Pediatric Cardiac Technical Advisory Panel Annual Report 2019

SUBMITTED BY THE AGENCY FOR HEALTH CARE ADMINISTRATION

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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. The Panel Chair and members hereby submit our first annual progress report on the activity and accomplishments of the Panel since inception in 2016 and through December 31, 2019. As this is the inaugural submission of the annual report, this communique will chronicle the history of the creation of the PCTAP, related statutory requirements, and the activities and progress of the Panel in the composition of recommendations to the Agency for administrative rule(s).

History 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 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 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 PCTAP members successfully organized into three sub-committees between June 1, 2018 and September 30, 2018. A total of 14 public subcommittee meetings were hosted. The resulting committee recommendations were compiled and the panel's aggregated report of recommended draft standards were submitted to the Agency in February, 2019. Agency staff reviewed the recommendations and formulated the preliminary draft rule language. The preliminary language was presented to the PCTAP physicians in mid-September 2019, and was vetted by the full PCTAP during public meetings on September 20th and October 15th. The PCTAP membership approved the preliminary draft language during the October 2019 meeting, paving the way for the Agency to initiate formal rule development. The Agency is currently working to schedule a public rule development workshop to present the draft language for public comment.

Subcommittees

- ***Surgical Rule Subcommittee*** - tasked with the development of recommendations for standards of the surgical components for the pediatric cardiac surgery program draft rule. The committee met five times with 9 active members.
- ***Cardiology Rule Subcommittee*** - tasked with the development of recommendations for standards for the cardiology components of the pediatric cardiac surgery program draft rule. The committee met six times with 16 active members.
- ***Public Reporting and Transparency Subcommittee*** - tasked with developing recommendations for which measures and outcomes from the Society of Thoracic Surgery database and the American College of Cardiology (ACC) registries are most meaningful for public reporting. The committee met 7 times with 11 active members.

Public Reporting

Society of Thoracic Surgeons (STS) National Database

The STS has developed a national 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 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***.

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 2018-2019 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. 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.

Rule Development for Pediatric Cardiac Surgery Programs

The members of the PCTAP are committed to participate, when possible, in public rule workshops regarding the proposed Agency rule for Pediatric Cardiac Surgery Programs.

Conclusion

Throughout the 2018-2019 fiscal year, the PCTAP and its subcommittees met a total of 31 times to accomplish the Panel's two primary goals: development of 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 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

Arnold Palmer Medical Center Surgeons
Kamal Pourmoghadam, MD
William DeCampli, MD, PhD

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

Florida Hospital for Children Surgeons
Constantine Mavroudis, MD
Frank Pigula, MD
Tomas Martin, MD

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

Jackson Memorial Hospital Surgeons
Eliot Rosenkranz, MD

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

Joe DiMaggio Children's Hospital Surgeons
Frank Scholl, MD
Immanuel Turner, MD
Richard Perryman, MD
Steven Bibevski, MD

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

Johns Hopkins All Childrens Hospital Surgeons
Constantine Mavroudis, MD
James Quintessenza, MD
Jeffrey Jacobs, MD
Luca Vricella, MD
Nhue Lap Do, MD
Tom Karl, MD

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

Nicklaus Childrens Hospital Surgeons
Kristine Guleserian, MD
Redmond Burke, MD
Robert Hannan, MD

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

St. Joseph's Children's Hospital BayCare Health System Surgeons
Farshad Anvari, MD
Melita Viegas, MD
Peter Wearden, MD
Stephen Langley, MD
Victor Morell, MD

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

UF Health Shands Children's Hospital Surgeons
Karl Reyes, MD
Mark Bleiweis, MD
Michael Shillingford, MD
Tiago Machuca, MD, Ph.D
William Stein, MD

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

Wolfson Children's Hospital Surgeons
Eric Ceithaml, MD
Mark Bleiweis, MD
Michael Shillingford, MD

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)