PSRC Recommendations for Reporting Events and Interventions

The Pediatric Sedation Research Consortium (PSRC) employs and **intervention-based event reporting paradigm.** This means events are only documented and considered to be clinically significant if associated with an intervention performed in response to said event.

The severity of documented events can be designated based on the nature of the event itself, or based on the intervention associated with the event. We recommend classifying events into one of three categories:

1. **Critical event** — Life-threatening, requires immediate attention and intervention.
2. **High risk event** — Requires advanced level of skill and/or capacity to manage, and has potential to become a critical event if untreated.
3. **Event** — Any other event that does not meet the criteria for a critical or high risk event.

A **critical event** includes the following:

1. Death
2. Cardiac arrest
3. Clinical/radiologic suspicion for pulmonary aspiration
4. Allergic reaction, anaphylaxis
5. Any event (other than the aforementioned) requiring:
    a. ETT/NTT
    b. Supraglottic/LMA
    c. Chest compressions
    d. Epinephrine, IV or IM
    e. Muscle relaxant/paralytic agent
    f. Vasopressor, IV (not incl. epi)
    g. RRT, code team, or emergency anesthesia

An example of how **critical events** would be reported:

Critical event	**n (%) N=30,000**
Clinical/radiologic suspicion for pulmonary aspiration	5 (0.02)
Cardiac arrest	1 (0.003)
Death	1 (0.003)
Airway obstruction, complete[1]	50 (0.2)
Apnea[2]	100 (0.3)
Hypoxia[3]	200 (0.7)

[1]Requiring ETT/NTT, muscle relaxant/paralytic agent, and/or chest compressions
[2]Requiring ETT/NTT, and/or muscle relaxant/paralytic agent
[3]Requiring ETT/NTT, epinephrine, IV or IM, and/or RRT, code team, or emergency anesthesia called.

A **high risk event** includes the following:

1. Apnea
2. Airway obstruction, complete
3. Laryngospasm
4. Seizure
5. Any event (other than the aforementioned) requiring:
    a. BMV
    b. CPAP/PEEP
    c. Oral airway
    d. Laryngospasm notch
    e. Additional sedative to relieve laryngospasm
    f. Atropine
    g. Flumazenil
    h. Naloxone
    i. Unplanned hospital admission or increase in level of care

An example of how **high risk events** would be reported:

High risk event	**n (%)** **N=30,000**
Apnea	240 (0.8)
Airway obstruction, complete	150 (0.5)
Laryngospasm	150 (0.5)
Seizure	30 (0.1)
Hypoxia[1]	300 (1)
Bradycardia[2]	30 (0.1)

[1]Requiring BMV, oral airway, naloxone
[2]Requiring atropine, unplanned hospital admission or increase in level of care

An event can be attributed to only one of the three categories; each event occurrence is exclusive to a single category. It can only be a critical event, high risk event, or an event. You cannot have an occurrence that is both a critical and high risk event, nor can you have an occurrence that is both a high risk event and an event.

Investigators may wish to study outcomes that reflect specific systems (e.g. airway/breathing, cardiovascular). Events and interventions are already categorized in the database by system. One way to report these outcomes would be to report only the events specific to the system of interest in the categories of critical events, high risk events, and events (e.g. airway/breathing critical events, airway/breathing high risk events, airway/breathing events). For example, airway/breathing high risk events could be reported as follows:

Airway/breathing high risk event	**n (%)** **N=30,000**
Apnea	240 (0.8)
Airway obstruction, complete	150 (0.5)
Laryngospasm	150 (0.5)
Hypoxia[1]	300 (1)

[1]Requiring BMV, oral airway, naloxone

Alternatively, investigators may report each system-based event and the frequency of interventions associated with each type of event, without using the designations of critical or high risk. For example:

Event	n (%) N=30,000	Intervention	n (%) N=30,000
Apnea	100 (0.3)	BMV Supplemental oxygen	100 (0.3) 100 (0.3)
Airway obstruction, complete	50 (0.2)	ETT/NTT Repositioning Supplemental oxygen	5 (0.02) 50 (0.2) 50 (0.2)
Laryngospasm	15 (0.05)	Laryngospasm notch Muscle relaxant/paralytic agent	15 (0.05) 5 (0.02)
Hypoxia	500 (0.7)	ETT/NTT Supplemental oxygen Repositioning	10 (0.03) 500 (0.7) 500 (0.7)
Wheezing/bronchospasm	100 (0.3)	Supplemental oxygen Albuterol Epinephrine, IV or IM	10 (0.03) 90 (0.3) 10 (0.03)

Note that the number of interventions listed for one event may not equal the number of events due to the fact that multiple interventions can be performed in response to one single event.

Here is an example of how events (that are neither critical or high risk) could be reported:

Event	n (%) N=30,000	Intervention	n (%) N=30,000
Excessive secretions	600 (2)	Suction Repositioning	600 (2) 50 (0.2)
Inadequate depth of sedation	300 (1)	Unanticipated pause in procedure Discontinued procedure Aborted procedure Child Life Specialist Physical restraints	240 (0.8) 30 (0.1) 30 (0.1) 240 (0.8) 120 (0.4)
Vomiting	300 (1)	Suction Ondansetron Unanticipated pause in procedure	200 (0.7) 100 (0.3) 300 (1)

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