

Physiologic Monitoring Practices During Pediatric Procedural Sedation

A Report From the Pediatric Sedation Research Consortium

Melissa L. Langhan, MD; Michael Mallory, MD, MPH; James Hertzog, MD; Lia Lowrie, MD; Joseph Cravero, MD; for the Pediatric Sedation Research Consortium

Objectives: To describe the frequency of different physiologic monitoring modalities and combinations of modalities used during pediatric procedural sedation; to describe how physiologic monitoring varies among different classes of patients, health care providers (ie, ranging from anesthesiologists to emergency medicine physicians to nurse practitioners), procedures, and sedative medications employed; and to determine the proportion of sedations meeting published guidelines for physiologic monitoring.

Design: This was a prospective, observational study from September 1, 2007, through March 31, 2011.

Setting: Data were collected in areas outside of the operating room, such as intensive care units, radiology, emergency departments, and clinics.

Participants: Thirty-seven institutions comprise the Pediatric Sedation Research Consortium that prospectively collects data on procedural sedation/anesthesia performed outside of the operating room in all children up to age 21 years.

Main Outcome Measures: Data including demographics, procedure performed, provider level, adverse

events, medications, and physiologic monitors used are entered into a web-based system.

Results: Data from 114 855 subjects were collected and analyzed. The frequency of use of each physiologic monitoring modality by health care provider type, medication used, and procedure performed varied significantly. The largest difference in frequency of monitoring use was seen between providers using electrocardiography (13%-95%); the smallest overall differences were seen in monitoring use based on the American Society of Anesthesiologists classifications (1%-10%). Guidelines published by the American Academy of Pediatrics, the American College of Emergency Physicians, and the American Society of Anesthesiologists for nonanesthesiologists were adhered to for 52% of subjects.

Conclusions: A large degree of variability exists in the use of physiologic monitoring modalities for pediatric procedural sedation. Differences in monitoring are evident between sedation providers, medications, procedures, and patient types.

Arch Pediatr Adolesc Med. 2012;166(11):990-998.
Published online September 10, 2012.
doi:10.1001/archpediatrics.2012.1023

CHILDREN UNDERGOING painful procedures or diagnostic imaging often are aided by the receipt of medication to reduce their pain and anxiety. Procedural sedation is provided to children to facilitate a variety of procedures in multiple settings. Furthermore, health care providers ranging from anesthesiologists to emergency medicine physicians to nurse practitioners, working within different systems for sedation provision, are involved in the provision of this care.

The safety of children who receive sedation is of paramount importance. Clinical practice guidelines for the physiologic monitoring of children during procedural sedation vary by specialty and by institu-

tion.^{1,2} More than a dozen professional organizations, including the American Academy of Pediatrics (AAP), American Academy of Pediatric Dentistry (AAPD), the American College of Emergency Physicians (ACEP), and the American Society of Anesthesiologists (ASA), have published

For editorial comment see page 1067

guidelines for physiologic monitoring during pediatric procedural sedation, while the Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations) sets hospital standards for anesthesia and sedation care and regulates this care.¹⁻⁷

Author Affiliations are listed at the end of this article.

Group Information: The member hospitals that comprise the Pediatric Sedation Research Consortium are listed at the end of the article.

Table 1. Summary of Monitoring Recommendations by Professional Organization

Organization	Sp _o ₂	Respiratory Rate	Heart Rate	Blood Pressure	ETCO ₂
AAP/AAPD	Continuous	Intermittent	Continuous	Intermittent	Encouraged
ASA for anesthesiologists	Continual	Continual	Continuous	Intermittent	Continual
ASA for nonanesthesiologists	Continuous	Continuous	Continuous	Intermittent	Consider
ACEP	Unknown frequency	Unknown frequency	Consider	Unknown frequency	No

Abbreviations: AAP, American Academy of Pediatrics; AAPD, American Academy of Pediatric Dentistry; ACEP, American College of Emergency Physicians; ASA, American Society of Anesthesiologists; ETCO₂, end-tidal carbon dioxide; Sp_o₂, pulse oximetry.

Appropriate physiologic monitoring does not guarantee desired outcomes. The goal of such monitoring is to alert the practitioner of physiologic derangements during procedural sedation such that medical intervention may be provided and adverse events avoided.⁸ The modes and frequency of monitoring vary extensively in clinical practice. Evidence is lacking regarding optimal physiologic monitoring during pediatric procedural sedation.⁶ While specific monitors (eg, pulse oximetry) have been shown to be useful in alerting practitioners to dangerous patient states, no data exist to indicate that specific monitoring systems actually change the outcomes of sedation encounters.

To our knowledge, the present study represents an effort to summarize the findings of the first large-scale, multispecialty study to report the monitors that are actually used during pediatric sedation across a wide spectrum of practices. We examined data from the Pediatric Sedation Research Consortium (PSRC), which is a collaborative group of 37 institutions that prospectively collects data about pediatric procedural sedation/anesthesia outside of the operating room to better understand this practice and its safety. Using its large database, our primary goal is to describe the frequency of different physiologic monitoring modalities and combinations of modalities used during pediatric procedural sedation within the experience of the PSRC. Our secondary goals are to describe how physiologic monitoring varies among different classes of patients, health care providers, procedures, locations, and sedative medications employed, as well as to determine the proportion of sedations that meet different published guidelines within the experience of the PSRC.

METHODS

STUDY DESIGN

We performed an analysis of consecutive pediatric sedations entered prospectively into a large multicenter database. Pediatric Sedation Research Consortium participants collected the data for this analysis from September 1, 2007, through March 31, 2011. We included subjects younger than 21 years old.

DATA COLLECTION SETTING AND PROCESSING

The PSRC Database

The data collection method used by the PSRC has been described in a report about the first 30 000 sedations that were performed.⁹ Thirty-seven locations, including large children's hospitals, children's hospitals within hospitals, and general/community hospitals, self-selected for involvement in the PSRC

data sharing group. There were no specific selection criteria for participation in the consortium; however, any interested institutions were required to obtain institutional review board approval for data collection, identify a primary investigator, and agree to a standardized method for data collection on a consecutive sample. Health care providers self-identified their specialty on the data forms.

The PSRC data tool is a web-based data collection tool. For a more detailed description of the logic and questions used in this data instrument, please see "Web Tool Content" on the consortium website at <http://www.pediatricsedationrc.org>. The data collection tool consisted of 25 primary screens and dynamically generated an interface for each subsequent question based on the responses from the previous question. Some items, such as medications used for sedation and locations in which sedation was provided, may have more than one response per subject.

Data gathered regarding monitoring during sedation included the following: noninvasive pulse oximetry (Sp_o₂), 3-lead electrocardiography (ECG), noninvasive blood pressure monitoring, capnography/end-tidal carbon dioxide monitoring (ETCO₂), precordial stethoscopy, temperature monitoring, bispectral index monitoring, impedance plethysmography, and other.

All the participating institutions (and primary investigators) were blinded to the data submitted from any individual institution other than their own. Study authors were also blinded to referring institution. All the site-specific primary investigators were required to perform data audits on 10 medical records every 6 months and report the accuracy of the data transmitted. In addition, the primary investigator was required to review total counts of sedations performed in his or her institution (independently recorded) vs that of the number of records submitted to the PSRC. Any discrepancies in numbers provided vs sedations performed or confirmed inaccuracies of data at the institution required a complete review of the data-gathering method at the institution.

Definition of Guidelines

The recommendations published by the AAP/AAPD, ASA, and ACEP are summarized in **Table 1**. The ASA has published guidelines for sedation by nonanesthesiologists as well as standards for basic anesthetic monitoring performed by anesthesiologists, which include some specifications for moderate and deep sedation. A variety of devices have the capability to monitor either heart rate or respiratory rate. It is not stipulated within these guidelines that a specific monitor should be used to monitor either heart rate or respiratory rate. Therefore, for analyzing adherence to guidelines, the use of Sp_o₂, ECG, or stethoscopy was consider a positive monitor for heart rate, and the use of ETCO₂, impedance plethysmography, or stethoscopy was considered a positive monitor for respiratory rate. For example, an ECG monitor is not required by the AAP/AAPD to continuously monitor heart rate, and thus Sp_o₂ would be an appropriate monitor of both oxygenation and heart rate.

Table 2. Demographic Information of 114 855 Children^a

Variable	Value
Age, median (IQR), mo	48 (23-96)
Range	<1-252
Weight, kg	17.3 (11.8-29)
Range	1-280
Characteristics for >1% of participants	
Sex ^b	
Female	51 339 (45)
Male	62 983 (55)
ASA (n = 112 343) ^c	
1	29 603 (26)
2	63 319 (56)
3	19 046 (17)
4	372 (<1)
5	3 (<1)
Primary diagnosis	
Neurological	43 214 (38)
Hematologic/oncologic	25 623 (22)
Gastrointestinal	11 567 (10)
Infection	6663 (6)
Renal	6088 (5)
Other	4794 (4)
Orthopedic	4775 (4)
Metabolic/genetic	1940 (2)
Cardiovascular	1873 (2)
Respiratory: lower airway	1781 (2)
Surgical/wound management	1487 (1)
Craniofacial abnormalities	1470 (1)
Trauma, in the last 24 h or reason for current hospitalization	1433 (1)
Type of procedure performed	
Radiology	67 937 (59)
Hematology/oncology	16 546 (14)
Gastroenterology	10 406 (9)
Surgical or invasive procedure	9070 (8)
Nerve/brain/ear	6640 (6)
Bone/joint/skeletal	2489 (2)
Cardiology	1538 (1)
Airway/pulmonary	1156 (1)
Sedative used (n = 113 933)	
Propofol	81 372 (71)
Midazolam	27 747 (24)
Ketamine hydrochloride	7725 (7)
Dexmedetomidine hydrochloride	7497 (7)
Pentobarbital sodium	7426 (7)
Chloral hydrate	6360 (6)
Provider responsible (n = 11 697)	
Pediatric intensivist	57 752 (50)
PEM physician	24 926 (22)
Pediatrician/subspecialist	13 085 (11)
Pediatric anesthesiologist	10 390 (9)
Anesthesiologist/intensivist	2557 (2)
Radiologist	2545 (2)
Location of procedure	
Radiology	58 772 (51)
Sedation unit	49 170 (43)
Pediatrics/specialty clinic	9202 (8)
Other	3889 (3)
Critical care, ICU/PACU	3754 (3)
Pediatric floor	2238 (2)
Emergency department	1819 (2)

Abbreviations: ASA, American Society of Anesthesiologists; ICU, intensive care unit; PACU, postanesthesia care unit; PEM, pediatric emergency medicine.

^aData are given as number (percent) unless otherwise indicated.

^bData were missing for sex and, therefore, do not total 112 343.

^cThe American Society of Anesthesiologists physical status classifications system is as follows: 1 indicates a normal healthy patient; 2, a patient with mild systemic disease; 3, a patient with severe systemic disease; 4, a patient with severe systemic disease that is a constant threat to life; and 5, a moribund patient who is not expected to survive without undergoing an operation.

Table 3. Physiologic Monitoring Modalities Used During Sedation in 114 855 Children

Monitoring Modality	No. (%)
SpO ₂	109 297 (95)
Noninvasive BP	99 840 (87)
ECG	76 977 (67)
ETCO ₂	51 318 (45)
Impedance plethysmography	22 533 (20)
Stethoscopy	253 (0.22)

Abbreviations: BP, blood pressure; ECG, 3-lead electrocardiography; ETCO₂, end-tidal carbon dioxide; SpO₂, pulse oximetry.

In this analysis, adherence to guidelines was not stratified based on the type of health care provider. For example, the frequency of sedations that met the monitoring guidelines set forth by the AAP/AAPD was analyzed across all the health care providers, not just pediatricians. However, subanalyses by health care provider type were performed.

STATISTICAL ANALYSIS

We performed descriptive analyses using Intercooled STATA/SE 11.2 (StataCorp LP). χ^2 Analyses were performed to assess the differences in the use of each monitoring modality on the basis of ASA physical status classification groups (1-2 vs 3-5) as well as by each type of practitioner. These comparisons were impossible for type of drug or procedure because choices in these categories were not mutually exclusive.

RESULTS

Data from 114 855 sedations were reviewed. There were a wide variety of sedation procedures, health care providers, medications administered to provide sedation, primary diagnoses, and locations where sedation was provided (**Table 2**). More than one administered medication or location for sedation procedure was possible for each subject. The most common procedures within the categories listed include magnetic resonance imaging for radiology, lumbar puncture with intrathecal medication administration and bone marrow biopsy for hematology/oncology, upper endoscopy and colonoscopy for gastroenterology, brainstem auditory response test and lumbar puncture for nerve/brain/ear, fracture reduction and botulism toxin injection for bone/joint/skeletal, catheter insertion or removal, incision and drainage, aspirations or biopsy specimens for surgical, echocardiography for cardiology, and bronchoscopy for airway/pulmonary.

The overall frequencies of use for each monitoring modality are provided in **Table 3** and frequencies of various combinations of devices are given in **Table 4**. A minimum of SpO₂, heart rate monitoring, respiratory monitoring, and intermittent blood pressure monitoring as recommended by the AAP/AAPD and ASA for nonanesthesiologists was used in 52% of children. ACEP standards were similarly met in 52% of children. The stricter ASA guidelines for anesthesiologists, which require ECG and ETCO₂ monitoring in addition to SpO₂ and blood pressure monitoring, were adhered to in 33% of cases. Only 2421 (18.3%) of the

Table 4. Use of Combinations of Monitoring Devices^a

Monitoring Combination	No. (%)
SpO ₂ , ECG, ETCO ₂ , BP, impedance plethysmography	5717 (5)
SpO ₂ , ECG, BP, impedance plethysmography	19 711 (17)
SpO ₂ , BP, impedance plethysmography	20 246 (18)
SpO ₂ , ECG, ETCO ₂ , BP	37 946 (33)
SpO ₂ , ETCO ₂ , BP	44 863 (39)
SpO ₂ , ETCO ₂	50 734 (44)
SpO ₂ , ECG, BP	71 658 (63)
SpO ₂ , BP	98 780 (86)

Abbreviations: BP, blood pressure; ECG, 3-lead electrocardiography; ETCO₂, end-tidal carbon dioxide; SpO₂, pulse oximetry.

^aThis information does not exclude the use of additional monitoring devices (N = 114 855).

Table 5. Frequency of Monitoring Use by ASA Classification for 112 343 Children^a

Monitoring Modality	ASA 3, 4, or 5		P Value
	ASA 1 or 2 (n = 92 922) ^b	ASA 3, 4, or 5 (n = 19 421) ^b	
SpO ₂	89 034 (96)	18 534 (95)	.01
BP	80 028 (86)	18 229 (94)	<.001
ECG	61 017 (66)	14 359 (74)	<.001
ETCO ₂	41 693 (45)	8440 (43)	<.001
Impedance plethysmography	16 904 (18)	5361 (28)	<.001
Stethoscopy	167 (0.18)	73 (0.38)	<.001

Abbreviations: ASA, American Society of Anesthesiologists; BP, blood pressure; ECG, 3-lead electrocardiography; ETCO₂, end-tidal carbon dioxide; SpO₂, pulse oximetry.

^aData are given as number (percent).

^bThe American Society of Anesthesiologists physical status classifications system is as follows: 1 indicates a normal healthy patient; 2, a patient with mild systemic disease; 3, a patient with severe systemic disease; 4, a patient with severe systemic disease that is a constant threat to life; and 5, a moribund patient who is not expected to survive without undergoing an operation.

13 259 health care providers who identified themselves as anesthesiologists (a group including anesthesiologists, pediatric anesthesiologists, and anesthesiologists/intensivists) used a monitoring combination that met requirements of the guidelines set forth by the AAP and ASA for nonanesthesiologists. However, 56 772 (55.9%) of the 101 596 health care providers not identified as anesthesiologists were adherent to the guidelines (unadjusted odds ratio [OR], 0.176; 95% CI, 0.168-0.185). While the overall rate of adherence to ACEP guidelines was 52%, among physicians who identified as emergency medicine physicians (emergency medicine physicians or pediatric emergency medicine physicians), this rate was 71.8% (17 922 of 24 952) (unadjusted OR, 3.0; 95% CI, 2.9, 3.1). The rate was 45.9% among those not identifying themselves as an emergency medicine physician ($P < .001$).

There was statistically significant variation in monitoring used when patients were considered by ASA classification (**Table 5**); however, these groups had the smallest differences in frequency of use of each monitoring type (maximum difference 10% for plethysmography). There

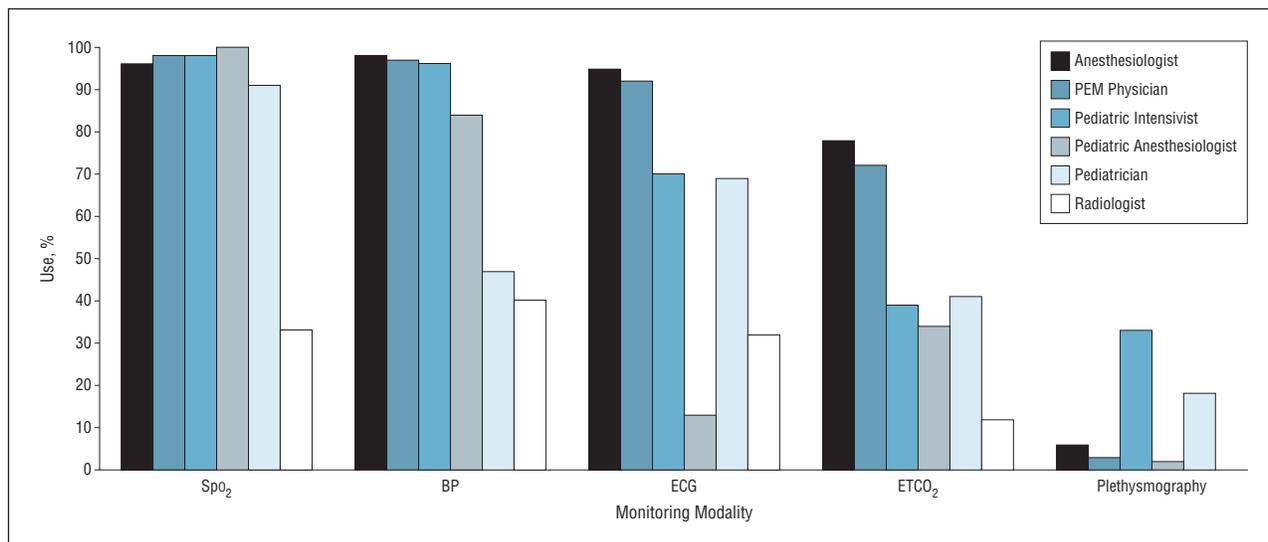


Figure 1. Percent use of each monitoring modality by health care provider type. Refer to Table 2 for frequencies of health care providers. All the *P* values for the comparison of each monitoring modality by health care provider are less than .001. BP indicates blood pressure; ECG, 3-lead electrocardiography; ETCO₂, capnography/end-tidal carbon dioxide; PEM, pediatric emergency medicine, and SpO₂, noninvasive pulse oximetry.

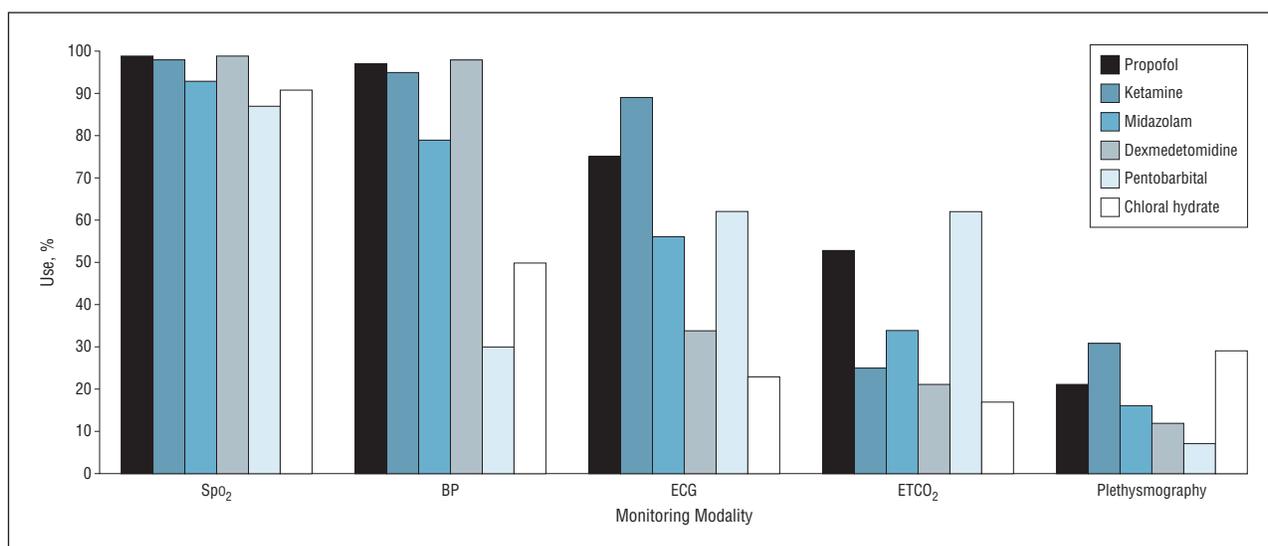


Figure 2. Percent use of each monitoring modality by medication used for sedation. Refer to Table 2 for frequencies of medication use. BP indicates blood pressure; ECG, 3-lead electrocardiography; ETCO₂, capnography/end-tidal carbon dioxide; and SpO₂, noninvasive pulse oximetry.

were also significant variations in the use of each monitoring device among health care providers (**Figure 1**). Stethoscopy was used in 4.8% of cases by anesthesiologists but in less than 1% of cases for all the other health care providers. The overall largest difference in monitoring use was seen in the frequency of ECG monitoring between anesthesiologists, those in general practice or in a subspecialty other than pediatrics (95%), and those who self-identified as pediatric anesthesiologists (13%). Generally, radiologists were the least frequent users of all the monitoring devices with the exception of ECG. Notably, radiologists did not use any monitor in more than 40% of children, and only 33% of radiologists used SpO₂. Similar differences were seen when plotting monitoring use by medications used (**Figure 2**) and by type of procedure for which sedation was required (**Table 6**). Stethoscopy was reportedly used in less than 1% of all the cases

for all the medications used. Notably, ETCO₂ monitoring was used most frequently during sedation for magnetic resonance imaging and pentobarbital sodium sedation; however, pentobarbital had the least frequent monitoring with SpO₂, blood pressure, and plethysmography.

COMMENT

To safely and comfortably perform diagnostic or therapeutic studies in children, sedation has become a part of the comprehensive care provided to this population.¹⁰⁻¹² Guidelines concerning the provision of sedation (in particular monitoring during sedation) are intended to improve the safety and effectiveness of this care. Because large, randomized controlled trials that evaluate outcomes of sedation activity related to monitoring sys-

Table 6. Frequency of Utilization for Each Monitoring Modality by Type of Procedure^a

Monitoring Modality	MRI (n=50 904)	Radiology (n=17 033)	Hematology/ Oncology (n=16 546)	Gastroenterology (n=10 406)	Surgical (n=9070)	Nerve/ Brain/Ear (n=6640)	Bone/Joint/ Skeletal (n=2489)	Cardiology (n=1538)	Airway/ Pulmonology (n=1156)
SpO ₂	49 076 (96)	15 592 (92)	15 743 (95)	10 154 (98)	8909 (98)	6520 (98)	2462 (99)	1008 (66)	1093 (95)
BP	43 062 (85)	13 315 (78)	15 526 (94)	10 150 (98)	8725 (96)	6097 (92)	2359 (95)	963 (63)	1035 (90)
ECG	34 089 (67)	9364 (55)	12 050 (73)	7761 (75)	6883 (76)	4406 (66)	2068 (83)	593 (39)	795 (69)
ETCO ₂	38 964 (77)	3201 (19)	2745 (17)	2987 (29)	1562 (17)	1962 (30)	217 (9)	268 (17)	138 (12)
Impedance plethysmography	5611 (11)	2592 (15)	5250 (32)	3536 (34)	3107 (34)	1631 (25)	514 (21)	402 (26)	549 (47)

Abbreviations: BP, blood pressure; ECG, 3-lead electrocardiography; ETCO₂, end-tidal carbon dioxide; MRI, magnetic resonance imaging; SpO₂, pulse oximetry.

^aData are given as number (percent).

tems are not generally available, these guidelines are varied and rely on expert opinion based on review of the available literature rather than strong, evidence-based data.⁸ To our knowledge, we present the first study to describe the monitoring practices of a large, multispecialty group of sedation health care providers. This is meant provide general information on the types of monitoring that is being used by high-functioning pediatric sedation systems. Our data suggest that large variations exist in the physiologic monitoring applied to children who are sedated outside of the operating room based on the health care providers involved, the medications used, and the tests performed.

The reasons for the differences in monitoring choices can only be elucidated through extensive qualitative research that considers multiple factors relating to the patient, the procedure, the sedation technique, and the health care providers involved. In clinical practice among the members of the PSRC, monitoring options seem to be tailored to the individual patient on the basis of his or her medical history, the procedure he or she is undergoing, and the safety profile of the medications that he or she will be receiving during sedation. A standard set of guidelines does not consider all the variables that the experienced clinician acknowledges prior to the initiation of sedation. On the other hand, unknown diagnoses and iatrogenic errors are difficult, if not impossible, to account for even by the most experienced clinician and argue for the standardization of this process. As such, guidelines need to set standards and allow for clinical judgment on how to achieve the monitoring goals of safe and effective care.

Despite the fact that most pediatric sedations occur in a relatively healthy population (ASA 1 or 2) that is free of heart disease, a 3-lead ECG is still recommended by many organizations as a routine part of monitoring.¹³ In fact, after reviewing quality assurance records of 1140 children receiving sedation, Malviya et al¹⁴ reported only 3 cases of altered heart rate, one of which occurred during cardiac catheterization. In addition, Coté et al¹⁵ reported that bradycardia was never the first observed event even among those with serious adverse events, although cardiac arrest was described. Even among those patients with heart disease, changes in heart rate and blood pressure requiring any intervention are rare.¹⁶ The ACEP guidelines do not recommend this monitor as a standard practice if there is no evidence of underlying car-

diopulmonary disease.³ As alterations in rhythm are rare in children, ECG monitoring may be best used in those patients with specific cardiac pathologic features or when a rhythm disturbance is present. It is logical to suspect that with the ubiquitous use of SpO₂, many health care providers are using this device as the monitor for heart rate in place of an ECG. Similarly, false-positive ECG alerts due to artifact for life-threatening disturbances, such as ventricular tachycardia, in a stable patient may steer health care providers away from this modality. Our data indicate that ECG use is not prevalent and that, in fact, sedation health care providers seem to use this monitor selectively based on the specific needs of the patient or risk involved in the procedure or depth of sedation. Having noted this, health care providers should also consider the potential serious adverse effects of medications being administered, such as dysrhythmias seen with dexmedetomidine hydrochloride administration or cardiac toxicity associated with lidocaine hydrochloride, as well as the potential for undiagnosed conditions, such as long-QT syndrome.

Literature has supported the use of SpO₂ to reduce the frequency of more severe hypoxic events.^{17,18} It is not surprising that this is the modality used most frequently across all types of sedations. The exception within this study is among radiologists, who only used this device in 33% of their patients compared with more than 90% usage among all the other health care providers. This may be due to use of oral medications or minimal sedation techniques; however, we cannot determine the depth of sedation among study patients in this data set. When SpO₂ is not used as a monitoring device, the development of hypoxemia may not be apparent until either cyanosis develops or more serious consequences of respiratory depression and hypoxemia, such as bradycardia and cardiac arrest, ensue. Mild hypoxemia, defined as pulse oximetry lower than 95% for longer than 60 seconds, has been reported to precede more serious adverse events and, thus, may be a prompt for interventions that prevent deterioration.¹⁷ Similarly, critical event analyses have documented that hypoxemia secondary to depressed respiratory activity is a principal risk factor for near misses and death during sedation, and thus early detection of these events through the use of SpO₂ is vital.^{14,15}

While the ASA only recently incorporated monitoring with capnography into its recommendations for anesthesiologists who are providing moderate sedation, our

study reveals that anesthesiologists and pediatric emergency medicine physicians use this device more regularly than other health care providers.⁷ A relatively low use of ETCO₂ monitoring has been documented for pediatric emergency medicine physicians in previous studies, but the data from this study point to a more global lack of use by nonanesthesiologists.¹⁹⁻²¹ The frequent use of this monitor by anesthesiologists is likely due to the fact that it has been readily available in the operating room environment for more than 30 years, yet this device has only recently become routinely available in other clinical settings.^{7,19,20,22} There has long been evidence that capnography improves detection of hypoventilation and apnea earlier than current monitoring devices (SpO₂, impedance plethysmography, and/or direct observations). More recent literature indicates the use of this monitor can reduce the frequency of oxygen desaturations—one of the more common adverse events seen during sedation.²³⁻²⁵ These studies support the claims that capnography provides an early warning to health care providers about hypoventilation, which they can then act on effectively and noninvasively before further sequelae develop. Likewise, when supplemental oxygen is routinely administered to patients receiving sedation, SpO₂ cannot accurately detect changes in higher levels of arterial oxygenation content until they begin to precipitously decline below normal, which may be delayed for several minutes.^{26,27} In this circumstance, capnography yields even more value in the detection of hypoventilation and apnea. Data from this study of sedation health care providers in the PSRC indicate who this monitor is used most commonly by health care providers that administer the deepest levels of sedation and in cases in which the most potent drugs for sedation are used.

Our study highlights variability in adherence to published clinical guidelines on monitoring during sedation. Strict adherence to guidelines is not universal for many reasons. Evidence-based guidelines for physiologic monitoring during sedation may be difficult to develop.^{6,28} In some settings (eg, the magnetic resonance imaging scanner), the environment itself may challenge the accuracy of many monitoring modalities. In other situations, the use of monitors themselves (eg, blood pressure cuffs) can disturb the sedated child and interfere with procedures that require absolute motion control. Most important, implementation of guideline-based monitoring may not, in fact, reduce adverse events.^{6,7} Studies to evaluate the effect of the use of individual monitors on serious adverse events while accounting for the multitude of variables encountered would require a large and standardized collaborative effort and is not addressed herein. From a human factors engineering perspective, the current study is interesting in that it indicates which monitors the high-performing sedation health care providers within the PSRC find useful enough to use on a day-to-day basis.

One difficulty in adherence to specific guidelines may be that the language used in these guidelines can be confusing or difficult to interpret and implement. For instance, in the ASA statement, a distinction is made between the terms *continual* and *continuous*.⁷ In the ACEP clinical policy, it is stated that vital sign monitoring may

include “assessment of blood pressure, pulse rate, respiratory rate and pulse oximetry,” but the nature of this monitoring, be it continuous or intermittent, is not specified.³ Furthermore, not all the patients may receive the same monitoring under this policy. The use of SpO₂ is recommended in emergency department patients at increased risk of developing hypoxemia or with significant comorbidities, and cardiac monitoring can be forgone in patients without a history of cardiopulmonary disease.³ Later policies, in fact, defer to departmental guidelines for monitoring practices.⁵

There are many difficulties when it comes to developing evidence-based guidelines for the safe and effective monitoring of pediatric patients undergoing sedation. First, serious adverse outcomes are rare. More common complications, such as oxygen desaturations and hypoventilation, may have various definitions and are of uncertain clinical significance.²⁹ Second, many complications or interventions depend on the threshold and behavior of the health care provider and, thus, are subject to their own inherent variability.⁹

Despite the variability in monitoring shown herein, serious adverse outcomes during procedural sedation were uncommon within this large database. The PSRC has previously published data concerning rates of complications arising from sedations with a total incidence rate of 340 per 10 000 cases.⁹ The most common complications were oxygen desaturations less than 90% (157 per 10 000 cases), secretions requiring suctioning (47 per 10 000 cases), and vomiting during the procedure (42 per 10 000 cases). Serious adverse events were found to be rare with no reported deaths and a single case of cardiac arrest among this large cohort.⁹ Continuing rigorous research on the use of monitoring modalities during procedural sedation with a focus on the detection of adverse events and prevention of serious outcomes, as well as cost-effectiveness, will be key in developing evidence-based guidelines for this population.

There are inherent limitations to the use of a large database, such as the inability to ensure complete consistency in reporting over a large number of institutions and health care providers. However, this is balanced by the ability to obtain a greater sample of participants with increased generalizability. Other limitations have been outlined in previous articles and include the self-selection of motivated institutions into this consortium.^{9,30} These groups likely have highly organized sedation systems and may represent best practice and, thus, they may have inherent and unexplained differences from other organizations in which sedations occur that are not included in this cohort.³⁰ Finally, we recognize that it is impossible to know the exact nature of the intended sedation levels for every case in this database or the sedation level that was achieved in every case. The monitoring data are clearly skewed by the fact that certain types of health care providers were aiming for different sedation levels than other health care providers and, therefore, may have influenced the monitoring needs. Even with this in mind, we believe the presentation of the variety of monitoring choices that individual health care providers make for their day-to-day work can help inform future research into the issue of what monitors are most necessary.

In conclusion, there is significant variability in the frequency of use of individual monitoring devices during the sedation of children outside of the operating room within the PSRC. These differences are seen among types of health care providers, medications used for sedation, and the types of procedures for which sedation is needed. There is also a lack of adherence to published guidelines about monitoring children during sedation. Despite these findings, the reported safety of sedation within our study consortium is excellent. Further research is needed to develop evidence-based guidelines regarding the appropriateness of various monitoring modalities and their effect on adverse outcomes that are associated with sedation.

Accepted for Publication: April 17, 2012.

Published Online: September 10, 2012. doi:10.1001/archpediatrics.2012.1023

Author Affiliations: Department of Pediatrics, Section of Emergency Medicine, Yale University School of Medicine, New Haven, Connecticut (Dr Langhan); Pediatric Emergency Medicine Associates, Children's Healthcare of Atlanta, Atlanta, Georgia (Dr Mallory); Department of Anesthesiology and Critical Care Medicine, A.I. duPont Hospital for Children, Wilmington, Delaware (Dr Hertzog); Division of Pediatric Critical Care, St Louis University School of Medicine at Cardinal Glennon Children's Medical Center, St Louis, Missouri (Dr Lowrie); and Department of Pediatric Anesthesiology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire (Dr Cravero).

Correspondence: Melissa L. Langhan, MD, Department of Pediatrics, Section of Emergency Medicine, Yale University School of Medicine, 100 York St, Ste 1F, New Haven, CT 06511 (Melissa.langhan@yale.edu).

Author Contributions: Drs Langhan, Mallory, Hertzog, Lowrie, and Cravero had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Langhan, Mallory, Hertzog, Lowrie, and Cravero. *Acquisition of data:* Mallory and Cravero. *Analysis and interpretation of data:* Langhan, Mallory, Hertzog, Lowrie, and Cravero. *Drafting of the manuscript:* Langhan. *Critical revision of the manuscript for important intellectual content:* Langhan, Mallory, Hertzog, Lowrie, and Cravero. *Statistical analysis:* Mallory and Cravero. *Administrative, technical, and material support:* Langhan. *Study supervision:* Langhan and Cravero.

Group Information: The following hospitals comprise the Pediatric Sedation Research Consortium: Akron Children's Hospital, Akron, Ohio; Alfred I. Dupont Children's Hospital, Wilmington, Delaware; Arizona Children's Center at Maricopa Medical Center, Phoenix; Avera McKennan Hospital, Sioux Falls, South Dakota; Backus Children's Hospital, Memorial Health University Medical Center, Savannah, Georgia; Blank Children's Hospital—Iowa Methodist Medical Center, Des Moines; Brenner Children's Hospital, Wake Forest Baptist Health, Winston-Salem, North Carolina; Cape Fear Valley Medical Center, Fayetteville, North Carolina; Children's Healthcare of Atlanta Egleston Campus, Atlanta, Georgia; Children's Healthcare of Atlanta Scottish Rite Campus; Children's Hospital at

the Medical Center of Central Georgia, Macon; Children's Hospital of Alabama, Birmingham; Children's Memorial Hospital—Emergency Department, Chicago, Illinois; Children's Memorial Hospital, Chicago; Children's Mercy Hospital—Emergency Department, Kansas City, Missouri; Chris Evert Children's Hospital, Fort Lauderdale, Florida; Columbus Children's Hospital, Columbus, Ohio; Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire; East Tennessee Children's Hospital, Knoxville; Eastern Maine Medical Center, Bangor; Florida Hospital for Children, Orlando; Gundersen Lutheran, LaCrosse, Wisconsin; Helen DeVos Children's Hospital, Grand Rapids, Michigan; Holtz Children's Hospital at the University of Miami/Jackson Memorial Medical Center, Miami, Florida; Joe DiMaggio Children's Hospital, Hollywood, Florida; Kentucky Children's Hospital, Lexington; Kosair Children's Hospital, University of Louisville, Louisville, Kentucky; Medical University of South Carolina, Charleston; North Central Baptist Hospital, San Antonio, Texas; Palmetto Health Richland Memorial Hospital, Columbia, South Carolina; Rainbow Babies and Children's Hospital, Cleveland, Ohio; The Children's Hospital at Providence, Anchorage, Alaska; UMass Memorial Medical Center, Worcester, Massachusetts; UNC Healthcare, Chapel Hill, North Carolina; University of Virginia, Charlottesville; Vanderbilt Children's Hospital, Nashville, Tennessee; Yale New Haven Children's Hospital, New Haven, Connecticut.

Financial Disclosure: Dr Langhan received an honorarium to participate in an expert panel at an advisory board meeting of Oridion Capnography, Inc in November 2011 during the revising of the manuscript.

Funding/Support: This study was supported in part by grant Clinical and Transitional Science Award U11RR024139 from the National Center for Advancing Translational Sciences, a component of the National Institutes of Health, and National Institutes of Health roadmap for Medical Research (Dr Langhan).

Previous Presentations: An abstract from these data was presented at the American Academy of Pediatrics National Conference and Exhibition; October 14, 2011; Boston, Massachusetts; and the Society for Pediatric Sedation Meeting; May 22, 2012; Cleveland, Ohio.

Additional Contributions: We would like to acknowledge the efforts of the PSRC in creating this database and collecting data across multiple institutions.

REFERENCES

1. Coté CJ, Wilson S; American Academy of Pediatrics; American Academy of Pediatric Dentistry; Work Group on Sedation. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures: an update. *Pediatrics*. 2006;118(6):2587-2602.
2. Holzman RS, Cullen DJ, Eichhorn JH, Philip JH; The Risk Management Committee of the Department of Anaesthesia of Harvard Medical School. Guidelines for sedation by nonanesthesiologists during diagnostic and therapeutic procedures. *J Clin Anesth*. 1994;6(4):265-276.
3. Godwin SA, Caro DA, Wolf SJ, et al; American College of Emergency Physicians. Clinical policy: procedural sedation and analgesia in the emergency department. *Ann Emerg Med*. 2005;45(2):177-196.
4. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists: an updated report by the American Society of Anesthesiologists.

- gists Task Force on Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology*. 2002;96(4):1004-1017.
5. American College of Emergency Physicians. Sedation in the emergency department. *Ann Emerg Med*. 2011;57(5):469.
 6. Poe SS, Nolan MT, Dang D, et al. Ensuring safety of patients receiving sedation for procedures: evaluation of clinical practice guidelines. *Jt Comm J Qual Improv*. 2001;27(1):28-41.
 7. American Society of Anesthesiologists. Standards for basic anesthetic monitoring. <http://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx>. Accessed September 8, 2011.
 8. American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists: a report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. *Anesthesiology*. 1996; 84(2):459-471.
 9. Cravero JP, Blike GT, Beach M, et al; Pediatric Sedation Research Consortium. Incidence and nature of adverse events during pediatric sedation/anesthesia for procedures outside the operating room: report from the Pediatric Sedation Research Consortium. *Pediatrics*. 2006;118(3):1087-1096.
 10. Krauss B, Green SM. Procedural sedation and analgesia in children. *Lancet*. 2006; 367(9512):766-780.
 11. Pino RM. The nature of anesthesia and procedural sedation outside of the operating room. *Curr Opin Anaesthesiol*. 2007;20(4):347-351.
 12. Hertzog JH, Havidich JE. Non-anesthesiologist-provided pediatric procedural sedation: an update. *Curr Opin Anaesthesiol*. 2007;20(4):365-372.
 13. Eichhorn V, Henzler D, Murphy MF. Standardizing care and monitoring for anesthesia or procedural sedation delivered outside the operating room. *Curr Opin Anaesthesiol*. 2010;23(4):494-499.
 14. Malviya S, Voepel-Lewis T, Tait AR. Adverse events and risk factors associated with the sedation of children by nonanesthesiologists. *Anesth Analg*. 1997; 85(6):1207-1213.
 15. Coté CJ, Notterman DA, Karl HW, Weinberg JA, McCloskey C. Adverse sedation events in pediatrics: a critical incident analysis of contributing factors. *Pediatrics*. 2000;105(4, pt 1):805-814.
 16. Heinstein LC, Ramaciotti C, Scott WA, Coursey M, Sheeran PW, Lemler MS. Chloral hydrate sedation for pediatric echocardiography: physiologic responses, adverse events, and risk factors. *Pediatrics*. 2006;117(3):e434-e441. doi:10.1542/peds.2005-1445.
 17. Coté CJ, Rolf N, Liu LM, et al. A single-blind study of combined pulse oximetry and capnography in children. *Anesthesiology*. 1991;74(6):980-987.
 18. Runciman WB, Webb RK, Barker L, Currie M. The Australian Incident Monitoring Study: the pulse oximeter: applications and limitations—an analysis of 2000 incident reports. *Anaesth Intensive Care*. 1993;21(5):543-550.
 19. Langhan M. Continuous end-tidal carbon dioxide monitoring in pediatric intensive care units. *J Crit Care*. 2009;24(2):227-230.
 20. Langhan ML, Chen L. Current utilization of continuous end-tidal carbon dioxide monitoring in pediatric emergency departments. *Pediatr Emerg Care*. 2008; 24(4):211-213.
 21. Shavit I, Leder M, Cohen DM. Sedation provider practice variation: a survey analysis of pediatric emergency subspecialists and fellows. *Pediatr Emerg Care*. 2010; 26(10):742-747.
 22. Ahrens T, Wijeweera H, Ray S. Capnography: a key underutilized technology. *Crit Care Nurs Clin North Am*. 1999;11(1):49-62.
 23. Anderson JL, Junkins E, Pribble C, Guenther E. Capnography and depth of sedation during propofol sedation in children. *Ann Emerg Med*. 2007;49(1): 9-13.
 24. Burton JH, Harrah JD, Germann CA, Dillon DC. Does end-tidal carbon dioxide monitoring detect respiratory events prior to current sedation monitoring practices? *Acad Emerg Med*. 2006;13(5):500-504.
 25. Lightdale JR, Goldmann DA, Feldman HA, Newburg AR, DiNardo JA, Fox VL. Microstream capnography improves patient monitoring during moderate sedation: a randomized, controlled trial. *Pediatrics*. 2006;117(6):e1170-e1178.
 26. Fu ES, Downs JB, Schweiger JW, Miguel RV, Smith RA. Supplemental oxygen impairs detection of hypoventilation by pulse oximetry. *Chest*. 2004;126(5): 1552-1558.
 27. Becker DE, Casabianca AB. Respiratory monitoring: physiological and technical considerations. *Anesth Prog*. 2009;56(1):14-22.
 28. Leroy PL, Nieman FH, Blokland-Loggers HE, Schipper DM, Zimmermann LJ, Knape JT. Adherence to safety guidelines on paediatric procedural sedation: the results of a nationwide survey under general paediatricians in the Netherlands. *Arch Dis Child*. 2010;95(12):1027-1030.
 29. Bhatt M, Kennedy RM, Osmond MH, et al; Consensus Panel on Sedation Research of Pediatric Emergency Research Canada (PERC) and the Pediatric Emergency Care Applied Research Network (PECARN). Consensus-based recommendations for standardizing terminology and reporting adverse events for emergency department procedural sedation and analgesia in children. *Ann Emerg Med*. 2009; 53(4):426-435.
 30. Cravero JP, Beach ML, Blike GT, Gallagher SM, Hertzog JH; Pediatric Sedation Research Consortium. The incidence and nature of adverse events during pediatric sedation/anesthesia with propofol for procedures outside the operating room: a report from the Pediatric Sedation Research Consortium. *Anesth Analg*. 2009; 108(3):795-804.