

Minutes from Pediatric Sedation Research Consortium (PSRC) Meeting 2009

Please see other included material such as published reports that are mentioned in the minutes below.

Dr. Joseph Cravero started the meeting with a discussion of the recent events surrounding the PSRC. He outlined the fact that the PSRC is now a part of the Society for Pediatric Sedation, supported by the Society and considered the research arm of the Society.

He mentioned that when the Consortium started we had a grant from the National Patient Safety Foundation that helped set up the database and pay for maintenance. At this point we are now depending on institutional memberships to fund the ongoing operations. Joye Stewart, Association Manager for the Society, mentioned the current finances. We had budgeted \$45,000 for all data management and statistical support services. We currently have raised about \$13,000 from our institutional members. Fortunately, we have not had a lot of expenses and as long as statistical expenses remain under control we should be able to maintain ourselves for this year.

Dr. Cravero then discussed his concern that we will need to “make a call” on the institutions that are sending data to the Consortium but are not institutional members (or individual members) of the PSRC or SPS. He stated that he needed to hear from these institutions to arrange either an institutional membership or an individual membership that will allow us to keep collecting the patient information from each institution. Dr. Cravero emphasized the fact that he did not want finances alone to get in the way of membership. In any case, by the end of the calendar year, institutions that have not communicated with Dr. Cravero personally or the SPS membership department will not be active participants in the PSRC project.

Dr. Cravero then pointed out that all information on the institutional memberships in the Consortium can be obtained from the website www.pedsedation.org under the “Institutional Memberships” tab. A brief conversation about the cost and types of memberships ensued.

Dr. Cravero then reviewed some of the most recent information on the data that has been collected from the PSRC.

- * Number of Records 9/2/2007 - 9/1/2008 = 33,674
- * Number of Records 9/2/2008 - 5/15/2009 = 23,627
- * Total Records since the 2007 edition = 57,301
- * Total Records in the 2004 to 2007 edition = 88,672

Dr. Cravero emphasized that the PSRC has been consistently collecting about 30,000 records per year. This opens up the option to think about specific issues that we wish to evaluate going forward. Each year, the PSRC could consider the next issue they wish to pursue and collect 30,000 records with information specific to that problem.

The next discussion was about the most recent project – since September of 2008, the PSRC has included information on the height and weight of each child. This is not a mandatory field, the data was reviewed on how many of the submitted records contained this information.

The length and height of the child was recorded in 8,259 cases yielding a rate of 36.6% of records. Dr. Cravero recognized that his own institution (DHMC) has not been very good at recording this data and he will endeavor to do better. He encouraged other investigators to do the same. Dr. Cravero then asked Mike Beach, MD, the statistician for the project, to comment on any preliminary information he had on the patients that are rated as “obese” by BMI vs. the entire database. Dr. Beach mentioned that he believes the data reveals a trend toward

increased incidence of adverse events in the obese subgroup, but the differences are likely small and we need more information before making any conclusions.

Data on the numbers of records submitted by various organizations was presented. See the enclosed Excel spread sheet.

At this point there was an open discussion as to whether or not to continue with BMI data collection for the next year – or to switch to another interesting factor, or cofactor. The group overwhelmingly wanted to continue with the data collection on obesity for now.

Latest data on rates of complications in the last two years, total of 57,000 records, was presented. Rates were noted to be similar to past reports, perhaps with some improvement overall.

Then reviewed was the last couple of papers that have been published from the Consortium including the report on propofol sedation published in *Anesthesia and Analgesia*. Dr. Cravero described the review process and the importance of this paper from the perspective of anesthesiologists. He included the fact that the paper had received a special review by the editor at the most recent Society for Pediatric Anesthesia meeting. He emphasized that this is having BIG impact. Some data from the study was presented.

- * Data submitted by 37 institutions - 49,836 sedation encounters utilizing primarily propofol

- * July 1 2004 - Sept 1, 2007

- * Data evaluated for complications and effectiveness of sedation

Various data from the paper were presented and discussed – please see paper enclosed

The data from the two codes that occurred in this cohort was reviewed.

Dr. Michael Mallory then reviewed his publication on the comparison of propofol vs. pentobarbital sedation for MRI imaging. He described a long and involved editorial process. The paper was ultimately accepted by the journal *Pediatric Anesthesia*.

At this point in the meeting, Dr. Cravero invited Dr. Charlie Coté (an editor for *Pediatric Anesthesia*) to comment on the papers that have resulted from Consortium data, and to give insight into what might be helpful for future projects. Dr. Cote´ noted that important questions should be posed. He thought the obesity data would be very interesting and that the impact of monitors such as CO2 monitoring would be helpful.

The next review was changes to the data collection tool in the last year, as follows:

- * Added new question: What is the length/height of the child in centimeters? Entry to one tenth cm accepted (e.g. 50.5). Enter -999 if not known.

- * Added new primary (and coexisting) diagnosis category: "Obstructive sleep apnea". If chosen ask follow-up question with the following response choices:

 - Documented OSA on sleep study

 - Pt uses CPAP/ BiPAP at home

 - Snoring with interruptions of breathing

 - Other

- * Remove snoring and sleep apnea as response choices from primary and coexisting upper respiratory problems.

- * Add new NPO question: What was the NPO status (in hours) of the time of sedation with respect to formula or milk?

- * Eliminate complication "inadequate sedation"

- * Add new complication "Procedure could not be completed due to problems related to sedation"

- * If complication "Allergic reaction" chosen ask follow-up question with following response choices:

 - Rash non-raised

Urticaria without systemic symptoms

Rash/urticaria with respiratory symptoms

Anaphylaxis

* Complication hypothermia : added text "(temperature < 35 C)"

* Complications laryngospasm : added text "(implies complete or nearly complete lack of air movement)"

Dr. Cravero then made several points about the current status of data audits:

* Generally, the PSRC is doing quite well with improved rates of reporting - approximately 85% of institutions reporting.

* Starting in September 2009, data will not count in research database if no audits are reported.

If institution is up to date in reimbursement, the Consortium will continue to generate reports.

Finally, Dr. Cravero presented a paper from a group of emergency medicine study groups that looked at the appropriate definition for adverse events in pediatric sedation. This paper emphasized the observation or recording of interventions in addition to recording of physiological data such as low O2 saturations. The methodology is not unlike what the PSRC has tried to employ in looking at both physiological and "unplanned" interventions. There was no enthusiasm in the group to revisit the current definitions and "retool" the data collection tool.

The meeting was adjourned.

Number Finalized	Site Name	SiteLocation
8622	Children's Healthcare of Atlanta Scottish Rite Campus	Atlanta, GA
6863	Kosair Children's Hospital, University of Louisville	Louisville, KY
6563	Helen DeVos Children's Hospital	Grand Rapids MI
4343	Children's Healthcare of Atlanta Egleston Campus	Atlanta, GA
3898	Rainbow Babies and Children's Hospital	Cleveland, Ohio
3351	Children's Memorial Hospital	Chicago, Il
3130	Columbus Children's Hospital	Columbus, OH
2433	Kentucky Children's Hospital	Lexington, KY
2257	Children's Hospital of Alabama	Birmingham, AL
2245	Palmetto Health Richland Memorial Hospital	Cola, SC
1865	Backus Children's Hospital	Savannah, GA
1674	Alfred I Dupont Children's Hospital	Wilmington DE
1527	University of Virginia	Charlottesville, VA
1217	Eastern Maine Medical Center	ME
1098	Chris Evert Childrens Hospital	Fort Lauderdale, FL
	Children's Mercy Hospital - Emergency Department	
1055		Kansas City, MO
990	Medical University of South Carolina	Charleston, SC
836	Dartmouth Hitchcock Medical Center	Lebanon, NH
	Jackson Memorial Hospital, University of Miami School of Medicine	
758		Miami, FL
692	The Children's Hospital at Providence	Anchorage, AK
595	Avera Mckennan Hospital	Sioux Falls, SD
464	Gundersen Lutheran	LaCrosse, WI
376	Cape Fear Valley Medical Center	Fayetteville, NC
260	Joe DiMaggio Children's Hospital	Hollywood, FL
165	Children's Memorial Hospital Emergency Dept.	Chicago, Il
16	East Tennessee Children's Hospital	Knoxville, TN
7	Yale New Haven Children's Hospital	New Haven, CT
1	UMass Memorial Medical Center	Worcester, MA
57301	Total	

Note:

Data collection into 2004 edition started 7/14/04 and stopped 9/1/07

Data collection into 2007 edition started 9/2/07

Number finalized records: 9/2/2007 thru 9/1/2008 33,674

Number finalized records: 9/2/2008 - 5/15/2009 23,627

Total number finalized records in 2007 edition 57,301

Total number finalized records in 2004 edition 88,672

		Records/ Week
Number of weeks in 2007 edition (to 5/15/09)	88	651 2007 edition
Number of weeks in 2004 edition	163	544 2004 edition

Number of records marked for review (as of 5/15/09) 873

New Question as of 9/15/2008:

What is the length/height of the child in centimeters?
Entry to one tenth cm accepted (e.g. 50.5). Enter -999 if not known.

Number supplying length / Number records w/question available 8,259 / 22,546
Percent supplying length 36.6