

Pediatric Cardiac Technical Advisory Panel Annual Report Calendar Year 2021

SUBMITTED BY THE AGENCY FOR HEALTH CARE ADMINISTRATION

December 2021



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 in § 20.052, the Panel Chair and members hereby submit our third annual progress report on the activity and accomplishments of the Panel since inception in 2016 and through December 31, 2021.

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 2017, the Florida Legislature enacted a new requirement for the Agency for Health Care Administration (AHCA) 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. The authorizing statute was amended in 2018² and again in 2019³ with minor changes to membership appointment guidelines and added authority for panel members to conduct site visits at active programs in the state respectively.

Currently, Florida Statute section 395.1055 requires the Agency to establish and administer the PCTAP, confirm appointments from the appropriate hospital Chief Executive Officers (CEOs), 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. The Secretary of AHCA may also appoint additional non-voting members from specific organizations listed in the statute; and may request site visits to be conducted by panel members.

¹ Laws of Florida, 2017-151: http://laws.flrules.org/2017/151

² Laws of Florida, 2018-24: http://laws.flrules.org/2018/24

³ Laws of Florida, 2019-138: http://laws.flrules.org/2019/138

Activities and Progress of the Panel

Rule Development

Proposed Rule 59A-3.248 was published in the Florida Administrative Register on March 10, 2021. The rule was challenged from multiple organizations, resulting in a Notice of Change published on May 25, 2021. The proposed rule was ultimately withdrawn on June 16, 2021. Further action on rule development and finalization are pending at this time.

Public Reporting

Society of Thoracic Surgeons (STS) National Database

The Society of Thoracic Surgeons (STS), a national membership organization of surgeons, researchers, and allied health professionals, 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.

The most current published reports 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, the PCTAP has recommended expanding on that transparency by requiring the publication and annual updates of surgical outcomes from each Florida center with electronic links to full raw data on the Agency's designated website.

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 2018-2021 indicate that the organization has not yet developed a statewide reporting methodology. 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.

⁴ Florida Administrative Register: https://www.flrules.org/gateway/ruleNo.asp?id=59A-3.248

Real Time Outcomes for Public Reporting

Real time outcomes for public reporting continues to be recommended by members of the Panel. One program in the state has developed a methodology for real-time reporting of specific outcomes. An adhoc subcommittee was formed to assess the feasibility and steps that would be required to expand the methodology statewide. The platform was developed in partnership with a private vendor, meaning that further investigation is needed to better understand how each program might best approach and implement the recommended solution. Although the COVID-19 pandemic delayed several PCTAP meetings during 2020-2021, the PCTAP members continue to explore the possibilities and opportunities of real-time data reporting.

Prospective Site Visits

The PCTAP members remain committed to the desire to conduct site visits at existing programs periodically, if requested by the Secretary. The panel has initiated discussion regarding the possibility of conducting a portion or all of the site visit activities virtually, in respect of hospital visitation and operational limitations during the continued COVID-19 pandemic.

Conclusion

Though challenged by the continued national pandemic, the members of the PCTAP were active in the finalization of proposed rule language as well as during public meetings regarding the proposed rule. The Agency also continued negotiations with the Society of Thoracic Surgeons (STS) regarding the establishment of a contract and Data Use Agreement to receive and publish STS quality measures and data for each of Florida's licensed Pediatric Cardiac Surgery programs.

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 <u>Website</u>

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 <u>Website</u>

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

<u>Website</u>

Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)						
# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)		
21 / 620	3.4%	3.4%	1 (0.62, 1.51)	2.8 (1.7, 4.2)		
0 / 183	0%	0.3%	0 (0, 6.44)	0 (0, 2.5)		
4 / 202	2%	1.4%	1.42 (0.39, 3.59)	2.1 (0.6, 5.4)		
2/62	3.2%	2.2%	1.46 (0.18, 5.05)	3.1 (0.4, 10.8)		
9 / 145	6.2%	8.1%	0.76 (0.35, 1.41)	4.8 (2.2, 8.9)		
6 / 28	21.4%	16%	1.34 (0.52, 2.56)	18.7 (7.2, 35.7)		
	# / Eligible 21 / 620 0 / 183 4 / 202 2 / 62 9 / 145	#/Eligible Observed 21 / 620 3.4% 0 / 183 0% 4 / 202 2% 2 / 62 3.2% 9 / 145 6.2%	#/Eligible Observed Expected 21 / 620 3.4% 3.4% 0 / 183 0% 0.3% 4 / 202 2% 1.4% 2 / 62 3.2% 2.2% 9 / 145 6.2% 8.1%	# / Eligible Observed Expected O/E Ratio (95% CI) 21 / 620 3.4% 3.4% 1 (0.62, 1.51) 0 / 183 0% 0.3% 0 (0, 6.44) 4 / 202 2% 1.4% 1.42 (0.39, 3.59) 2 / 62 3.2% 2.2% 1.46 (0.18, 5.05) 9 / 145 6.2% 8.1% 0.76 (0.35, 1.41)		

Johns Hopkins All Childrens Hospital

St. Petersburg, Florida

<u>Website</u>

Operative and Adjusted Operative Morta					Adi Data (OEN CI)
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

<u>Website</u>

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

<u>Website</u>

Operative and Adjusted Operative Mortality, Last 4 Years (January 2015 - December 2018)					
# / Eligible	Observed	Expected	O/E Ratio (95% CI)	Adj. Rate (95% CI)	
11 / 858	1.3%	2.2%	0.57 (0.29, 1.02)	1.6 (0.8, 2.9)	
0 / 243	0%	0.4%	0 (0, 4.15)	0 (0, 1.6)	
6 / 292	2.1%	1.2%	1.75 (0.65, 3.77)	2.6 (1, 5.7)	
0 / 71	0%	1.7%	0 (0, 2.9)	0 (0, 6.2)	
4 / 222	1.8%	4.3%	0.42 (0.11, 1.06)	2.6 (0.7, 6.7)	
1 / 30	3.3%	13.5%	0.25 (0.01, 1.28)	3.4 (0.1, 17.8)	
	# / Eligible 11 / 858 0 / 243 6 / 292 0 / 71 4 / 222	#/Eligible Observed 11 / 858	# / Eligible Observed Expected 11 / 858 1.3% 2.2% 0 / 243 0% 0.4% 6 / 292 2.1% 1.2% 0 / 71 0% 1.7% 4 / 222 1.8% 4.3%	# / Eligible Observed Expected O/E Ratio (95% CI) 11 / 858	

Wolfson Children's Hospital

Jacksonville, Florida

<u>Website</u>

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)

This information can be found at: Congenital Heart Surgery Public Reporting | STS Public Reporting

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