The Pediatric Sedation Unit: A Mechanism for Pediatric Sedation

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ABSTRACT. Objectives. We have created a pediatric sedation unit (PSU) in response to the need for uniform, safe, and appropriately monitored sedation and/or analgesia during procedures or studies in a large tertiary care medical center. The operational characteristics of the PSU are described in this report, as is our clinical experience in the first 8 months of operation.

Methods. A retrospective review of quality assurance data was performed. These data included patient demographics and chronic medical diagnoses, procedure, or study performed; sedative or analgesic medication given; complications (defined prospectively); and sedation and monitoring time. Patient-specific medical records related to the procedure and sedation were reviewed if a complication was noted in the quality assurance data.

Results. Briefly, the PSU was staffed with an intensivist and pediatric intensive care unit nurses. Patients were admitted to the PSU and assessed medically for risk factors during sedation. Continuous heart rate, respiratory rate, and pulse oximetry monitoring were used, and blood pressure was determined every 5 minutes. After sedation and stabilization, with monitoring continued, the patient was transported to the site to undergo the procedure or study. The pediatric intensive care unit nurse remained with the patient at all times. All necessary emergency equipment was transported with the patient. After the procedure or study was completed, the patient was returned to the PSU for recovery to predetermined parameters.

We were able to analyze 458 episodes of sedation for this review. Procedures and studies included radiologic examinations, cardiac catheterizations, orthopedic manipulations, solid organ and bone marrow biopsies, gastrointestinal endoscopy, bronchoscopy, evoked potential measurements, and others. Patients were 2 weeks to 32 years of age. The average time from initiation of sedation to last dose of medication administered was 84 minutes. The average time from initiation of sedation to full recovery was 120 minutes. Sedative and analgesia medications use was not standardized; however, the majority of children needing sedation received propofol or midazolam. For patients requiring analgesia, ketamine or fentanyl was added. In 79 of 458 (12%) sedation episodes, complications (defined prospectively) occurred; and sedation and monitoring times. Patient-specific medical records related to the procedure and sedation were reviewed if a complication was noted in the quality assurance data.

Conclusion. The PSU was created in response to the need for uniform, safe, and appropriately monitored sedation and/or analgesia during procedures or studies. Safe sedation is best ensured by appropriate pre-sedation risk assessment and with monitoring by a care provider trained in resuscitative measures who is not involved in performing the procedure itself. Uniformity of care in a large institution is a standard met by the creation of a centralized service, with active input from the department of anesthesiology. We present the PSU as a model for achieving these goals. Pediatrics 1998;102(3). URL: http://www.pediatrics.org/cgi/content/full/102/3/e30; conscious sedation, child, propofol, anesthesia.

ABBREVIATIONS: AAP, American Academy of Pediatrics; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; RB & C, Rainbow Babies and Childrens Hospital; PSU, pediatric sedation unit; PICU, pediatric intensive care unit; ASA, American Society of Anesthesiologists; MRI, magnetic resonance imaging.

Both pharmacologic and nonpharmacologic interventions may help children tolerate painful procedures or diagnostic studies requiring prolonged periods of immobility. The American Academy of Pediatrics (AAP) Committee on Drugs has issued guidelines categorizing pharmacologic intervention into three levels: conscious sedation, deep sedation, and general anesthesia. Conscious sedation refers to a state of depressed consciousness that "allows protective reflexes to be maintained" and "permits appropriate response by the patient to physical stimuli or verbal command." Deep sedation is defined in part as "partial or complete loss of protective reflexes" and lack of purposeful response to physical stimulation. The AAP guidelines suggest that conscious sedation may be effectively and safely delivered and monitored by practitioners with basic training in airway maintenance and management of medication-induced complications. Deep sedation requires the presence of personnel skilled in airway management and cardiopulmonary resuscitation. Concern has been raised that these guidelines essentially mandate the presence of an anesthesiologist at the bedside of all sedated children because "conscious sedation" as defined is practically impossible in infants and small children. Practitioners may tend to avoid this expensive and often unavailable “requirement” by labeling sedative events “conscious sedation” when in fact “deep sedation” is occurring. To complicate the issue of providing sedation or analgesia further, multiple “guidelines” for pediatric sedation also have been published by a variety of...
professional organizations.\textsuperscript{3–6} The standards suggested in one set of guidelines may or may not agree with standards from the other organizations.\textsuperscript{5} The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has sought to reduce the variation in levels of care provided to patients sedated in different areas of the same hospital by requiring the development of uniform guidelines of care for the sedated patient. Development of these guidelines by individual departments within the hospital must include input from the director of anesthesiology services.\textsuperscript{8}

Rainbow Babies and Childrens Hospital (RB & C) is the 244-bed tertiary care pediatric center for University Hospitals of Cleveland. It serves >86,000 children each year, with ~10,000 pediatric inpatient admissions annually. Historically, in this institution, sedation and analgesia for children outside of the operating room environment have been managed by individual medical and surgical divisions and individual practitioners in a variety of ways. In 1996 the staff of the Department of Pediatrics of Case Western Reserve University asked members of the Division of Pediatric Pharmacology and Critical Care based at RB & C to create a pediatric sedation unit (PSU) that would provide safe and effective sedation and analgesia for children scheduled for invasive procedures and noninvasive diagnostic studies. The PSU was expected to provide the presedation evaluation, pharmacologic management, monitoring, treatment, and discharge of children referred to RB & C from an inpatient or outpatient source. We describe here the operation of the PSU and our first 8 months of experience.

METHODS

The PSU

Because of major hospital-wide construction occurring during the first year of PSU operation, the physical plant of the PSU changed twice during the 8 months of this study. Both sites had a six- to eight-bed capacity arranged as a combination of four-bed ward rooms and two-bed semiprivate rooms. Equipment and supply storage, a controlled access area for secure drug storage, and a small secretarial area were located nearby. A family waiting room was easily accessible.

The PSU was open from 6:30 AM to 7:00 PM 5 days a week. It was staffed by pediatric critical care nurses and fellows and faculty from the pediatric intensive care unit (PICU) at RB & C. Nurses were scheduled to work in the PSU for staggered, overlapping 8- or 12-hour shifts. Shifting was done so that several nurses were available at busy times during the middle of the day; fewer staff members were present early and after 5:00 PM. Staff was shifted frequently between the PICU and PSU as dictated by patient numbers and care requirements. One faculty member was assigned to staff the PSU each week to provide direct patient care or to closely supervise a fellow. These physicians were not involved in other patient care in the PICU or elsewhere during the time they staffed the PSU. Child life workers and patient care assistants were available as needed from the PICU.

The practitioner performing the procedure or diagnostic study called either the PSU during regular operational hours or the PICU secretary after hours to schedule a patient for sedation/analgesia. Information requested of the practitioner is listed in Table 1. The patient was asked to arrive in the PSU 90 minutes before the scheduled procedure. The requesting practitioner was then responsible for informing the patient's family of the arrival time and the fasting requirements appropriate for that patient. Patients generally were scheduled no more than 1 hour apart, and none were scheduled for after 5:00 PM to allow adequate time for recovery. Requests for sedation/analgesia on an emergency or urgent basis were referred to the PICU admitting physician for triage to either the PSU or the PICU staff as dictated by staffing levels and patient census at the time.

On arrival, the child was screened by the PSU nurse and examined by the PSU physician. Screening questions are listed on the Sedation Flow Sheet (the standard form used for all patients, adult and pediatric, receiving sedation in University Hospitals) shown in Fig 1. Possible reasons for exclusion from PSU services included but were not limited to facial and neck physical abnormalities that could make airway support difficult, poorly controlled respiratory illness, severe myocardial depression, fever, morbid obesity, and history of adverse reactions to anesthesia or sedation. In general, American Society of Anesthesiologists (ASA) class I and II (Table 2) patients were routinely provided sedation/analgesia through the PSU.\textsuperscript{7} ASA class III patients required careful consideration on an individual basis, and ASA class IV patients were not provided sedation/analgesia through the PSU. After full assessment, the physician wrote orders for a sedative/analgesic regimen and determined vital sign parameters within which the patient was expected to remain. The physician discussed these orders with the patient's critical care nurse who then inserted an intravascular catheter. Continuous heart rate, respiratory rate (chest wall movement), and pulse oximetry were monitored electronically before, during, and after medication was administered. Blood pressure was measured every 5 minutes by automated cuff during the same period. Unless contraindicated, all patients received supplemental oxygen by nasal cannulae or simple face mask during sedation. Initial sedation was administered in the PSU in the presence of the physician. After the physician determined that the child was sedated adequately and had appropriate cardiopulmonary vital signs, the patient, still monitored continuously, was moved to the site of the procedure or study. Equipment transported with the child is listed in Table 3.

During transport and the procedure or study, the nurse stayed with the patient to provide monitoring and emergency airway or cardiovascular support and to administer any additional sedation/analgesia ordered by the PSU physician. The physician often chose to accompany a particularly difficult patient to the procedure site but, in any event, was available constantly for radio communication with the PSU nurse. The magnetic resonance imaging (MRI) suite posed special difficulties for both monitoring and communication. Continuous electrocardiographic monitoring was not possible, although we were able to continue blood pressure monitoring every 5 minutes, and the pulse oximeter provided a record of heart rate. Shielding in the area made radio communication impossible, thus, the usual hospital pager system was used to maintain nurse–physician contact.

After a procedure was completed, patients were returned to the PSU for monitoring until fully awake. Discharge criteria are listed on the Sedation Flow Sheet in Fig 1. Most often, a patient was “recovered” by the same nurse who provided sedation monitoring during the procedure. When the PSU was busy, a multibed room was used as a postsedation recovery area in which one nurse monitored several patients simultaneously. Procedure discharge teaching was performed by the practitioner who performed the procedure. Discharge teaching relevant to sedation/analgesia was provided by the PSU nurse and physician.

Retrospective Review

We retrospectively reviewed the experience in the PSU during the 8-month period from July 1, 1996, through February 28, 1997.
The data presented were compiled from the PSU scheduling book and weekly summary PSU data forms used to report quality improvement and performance issues to the PICU Multidisciplinary Committee. These forms were completed by the PSU supervising nurse who reviewed each Sedation Flow Sheet and noted the date, patient diagnosis and age, study or procedure performed, medications used, vital sign changes, treatments given, sedation time, and monitoring time. This information was then used by the Committee to review sedation-related complications, recommend system changes in the operation of the PSU to improve patient care.
reduce complication incidence, and track the outcome of those changes. For this study, if vital sign changes were noted on the weekly summary forms, the actual Sedation Flow Sheet for that patient was reviewed to characterize the complication specifically.

The following definitions were used for data abstraction:

1. sedation time, the time from first administration of medication to last bolus of medication or discontinuation of any constant infusion;
2. monitoring time, the time from first administration of medication to the time the child met discharge criteria from the PSU. Thus, monitoring time did not include the initial 90 minutes that the patient was in the PSU before the procedure;
3. inpatient, patients who were admitted to the hospital before the procedure;
4. outpatient, patients who came from home to enter the PSU, whether or not they were admitted to the hospital after the procedure;
5. sedation episode, episodes when medication was actually administered for sedation. Procedures for which no medication was given but that required PSU monitoring were not included. More than one procedure may have been performed during one sedation episode;
6. complications, a change in vital signs or patient status requiring intervention. Because our methods of sedation required close titration of medication, a need for more medication was not counted as a complication unless the procedure could not be completed because of failure of sedation.

### RESULTS

The PSU was operational for 174 days during the 8 months of this study. Based on information recorded in the scheduling book, 626 patients were scheduled for 665 procedures or studies (3.6 patients/day; range, 0 to 11 patients/day). Review of the scheduling book revealed that 52 (8%) procedures were canceled by the referring physician, and 12 (2%) patients did not appear for their scheduled procedures. For 72 scheduled procedures, the medical record was unavailable for analysis for this study. The PSU physician canceled 25 procedures after the patient was judged unsuited for safe sedation/analgesia. An additional 16 procedures were performed without the patient requiring sedation/analgesia. Sedation was administered for 431 single procedures. Another 57 procedures were performed during 27 episodes of sedation, ie, two to three procedures per sedation episode. Thus, there were 458 sedation episodes available for review in this report.

Many individuals were referred to the PSU repeatedly during the 8 months of operation. Counting an individual patient only once and using the age at the first referral to the PSU yields an age range of 2 weeks to 32 years for 399 individuals. This group had an average age of 5.6 years and a median age of 4 years. Outpatients accounted for 265 sedation episodes. Of the sedation episodes, 50% involved patients who carried a known diagnosis of congenital heart disease, seizure disorder, intracranial pathology (eg, tumors, hydrocephalus), cerebral palsy, chronic lung disease, hypotonia, autism, developmental delay, and attention deficit disorder. Table 4 lists the procedures or studies performed with sedation and monitoring through the PSU.

These procedures and studies took a total of 648 hours of sedation time and 914 hours of monitoring time. Including those patients who received no medication, the average sedation time per procedure was 84 minutes (median, 75 minutes; range, 0 to 420 minutes), and the average monitoring time per procedure was 120 minutes (median, 110 minutes; range, 0 to 440 minutes). Thus, recovery time averaged 34 minutes (median, 25 minutes; range, 0 to 180 minutes). The average sedation time for the more common procedures is shown in Table 4. Cardiac catheterization (199 minutes), bone scanning (111 minutes), and MRI (98 minutes) were the three commonly performed procedures with the longest average sedation times. Surprisingly, the average length of sedation time involved in a lumbar puncture was 92 minutes; however, this procedure was performed in older patients with severe scoliosis who required fluoroscopy for successful needle insertion.

The precise sedation regimen used depended on

### TABLE 2. ASA Physical Classification Scheme for Preanesthesia Risk Assessment

<table>
<thead>
<tr>
<th>Class</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Normal healthy individual without systemic disease</td>
</tr>
<tr>
<td>II</td>
<td>Individual with mild or moderate systemic disease</td>
</tr>
<tr>
<td>III</td>
<td>Individual with severe systemic disease</td>
</tr>
<tr>
<td>IV</td>
<td>Moribund individual not expected to survive without surgical intervention</td>
</tr>
<tr>
<td>V</td>
<td>Moribund individual expected to survive without surgical intervention</td>
</tr>
</tbody>
</table>

### TABLE 3. Equipment Transported With Patient From the PSU to Site of Procedure

- Self-inflating bag and appropriately sized mask
- Oxygen cylinder
- Monitor—Blood pressure, heart rate, respiratory rate, pulse oximeter
- IV infusion pump
- Tube kit
  - Oral airway (appropriate sizes)
  - Magill forceps
  - Tonsillar suction
  - Endotracheal tubes (appropriate sizes)
  - Stylets
  - Laryngoscope handle
  - Laryngoscope blades, Miller and MacGill (appropriate sizes)
- Tape
- Medication box
- Syringes
- Stopcocks
- Tubing sets
- Alcohol swabs
- Heparin flush
- Sterile water
- Needles
- Vecuronium
- Propofol
- Etomidate
- Midazolam
- Fentanyl
- Ketamine
- Furosemide
- Atropine
- Diphenhydramine
- Hydrocortisone
- Epinephrine
- Calcium chloride
- Sodium bicarbonate
- Glucose 50%
- Mannitol
- Lidocaine
- Naloxone
- 25% Albumin
- Hetastarch
- Normal saline
- Needleless system access devices
physician preference, patient characteristics, and procedure requirements for degree of immobility and analgesia. For studies not involving painful stimuli or multiple position changes, the PSU standard was propofol given intravenously, first as a slow bolus (1 to 2 mg/kg) and then a continuous infusion of 1 to 6 mg/kg per hour titrated as needed. Because propofol produces a burning sensation with the initial injection, some PSU physicians infused 1% lidocaine first or administered ketamine (1 mg/kg) before beginning the propofol infusion. Another successful regimen was to use propofol for titratable, continuous sedation and to give bolus doses of fentanyl or ketamine before noxious stimuli occurred during the procedure. Shorter or more invasive procedures generally were performed after patient sedation and analgesia was achieved with dosages of midazolam and ketamine. Atropine pretreatment was always used when ketamine was given. It also was frequently, but not universally, used with propofol. Other medications used are also listed in Table 5.

Complications of sedation are noted in Table 6. As documented in the weekly summary forms, 79 incidents of vital sign changes were noted in 458 sedation episodes (17.2%). Review of Sedation Flow Sheets for these 79 patients produced documentation supporting 54 actual complications (12% of 458 sedation episodes) requiring intervention or change in management as defined in Table 5. There was no clinical difference in median (3.5 years) or average (6 years) age of the patients experiencing complications compared with the total PSU patient group. The procedure or study was canceled in 11 of the 54 incidents (20% of complications; 2.4% of sedation episodes). Three of the patients experiencing complications were studied successfully later the same day when the PSU staff resedated the patient after intubation and stabilization. The remaining 8 were referred to the department of anesthesiology for their procedure. The complication noted most frequently was a decrease in blood pressure, often documented as a widening in pulse pressure without a clinically significant change in systolic pressure. This “hypotension” occurred most frequently during those procedures requiring the longest average sedation time (MRI, bone scan, cardiac catheterization). The next most frequently noted complication was a pulse oximetry reading <93%. Half of the pulse oximetry drops were associated with passage of a probe

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number</th>
<th>Average Sedation Time (Min)</th>
<th>Average Monitoring Time (Min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI</td>
<td>176</td>
<td>98</td>
<td>129</td>
</tr>
<tr>
<td>Computed tomography</td>
<td>77</td>
<td>52</td>
<td>84</td>
</tr>
<tr>
<td>Cardiac catheterization</td>
<td>41</td>
<td>199</td>
<td>247</td>
</tr>
<tr>
<td>Gastroesophagoduodenoscopy</td>
<td>20</td>
<td>31</td>
<td>62</td>
</tr>
<tr>
<td>Bone scan</td>
<td>19</td>
<td>111</td>
<td>135</td>
</tr>
<tr>
<td>Auditory evoked potentials</td>
<td>15</td>
<td>62</td>
<td>92</td>
</tr>
<tr>
<td>Cast manipulation</td>
<td>13</td>
<td>55</td>
<td>83</td>
</tr>
<tr>
<td>Burn care</td>
<td>13</td>
<td>22</td>
<td>38</td>
</tr>
<tr>
<td>Renal biopsy</td>
<td>12</td>
<td>45</td>
<td>110</td>
</tr>
<tr>
<td>Transesophageal echocardiography</td>
<td>9</td>
<td>47</td>
<td>133</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>9</td>
<td>38</td>
<td>81</td>
</tr>
<tr>
<td>Broviac removal</td>
<td>8</td>
<td>7</td>
<td>28</td>
</tr>
<tr>
<td>Lumbar puncture</td>
<td>7</td>
<td>92</td>
<td>107</td>
</tr>
<tr>
<td>Visual evoked potentials</td>
<td>6</td>
<td>85</td>
<td>133</td>
</tr>
<tr>
<td>Exchange transfusion</td>
<td>6</td>
<td>64</td>
<td>96</td>
</tr>
<tr>
<td>Percutaneous central venous catheter line placement</td>
<td>6</td>
<td>57</td>
<td>88</td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>6</td>
<td>64</td>
<td>100</td>
</tr>
<tr>
<td>Vaginal exam</td>
<td>5</td>
<td>22</td>
<td>68</td>
</tr>
<tr>
<td>Incision and drainage abscess</td>
<td>5</td>
<td>30</td>
<td>67</td>
</tr>
<tr>
<td>Transthoracic echocardiography</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone marrow aspiration/biopsy</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liver biopsy</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central line manipulation</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint aspiration/injection</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiography</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pin placement</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ph probe placement</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electromyography</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voiding cystourethrogram</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultrasound</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anal manometry</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rectal biopsy</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Halo traction manipulation</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tube thoracostomy</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Foreign body removal</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positron emission tomography</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Electroencephalography</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental exam</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intravenous pyelogram</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple studies per sedation episode</td>
<td>27</td>
<td>140</td>
<td>180</td>
</tr>
</tbody>
</table>

TABLE 4. Procedures for Which Patients Were Referred to the PSU and Average Sedation and Monitoring Time for Frequently Performed Procedures
through the pharynx during either bronchoscopy, transesophageal echocardiography, or gastroesophageal endoscopy. Apnea occurred during 7 procedures, 6 of which were prolonged, ie, four cardiac catheterizations lasting >3 hours and two MRI scans requiring 2.5 hours of sedation. All patients responded quickly to decreasing the propofol drip, bag/mask ventilation, and stimulation. One of these 6 patients was intubated to continue the cardiac catheterization, and another infant was rescheduled for MRI with intubation. No complication resulted in long-term morbidity or mortality.

DISCUSSION

This retrospective review describes our experience with providing a program of sedation and analgesia for children. It is presented as a strategy for efficiently and safely sedating a large number of children undergoing nonemergency procedures on a hospital-wide basis. We believe that our program represents some specific differences from sedation services or regimens reported previously and offers some striking advantages. Only one other report in abstract form of a centralized service within a large hospital offering sedation for multiple procedures and departments is available. Many other reports of sedation regimens exist that focus on the safety and efficacy of a particular drug combination for a specific procedure or patient population. Pediatric subspecialty services may develop expertise in administering sedation/analgesia as a specific routine in the endoscopy suite, the cardiac catheterization laboratory, or the radiology department. The emergency department is another area where specific drug regimens have been used successfully for short, painful procedures on generally healthy children on an emergency basis. Difficulty may arise when specific regimens are not appropriate for medically complex circumstances.

Children with complicated medical histories or chronic illnesses present particularly difficult issues for the practitioner delivering sedation. Review of our PSU patient demographics shows that 50% of the sedation episodes in the PSU occurred in children already diagnosed with brain tumor, seizure disorder, congenital heart disease, mental retardation, cerebral palsy, hypotonia, autism, and developmental delay. Additionally, many of the patients referred to the PSU underwent procedures or studies designed to diagnose more of such disorders. Of the 54 complications we documented, 30 occurred in children with one of these “difficult” diagnoses. Patients with these conditions may be judged to fit the ASA class III preoperative risk designation if their condition is poorly controlled. They represent special challenges for sedation, analgesia, and anesthesia and may require consultation with or referral to a pediatric anesthesiologist. Although the ASA classification scheme is useful, clinical judgment is required. Preventing the chronic disorder from becoming an uncontrolled problem with the added physiologic stress of sedatives and analgesics takes experience and preparation. The skills intensivists and critical care nurses use every day in the PICU may be needed to decide when referral to an anesthesiologist is necessary. That 20 complications occurred in children without diagnoses of concern simply emphasizes the need for the emergency monitoring and treatment skills common to the PICU staff.

### TABLE 5. Medications Used in the PSU

<table>
<thead>
<tr>
<th>Medication Regimen</th>
<th>Number of Sedation Episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propofol alone</td>
<td>135</td>
</tr>
<tr>
<td>Propofol plus ketamine as needed</td>
<td>121</td>
</tr>
<tr>
<td>Ketamine (one dose) followed by propofol alone</td>
<td>69</td>
</tr>
<tr>
<td>Propofol plus fentanyl as needed</td>
<td>47</td>
</tr>
<tr>
<td>Ketamine plus midazolam</td>
<td>49</td>
</tr>
<tr>
<td>Narcotic plus midazolam</td>
<td>7</td>
</tr>
<tr>
<td>Midazolam alone</td>
<td>9</td>
</tr>
<tr>
<td>Other (alone or in combination)</td>
<td>21</td>
</tr>
<tr>
<td>Etomidate</td>
<td></td>
</tr>
<tr>
<td>Ketamine</td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td></td>
</tr>
<tr>
<td>Seconal</td>
<td></td>
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<tr>
<td>Chloral hydrate</td>
<td></td>
</tr>
</tbody>
</table>

### TABLE 6. Sedation Complications in the PSU

<table>
<thead>
<tr>
<th>Complication</th>
<th>Number (%)*</th>
<th>Intervention</th>
<th>Study Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>20 (4.4%)</td>
<td>Fluid push</td>
<td>20</td>
</tr>
<tr>
<td>Hypoxemia</td>
<td>12 (2.6%)</td>
<td>Positioning, increase FIO₂</td>
<td>10</td>
</tr>
<tr>
<td>Apnea</td>
<td>7 (1.3%)</td>
<td>Intubation, positioning, bagging</td>
<td>6</td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>6 (1.3%)</td>
<td>Positioning, suctioning</td>
<td>3</td>
</tr>
<tr>
<td>Agitation</td>
<td>3 (0.7%)</td>
<td>Multiple medications</td>
<td>0</td>
</tr>
<tr>
<td>Seizure</td>
<td>2 (0.4%)</td>
<td>Basic support</td>
<td>1</td>
</tr>
<tr>
<td>Hiccups</td>
<td>2 (0.4%)</td>
<td>Intubation</td>
<td>1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1 (0.2%)</td>
<td>Nifedipine</td>
<td>0</td>
</tr>
<tr>
<td>Emesis</td>
<td>1 (0.2%)</td>
<td>Admit overnight</td>
<td>1</td>
</tr>
<tr>
<td>Totals</td>
<td>54 (12%)</td>
<td></td>
<td>43 (9.4%)</td>
</tr>
</tbody>
</table>

* Percentage of total sedation episodes (N = 458).

Hypotension indicates a decrease in blood pressure requiring intravascular fluid infusion ordered by the PSU physician; hypoxemia, a pulse oximetry reading <93% (in patients already receiving supplemental oxygen) or, for children with cyanotic congenital heart lesions, significantly lower than baseline; apnea, >10 seconds of no respiratory effort; airway obstruction, coughing, upper airway noise with respiratory distress; agitation, paradoxical agitation or movement after receiving sedation/analgesia; seizure, self-limited generalized tonic-clonic activity similar to known baseline seizures, not related to hypoxemia; hiccups, intractable hiccups after sedation producing head movement that prevented study completion; hypertension, blood pressure rise requiring treatment ordered by the PSU physician; emesis, emesis post sedation which prevented PO intake and necessitated admission to the hospital overnight.
The goal of sedation or analgesia is to achieve the least depressed level of consciousness necessary to perform the particular procedure or study scheduled. The PSU staff recognizes the general impossibility of conscious sedation as defined in the AAP guidelines in infants and toddlers whose appropriate response to stimuli during sedation is to actively evade the stimulus. Our model of monitoring and response involves preparation in the event that deep sedation occurs. The personnel used are similar to those used in pediatric critical care transport in which experienced nurses and affiliated personnel provide monitoring and emergency treatment with physician direction.26–28 Our PSU system expands on this model with full pediatric critical care physician assessment of the patient and constant availability of that physician who has no concurrent responsibilities. Critical care nurses use the monitoring, assessment, and emergency response skills needed to judge and respond to vital signs, airway patency, and adequacy of ventilation every day in the PICU with critically ill children. In addition, the PSU nurses have at least 3 years of pediatric critical care experience and undergo written and practical competency testing on sedative and emergency drug effects, dosing and administration techniques, and emergency airway maintenance skills.

This PSU model has demonstrated effective recognition and treatment of the emergencies created by any sedation regimen including cardiovascular depression, airway obstruction, and apnea. The most common complication noted in the PSU experience is “hypotension.” The definition of hypotension for this review depended on the judgment of the individual physician, and treatment was often initiated in patients who had a change in blood pressure from baseline that was still within a normal range for age. Decrease in blood pressure or widening of pulse pressure is a common and expected complication with use of propofol, the most frequently used drug in the PSU. Anesthesia induction with propofol was associated with a 20% to >40% decrease in blood pressure in 43.8% of patients in one study.30 Appropriate monitoring during sedation will identify hypotension, whatever the definition, and treatment with an infusion of fluid either before or during the sedation did not preclude completion of any study or procedure.

Apnea is a serious complication of any sedation regimen. Six of the seven patients from the PSU who became apneic did so only after at least 1 hour of continuous infusion of propofol with a bolus given for too much movement. The pharmacokinetics of propofol predict that high serum levels of propofol tend to occur after propofol is given as a large, quickly infused bolus or after a bolus given after a prolonged constant infusion.31 Fortunately, the pharmacokinetics of propofol also predict a short duration of action after discontinuation of the drug, and this property shortens the time needed for emergency airway support during apnea. The PSU experience has resulted in a decrease in the bolus dose of propofol delivered when increased sedation is needed after 1 hour of continuous infusion.

The PSU is unusual in the extensive use of propofol for pediatric sedation outside of the operating room or intensive care unit. Propofol became the sedative of choice for children in the PICU at RB & C after we undertook and continue extensive pharmacokinetic and pharmacodynamic study of its use in children.32 All PSU staff are thus familiar with the drug and its effects. The ability to titrate the amount of drug needed for each patient and the very short recovery times with little postsedation nausea and vomiting have proven ideal for PSU patients. These same characteristics of propofol use for sedation outside of the operating room are cited in a review33 and in reports of its use for sedation during imaging studies,34–38 cardiac catheterization,39,40 and radiation therapy.41 The doses used for PSU patients are similar to or lower than doses reported in these and other nonoperating-room environments,42,43 and much lower than the doses used for intubated patients in our PICU. The other drug used most commonly in the PSU was ketamine, especially when analgesia was desired. It has been used successfully for pediatric sedation for short, painful procedures in doses similar to our own.11,39,44–48

Our choice of sedation medications also has been driven by the remarkably long sedation time necessary for the average PSU patient. Cardiac catheterization and MRI, two of the most frequently referred procedures to the PSU, may take hours to perform. Despite long periods of sedation, with the use of propofol, the average recovery time was ~30 minutes. Transport time to the site of procedures and back to the PSU did not appreciably affect sedation or recovery time because the longest transport time (to the MRI suite) was 5 minutes even when elevator access was not controlled. We will be fortunate to situate the PSU immediately adjacent to the endoscopy suite and cardiac catheterization laboratory when hospital construction is completed. Short procedures such as cast manipulation, burn care, liver biopsy, and vaginal examinations were performed in the PSU, as were portable radiologic examinations including renal biopsy and echocardiography.

The number of children referred to our PSU in just the first 8 months of operation reflects the widespread need for safe, effective sedation/analgesia for a large number of patients and a variety of procedures in a large children’s hospital. The creation of a single, centralized service makes available sedation to many practitioners with just a single phone call. We also have been able to arrange for multiple procedures scheduled by different departments for an individual patient during a single exposure to sedation/analgesia. Because sedation for pediatric patients in our institution was decentralized previously, we have no data to compare the success and safety of our sedation regimens with previous institutional experience. An anecdotal letter from the Pediatric Neurology Division reported that their rate of attaining successful, high-quality studies in their patient population with potential sedation difficulties had risen from ~75% to 98%. They received good feedback from their patients referred to the PSU and found the scheduling mechanism easy to use (un-
published observations). A patient follow-up program focusing on identifying patient satisfaction issues for PSU patients is underway.

The Division of Pediatric Critical Care at RB & C is fortunate to have a strong and long-standing relationship with the Department of Anesthesiology at University Hospitals. One of the pediatric anesthesiologists serves as the official liaison for the PSU, providing ongoing advice and constructive criticism. He and other pediatric anesthesiologists are available routinely for patient consultations. With the development of strict policies and procedures, we have tried to clearly define a patient population for which we will provide sedation that is quite distinct from our population of critically ill patients in the PICU. For instance, early in the PSU experience, if a patient could not be sedated safely without impending respiratory compromise, the child may have been intubated to proceed with the study or procedure. This approach blurs the distinction between intensive care, response to emergencies created by sedation, and general anesthesia. It also is very expensive in terms of unplanned time and labor needs, which interfered with provision of routine PSU services to other patients. We no longer provide critical care to patients needing elective intubation. Instead, the procedure is rescheduled and the patient is referred to the Department of Anesthesiology. We have developed evaluative mechanisms for services requiring PSU management of invasive, potentially painful procedures that allow us to refer the patient to an anesthesiologist when the service requires true immobility of the patient and no response to pain.

We also have taken literally the requirement by JCAHO that sedation practices within an institution be uniform. The PSU requirements for length of time that the patient should receive no food or liquids before a procedure are the same as those for the Department of Anesthesiology. Also, following anesthesiology practice, procedures for infants referred at <45 weeks’ postconceptional age are postponed until these patients are older. If the procedure cannot be safely postponed, these patients are admitted to the hospital overnight to monitor for apnea that may occur after sedation in this age range. Premature infants <60 weeks’ postconceptional age have an even greater risk of apnea and are treated similarly. This ability to collaborate with the department of anesthesiology staff, mandated by excellence in patient care and by the JCAHO, has contributed greatly to the success of the PSU at our institution.

ACKNOWLEDGMENTS

We thank Paul A. Tripi, MD, Department of Anesthesiology, who worked extensively with us to develop policies and procedures for the PSU. We also thank Jeffrey L. Blumer, PhD, MD; Paul Smith, DO; Phil Toltzis, MD; MaryBeth Thoburn, RN; and the entire PSU nursing staff for their tireless commitment to the PSU.

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