



# Pediatric Cardiac Technical Advisory Panel Annual Report 2020

SUBMITTED BY THE AGENCY FOR HEALTH CARE ADMINISTRATION

December 2020



**Better Health Care for All Floridians**

## Introduction

Florida Statute section 395.1055 establishes the Pediatric Cardiac Technical Advisory Panel (PCTAP or “Panel”) for Florida, provides direction to the panel, and requires the submission of an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives beginning in January of 2020. As required by s 20.052, the Panel Chair and members hereby submit our second annual progress report on the activity and accomplishments of the Panel since inception in 2016 and through December 31, 2020. The previous Annual Report from 2020 chronicled the history of the creation of the PCTAP and the enacting legislation as well as the significant work done by the Panel in creating licensure standards for Florida’s ten existing pediatric cardiovascular centers that were referenced in the pediatric medical literature as best practice recommendations.

## History of the PCTAP

Various advocates for children and adults with congenital heart disease have long recognized the unique requirements for hospitals that perform complex invasive procedures in the treatment of often critical heart malformations. Such unique requirements embody criteria such as specialized fellowship training for the cardiac surgeon in congenital heart disease repair, cardiac perfusionists who can safely sustain a heart varying in size from a “walnut” to the standard adult heart intraoperatively, specialists in pediatric cardiac anesthesia, pediatric cardiac critical care, and nursing and respiratory staff who are familiar with the pre and post-operative management of complex cardiac malformations. Standards for such a specialized system of care were developed and functioned successfully in the Division of Children’s Medical Services (CMS) of the Department of Health (DOH) for over four decades. These standards were written by experts in pediatric cardiology and pediatric cardiac surgery and revised every four years to keep pace with technological changes in the field.

## Enacting Legislation

In 2016, the Florida Legislature enacted a new requirement for the Agency for Health Care Administration to establish a pediatric cardiac technical advisory panel (PCTAP) to assist in the development of procedures and standards for measuring outcomes of pediatric cardiac catheterization and surgery programs; and to make recommendations to the Agency regarding regulatory guidelines to govern pediatric cardiac catheterization programs and pediatric open-heart surgery programs in the state.

As a result, Florida Statute section 395.1055 requires the Agency to establish the PCTAP, confirm appointments from the appropriate hospital Chief Executive Officers (CEOs) and appoint at-large members, conduct and document meetings, take recommendations from the panel, coordinate the development of work products from the panel, and develop administrative rule(s) that include minimum quality standards for the pediatric cardiac catheterization programs and pediatric cardiovascular surgery programs in the state.

## Activities and Progress of the Panel

### Rule Development

The Florida Legislature enacted multiple bills during the 2019 legislative session that began in March and ended in May which impacted the Panel's work, including changes to hospital licensure laws, a repeal of hospital Certificate of Need requirements, and revisions to the required composition and authorized scope of duties for the PCTAP.

### Rule Status

As of December 31, 2020, the licensure standards developed by the Panel of physicians with expertise in multiple disciplines including pediatric cardiac surgery, interventional cardiac catheterization, electrophysiology, and complex cardiac imaging were presented for public comment at a rule workshop held February 27, 2020. Comments received were incorporated into the draft rule and approved by the PCTAP members. AHCA is currently preparing to submit the proposed language to the Joint Administrative Procedures Committee (JAPC) and to publish the rule for final public review. A formal hearing may be scheduled if requested prior to the rule becoming final.

The physician members of the PCTAP would like the Governor and leaders of the Florida Legislature to be aware that, despite meeting 3 times in 2020, significant delays occurred between the Rule Workshop on February 27, 2020 and final approval of the public's comments by the PCTAP on October 29, 2020. Leadership of the PCTAP attributes this delay to significant AHCA staff workload with other State issues related to the COVID pandemic. Additional delays in posting the surgical outcomes data and the compilation of the Florida aggregate data report occurred due to the Society of Thoracic Surgeons transitioning data warehouse vendors. The contract should be finalized soon allowing AHCA to begin publicly posting data in 2021.

## Public Reporting

### Society of Thoracic Surgeons (STS) National Database

The STS has developed a national registry and database where pediatric cardiac surgery programs across the nation submit clinical outcomes for specific procedures and conditions, including surgeries for congenital heart conditions. In return, the individual programs receive detailed statistical reports that include how the program compares to national benchmarks. The STS also hosts and maintains a public reporting website, including data specific to congenital heart surgeries, so that consumers can look up and compare outcomes across various programs. Participation in the STS congenital heart surgery registry is statutorily required of Florida-licensed pediatric cardiac surgery programs. The STS public website lists participating programs and displays mortality ratings based on the severity of procedures (in tiers).

The current published results for Florida's pediatric cardiac surgery programs are included as Appendix A to this report. Additionally, the underlying STS congenital surgery data from Florida's licensed pediatric cardiac surgery programs will be obtained by the Agency, through a contract with the STS as required in statute, for publication on the Agency's consumer-friendly health care transparency website, **FloridaHealthFinder.gov**. Additionally, due to past publicized concerns regarding quality surgical outcomes, the PCTAP recommends improving transparency by requiring annual posting of surgical outcomes from each Florida center with electronic links to full raw data on a publicly accessible website through the Agency.

## Future Panel Endeavors

### American College of Cardiology (IMPACT) Registry

The American College of Cardiology (ACC) hosts a number of patient data registries and produces statistical reports for participating cardiology programs, allowing individual programs to compare their quality and performance outcomes against national benchmarks. The ACC's *IMPACT* registry is specific to congenital heart disease. Communications with the ACC during 2018-2020 indicated that the organization has not yet developed a statewide reporting methodology but is willing to work with states to develop a platform. The Agency and PCTAP members will continue to explore options for which types of data would be most meaningful to consumers for public reporting and will continue to collaborate with the ACC.

### Real Time Outcomes for Public Reporting

Real time outcomes for public reporting was recommended by members of the Panel in 2019 and 2020. One program in the state has developed a methodology for real-time reporting of specific outcomes. An ad-hoc subcommittee has been developed to assess the steps required and make a recommendation to the Panel regarding the establishment of a real-time outcomes reporting initiative statewide. Although the COVID-19 pandemic delayed several PCTAP meetings for the year 2020, the Agency and PCTAP members continue to explore the possibilities and opportunities of real-time data reporting.

### Rule Development for Pediatric Cardiac Surgery Programs

The members of the PCTAP are committed to participate, when possible, in any and all future rule processes proposed by the Agency for Pediatric Cardiac Surgery Programs.

### Prospective Site Visits

Prospective site visits for Florida's ten existing pediatric cardiovascular surgical programs is one of the foundational beliefs of the PCTAP, documented by five decades of success within the Division of Children's Medical Services of the Florida Department of Health. Under the previous structure, members of the body had been conducting regularly scheduled on-site surveys of each center to review their facilities, conduct staff interviews, perform random chart reviews, and review adverse outcomes and deaths. These site visits, as recommended by the Panel, are ideally to occur with each center every three years. Delays in instituting these site visits have occurred due to several factors:

1. The need to establish a process to consider the PCTAP reviewer findings of potential regulatory concerns within the licensure and certification requirements for hospitals. To address statutory language regarding site visits, the Panel's findings of minor deviations from recommended quality standards may be addressed by the PCTAP with the authorization and approval of the AHCA Secretary. Deviations from statutory or regulatory requirements will be referred by the PCTAP to the Agency for further review and action as needed.
2. The era of COVID has created the need to develop new mechanisms for site visits to occur to respect the need for social distancing and hospital visitation policies. Therefore, a subpanel of the PCTAP has created suggestions for virtual site visits with review of the STS surgical reports, cardiac catheterization outcomes, and other data with one-on-one subspecialist interviews by electronic means. All of the impressions and recommendations of each reviewer would be compiled in a composite report, reviewed by the PCTAP, and forwarded to the Secretary of AHCA and staff for their final recommendations and approval.

## Conclusion

During the 2019-2020 fiscal year, the PCTAP met a total of 3 times to accomplish the Panel's two primary goals: to finalize rule language recommendations to the Agency for standards and outcomes related to pediatric cardiac surgery programs, and the selection of specific reporting components to request from the Society of Thoracic Surgeons (STS) for enhanced public transparency. The Panel members express their sincere appreciation for the continued opportunity to serve the State of Florida's most vulnerable residents and look forward to our continued work with the Agency to build on these accomplishments toward our mutual goal of the highest possible quality of care for children in Florida.

## Appendix A

As a national leader in health care transparency and accountability, The Society of Thoracic Surgeons (STS) established the STS Public Reporting initiative, which allows participants in the STS National Database to voluntarily report their surgical outcomes to the public on the STS website. Public reporting is available for the following STS National Database components: The Adult Cardiac Surgery Database, General Thoracic Surgery Database, and Congenital Heart Surgery Database.

Available data reported from the Congenital Heart Surgery Database is shown below for each of Florida's licensed pediatric cardiac surgery programs.

### Arnold Palmer Medical Center

Orlando, Florida

[Website](#)

#### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	11 / 480	2.3%	3.6%	0.64 (0.32, 1.14)	1.8 (0.9, 3.2)
STAT Mortality Category 1	0 / 125	0%	0.4%	0 (0, 7)	0 (0, 2.7)
STAT Mortality Category 2	2 / 183	1.1%	2.1%	0.53 (0.06, 1.88)	0.8 (0.1, 2.8)
STAT Mortality Category 3	1 / 52	1.9%	3.1%	0.62 (0.02, 3.3)	1.3 (0, 7.1)
STAT Mortality Category 4	5 / 88	5.7%	6.9%	0.82 (0.27, 1.84)	5.2 (1.7, 11.6)
STAT Mortality Category 5	3 / 32	9.4%	16.1%	0.58 (0.12, 1.56)	8.1 (1.7, 21.7)

### Florida Hospital for Children

Orlando, Florida

[Website](#)

#### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	15 / 477	3.1%	2.3%	1.39 (0.78, 2.27)	3.9 (2.2, 6.4)
STAT Mortality Category 1	0 / 139	0%	0.3%	0 (0, 7.68)	0 (0, 3)
STAT Mortality Category 2	4 / 202	2%	1.3%	1.5 (0.41, 3.79)	2.3 (0.6, 5.7)
STAT Mortality Category 3	3 / 42	7.1%	2.8%	2.51 (0.53, 6.84)	5.4 (1.1, 14.7)
STAT Mortality Category 4	8 / 85	9.4%	6%	1.57 (0.69, 2.96)	9.9 (4.4, 18.6)
STAT Mortality Category 5	0 / 9	0%	15.2%	0 (0, 2.21)	0 (0, 30.8)

## Jackson Memorial Hospital

Miami, Florida

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	11 / 328	3.4%	2%	1.66 (0.83, 2.93)	4.7 (2.3, 8.2)
STAT Mortality Category 1	1 / 119	0.8%	0.3%	2.69 (0.07, 14.73)	1.1 (0, 5.8)
STAT Mortality Category 2	2 / 114	1.8%	1.2%	1.47 (0.18, 5.19)	2.2 (0.3, 7.8)
STAT Mortality Category 3	0 / 22	0%	1.5%	0 (0, 10.59)	0 (0, 22.7)
STAT Mortality Category 4	6 / 61	9.8%	4%	2.45 (0.92, 5.03)	15.4 (5.8, 31.7)
STAT Mortality Category 5	2 / 12	16.7%	17.7%	0.94 (0.12, 2.73)	13.1 (1.6, 38.1)

## Joe DiMaggio Children's Hospital

Hollywood, Florida

[Website](#)

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	21 / 620	3.4%	3.4%	1 (0.62, 1.51)	2.8 (1.7, 4.2)
STAT Mortality Category 1	0 / 183	0%	0.3%	0 (0, 6.44)	0 (0, 2.5)
STAT Mortality Category 2	4 / 202	2%	1.4%	1.42 (0.39, 3.59)	2.1 (0.6, 5.4)
STAT Mortality Category 3	2 / 62	3.2%	2.2%	1.46 (0.18, 5.05)	3.1 (0.4, 10.8)
STAT Mortality Category 4	9 / 145	6.2%	8.1%	0.76 (0.35, 1.41)	4.8 (2.2, 8.9)
STAT Mortality Category 5	6 / 28	21.4%	16%	1.34 (0.52, 2.56)	18.7 (7.2, 35.7)

## Johns Hopkins All Childrens Hospital

St. Petersburg, Florida

[Website](#)

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	21 / 515	4.1%	3%	1.36 (0.85, 2.06)	3.8 (2.4, 5.8)
STAT Mortality Category 1	0 / 121	0%	0.4%	0 (0, 7.28)	0 (0, 2.8)
STAT Mortality Category 2	2 / 194	1%	1.3%	0.8 (0.1, 2.86)	1.2 (0.1, 4.3)
STAT Mortality Category 3	3 / 55	5.5%	2.1%	2.58 (0.54, 7.15)	5.5 (1.2, 15.3)
STAT Mortality Category 4	11 / 117	9.4%	6.5%	1.46 (0.74, 2.51)	9.2 (4.7, 15.8)
STAT Mortality Category 5	5 / 28	17.9%	13.1%	1.36 (0.46, 2.81)	18.9 (6.4, 39.2)

## Nemours Children's Hospital

Orlando, Florida

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Hospital is enrolled in public reporting but did not receive composite measure results for January 2015 - December 2018.

## Nicklaus Childrens Hospital

Miami, Florida

[Website](#)

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	29 / 1005	2.9%	2.6%	1.1 (0.74, 1.57)	3.1 (2.1, 4.4)
STAT Mortality Category 1	1 / 325	0.3%	0.4%	0.77 (0.02, 4.26)	0.3 (0, 1.7)
STAT Mortality Category 2	5 / 390	1.3%	1.5%	0.85 (0.28, 1.96)	1.3 (0.4, 2.9)
STAT Mortality Category 3	0 / 79	0%	1.8%	0 (0, 2.54)	0 (0, 5.4)
STAT Mortality Category 4	16 / 174	9.2%	6.7%	1.37 (0.79, 2.15)	8.6 (5, 13.6)
STAT Mortality Category 5	7 / 37	18.9%	16.3%	1.16 (0.49, 2.16)	16.2 (6.8, 30.1)

## St. Joseph's Children's Hospital BayCare Health System

Tampa, Florida

[Website](#)

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	13 / 641	2%	2.9%	0.7 (0.38, 1.19)	2 (1.1, 3.3)
STAT Mortality Category 1	0 / 194	0%	0.3%	0 (0, 6.06)	0 (0, 2.4)
STAT Mortality Category 2	2 / 231	0.9%	1.3%	0.66 (0.08, 2.37)	1 (0.1, 3.6)
STAT Mortality Category 3	1 / 68	1.5%	2.4%	0.61 (0.02, 3.26)	1.3 (0, 7)
STAT Mortality Category 4	8 / 130	6.2%	7.7%	0.8 (0.35, 1.53)	5 (2.2, 9.6)
STAT Mortality Category 5	2 / 18	11.1%	17.8%	0.62 (0.08, 1.95)	8.7 (1.1, 27.1)



## UF Health Shands Children's Hospital

Gainesville, Florida

[Website](#)

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	11 / 858	1.3%	2.2%	0.57 (0.29, 1.02)	1.6 (0.8, 2.9)
STAT Mortality Category 1	0 / 243	0%	0.4%	0 (0, 4.15)	0 (0, 1.6)
STAT Mortality Category 2	6 / 292	2.1%	1.2%	1.75 (0.65, 3.77)	2.6 (1, 5.7)
STAT Mortality Category 3	0 / 71	0%	1.7%	0 (0, 2.9)	0 (0, 6.2)
STAT Mortality Category 4	4 / 222	1.8%	4.3%	0.42 (0.11, 1.06)	2.6 (0.7, 6.7)
STAT Mortality Category 5	1 / 30	3.3%	13.5%	0.25 (0.01, 1.28)	3.4 (0.1, 17.8)

## Wolfson Children's Hospital

Jacksonville, Florida

[Website](#)

### Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)

Population: Neonates, Infants, Children & Adults	# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)
Overall	13 / 525	2.5%	1.5%	1.6 (0.86, 2.72)	4.5 (2.4, 7.6)
STAT Mortality Category 1	1 / 178	0.6%	0.3%	2.02 (0.05, 11.1)	0.8 (0, 4.3)
STAT Mortality Category 2	6 / 201	3%	1.3%	2.29 (0.85, 4.89)	3.4 (1.3, 7.3)
STAT Mortality Category 3	3 / 68	4.4%	1.6%	2.74 (0.57, 7.67)	5.9 (1.2, 16.5)
STAT Mortality Category 4	2 / 67	3%	4.5%	0.66 (0.08, 2.29)	4.2 (0.5, 14.5)
STAT Mortality Category 5	1 / 11	9.1%	7.8%	1.16 (0.03, 5.28)	16.2 (0.4, 73.7)