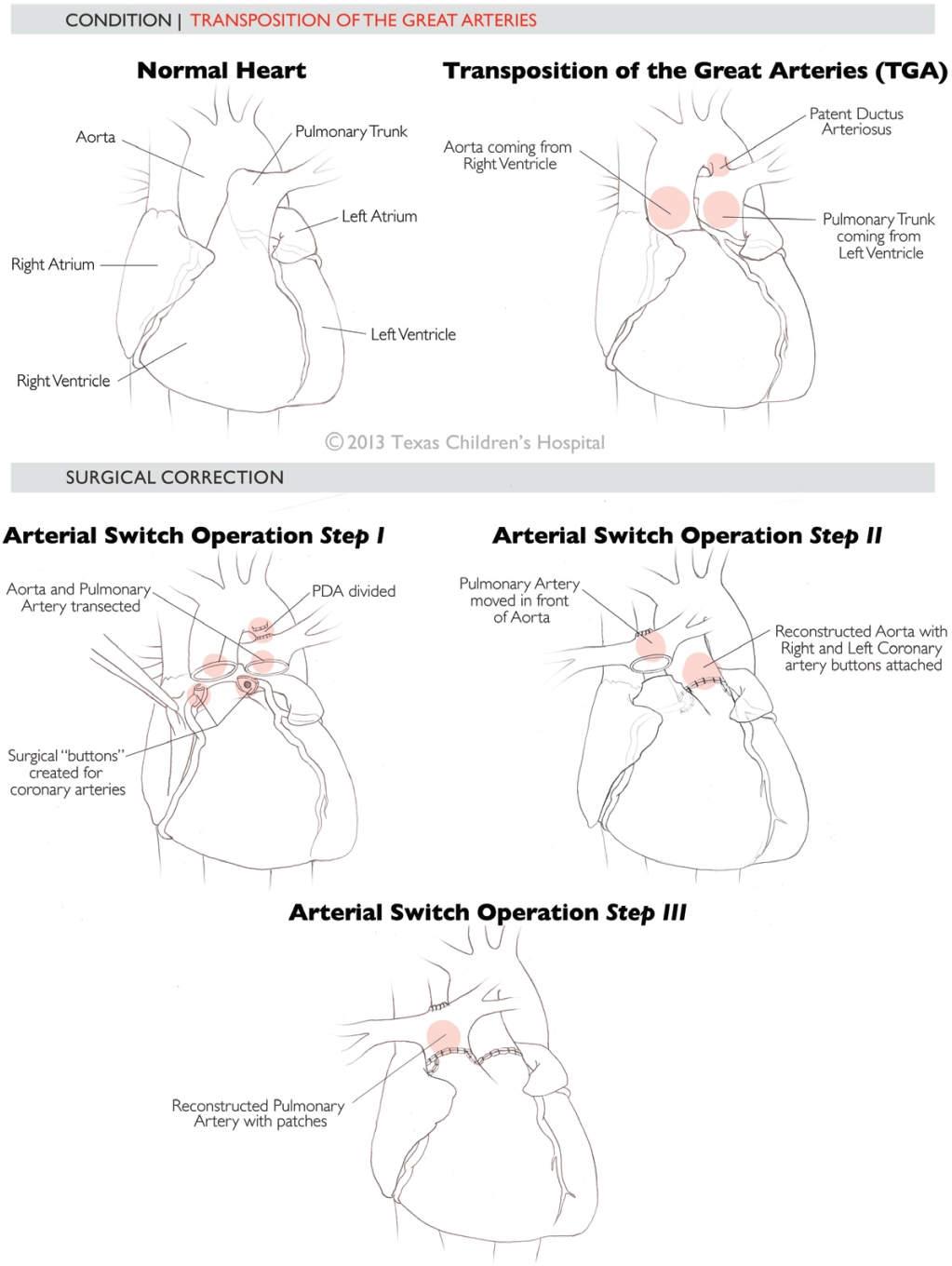
Appendix

Ventricular Septal Defect Repair



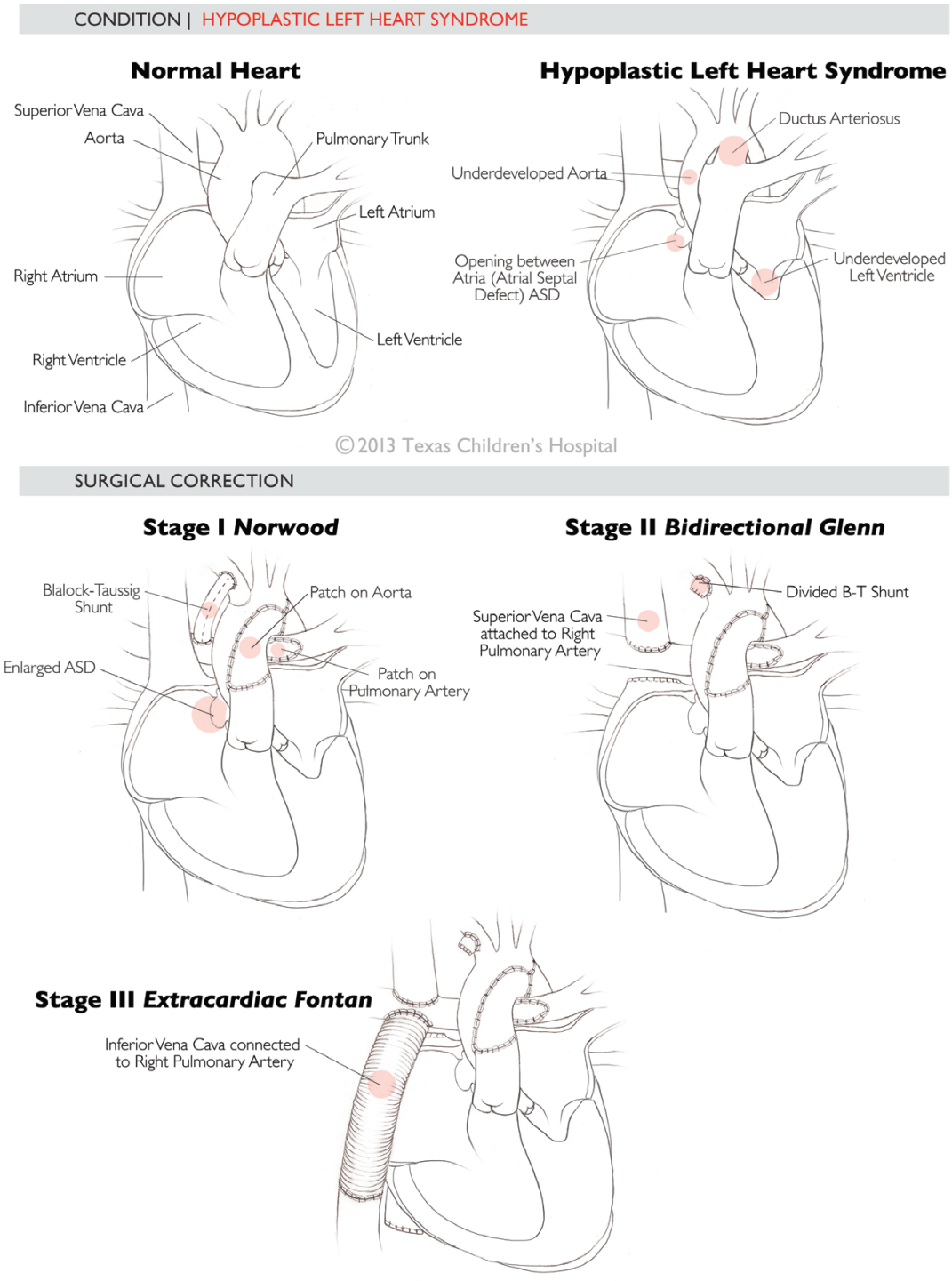
Source: Casewriter, based on company documents.

Arterial Switch Operation



Source: Casewriter, based on company documents.

Norwood Operation



Source: Casewriter, based on company documents.

Endnotes

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