

DRAFT MINUTES

Agency for Health Care Administration (AHCA)

Pediatric Cardiac Technical Advisory Panel (PCTAP or Advisory Panel) **PCTAP Public Reporting & Transparency Subcommittee**

Date: May 16, 2019

Time: 5:30 pm – 6:30 pm

Location: Webinar

PCTAP Public Reporting & Transparency Subcommittee Members Present: Mark Bleiweis, MD; Eric Eason, MD; Jorge McCormack, MD; Vice-Chair Frank Scholl, MD; Peter Wearden, MD;

PCTAP Members Present: Alfred Asante-Korang, MD; Joel Hardin, MD; Jeremy Ringewald, MD; Sethuraman Swaminathan, MD;

Staff Present: Nikole Helvey, Bureau Chief, Florida Center; Jack Plagge, Manager, Hospital and Outpatient Services Unit; Patricia Vidal, Data Dissemination and Communication Manager, Florida Center; Jess Hand and Adrienne Henderson, Florida Center.

Interested Parties Present: Bill Blanchard, MD; Bob Hannan, MD; Janet Kreutzer; Jason Rodriguez; Gerold Schiebler, MD; Joni Silvestri; Rosie Tuzik

Call to Order, Welcome and Roll Call: Dr. Frank Scholl called roll, welcomed the members and called the meeting to order.

STS Data Discussion: Dr. Scholl provided an overview of the five tabs of the STS Data excel spreadsheet circulated with the meeting materials. These tabs include:

1. Excel Tab: STS Letter
2. Excel Tab: STS Congenital Heart Surgery Database
3. Excel Tab: Nicklaus Real Time Outcomes
4. Excel Tab: ACC IMPACT Registry
5. Excel Tab: STS Public Reporting Data

Dr. Bob Hannan asked how the validity of the data reported by the programs to STS would be ensured. Dr. Scholl referred to the lines related to STS data audits on Tab 1 of the excel document. Dr. Scholl stated that the purpose of the subcommittee is to clarify the information (in granular detail) the panel is requesting from the STS.

Dr. Bill Blanchard and Dr. Scholl discussed the possibility of integrating site visits with sovereign immunity into the auditing process of the pediatric cardiac programs. Dr. Scholl asked whether more than one member of PCTAP could be present on a site visit without violating Sunshine Law. Dr. Gerold Schiebler requested the Agency Secretary review the application of Sunshine Law to site visits. Ms. Nikole Helvey clarified that Sunshine Law prohibits two members of the panel from discussing (outside of a publicly noticed meeting) any business that

may come before the Panel. Dr. Scholl suggested that the site visits might need to be conducted by one member of the Panel and several non-members who work in the field of pediatric cardiology or cardiac surgery. Dr. Scholl requested that further discussion of site visits be tabled for the next meeting of the full panel of PCTAP.

Dr. Scholl discussed the legislation related to term limits of members. Ms. Helvey responded that the Agency legal team is currently discussing the term limits outlined in the new legislation and will have a response at the time of the next meeting. Dr. Schiebler recommended that the term limits begin with the implementation of the new law on July 1, 2019 to minimize disruption to the Panel. Dr. Schiebler asked for a timeline from AHCA to finalize the rulemaking process. Ms. Helvey responded that draft language for the proposed rule is being circulated internally and should be forthcoming to the Panel. Dr. Schiebler urged that progress on rulemaking be a top priority. Dr. Scholl requested that an update on the rule making process be an agenda item at the next meeting of the full Panel. Dr. Schiebler requested the Agency circulate a draft of the recommendations before the next meeting. Ms. Helvey agreed to circulate this before the next meeting.

Members affirmed that they are in agreement with the list of items requested from STS on Tab 1 of the excel document. Dr. Eason asked what 'complications' line 20 of Tab 1 refer to specifically. Dr. Scholl explained that this is a reference to a standardized STS list of postoperative complications. Dr. Hannan added that there are five such categories available from STS. Dr. Jeremy Ringewald asked whether the Panel could request from STS the number of patients free from any major adverse incident for each benchmark operation. Dr. Scholl responded that such a request could be added as item F on Tab 1: *freedom from all adverse events for each stat category and benchmark operation*. Agency staff agreed to add this language to the excel document. Dr. Scholl added that the Panel should request from STS the cost of doing the audits of 3 to 4 programs each year. Dr. Schiebler clarified that requesting all ten pediatric cardiac programs be evaluated every three years is a better way to frame the request. Dr. Blanchard noted that STS is an ideal option for auditing the programs due to STS knowledge of the relevant data. Dr. Scholl requested that Agency staff strike lines 25 and 27 from Tab 1 and only include line 26 (which requests the cost of audits for all ten programs once every three years).

Dr. Scholl discussed the program at Johns Hopkins All Children's Hospital in order to determine whether they are still active members of the Panel. Dr. Schiebler stated that if a program is not compliant with the standards, that program has advisory member only on the PCTAP per the current statute. Dr. Schiebler requested that the Agency Secretary confirm the noncompliance of Johns Hopkins and the status of the program as a member of the PCTAP. Dr. Scholl noted the PCTAP standards must be turned into rule in order to apply those standards to determine compliance of a program.

Dr. Scholl discussed the possible format of the STS report and noted Tabs 2 and 5 of the excel document are the format the Panel would like to utilize in the final display of the data. In particular, Tab 5 shows many of the data elements already publicly reported by STS, and the

breakout of data elements by individual operations on Tab 2 would be an ideal addition. Dr. Scholl noted the Agency website vendor would be able to format the data into a user-friendly layout. Dr. Jorge McCormack stated his support for obtaining as much data as the Panel wishes and presenting a simplified form to the public, with links to the complex data for those who want to see more detailed data sources. Dr. Scholl agreed that this is essentially the plan of the Panel.

Dr. Scholl discussed Tab 4, which demonstrates a layout for ACC data. He stated that a Florida report will have to be requested from ACC. Dr. McCormack noted the ACC data would not be as granular as STS data. Dr. Ringewald stated that the test metrics for ACC data are not validated, and that publicly reporting unvalidated data is concerning. Dr. Scholl agreed that the Panel needs to discuss the validation of these metrics as part of the decision process for the data request. Members noted that Dr. David Nykanen (not present) is the subject matter expert to consult. Dr. McCormack added that acute complications are not common with electrophysiology (EP), but recurrence rates are more relevant to EP and yet not widely reported. Dr. Hannan suggested sending STS table reports to AHCA so that AHCA may collate the data. This would sidestep the necessity of any intervention from STS. Dr. Hannan noted this approach is utilized with U.S. News and World Reports. Dr. Scholl agreed that this solution should be considered pending whether STS can meet the Panel's data request and how much the STS data will cost.

Dr. Schiebler stated the letter to STS is a top priority and suggested Dr. Scholl and Dr. Nykanen work with Dr. Blanchard as an intermediary to finalize the letter.

Dr. Asante-Korang asked for clarification of the article mentioned by Dr. Scholl concerning Johns Hopkins All Children's Hospital. Dr. Scholl agreed to have Agency staff circulate the article among members. Dr. Asante-Korang clarified that the heart institute at Johns Hopkins All Children's Hospital is not closed, but the surgical program is temporarily inactive.

Members requested that the next meeting of the subcommittee discuss the scalability of the real times outcomes. Dr. Hannan agreed to discuss this issue and share ideas at the next meeting. Dr. Scholl discussed the use of disparate EHRs by the ten pediatric cardiovascular programs and suggested that perhaps by collaborating with a vendor like Cardio Access, data may be better obtained. Dr. Scholl asked that this topic be added to the agenda for the next subcommittee meeting.

Dr. Schiebler stated that he would ask Senator Gayle Harrell to recommend that Panel term limits begin with the implementation of the new law on July 1, 2019.

Public Comment: There were no public comments.

Meeting Summary and Next Steps:

Meeting Follow-up:

- Agency staff will add to the agenda of the next FULL Panel Meeting: (1) a discussion of site visits; (2) an update from the Agency on the rule making process; and (3) an update from the Agency on the term limits outlined in the new legislation.
- Agency staff will circulate a draft of the rulemaking recommendations *before* the next full Panel meeting.
- Agency staff will add as item F on Tab 1 of the Excel Document: *freedom from adverse events for each stat category and benchmark operation*.
- Agency staff will strike lines 25 and 27 from Tab 1 and only include line 26 (which requests the cost of audits for all ten programs once every three years).
- Agency staff will circulate to Panel members the article submitted by Dr. Scholl concerning Johns Hopkins All Children's Hospital.
- Agency staff will add to the next subcommittee meeting agenda a discussion of the scalability of real-time outcome data.

Adjourn: Dr. Scholl adjourned the meeting at 6:41 PM.