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Incidence and Nature of Adverse Events During Pediatric Sedation/Anesthesia for Procedures Outside the Operating Room: Report From the Pediatric Sedation Research Consortium

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The authors have indicated they have no financial relationships relevant to this article to disclose.

ABSTRACT

OBJECTIVE. We sought to use a large database of prospectively collected data on pediatric sedation and/or anesthesia for diagnostic and therapeutic procedures to delineate the nature and the frequency of adverse events that are associated with sedation/anesthesia care for procedures that are performed outside the operating room in children.

METHODS. Data were collected by the Pediatric Sedation Research Consortium, a collaborative group of 35 institutions that are dedicated to improving sedation/anesthesia care for children internationally. Members prospectively enrolled consecutive patients who were receiving sedation or anesthesia for procedures. Data on demographics, primary illness, coexisting illness, procedure performed, medications used, outcomes, airway interventions, and adverse events were collected and reported on a Web-based data collection tool.

RESULTS. A total of 26 institutions submitted data on 30 037 sedation/anesthesia encounters during the study period from July 1, 2004, to November 15, 2005. Serious adverse events were rare in the institutions involved in this study; there were no deaths. Cardiopulmonary resuscitation was required once. Less serious events were more common with O_2 desaturation below 90% for >30 seconds, occurring 157 times per 10 000 sedations. Stridor and laryngospasm both occurred in 4.3 per 10 000 sedations. Unexpected apnea, excessive secretions, and vomiting had frequencies of 24, 41.6, and 47.2 per 10 000 encounters, respectively.

CONCLUSIONS. Our data indicate that pediatric sedation/anesthesia for procedures outside the operating room is unlikely to yield serious adverse outcomes in a collection of institutions with highly motivated and organized sedation services. However, the safety of this practice depends on the systems' ability to manage less serious events.

www.pediatrics.org/cgi/doi/10.1542/peds.2006-0313

doi:10.1542/peds.2006-0313

Key Words
pediatric sedation, adverse events, complications

Abbreviations
AAP—American Academy of Pediatrics
PSRC—Pediatric Sedation Research Consortium
ASA—American Society of Anesthesiologists
NPO—nil per os
CPR—cardiopulmonary resuscitation

Accepted for publication Apr 17, 2006

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OF ALL PATIENTS who receive sedation/anesthesia for diagnostic and therapeutic procedures, the pediatric population represents the highest risk, lowest error tolerance subgroup.[1,2] Pediatric patients require sedation/anesthesia more often than adults (you cannot ask a 2-year-old who is in pain to hold perfectly still for a 45-minute MRI scan). In addition, sedation/anesthesia for children must be "deeper" than that given adults to achieve acceptable "conditions" during a procedure. Most important, because of their physiology, children are at higher risk for respiratory depression and life-threatening hypoxia.[3] The study of this area of practice is confounded further by the fact that different provider groups will choose widely different techniques and depths of sedation/anesthesia to accomplish the same procedure. For example, some institutions give general anesthesia for MRI scans in children who are younger than 1 year, whereas others choose sedation with oral chloral hydrate. Furthermore, providers often describe their practice as "sedation" when it might easily meet the definition of "anesthesia."[4] This confusion is understandable because children can slip easily from one level to another, and one would have to be stimulating children constantly to test their responsiveness to truly define their state.[5]

Unfortunately, there is no quick solution to the problem of providing safe pediatric sedation to all patients who require this service. Even clinicians who adhere to current practice guidelines for pediatric procedural sedation seem to be at risk for causing iatrogenic injuries. One center implemented the American Academy of Pediatrics (AAP) guidelines for pediatric sedation and then prospectively followed 1140 children (aged 2.96 ± 3.7 years) who were sedated for procedures by nonanesthesiologists using a quality assurance tool; approximately 13% of the children received inadequate sedation. They also reported a 5.3% incidence of respiratory events, including 1 in which a child had apnea that required extensive resuscitation.[6] In the most commonly cited studies in the field of pediatric sedation safety, Coté et al[1,2] focused on analysis of critical events that occurred over many years through retrospective evaluation of national reporting systems. These investigations helped highlight that sedation events can lead to devastating injury and are largely preventable. Unfortunately, these studies were designed to look at adverse events only in the broadest sense (severe hypoxia, neurologic injury, etc) and had no way of estimating the frequency of these critical incidents. Other investigators have looked at adverse events in systematic reviews of their institutional practice. Pena et al[7] evaluated sedation safety in relatively small numbers (1180 patients) using a single venue (emergency department) through retrospective means. Most recently, Sanborn et al[8] investigated a larger cohort of patients who underwent radiology procedures, but, once again, this study came from a single institution and limited procedure types.

In considering adverse events in pediatric sedation, provider issues are a common theme. Unfortunately, investigations into sedation safety have been hampered by a distinct lack of cooperation among the various groups of providers who are involved in providing this care. Studies of pediatric procedural sedation/analgesia consist almost exclusively of small selected cohorts that are sedated using a single common method. Furthermore, there have been no large (tens of thousands of patients), multicenter studies with sufficient power to estimate the incidence of relatively rare events associated with morbidity or mortality as a result of sedation. Indeed, most studies that claim to describe "safe" sedation practice do so in error, because the patient cohorts (with only tens or hundreds of patients) clearly are statistically underpowered to provide information on occurrences that should have a frequency of no more than 1 in many thousands. In summary, existing literature fails to estimate the nature and the frequency of adverse events that are associated with sedation care.

To allow a more comprehensive approach to the study of the safety and the reliability of pediatric sedation, the Pediatric Sedation Research Consortium (PSRC) was created as a collaborative group of 35 institutions that are dedicated to improving sedation/anesthesia practice through sharing of prospective observational outcome data on procedural encounters. Research support from the National Patient Safety Foundation has funded the design, development, and management of the database.

In reporting the outcomes from our collective data, the PSRC hopes to provide data on meaningful outcomes that may help in improving the safety, efficiency, and effectiveness of sedation care. Similar research in the fields of anesthesiology, public health, and surgery has helped to focus patient safety research. Identifying specific threats to patient safety and correcting problems in equipment, standards, and training have reduced the anesthesia mortality rate and made the specialty of anesthesiology a leader in patient safety.[9] In this report, we present the findings from the first 30 000 pediatric procedural sedation/anesthesia encounters that were submitted to our database and associated adverse events: their incidence and demographics and the nature of the events themselves. There is no intention to draw cause and effect from the data in this particular report; rather, this is a description of the complications that have been submitted to date.

METHODS

Beginning in 2003, institutions across the United States, Canada, Europe, and Australia were invited to become part of a long-term data sharing collaborative involving the practice of pediatric sedation. Ultimately, 35 institu-

tions self-selected for involvement in the PSRC data sharing group. Of these institutions, all participated in meetings to plan data collection, but only 26 submitted data to the database. Those who did not participate cited issues with personnel and time required to enter data as factors that prevented participation. There were no specific selection criteria for participation in the consortium; however, any interested institutions were required to identify a primary investigator and agree to a standardized method for data collection and quality oversight from sedation sites at their location. As such, the PSRC consists of anesthesiologists, pediatric medical subspecialists, emergency physicians, pediatric intensivists, nurses, physician assistants, and health care research personnel who seek to improve continuously the quality, safety, effectiveness, and cost of pediatric sedation practice. The group maintains a prospective registry of patients who receive sedation at various locations within participating institutions. The Institutional Review Boards (or equivalents) of all participating centers approved this study. A list of participating institutions is presented in the acknowledgments.

The consortium first met as a study group in May 2003 in Chicago, IL. At that time, the group decided on a mission statement and priorities for data collection. Decisions were based on guidelines from the AAP,[3,10] the American Society of Anesthesiologists (ASA),[11] and the American College of Emergency Physicians[12] regarding sedation of pediatric patients; a review of the literature; and the collective opinion of the consortium members. A Web-based data collection tool was developed to collect the desired data elements. The general categories of data collected on each patient are outlined in Table 1. For a more detailed description of the logic and questions used in this data tool, please see "Web Tool Content" on the consortium Web site at www.pediatricsedationrc.org.

In addition to the key data elements to be collected, the group selected a taxonomy for data collection with standard definitions for each term used in the data collection tool. Subsequent to this meeting, a user manual for the Web tool was written to delineate terms and data required for each field (www.pediatricsedationrc.org).

These data were entered directly into the study database using the Web-based data collection system developed by the BioInformatics group at Dartmouth Medical School. The Web-based tool consisted of 25 primary screens. The data collection system is designed to ask 1 question per screen, dynamically generating an interface for each subsequent question on the basis of the responses from the previous question. Data entry was accomplished by clicking on appropriate check boxes and radio buttons, with free text added as needed. The development of standard answer sets allowed clear coding and interpretation of responses, as well as rapid movement through the survey. A survey of the participating centers revealed that data entry requires ~3 to 4 minutes for an average patient. The system includes computer code designed to validate data at the time of data entry, preventing logical errors, and branching logic, which ensures that only relevant questions are asked, thereby minimizing the total number of questions asked in each survey.

TABLE 1 Data Elements Collected for PSRC

Age
Weight
Sex
ASA status
Primary diagnosis
Coexisting diagnoses
Procedures 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
Airway management (unexpected)
Transport during sedation?
Conditions produced during the procedure

The study data are collected using the Sybase database management system, with interfaces dynamically generated using Java and HTML coding. The production database resides on a server within the BioInformatics facility at Dartmouth, with a parallel development instance of the system loaded on a separate machine to accommodate the alteration and testing of the data collection system. The study Web site and data entry portal are secured using Secure Socket Layer, and each study participant is authenticated through the Web site and authorized to access only the parts of the Web site that are relevant to his or her institution. All data that travel among participating institutions are encrypted to ensure that data are neither intercepted nor corrupted in transfer. In addition, all data collected in this study met Health Insurance Portability and Accountability Act requirements for de-identification. No patient-identifiable data were transmitted during this study.

After 3 months (5000 records) of pilot testing, the content of the data collection tool was refined at the next meeting of all consortium members in May 2004. Subsequent changes to the data collection tool have not changed the essential nature of this instrument but only added options for answers to the queries and so forth. Data collection for the study began on July 1, 2004.

The study was a prospective observational evaluation of sedation/anesthesia practice. No alteration of sedation practice was made at any participating institution for the purposes of this study. An example of the computer screens that were used for data entry is found in Fig 1. In this particular case the screen is intended to input data on the primary problem for which the patient is having the procedure. Similar screens are used for input on the actual procedure performed, complications encountered, and so forth.

Complication Data

The data tool included 3 separate screens or question sets that related to complications during sedation. One screen collected data on complications during the procedure. The options available in this category are defined in Table 2. As with all screens in the tool, questions included logic that prompted additional questions to define clearly the nature of the complication selected. For example, if "Desaturation" was selected, then additional screens would be activated to define the level and the duration of desaturation involved in a given incident. Another screen related to complications specifically asked for clarification of "unexpected airway management required." The selections in this category are listed in Table 3. Finally, the Web tool concluded with a question that asked for information on the "conditions present during the procedure," which was intended to allow us to understand whether the sedation/anesthesia that was provided met the needs of the procedure or was insufficient for optimal procedure performance. Detail on the options that are available on this screen is seen in Table 4.

In all of the categories of data collection, participants were allowed to write in any additional complications that occurred during the course of the procedure and that are not accounted for by our standard list. All of these "free text" entries then were evaluated individually. In cases in which it was clear that the written

TABLE 2 **Definitions: Complication and/or Unplanned Treatment During Sedation**

None
Agitation/delirium
Airway obstruction
Allergic reaction
Apnea >15 s
Aspiration
Cardiac arrest
Coughing
Death
Desaturation: O_2 saturation (below baseline) for >30 s
Emergency anesthesia consultation required
Hypothermia
Inadequate sedation
IV-related complication
Laryngospasm
Prolonged recovery time
Prolonged sedation
Secretions requiring treatment
Stridor
Unexpected change in HR, BP, RR of > or < 30%
Unexpected need for bag-mask ventilation
Unintended deep level of sedation
Unplanned admission to hospital or increase in level of care
Unplanned intubation
Use of reversal agents (unplanned)
Vomiting (non-GI procedure)
Wheezing
Other

HR indicates heart rate; BP, blood pressure; RR, respiratory rate; GI, gastrointestinal.

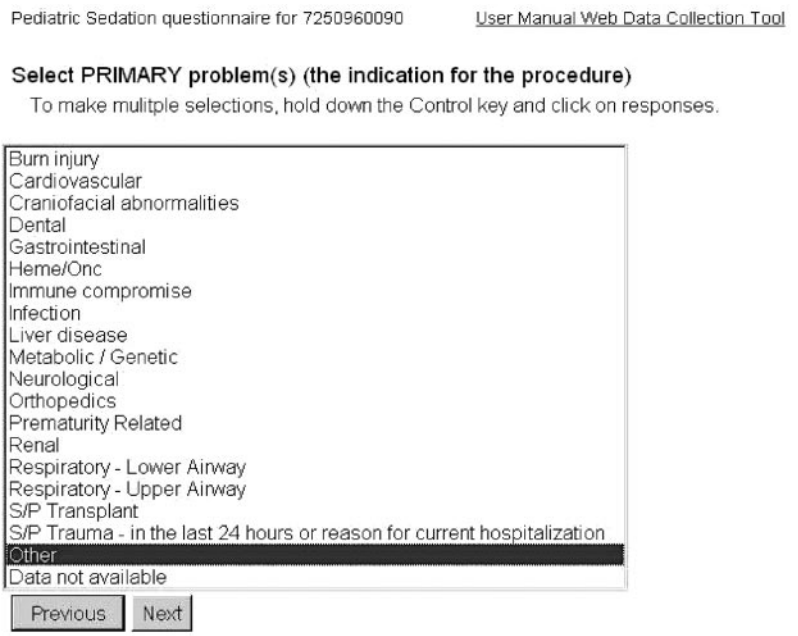

FIGURE 1
Computer screen for data entry for PSRC.

TABLE 3 **Unexpected Airway Management Choices**

Endotracheal tube
Jaw thrust
LMA
Nasotracheal tube
Nasal-pharyngeal airway
O_2 mask or nasal cannula blow-by
Oral airway
Bag-mask ventilation
Repositioning
Suction
Other

LMA indicates laryngeal mask airway.

TABLE 4 **Conditions Present During the Procedure**

1. Ideal conditions—patient calm and still during procedure
2. Procedure performed—conditions not ideal
3. Procedure could not be completed because of problems not related to sedation
4. Procedure could not be completed because of complications with sedation
5. Procedure could not be completed because of inadequate sedation

complication fit into an existing category, the appropriate selection box was clicked. In cases in which the written complication was distinct from any standard choice on the collection tool, the choice was recorded and grouped with similar complications that were submitted for other patients. On rare occasions, a free-text entry was noted often enough to be added to the standard list of complications.

Participating centers receive quarterly reports on their performance using a standard reporting form that includes data on each of the standard fields outlined in Table 1. Through the database system authorization process, participating centers also are granted open access to the data that they have submitted to the consortium and are able to compare their data with that of the entire consortium. All participating institutions (and primary investigators) are blinded to the data that are submitted from any individual institution other than their own. Study authors also were blinded to referring institution, thereby minimizing disincentive for centers to submit data on complications on the basis of concern for their reputation or standing in the PSRC. All primary investigators were charged with selecting locations within their institutions where collection of sedation data was feasible and ensuring nonselective data submission through regular inventories of their data submissions. In addition, these investigators were required to review total counts of sedations performed in their institution (independently recorded) versus that of the number of records submitted to the PSRC. Our primary outcome analysis was the rate of complications during sedation/anesthesia activity.

RESULTS

During the study period, a total of 30 037 records were submitted to the database. The data presented here represent a cumulative total of the descriptive information and complication data selected for the population studied. The data were calculated by summing the total number of selection boxes that were clicked in answer to each question.

The ASA distribution, gender distribution, emergency status, and age data on the study population are presented in Table 5. Because nil per os (NPO) status is thought to bear on the likelihood of aspiration or pulmonary complications, we present the data on NPO status for the study population in Table 6. Our data tool did not distinguish clear fluids from other fluids. In addition, we were not able to distinguish between fatty solids (hamburger) and a nonfatty meal, such as toast.

The distribution of providers who were responsible for the oversight of the sedation is presented in Table 7. It should be noted that some of these providers would have been delivering the medication and monitoring the patient, whereas others would have been responsible simply for the conduct of the sedation and may not have had direct patient contact. The data reflect a preponderance of anesthesiologists, emergency physicians, and intensivists involved in our study cohort.

The distribution of procedure categories performed is outlined in Table 8. In lieu of listing the hundreds of procedures performed, we have listed categories. Although we do not present specifically painful versus nonpainful procedures, one can reasonably assume that the predominance of the orthopedic procedures were painful in nature, whereas 98% of the radiologic procedures consisted of MRI scan and CT scans that are not painful.

TABLE 5 **Demographics of the Patient Population**

Baseline ($N = 30037$)	%	*n*	95% CI
ASA classification			
I	33.2	9966	32.6–33.7
II	46.7	14035	46.2–47.3
III	11.6	3479	11.2–11.9
IV	0.6	166	0.5–0.6
V	0.007	2	0.0–0.0
IE	5.5	1638	5.2–5.7
IIE	0.1	36	0.1–0.2
IIIE	0.04	13	0.0–0.1
IVE	0.01	3	0.0–0.0
Missing	2.3	699	2.2–2.5
Female	44.7	13441	44.2–45.3
Emergency sedation	8.0	2389	7.6–8.3
Age			
<6 mo	6.4	1930	6.2–6.7
6 mo–2 y	23.1	6944	22.6–23.6
2–8 y	47.0	14108	46.4–47.5
>8 y	23.5	7055	23.0–24.0

CI indicates confidence interval.

TABLE 6 **NPO Status**

NPO for liquids, h	%	*n*	95% CI
<2	1.4	426	1.3–1.6
2–4	23.9	7186	23.4–24.4
4–6	14.4	4327	14.0–14.8
6–8	10.4	3132	10.1–10.8
≥ 8	46.6	13996	46.0–47.2
Missing	3.2	970	3.0–3.4
NPO for solids, h			
<2	0.2	66	0.2–0.3
2–4	0.8	232	0.7–0.9
4–6	3.9	1168	3.7–4.1
6–8	17.0	5108	16.6–17.4
≥ 8	75.2	22591	74.7–75.7
Missing	2.9	872	2.7–3.1

CI indicates confidence interval.

TABLE 7 **Provider Categories**

Provider	%	*n*	95% CI
Anesthesiologist	19.2	5781	18.8–19.7
APRN/PNP/PA	9.7	2907	9.3–10.0
ER doctor	27.9	8378	27.4–28.4
Fellow	3.9	1172	3.7–4.1
Housestaff	1.1	316	0.9–1.2
Intensivist	28.4	8535	27.9–28.9
Pediatrician	6.9	2071	6.6–7.2
Radiologist	2.1	616	1.9–2.2
Other	0.9	256	0.8–1.0
Missing	0.001	5	0.0–0.0

APRN indicates advanced practice registered nurse; PNP, pediatric nurse practitioner; PA, physician's assistant; ER, emergency room.

TABLE 8 **Procedure Categories of Procedures**

Procedure Category	%	*n*	95% CI
Cardiovascular	2.0	591	1.8–2.1
Dental	1.1	317	0.9–1.2
Gastroenterology	6.1	1846	5.9–6.4
Hematology-oncology	8.9	2680	8.6–9.3
Neurological	5.9	1770	5.6–6.2
Ophthalmology	0.1	43	0.1–0.2
Orthopedic	5.6	1693	5.4–5.9
Pulmonary	1.1	342	1.0–1.3
Radiological	61.6	18490	61.0–62.1
Sexual Abuse	0.05	15	0.0–0.1
Surgical Invasive	8.1	2434	7.8–8.4
Other	1.7	501	1.5–1.8

TABLE 9 **Categories of Primary Diagnosis for the Procedure**

Variable	%	*n*	95% CI
Burn	1.4	433	1.3–1.6
Cardiac	5.3	1599	5.1–5.6
Congenital malformations	0.4	111	0.3–0.4
Cranial	1.7	500	1.5–0.8
Dental	0.9	275	0.8–1.0
Dematologic	0.2	64	0.2–0.3
Gastroenterological	11.9	3566	11.5–12.2
Hematology-oncology	18.0	5404	17.6–18.4
Immune-related	0.7	196	0.6–0.8
Infectious	8.0	2409	7.7–8.3
Liver-related	0.7	224	0.7–0.8
Metabolic	4.0	1195	3.8–4.2
Neurological	41.0	12330	40.5–41.6
Orthopedic	8.9	2667	8.6–9.2
Prematurity-related	1.4	419	1.3–1.5
Renal	5.7	1726	5.5–6.0
Respiratory (lower)	8.5	2552	8.2–8.8
Respiratory (upper)	9.8	2950	9.5–10.2
Rheumatological	0.1	26	0.1–0.1
Transplant	1.0	301	0.9–1.1
Trauma	1.9	563	1.7–2.0
Surgical/invasive	0.6	180	0.5–0.7
Other	10.2	3074	9.9–10.6
No data	0.3	85	0.2–0.3

CI indicates confidence interval.

TABLE 10 **Coexisting Illnesses**

Variable	%	*n*	95% CI
Burn injury	1.4	426	1.3–1.6
Cardiac	2.7	798	2.5–2.8
Congenital malformations	0.1	45	0.1–0.2
Cranial	1.3	386	1.2–1.4
Dental	0.9	271	0.8–1.0
Dermatology	0.2	55	0.1–0.2
Gastroenterological	7.1	2140	6.8–7.4
Hematologic-oncologic	16.9	5091	16.5–17.4
Immune related	0.3	103	0.3–0.4
Infectious	7.0	2094	6.7–7.3
Liver related	0.5	162	0.5–0.6
Metabolic	1.6	488	1.5–1.8
Neurologic	35.5	10 669	35.0–36.1
Orthopedic	8.3	2493	8.0–8.6
Prematurity	0.3	80	0.2–0.3
Renal	4.8	1447	4.6–5.1
Respiratory (lower)	1.7	518	1.6–1.9
Respiratory (upper)	1.1	338	1.0–1.3
Rheumatologic	0.1	20	0.0–0.1
Surgical	0.5	164	0.5–0.6
Transplant	0.7	217	0.6–0.8
Trauma	1.8	533	1.6–1.9
Other	7.9	2386	7.6–8.3
No data	0.5	153	0.4–0.6

CI indicates confidence interval.

The primary diagnoses (those that prompted the need for the test/procedure for which the sedation was being delivered) for the patients in the database are listed in Table 9. The coexisting illness data (underlying illness that was not directly responsible for the condition that prompted the test/procedure for which sedation was given) is presented in Table 10. The distribution of drugs that were used for the sedation provision in each case is presented in Table 11.

For total number of records (30 037) in the data set, there are 1601 records for which some form of complication (by our definition) was recorded, amounting to a 5.3% incidence of complications overall. Adverse events that were reported to the database are listed in Table 12. Airway interventions were collected in our database and were differentiated clearly between expected and unex-

TABLE 11 Sedatives/Analgesics and Frequency of Use

	% of All Sedations	No. of Times Used
Sedative		
Ativan	0.2	46
Chloral hydrate	11.7	3507
Dexmedetomidine	1.3	393
Etomidate	2.1	639
Ketamine	13.6	4075
Methohexital	0.4	113
Midazolam	27.1	8142
Pentobarbital	13.2	3953
Propofol	50.1	15 059
Thiopental	0.5	151
Valium	0	10
Opiate		
Fentanyl	8	2417
Meperidine	0.2	54
Morphine	1.8	552
Nalbuphine	0	9
Remifentanil	0.3	77

pected. For instance, if the provider intended to deliver a large dose of sedative that would result in deep sedation or anesthesia and (perhaps) require airway management, then that was not collected as a complication. Only incidents that would not have been expected to be part of the normal management of a patient's receiving sedation (with the medications used) were recorded in the complication category. Several categories of complications were not initially included in the data collection tool. These included "allergic reaction," "coughing that interfered with the sedation," and "intravenous related problems." After review of the first 10 000 records, these complications were submitted in free-text format more often than 1 per 1000 sedations and therefore were thought to warrant their own categories on the data collection tool.

One incident of aspiration was recorded. The case involved a 5-year-old, 17-kg girl who had a history of marked prematurity and had undergone a multivisceral transplant. She was undergoing an elective diagnostic colonoscopy with propofol sedation in a PICU. During the sedation/anesthesia, she required bag-mask ventilation as a result of respiratory depression. She vomited and was suctioned immediately. She had been NPO for >8 hours. She subsequently was admitted to the hospital (not planned). We do not have details of the required care, but she was discharged in good condition.

The database also recorded 1 case in which cardiopulmonary resuscitation (CPR) was required. This was a 9-year-old boy who underwent a bronchoscopy for chronic cough under propofol sedation in a PICU. The child had a history of tracheoesophageal fistula that had been repaired at the time of birth. The text description of the case states that the patient experienced laryngospasm and profound hypoxia that led to bradycardia and the requirement of CPR and epinephrine. The child responded to bag-mask ventilation and drug treatment. Two hours after the episode, he was back to his baseline state. He was discharged from the hospital after overnight observation.

DISCUSSION

Modern medicine is winning the battle against many diseases in children. Unfortunately, the treatments that are used to obtain this progress often are invasive, stressful, and a source of significant suffering in this patient population. Because these procedures often are performed in an urgent manner and in a variety of locations, anesthesiologists, emergency medicine specialists, cardiologists, pediatricians, radiologists, nurses, and (often) house officers all are asked to provide sedation when indicated. The choice of which providers deliver this care and which techniques and medications are used is essentially idiosyncratic to each institution and largely dependent on the personnel available. The medications used, depth of sedation (or anesthesia) provided, monitoring used, and degree of training for this task vary greatly from one institution to another despite that the goals for sedation are identical. As a result, the practice of sedating or anesthetizing pediatric patients for diagnostic or therapeutic procedures in the hospital is poorly standardized and (historically) not well studied or understood.

Safety concerns about pediatric sedation as it currently is practiced have moved several national organizations to produce statements or guidelines concerning the delivery of this care. The Joint Commission on Accreditation of Hospitals,[5] the ASA, the AAP,[13] the American College of Emergency Physicians,[12] and the American Academy of Pediatric Dentistry[14] all have published some form of guidelines concerning the sedation of children. Unfortunately, all of these recommendations have been made in the absence of data on the actual incidence of complications in sedation other than those that are available in the more limited studies mentioned in our introduction. The PSRC is intended to allow a more broad-based and systematic evaluation of adverse events that can direct a systematic approach to improve the reliability and the safety of pediatric procedural sedation. Similar human factors that are grounded in research in the field of anesthesiology has led to changes in equipment, monitoring standards, and training that reduced the mortality rate in children from 1 in 10 000 to 1 in 60 000 cases.[15–17]

This epidemiologic investigation was conceived to fill the void of direct data as to the incidence and the nature of adverse events in pediatric sedation. Voluntary enrollment of 26 PSRC institutions has allowed 30 037 sedation encounters to be captured in a database. These data clearly show that serious adverse events are rare in the practice of pediatric sedation/anesthesia for procedures;

TABLE 12 **Complications**

	Incidence per 10 000	*n*	95% CI
Adverse events			
Death	0.0	0	0.0–0.0
Cardiac Arrest	0.3	1	0.0–1.9
Aspiration	0.3	1	0.0–1.9
Hypothermia	1.3	4	0.4–3.4
Seizure (unanticipated) during sedation	2.7	8	1.1–5.2
Stridor	4.3	11	1.8–6.6
Laryngospasm	4.3	13	2.3–7.4
Wheeze (new onset during sedation)	4.7	14	2.5–7.8
Allergic reaction (rash)	5.7	17	3.3–9.1
Intravenous-related problems/complication	11.0	33	7.6–15.4
Prolonged sedation	13.6	41	9.8–18.5
Prolonged recovery	22.3	67	17.3–28.3
Apnea (unexpected)	24.3	73	19.1–30.5
Secretions (requiring suction)	41.6	125	34.7–49.6
Vomiting during procedure (nongastrointestinal)	47.2	142	39.8–55.7
Desaturation below 90%	156.5	470	142.7–171.2
Total adverse events	339.6 (1 per 29)	1020	308.1–371.5
Unplanned treatments			
Reversal agent required (unanticipated)	1.7	5	0.6–3.9
Emergency anesthesia consult for airway	2.0	6	0.7–4.3
Admission to hospital (unanticipated; sedation related)	7.0	21	4.3–10.7
Intubation required (unanticipated)	9.7	29	6.5–13.9
Airway (oral; unexpected requirement)	27.6	83	22.0–34.2
Bag-mask ventilation (unanticipated)	63.9	192	55.2–73.6
Total unplanned treatments	111.9 (1 per 89)	336	85.3–130.2
Conditions present during procedure			
Inadequate sedation, could not complete	88.9 (1 per 338)	267	78.6–100.2

no deaths occurred, and only 1 cardiac arrest was reported. It should be noted that adverse events that required unanticipated admission to the hospital did occur approximately once per every 1500 sedation encounters. The observed (low) incidence of mortality is not unexpected and is consistent with the low incidence of mortality that currently is associated with the provision of general anesthesia. Conversely, more minor but potentially serious adverse events clearly are not rare. Although only 1 aspiration was reported, vomiting (in a nongastrointestinal procedure) occurred approximately once in every 200 procedures. Approximately 1 in 400 procedures is associated with stridor, laryngospasm, wheezing, or apnea that could progress to poor outcomes if not managed well. Indeed, 1 in every 200 sedations required airway and ventilation interventions ranging from bag-mask ventilation to oral airway placement to emergency intubation. We believe that our results do not simply reassure providers that the sedation of children is low risk; rather, they help to define the core competencies that are required to deliver this care. The reported incidence of apnea and airway obstruction adds weight to the argument that provision of sedation must be accompanied by proof that providers have the skills to manage airway obstruction and respiratory depression or have immediate and completely reliable access to such assistance. Similarly, that airway secretions appeared as a management issue in a significant percentage of our patients argues for the need to have suction equipment present for all cases of moderate or deep sedation in children. Of note, although oxygen desaturation has tended to be used as a proxy for respiratory complications that are associated with sedation (and our data verified desaturation as the most common adverse event), the distribution of causes previously was unclear. These data now provide insight into the array of respiratory compromise that can be encountered with the provision of pediatric procedural sedation and anesthesia.

Two cases of major morbidity were captured: 1 aspiration and 1 hypoxic episode that led to the need for CPR. Both cases involved patients with serious underlying health issues. These cases accent that sedation and anesthesia risk depends heavily on patient status, and this will be a focus of future data evaluation in our consortium. The cases also accent the issue of appropriate "rescue" capability in that neither case led to permanent injury, a testament to the fact that they were undertaken in a highly monitored environment and in institutions that could provide the kind of ultimate safety net and definitive care that are required for patients with complex comorbid conditions.

Prolonged sedation/recovery and "failed sedation" rates also were delineated by these data, occurring 36 and 89 times per 10 000 sedation encounters, respectively. That <1% of sedations produced conditions that

would not allow the procedure to be completed is an astonishing record of effectiveness. However, we must recognize that the cohort of participants who collected data in this consortium represents specialized pediatric sedation care. The previously reported incidence of failed sedations ranges from 0.2% to 50%.[7,18,19] These studies did not have dedicated sedation programs and consisted of retrospective chart reviews by procedure type, such as MRI.

Some adverse events were unexpected. The frequency of intravenous-related issues that interfered with accomplishing the procedure surprised us. Without prompting through a text button, 95 instances of intravenous access problems that prevented the completion of tests or procedures were reported. We believe that this clearly indicates a need to ensure systems for access and maintenance of intravenous access as an important measure to avoid incomplete tests and procedures. Likewise, we did not anticipate that issues related to allergic reactions would be as common as they were in our data. When one combines the incidence of rash with the incidence of new onset of wheezing (although this could be from many sources), it could be assumed that some type of significant allergic reaction may occur as often as 1 per 1000 sedations. Although not common, this incidence requires providers to be prepared for this complication.

The limitations of a study such as ours are clear. The institutions that are involved in this study selected themselves for inclusion and are voluntarily reporting their outcomes. As such, it is very likely that we are looking at a highly motivated and organized set of sedation systems that would outperform other, less controlled systems and may (in fact) represent "best practice." This is similar to the selection bias that was inherent in previously reported prospective studies of sedation practice from single centers that chose to study their own practice. Indeed, the observed rates of complications and unplanned treatments are consistent with practice patterns of a highly competent cohort that may not generalize to all clinical settings in which sedation care is provided. For example, expert consensus recommends initial treatment of apnea with bag-mask ventilation rather than the routine use of reversal agents (especially maximal doses).[11] Our reporting centers seem to follow this practice recommendation. Unplanned bag-mask ventilation occurred 192 times, whereas reversal agents (eg, naloxone, flumazenil) were administered only 5 times. In contrast, multiple studies have advocated the routine use of benzodiazepine reversal with flumazenil as a strategy for achieving deeper levels of sedation and yet maintaining efficient and economic patient throughput to hasten emergence for the sedated state.[20,21] There is concern that this practice may create a dangerous dependence on reversal agents as the sole strategy for managing sedation-induced respiratory depression. We caution that sedation services that use predominantly benzodiazepines and narcotics with a reliance on reversal agents as the primary rescue strategy should not conclude that the outcomes that we report would apply to their practice.

As stated, this study is prospective and observational in nature. Because there is no control group, we did not attempt to draw direct cause and effect from these data with respect to adverse outcomes. Rather, we concentrated on reporting the complications that rise to the level of concern, with the caveat that this information is a marked improvement over previous investigations that were limited in patient numbers, geography, and scope. We recognize that the methods that were used to perform sedation for the multitude of procedures that were captured in this database are extremely varied. They range from general anesthesia to moderate sedation. Because this is the nature of pediatric sedation practice, we believe that it is necessary to include all of these methods in our analysis to obtain an accurate picture of the aggregate risk to which children are exposed in this practice. The data from this study will be used to focus research efforts to improve the safety and the reliability of pediatric procedural sedation. This large data set will allow for predictors of important adverse events to be researched further and will spur future prospective, randomized investigations in the areas of concern that have been identified. The potential to link markers of risk and adverse outcomes represents a significant research potential. For instance, investigators traditionally have reported on the rate of minor oxygen desaturation events that occur during sedation studies on the assumption that these events are surrogates for more concerning outcomes. The large database that the PSRC has generated in fact may support or refute this assumption and link the truly worrisome outcomes with factors that must be combined with (or completely separate from) these events.

Data collection in the PSRC is continuing, and future analysis will focus on evaluating the association of adverse outcomes with various provider types, monitoring standards, and medications used. Additional efforts will be aimed at evaluating effectiveness and efficiency of various sedation systems with the possibility of defining and promoting the system characteristics that lead to the best outcomes.

CONCLUSION

In the hospital setting of the institutions that participate in the PSRC, the reported incidence of serious adverse events in pediatric sedation is low. However, the reported incidence of events that have potential to harm and that require timely rescue interventions is significant, occurring once per 89 sedation encounters. The reported incidence of these adverse events will direct targeted research and support the continued efforts of

those who seek to encourage improved safety and reliability in the provision of pediatric procedural sedation.

ACKNOWLEDGMENTS

Research support is provided by the National Patient Safety Foundation.

The following institutions participated in this study: Alfred I. duPont Children's Hospital; Avera Mckennan Hospital; Cape Fear Valley Medical Center; Children's Healthcare of Atlanta, Egleston Campus; Children's Healthcare of Atlanta, Scottish Rite Campus; Children's Hospital of Philadelphia; Children's Hospital Omaha; Children's Mercy Hospital; Chris Evert Children's Hospital; Columbus Children's Hospital; Dartmouth Hitchcock Medical Center; Denver Children's Hospital; DeVos Children's Hospital; Eastern Maine Medical Center; Gundersen Lutheran; Jackson Memorial Hospital, University of Miami School of Medicine; Kosair Children's Hospital, University of Louisville; LeBonheur Children's Medical Center; Medical University of South Carolina; and New York University School of Medicine.

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