

HISTORY OF THE DEVELOPMENT OF
PEDIATRIC CARDIAC STANDARDS IN
THE STATE OF FLORIDA:
PAST AND PRESENT

ADAPTED FROM
FRANCISCO HERNANDEZ ANNUAL
PEDIATRIC CARDIOLOGY LECTURE

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OBJECTIVES

- ▶ REVIEW HISTORY OF CHILDREN'S MEDICAL SERVICES (CMS) IN FLORIDA AND DEVELOPMENT OF CARDIAC STANDARDS TO PRESENT
- ▶ FAMILIARIZE AUDIENCE WITH HOW DID WE GET HERE FROM CMS TO AHCA

DISCLOSURES

- ▶ No financial conflicts of interest to disclose
- ▶ Prior to recent retirement, employed half career by Sacred Heart Health System and other half by Nemours Children's Clinic-Pensacola
- ▶ My comments do not represent those of the administrations of either Sacred Heart Health System or Nemours

▶ AND

FRANCISCO A. HERNANDEZ

FLORIDA'S FIRST PEDIATRIC CARDIOLOGIST



HISTORY OF CARDIAC STANDARDS PARALLELS THE HISTORY OF CMS

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Dr. Gerold Schiebler- Florida's Second Pediatric Cardiologist

DEVELOPMENT OF FLORIDA'S CARDIAC STANDARDS- PAST HISTORY

- ▶ Three attempts to establish a “crippled children's “ program in 1906, 1911, and 1921 failed for various reasons. ¹.
- ▶ 1929 Florida legislature creates Florida Commission for Crippled Children (FCCC) charging that “every indigent or partially indigent child in Florida might have promptly and efficiently the best surgical and medical care available in the State.” FCCC became a decentralized program, public/private partnership with an orthopedic focus. 3 nurse case managers appointed to direct the program in North, Central, and South Florida. ².

1. **The History of Florida Children's Medical Services Program, Taylor, Ann B. , November 28, 2007.**

2. **Schulkind and Ausbon, 1985.**

CARDIAC STANDARDS- PAST HISTORY

- ▶ Title V of Social Security Act in 1935 adds Federal dollars to program which expands to 5 districts by 1939. Children served increased from 3766 in 1940 to 10,598 in 1961. Covered ages birth-21 years.
- ▶ **1953-** Cardiac Rehabilitation Program started under FCCC for children with operable heart disease with help of Title V administration, Florida Heart Association, and the Florida State Board of Health and the first Cardiac Advisory Committee was formed to oversee the Program.
- ▶ Cardiac diagnostic and surgical services were provided and coordinated with Minnesota and Maryland Crippled Children's Services (CCS) and enabled cardiac services to be provided at Mayo Clinic, University of Minnesota, and Johns Hopkins Cardiac Centers. University of Florida added as a center in late 1950's.

CARDIAC STANDARDS- PAST HISTORY

- ▶ Nemours Foundation in 1948 founded program to give aid to crippled children in Florida. From 1948-1960 Foundation donated \$535,830 for 87,760 days of hospital care and surgical services at Alfred I. DuPont Hospital for Children at no cost to the FCCC.
- ▶ 1951- Nemours sponsored conference on team concept in care of children with cleft lip/palate. First multidisciplinary cleft lip/palate clinic opened in Jacksonville.
- ▶ **1960-** Dr. Simon Doff from Jacksonville, first Chairman of Cardiac Advisory Council ⁴
- ▶ 1969- FCC reorganized as Bureau of Crippled Childrens Services, a freestanding bureau within the Department of Health and Rehabilitative Services for one year then moved to Division of Vocational Rehabilitation.
- ▶ 1973- BCC elevated to new Division of Children's Medical Services within HRS through efforts of Drs. Ed Rushton, Gerold Schiebler, Reed Bell, John Whitcomb, and James Talbert.

CARDIAC STANDARDS-PAST HISTORY

- ▶ 1/1/1977 First set of cardiac standards drafted, amended 2/11/85 and passed in legislature. Standards endorsed by AAP, AHA, ACC and STS. Reviewers included Welton Gersony and Kathy Jenkins.
- ▶ Despite legislative repeal of CMS cardiac rules in 2001, all CMS centers have continued to be site visited and reevaluated every three years to ensure compliance with standards.
- ▶ Standards revised ~every 4-5 years to change as technological changes occur. Last update 2/12/13 presented at public hearing included new standards for EP and exercise testing.
- ▶ By 2010 all eight CMS approved centers submit their data to STS and an annual statewide report is made to CMS leadership.

CARDIAC STANDARDS-PAST HISTORY

- ▶ 2013- On advice of DOH General Counsel, advised that statutory authority for CMS standards no longer existed. Cardiac Advisory Council then reorganized as the Cardiac Technical Advisory Panel to the Surgeon General in a document signed by then Surgeon General John Armstrong on 10/21/2013. A memorandum of agreement between SG Armstrong and Secretary Elizabeth Dudek of ACHA signed on 12/3/2013 agreeing to joint discussions between physicians of CTAP and ACHA staff and supportive on public reporting of national STS data for Florida.
- ▶ Discussions occurred with CMS staff on making the cardiac standards voluntary and reorganizing as a “quality collaborative.”

CARDIAC STANDARDS-PAST HISTORY

- ▶ July, 2015-Announcement made in Florida Administrative Registry of Notice of Intent to repeal CMS Cardiac Standards. Request for hearing made on 7/31/2015.
- ▶ 10/12/2015- Hearing held at DOH Conference room and statements of opposition to repeal of standards made by Drs. Blanchard, Jacobs, Gessner, Peitra, St. Petery, and McCormack.
- ▶ Legal request filed 10 days later to stay the repeal of standards and assigned to Administrative Law Judge VanLaningham.
- ▶ 12/16/15 Judge Van Laningham rules against plaintiff's case- "lack of standing." Legal threshold for standing must show plaintiff is "substantially affected"if rule is repealed. ⁵

CARDIAC STANDARDS- PAST HISTORY

- ▶ Appeal made to 3rd District Court of Appeals (DCOA); agreed to hear and arguments presented to court on July 12, 2016.
- ▶ To date, no ruling on standing from DCOA.
- ▶ Current successful creation of Pediatric Cardiac Technical Advisory Panel (PCTap) likely makes the appeal “moot” and will be withdrawn from the court for consideration.

CARDIAC STANDARDS-PRESENT

- ▶ CMS Cardiac standards remain in place pending ruling from DCOA
- ▶ DOH attorneys have communicated to current Deputy Secretary of CMS their intent to proceed with repeal of standards if DCOA ruling is against CMS physicians.
- ▶ CTAP remains in place. No meetings or site visits have occurred however since late 2014.
- ▶ In 2015, SB 378 (Sen. Aaron Bean) and companion HB (Rep. Mike Hill) filed, but failed to progress due to refusal of House to hear this in committee.
- ▶ 2016/2017- SB 62 introduced by Sen. Aaron Bean seeking to reestablish statutory authority for CTAP and cardiac standards. SB 62 approved by Senate Health Policy Committee 1/24/2017, Senate Committee on Government Operations and Accountability 2/7/2017. Companion bill filed by Rep. Cary Pigman (HB 59).

CARDIAC STANDARDS-PRESENT

- ▶ The pediatric cardiac portions of HB 59 were shortened and placed as amendments to several House bills, eventually added to HB 1121 sponsored by Rep. Cindy Stephenson.
- ▶ The combined bills passed on the last day of the legislative session and were signed by the officers of the legislature and the Governor and became law in June of 2017.
- ▶ Secretary Justin Senior of Agency for Health Care Administration appointed Nikole Helvey as the Bureau Chief in charge of implementing the operation of appointing the pediatric cardiac advisory committee as outlined in HB 1121.

CARDIAC STANDARDS-PRESENT

- ▶ AHCA created the Pediatric Cardiac Technical Advisory Panel (PCTap) designation and posted applications on their website and sent letters to the 10 designated pediatric cardiac hospitals' CEO's to appoint the primary voting members and their alternates as prescribed in statute.
- ▶ Letters of appointment sent out by Secretary Senior after receipt from the hospital CEOs of their appointments. At Large members and their alternates appointed after reviewing applications by Secretary Senior.
- ▶ First meeting of PCTap on 11/2/2017 at Jacksonville University.

REFERENCES

- ▶ 1. HISTORY OF DR. HERNANDEZ INFORMATION COURTESY OF DR. DELORES TAMER.
- ▶ 2. TAYLOR, AB (Ed.D): HISTORY OF FLORIDA CHILDREN'S MEDICAL SERVICES, November 28, 2007, pp. 1-140.
- ▶ 3. SHULKIND AND AUSBON, 1985.
- ▶ 4. PERSONAL COMMUNICATION, DR. GEROLD SCHIEBLER.
- ▶ 5. PERSONAL COMMUNICATION, KAREN PUTNAL, Esq. –ATTORNEY OF RECORD FOR PLAINTIFFS
- ▶ 6. Donabedian A. Evaluating the quality of medical care. *Milbank Mem Fund Q.* 1966; 44 (Suppl): 166-206.
- ▶ 7. Porter ME, PhD. Perspective: What is value in health care? *N Engl J Med* 2010; 363: 2477-2481.
- ▶ 8. Jacobs, JP, O'Brien, SM, Pasquali, SK, et. al. Variation in outcome for benchmark operations: an analysis of the Society of Thoracic Surgeons congenital heart surgery database. *Ann Thorac Surg*; 92: 2184-2192.

REFERENCES

- ▶ 9. Jacobs, JP, O'Brien, SM, Pasquali, SK, et. al. Variation in outcomes for risk stratified pediatric cardiac surgical operations: An analysis of the STS Congenital Heart Surgery Database. *Ann Thorac Surg*, August, 2012; vol. 94, issue 2: p. 564-512.
- ▶ 10. Welke, KF, O'Brien, SM, Peterson, ED, et. al. The complex relationship between pediatric cardiac surgical case volumes and mortality rates in a national clinical database. *J Thorac Cardiovasc Surg* 2009; 137: 1133-1140..
- ▶ 11. Jacobs JP, O'Brien SM, Pasquali SK, Kim S, Gaynor JW, Tchervenkov CI, Karamlou T, Welke KF, Lacour-Gayet F, Mavroudis C, Mayer JE Jr, Jonas RA, Edwards FH, Grover FL, Shahian DM, Jacobs ML. The importance of patient-specific preoperative factors: An analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database. *Ann Thorac Surg*. 2014 Nov;98(5):1653-9. doi: 10.1016/j.athoracsur.2014.07.029. Epub 2014 Sep 26. PMID: 25262395.
- ▶ 12. Jacobs, JP. Presentation to Third Joint Meeting of the Congenital Heart Surgeon's Society (CHSS) and the European Congenital Heart Surgeons Association (ECHSA), July 24, 2016; Venice, Italy.
- ▶ 13. Jacobs JP, Jacobs ML, Maruszewski B, Lacour-Gayet FG, Tchervenkov CI, Tobota Z, Stellin G, Kurosawa H, Murakami A, Gaynor JW, Pasquali SK, Clarke DR, Austin EH 3rd, Mavroudis C. Initial application in the EACTS and STS Congenital Heart Surgery Databases of an empirically derived methodology of complexity adjustment to evaluate surgical case mix and results. *Eur J Cardiothorac Surg*. 2012 Nov;42(5):775-80. doi: 10.1093/ejcts/ezs026. Epub 2012 Jun 14. PMID: 22700597
- ▶ 14 Paraphrase of court proceedings from Justice Potter Stewart, US Supreme Court, 1964: *Jacobellius vs. Ohio*.
- ▶ 15. Personal communication Chrishonda Jenkins, R.N. , CMS Nurse Director for Pediatric Cardiology, Tallahassee, FL.
- ▶ 16. <http://www.usnews.com/news/national-news/articles/2017-01-31/risky-childrens-hospitals-highlighted-in-telltale-database>
- ▶ 17. <http://www.usnews.com/news/national-news/articles/2017-01-31/in-florida-fighting-to-fix-childrens-hearts>
- ▶ 18. <http://www.usnews.com/news/national-news/articles/2017-01-31/hospitals-look-for-allies-in-struggle-to-survive>

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