PSRC Database Revision Guidelines

The Pediatric Sedation Research Consortium (PSRC) database requires revisions to make sure it addresses research and quality improvement needs of the society and its members. The goal of these guidelines is to establish a process for revising the database that closely involves research committee members.

Criteria for Making Revisions

Revisions will be based on relevant survey results from institutions that contribute data to the database, review of database free text entries, and review of most common, least common, and median entries of variables in each category (e.g., primary diagnosis, procedures, sedatives/analgesics, etc.).

To help determine the appropriate thresholds for adding new variables (or removing old variables), the following tables give examples of most common, least common, and median entries for all variables in each category in the database:

	Procedure(s) performed	Entries since Apr 2020	Entries per year
Most common	MRI/MRA/MRV/MRS LP (chemotherapy) Bone marrow biopsy/aspirate	34,462 16,257 4572	11,487 5419 1524
Least common	Tonometry Cardiac catheterization/EP study/ablation Laryngoscopy	9 4 2	3 1 <1
Median		562	187

	Primary reason for procedure	Entries since Apr 2020	Entries per year
Most common	Leukemia Seizure disorder Neurological, NOS	15,913 7261 6216	5304 2420 2072
Least common	Type 2 DM Trisomy 18 Bradycardia	1 1 0	<1 <1 <1
Median		210	70

	Co-existing medical problems	Entries since Apr 2020	Entries per year
Most common	Developmental/behavioral, NOS Autism spectrum disorder Asthma/reactive airway disease	4665 4295 4060	1555 1431 1353
Least common	Ankylosing spondylitis Foreign body, upper airway Foreign body, upper GI	1 0 0	<1 0 0
Median		146	48

	Sedatives/analgesics	Entries since Apr 2020	Entries per year
Most common	Propofol Midazolam Fentanyl	71,687 24,729 15,734	23,895 8243 5244
Least common	Hydromorphone Etomidate Chloral hydrate	67 4 0	22 1 0
Median		1277	425

	Events	Entries since Apr 2020	Entries per year
Most common	Airway obstruction, partial Hypoxia Excessive secretions	4100 2809 1985	1366 936 661
Least common	Hypothermia Cardiac arrest Death	4 1 1	1 <1 <1
Median		67	22

	Interventions (pre-emptive)	Entries since Apr 2020	Entries per year
Most common	Supplemental oxygen Neck roll Child life specialist	55,459 31,630 24,523	18,486 10,543 8174
Least common	Laryngospasm notch Chest compressions Flumazenil	0 0 0	0 0 0
Median		108	36

	Interventions (in response)	Entries since Apr 2020	Entries per year
Most common	Repositioning (jaw thrust) Suction Supplemental oxygen	4926 2624 1504	1642 874 501
Least common	Vasopressor, IV Hydroxyzine Other local/topical anesthetic	1 0 0	<1 0 0
Median		53	17

When deciding a <u>threshold to eliminate/add variables</u> the following factors should be considered:
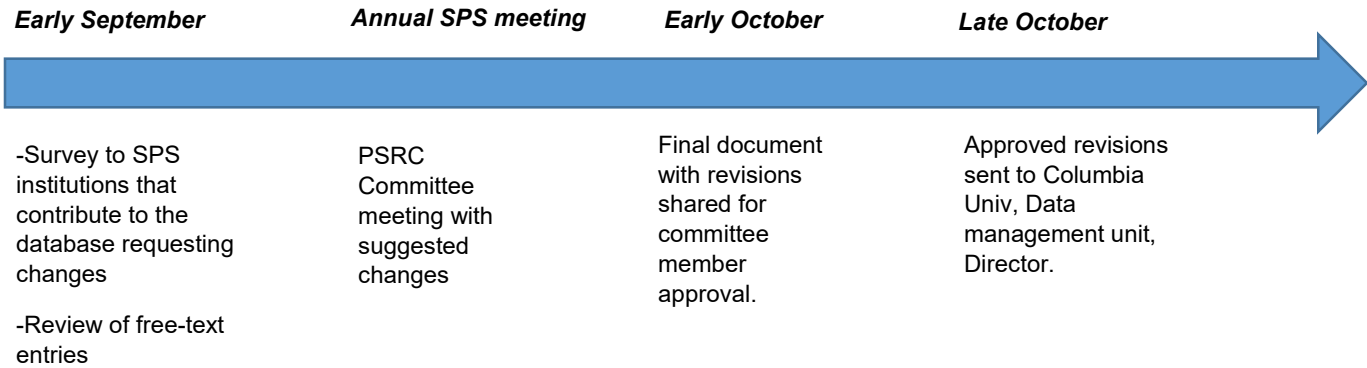
- Frequency of the variable in relation to most common, least common, and median of all variables in a category (e.g., primary diagnosis, procedures, sedatives/analgesics, etc.)
- Nature of the variable. For example, critical events and interventions have very low frequency but are important safety outcomes in sedation.
- Variables added for research should be part of a formal research proposal approved by the scientific committee.

Frequency of database revisions

Major database revisions significantly impact database analysis because they make it difficult (if not impossible) to compare different versions of the database. Therefore, <u>major database revisions should happen NO more often than every 5 years.</u>

Minor database revisions that do not significantly impact database analysis (i.e., adding/eliminating a few variables in a category) should happen as needed based on research proposals or members' feedback.

Timeline of database revisions

Early September   *Annual SPS meeting*   *Early October*   *Late October*

-Survey to SPS institutions that contribute to the database requesting changes

-Review of free-text entries

PSRC Committee meeting with suggested changes

Final document with revisions shared for committee member approval.

Approved revisions sent to Columbia Univ, Data management unit, Director.

Criteria to approve database revisions

• SPS Research Committee members will be given 1 week to e-mail their vote to the Chair/Vice Chair to approve the final document.

• The changes will be approved based on ≥ 2/3 majority of the votes AND ≥ 50% of SPS Research Committee members' votes cast.

END.