Emergency Physician–Administered Propofol Sedation: A Report on 25,433 Sedations From the Pediatric Sedation Research Consortium

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Study objective: We describe the adverse events observed in a large sample of children sedated with propofol by emergency physicians and identify patient and procedure characteristics predictive of more serious adverse events.

Methods: We identified sedations performed by emergency physicians using propofol as the primary sedative, included in the Pediatric Sedation Research Consortium database from July 2004 to September 2008. We describe the characteristics of the patients, procedures, location, adjunctive medications, and adverse events. We use a multivariable logistic regression model to identify predictors of more serious adverse events.

Results: Of 25,433 propofol sedations performed by emergency physicians, most (76%) were performed in a radiology department. More serious adverse events occurred in 581 sedations (2.28%; 95% confidence interval 2.1% to 2.5%). There were 2 instances of aspiration, 1 unplanned intubation, and 1 cardiac arrest. Significant predictors of serious adverse events were weight less than or equal to 5 kg, American Society of Anesthesiologists classification greater than 2, adjunctive medications (benzodiazepines, ketamine, opioids, or anticholinergics), nonpainful procedures, and primary diagnoses of upper respiratory illness or prematurity.

Conclusion: We observed a low adverse event prevalence in this largest series of propofol sedations by emergency physicians. Factors indicating greater risk of more serious adverse events are detailed. [Ann Emerg Med. 2011;57:462-468.]

Please see page 463 for the Editor's Capsule Summary of this article.

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0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2011.03.008

SEE EDITORIAL, P.470.

INTRODUCTION

Background

Propofol sedation outside of the operating room is now commonplace, as documented by multiple studies in various clinical settings.[1-6] The largest of these, a 2009 report from the Pediatric Sedation Research Consortium,[3] characterized 49,836 pediatric sedations for which propofol was used as the primary sedative. Emergency physicians supervised 36% of the cases in that report. Although there was no difference in reported respiratory events between anesthesiologists and other providers, outcomes by emergency physicians were not explicitly delineated.

Smaller studies suggest that propofol is more effective than other fast-acting sedatives, with a similar or superior adverse event profile.[7-9] Documenting the safety profile of propofol by emergency physicians has been limited by small sample sizes, inconsistent definitions of adverse events, and the variability of patient populations. Severe adverse events, such as laryngospasm and aspiration, are so rare that their study requires extremely large samples.[2,3,10,11] Previous pediatric emergency department (ED) studies have reported adverse airway events ranging from 0.6% to 30% of propofol sedations, underscoring the importance of clear definitions.[1,4,12,13] Emergency physicians are increasingly called on to sedate outside the ED (eg, radiology, sedation services).[14-16]

Importance

Given the growing popularity of propofol administration by emergency physicians, it is important to accurately characterize the adverse event profile associated with its use by these providers.

Editor's Capsule Summary

What is already known on this topic

Emergency physicians frequently administer propofol to accomplish deep procedural sedation.

What question this study addressed

What is the adverse effect profile of propofol administration by emergency physicians?

What this study adds to our knowledge

Serious adverse effects were rare and without adverse outcome in this series of 25,433 pediatric propofol administrations by emergency physicians. Emergency physician–led sedation services composed the majority of sedations in this sample.

How this is relevant to clinical practice

This large study strongly corroborates the safety of propofol administration by emergency physicians.

Goals of This Investigation

We wished to describe the adverse events observed in a large sample of children sedated with propofol by emergency physicians and to identify patient and procedural factors that predict the more serious adverse events.

MATERIALS AND METHODS

Study Design

We analyzed consecutive pediatric propofol sedations overseen by emergency physicians from the Pediatric Sedation Research Consortium database between July 2004 and September 2008.

Data Collection and Processing

The Pediatric Sedation Research Consortium data collection methodology has been detailed in a report of its first 30,000 sedations.[17] The Pediatric Sedation Research Consortium data sharing group comprises 37 self-selected locations, including children's hospitals (both within and separate from general hospitals), and general/community hospitals (Appendix). Participating institutions were required to obtain institutional review board approval for data collection, identify a primary investigator, and agree to a standardized methodology for consecutive data collection.

The Pediatric Sedation Research Consortium uses a Web-based data collection tool (see "Web Tool Content" at http://www.pediatricsedationrc.org) composed of 25 primary screens and a dynamically generated interface for each subsequent question according to previous responses.

The Pediatric Sedation Research Consortium database records demographic data, the location and nature of the procedure performed, the use of adjunctive medications, and the presence or absence of the following adverse events: agitation/delirium, airway obstruction (no air movement for ≥15 seconds despite respiratory effort), allergic reaction, apnea (no respiratory effort for ≥15 seconds), aspiration (persistent cough, obstruction, or respiratory distress, or new oxygen requirement that exists after recovery from sedation—associated with observed gastric contents in the mouth or active vomiting at some point during the sedation), cardiac arrest, coughing, death, oxygen desaturation (less than 90% for ≥30 seconds: use ≈5% below baseline if baseline below 90%), emergency anesthesia consultation, hypothermia, inadequate sedation, intravenous line–related problem, laryngospasm (stridor or airway obstruction not responsive to airway repositioning), prolonged recovery time, prolonged sedation, secretions excessive enough to require treatment, unexpected change in pulse rate or respiratory rate or blood pressure of greater than or equal to 30%, unexpected need for bag-valve-mask ventilation, unintended deep level of sedation, unplanned admission to hospital or increase in level of care, unplanned intubation, unplanned use of reversal agents, vomiting (not associated with a gastrointestinal procedure), wheezing, and "other." As with all screens in the tool, questions included logic that prompted further questions to clearly define the nature of the adverse event selected.

Pediatric Sedation Research Consortium primary investigators are required to monitor the accuracy of the data entered. They must perform audits on 10 charts every 6 months and contrast an accurate independent count of sedations performed in their institution versus the number submitted to the Pediatric Sedation Research Consortium. Any discrepancies require a complete review of the data-gathering methodology at the institution.

Outcome Measures

We defined more serious adverse events as airway obstruction, desaturation, apnea, laryngospasm, aspiration, unplanned admission, cardiac arrest, emergency call for anesthesiologist, unplanned intubation, or death.

Primary Data Analysis

We descriptively report the characteristics of our patients, their sedations, and their adverse events.

We developed a multivariable logistic regression model to identify predictors of the more serious adverse events. We chose the following candidate predictor variables according to their demonstrated or physiologically plausible association with such events: age, weight, American Society of Anesthesiologists physical status of greater than or equal to 3, sex, painful procedure (defined as orthopedic procedures other than simple casting; procedures in which the skin was punctured, incised, or repaired; or procedures involving the insertion or manipulation of a tube or other device into or below the surface of the skin), nil per os solids for less than 6 hours, nil per os clear liquids for less than 2 hours, adjunctive ketamine, benzodiazepines, opioids,

anticholinergics, and primary diagnoses of upper respiratory disease, gastrointestinal disease, and prematurity. Given the expected colinearity of age and weight (r=.870), we included only weight in the model and for simplicity dichotomized it at less than or equal to 5 kg according to our experience and perception of clinical usefulness.

Given that 6.0% of sedation records (1,523/25,433) had missing data for 1 or more candidate predictors, we performed listwise deletion of these entries. Descriptive information for both full and effective samples was essentially identical, introducing trivial, if any, sampling bias. None of the deleted sedations included occurrences of cardiac arrest, unplanned intubation, or death.

We performed statistical analyses with SAS (version 9.2; SAS Institute, Inc., Cary, NC) and Stata SE 11 (StataCorp, College Station, TX).

RESULTS

Characteristics of Study Subjects

The Pediatric Sedation Research Consortium database recorded 123,938 sedations from July 2004 through September 2008, and of these, 25,469 primarily used propofol and were administered by emergency physicians. We excluded 36 subjects for being aged 21 years or older, leaving 25,433 for our study sample. Demographics and sedation characteristics are shown in Table 1, with most children relatively young (Figure). Of the 19,415 sedations that were performed in a radiology department, 17,602 were for magnetic resonance imaging (MRI) scans.

We observed 1 or more adverse events in 1,483 sedations (5.83%; 95% confidence interval [CI] 5.55% to 6.13%), with 1 or more serious events in 581 sedations (2.28%; 95% CI 2.10% to 2.48%) (Table 2). There were no cases of death and no instances in which the procedure could not be completed because of a sedation-related problem.

The 2 episodes of aspiration and 1 cardiac arrest are described in greater detail in Table 3. None of these subjects required intubation. We did not observe aspiration in any of the 302 (1.19%) sedations in which clear liquids had been consumed within 2 hours, nor in any of the 452 (1.78%) in which solids had been consumed within 6 hours.

Our multivariable model included the 23,910 records with complete data on all specified predictors and found that 9 of the 13 variables studied independently predicted the more serious adverse events (Table 4).

LIMITATIONS

The limitations of the Pediatric Sedation Research Consortium database have been enumerated in various articles.[3,9,17,18] We have attempted to minimize coding variability by using largely objective endpoints with clear definitions and through group discussion at yearly Pediatric Sedation Research Consortium meetings. Though the rules of the database dictate strict institutional anonymity, a bias toward

Table 1. Characteristics of sedation subjects (n=25,433 except where noted in parentheses).*

Characteristic	(n) (Except for continuous variables–age and weight–where median and range are provided)	%
Age, months	Median 36; IQR 20, 84; range <1–240	
Weight, kg	Median 16; IQR 11.2, 24; range 2–162	
Sex (25,416)		
Male	14,388	56.6
ASA physical status (24,737)		
1	9,806	39.6
2	10,928	44.2
3	3,703	15.0
4	298	1.2
5	2	0.01
NPO clear liquids, hours (25,353)		
<2	302	1.2
≥2–<4	6,599	26.0
≥4–<6	4,575	18.0
≥6–<8	3,426	13.5
≥8	10,462	41.3
NPO solids, hours (25,353)		
<2	12	0.1
≥2–<4	63	0.3
≥4–<6	377	1.5
≥6–<8	6,318	24.9
≥8	18,583	73.3
Painful procedure (24,663)	2,354	9.54
Propofol administration		
Bolus only	4,345	17.1
Infusion only	365	1.4
Bolus and infusion	20,679	81.3
Place of sedation		
Radiology	19,415	76.3
Sedation unit	4,346	17.1
Pediatric specialty clinic	918	3.6
Other location	343	1.4
ED	211	0.8
ICU	200	0.8
Adjunctive medications		
Opioids (either morphine or fentanyl)	1,619	6.4
Anticholinergics	629	2.5
Midazolam	443	1.7
Ketamine	401	1.6
Ketamine and midazolam	29	0.1
Pentobarbital and midazolam	20	0.1
Lorazepam	20	0.1
Etomidate	20	0.1
Methohexital	16	0.1
Pentobarbital	6	0.02
Chloral hydrate	6	0.02
Ketamine and lorazepam	1	<0.01

IQR, Interquartile range; *ASA*, American Society of Anesthesiologists; *NPO*, nil per os.
*Some sedation records indicate that sedation was performed in more than 1 location.

Table 2. Adverse events (full sample and effective sample).

	Full Sample (n=25,433)			Effective Sample in Model (n=23,910)		
Adverse Event*	**n**	**%**	**95% CI†**	**n**	**%**	**95% CI†**
More serious	**581**	**2.3**	**2.10–2.48**	**530**	**2.22**	**2.03–2.40**
Airway obstruction	245	0.96	0.84–1.08	230	0.96	0.84–1.09
Desaturation	239	0.94	0.82–1.06	215	0.90	0.78–1.02
Apnea	125	0.49	0.41–0.58	111	0.46	0.38–0.55
Laryngospasm	28	0.11	0.07–0.15	26	0.11	0.07–0.15
Aspiration	2	0.01	0–0.02	2	0.01	0–0.02
Unplanned admission	12	0.05	0.02–0.07	12	0.05	0.02–0.08
Cardiac arrest	1	<0.01	0–0.01	1	<0.01	0–0.01
Emergency anesthesia call	1	<0.01	0–0.01	1	<0.01	0–0.01
Unplanned intubation	1	<0.01	0–0.01	1	<0.01	0–0.01
Death	0			0		
Other adverse events	**902**	**3.55**	**3.32–3.77**	**818**	**3.42**	**3.19–3.65**
Unexpected need for PPV	349	1.37	1.23–1.52	309	1.29	1.15–1.44
Secretions requiring suction	237	0.93	0.81–1.05	221	0.92	0.80–1.05
Inadequate sedation	221	0.87	0.75–0.98	196	0.82	0.71–0.93
Coughing	220	0.87	0.75–0.98	206	0.86	0.74–0.98
Other complication (various text entries)	192	0.75	0.65–0.86	172	0.72	0.61–0.83
Unexpected physiologic change	153	0.60	0.51–0.70	142	0.59	0.50–0.69
Stridor	80	0.31	0.25–0.38	73	0.31	0.24–0.38
IV-related complication	38	0.15	0.10–0.20	36	0.15	0.10–0.20
Wheezing	26	0.10	0.06–0.14	24	0.10	0.06–0.14
Prolonged recovery	25	0.10	0.06–0.14	22	0.09	0.05–0.13
Vomiting	18	0.07	0.04–0.10	17	0.07	0.04–0.10
Prolonged sedation	17	0.07	0.04–0.10	17	0.07	0.04–0.10
Myoclonus	15	0.06	0.03–0.09	13	0.05	0.02–0.08
Unplanned admission	12	0.05	0.02–0.07	12	0.05	0.02–0.08
Seizures	8	0.03	0.01–0.05	8	0.03	0.01–0.06
Allergic reaction	7	0.03	0.01–0.05	6	0.03	0.01–0.05
Unintended too deep sedation	2	0.01	0–0.02	2	0.01	0–0.02
Reversal agent	2	0.01	0–0.02	1	<0.01	0–0.01
Hypothermia	1	<0.01	0–0.01	1	<0.01	0–0.01

IV, Intravenous catheter; *CI*, confidence interval limits.
*Any single sedation may have multiple corresponding events recorded.
†Negative confidence interval limits for percentages were replaced by 0.

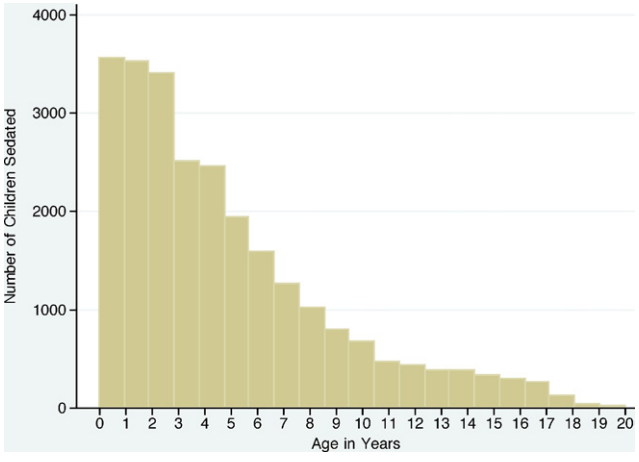

Figure. Histogram demonstrating distribution of ages of study subjects.

underreporting potentially embarrassing adverse event data could exist. We believe this to be unlikely because of our framework of data audits.

Pediatric Sedation Research Consortium institutions are self-selected and voluntarily submit their data, thus likely representing groups with superior experience, organization, and commitment to optimal sedation practice.

Because of the institutional anonymity characteristic of the database, we were unable to control for the practices and biases at particular institutions.

DISCUSSION

In this large sample of children sedated with propofol by emergency physicians, we observed a prevalence of adverse events that compares favorably with that of other sedatives commonly administered by emergency physicians and that of sedation administered by anesthesia providers. Our observed frequency of propofol-associated laryngospasm (0.11%) is less than that reported by Vespasiano et al[5] (0.27%) in their intensive care setting. This

Table 3. Characteristics of patients who had either aspiration or cardiac arrest.

Event	Age	Weight, kg	ASA Status	Procedure	Primary Diagnosis	NPO Status
Aspiration*	31 mo	9	I	MRI	Neurologic	Clears >2 h, solids >6 h
Aspiration†	5 y	48.5	I	MRI	Other (no text entry)	Clears >4 h, solids >6 h
Cardiac arrest‡	16 y	63	I	Colonoscopy	Gastrointestinal	Clears >4 h, solids >8 h
Unplanned intubation§	3 mo	5.1	II	MRI and CT scan	Transplant	Clears >2 h, solids >6 h

*The event occurred in recovery. The patient received positive-pressure ventilation and did not require escalation of care/admission.
†The event occurred before the procedure and caused its cancellation. Desaturation occurred and the patient received positive-pressure ventilation. The event was accompanied by an allergic reaction. He underwent an unplanned admission for the event.
‡The patient had apnea and profound bradycardia during the procedure that prompted chest compressions and administration of epinephrine. He responded promptly, was admitted to the pediatric ICU, and was discharged from the pediatric ICU the following day.
§The patient was being transferred from MRI to CT and received a 3 to 4 mg/kg bolus of propofol to maintain sedation during transport. The patient became apneic. Bag-valve-mask ventilation was difficult and the patient was intubated. He was taken to the pediatric ICU, where he was monitored, extubated, and discharged the following day.

Table 4. Multivariable logistic regression model with outcome set as the more serious adverse event.

Predictor Variable	Odds Ratio	(95% CIs for Odds Ratio)
Primary diagnosis upper respiratory	4.69	(2.51–8.75)
Primary diagnosis prematurity	4.02	(1.42–11.43)
Adjunctive benzodiazepine	3.09	(2.14–4.46)
Adjunctive ketamine	2.56	(1.51–4.33)
Anticholinergic given	2.51	(1.67–3.77)
Adjunctive opioids	2.23	(1.48–3.34)
Weight ≤5 kg	2.21	(1.15–4.23)
ASA ≥3	1.95	(1.60–2.37)
NPO solids for <6 h	1.43	(0.81–2.51)
Primary diagnosis gastrointestinal	1.31	(0.84–2.03)
Female sex	1.22	(1.02–1.46)
Procedure deemed painful	0.62	(0.42–0.92)
NPO clear liquids for <2 h	0.57	(0.21–1.55)

Pediatric Sedation Research Consortium report included 1 "code" event in a child who ultimately recovered completely within 24 hours. This rate of 0.4 code events per 10,000 sedation encounters is identical to the rate of code events in the larger study of propofol sedation from the Pediatric Sedation Research Consortium, which included anesthesiologists, intensivists, emergency physicians, and hospitalists.[3] The lack of any persistent adverse consequence or mortality in this report of more than 25 thousand cases reassures that this practice, among the practitioners involved in this investigation, approaches the high standards for sedation/anesthesia safety that have been set by other specialties.

Most of our sedations were performed by emergency physicians for elective diagnostic procedures outside of the ED, most notably in a radiology setting. Although this study thus cannot directly address the sedation issues unique to the ED setting or emergency procedures, it does strongly support the deep sedation skills of emergency physicians. Our data also document a national trend toward the increased administration of propofol by emergency physicians for elective procedures outside of the operating room, eg, radiology, sedation services. First reported by Bassett et al[1] in 2003, our much larger study confirms that such emergency physician–led sedation can be very safe, and we believe that such practice will continue to grow.

We observed that the risk of serious adverse events was approximately twice as high in children with substantial underlying illness (American Society of Anesthesiologists classification of greater than 2) or those who were very small (≤5 kg). These findings are consistent with those of other similar research.[3,10,19,20] Although American Society of Anesthesiologists physical status is far from an exacting description of a patient's condition,[21,22] it is widely used to gauge sedation or anesthesia risk. Other studies have also documented increasing risk associated with young age and small size.[17,23]

Additional factors demonstrating increased risk of serious adverse events included receipt of adjunctive anticholinergics or a primary diagnosis of either upper airway disease or prematurity. These factors match well with previous reports concerning propofol sedation and pediatric sedation in general. A recent meta-analyses by Green et al[24] found an increased risk of adverse events when anticholinergics were used with ketamine. Given the nature of the Pediatric Sedation Research Consortium database, however, it is difficult to know whether to attribute this risk to prophylactic use of anticholinergics in the context of more risky patients (eg, concurrent upper respiratory infections, baseline difficulty managing secretions) or to the drugs themselves.

Vespasiano et al[5] also identified upper respiratory illness as a predictor for adverse events. Sanborn et al[25] observed that the single patient factor predicting an increased of adverse events during computed tomography (CT)/MRI sedation was airway/pulmonary pathology. Our data are thus consistent with others, suggesting that airway issues and prematurity should be considered when sedation risk is stratified.

Our finding that children undergoing painful procedures were less likely to experience adverse events likely has a multifaceted explanation. Because propofol lacks analgesic properties, it is possible that despite sedation, procedural stimulation increases the respiratory activity and arousal of the patient, thus counteracting respiratory depression. Another possibility is that painful procedures (eg, lumbar puncture) are generally shorter than the

most common nonpainful procedures (MRI scans), providing a shorter opportunity for adverse events to occur. Finally, many painful procedures may tolerate some degree of movement, whereas imaging studies such as MRI scans require immobility and thus perhaps a deeper level of sedation. Regardless of the specific basis for the finding, our data suggest that painless procedures pose greater risk than those that involve significant stimulation.

The concurrent administration of benzodiazepines, ketamine, and opioids was associated with a greater risk of adverse events. This finding is consistent with those of previous studies, including the sentinel study by Cote et al,[26] which found that a common element among sedation accidents was the coadministration of multiple sedatives. A recent meta-analysis by Green et al[19] likewise found that adding benzodiazepines to ketamine sedation increased the likelihood of adverse outcomes.

In summary, we report the largest sample of propofol sedations performed by emergency physicians. The prevalence of observed adverse events compares favorably to that in reports concerning other sedatives commonly administered by emergency physicians, suggesting a wide margin of safety for this form of sedation. We have identified multiple factors predicting greater risk of more serious adverse events. Finally, our data corroborate the success and safety of emergency physician sedation in a number of sites outside the ED.

Supervising editor: Steven M. Green, MD

Author contributions: MDM, ALB, and JPC conceived the study design and wrote the article. MDM and DJY performed data analysis. All authors contributed substantially to its revision. MDM takes responsibility for the paper as a whole.

Funding and support: By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article that might create any potential conflict of interest. See the Manuscript Submission Agreement in this issue for examples of specific conflicts covered by this statement. Financial support for the establishment of the Pediatric Sedation Research Consortium database was provided by a grant from the National Patient Safety Foundation.

Publication dates: Received for publication November 4, 2010. Revision received February 25, 2011. Accepted for publication March 1, 2011.

Presented at the 2010 Pediatric Academic Societies meeting, May 2010, Vancouver, British Columbia, Canada.

Reprints not available from the authors.

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Appendix. Participating centers in the pediatric sedation research consortium.

Alfred I duPont Children's Hospital	Wilmington, DE
Avera McKenna Hospital	Sioux Falls, SD
Backus Children's Hospital	Savannah, GA
Cape Fear Valley Medical Center	Fayetteville, NC
Children's Healthcare of Atlanta, Egleston Campus	Atlanta, GA
Children's Healthcare of Atlanta, Scottish Rite Campus	Atlanta, GA
Children's Hospital of Alabama	Birmingham, AL
Children's Memorial Hospital	Chicago, IL
Children's Memorial Hospital Emergency Department	Chicago, IL
Children's Mercy Hospital ED	Kansas City, MO
Chris Evert Children's Hospital	Fort Lauderdale, FL
Columbus Children's Hospital	Columbus, OH
Dartmouth-Hitchcock Medical Center	Lebanon, NH
Eastern Maine Medical Center	Bangor, ME
Gundersen Lutheran	LaCrosse, WI
Helen DeVos Children's Hospital	Grand Rapids, MI
Jackson Memorial Hospital	Miami, FL
Joe DiMaggio Children's Hospital	Hollywood, FL
Kentucky Children's Hospital	Lexington, KY
Kosair Children's Hospital	Louisville, KY
Medical University of South Carolina	Charleston, SC
Palmetto Health Richland Memorial Hospital	Cola, SC
Rainbow Babies and Children's Hospital	Cleveland, OH
The Children's Hospital at Providence	Anchorage, AK
University of Virginia	Charlottesville, VA
Children's Hospital of Philadelphia	Philadelphia, PA
Children's Hospital Omaha	Omaha, NE
Children's Hospitals and Clinics	Minneapolis/St Paul, MN
Children's Mercy Hospital	Kansas City, MO
Denver Children's Hospital	Denver, CO
Dr. Alan R. Milnes, Inc.	Kelowna, British Columbia, Canada
East Tennessee Children's Hospital	Knoxville, TN
LeBonheur Children's Medical Center	Memphis, TN
New York University School of Medicine	New York, NY
Tod Children's Hospital	Youngstown, OH
UMass Memorial Medical Center	Worcester, MA
University of Florida	Gainesville, FL

Appendix E1. Data elements collected for the pediatric sedation research consortium.

Age
Weight
Sex
ASA status
Primary diagnosis
Coexisting diagnoses
Procedure(s) performed
Sedation location
Medications used
Monitor type
Provider responsible for sedation oversight
Provider delivering sedation
Provider monitoring the patient during sedation
Is the sedation supervisor performing procedure?
Planned airway management
Planned depth of sedation
Sedation start time
Procedure end time
Discharge time
NPO interval for liquids
NPO interval for solids
Complications
(Unexpected) airway management
Transport during sedation
Conditions produced during the procedure