

# Pride, Prejudice, and Pediatric Sedation: A Multispecialty Evaluation of the State of the Art

Report from a  
Dartmouth Summit  
on Pediatric Sedation

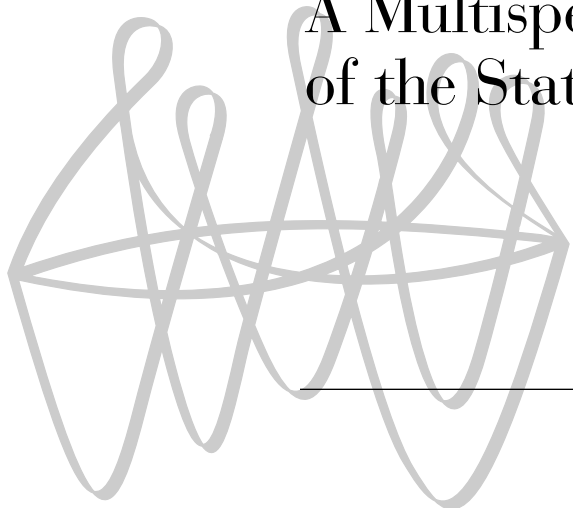
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The information contained in *Pride, Prejudice, and Pediatric Sedation: A Multispecialty Evaluation of the State of the Art* came from the Dartmouth Summit on Pediatric Sedation held at the Dartmouth Hitchcock Medical Center (September 9th, 2000). This summit brought together a group of health care professionals from a variety of specialties to discuss pediatric sedation. The meeting was organized and coordinated by Joseph P. Cravero, MD, Associate Professor of Anesthesiology and Pediatrics at Dartmouth Medical School and his colleague, George T. Blike, MD, Associate Professor of Anesthesiology at Dartmouth Medical School and Director of the Dartmouth Medical Interface Laboratory, along with the departments of Anesthesiology, Pediatrics and the Center for Continuing Education in the Health Sciences at Dartmouth Hitchcock Medical Center.

The complete report is 52 pages long. It is available for online viewing at <http://www.npsf.org>.



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**Foreword**

This report on pediatric sedation marks the second in a series of workshops on patient safety convened by the National Patient Safety Foundation (NPSF). The first workshop, sponsored by the NPSF, the Agency for Healthcare Research and Quality, and the Department of Veterans Affairs, led to the report “A Tale of Two Stories” (<http://www.npsf.org/exec/toc.html>). That workshop surveyed the landscape of patient safety and identified productive and unproductive approaches to learning more about how safety is created and eroded in healthcare. A recurring theme in that report is that insight into safety comes from close examination of the conflicting goals and pressures present at the sharp end of practice and detailed study of the technical work that occurs there. This current report, “Pride, Prejudice, and Pediatric Sedation: A Multispecialty Evaluation of the State of the Art” describes such a close, detailed look and demonstrates how the approach envisioned in “A Tale of Two Stories” can work.

Within the landscape of patient safety, pediatric sedation is positioned close to the organizational and institutional fault lines that lie below the visible surface of healthcare. Because pediatric sedation is conducted by people from different professions, with different experiences, and on patients with a wide variety of diseases and physiological derangements, exploring pediatric sedation issues necessarily creates a map of the fault lines, their depth and character, and their consequences.

Typically, the consequences of these fault lines often leads an organization to search for some compromise that can balance the demands for production, the cost of personnel and facilities, and the perceived and demonstrated risks of sedation. Such compromises are enshrined in sedation “policies.” The tortuous legal language of such policies is itself a demonstration of the fragility and ad hoc character of the compromises. These policies are like the complicated building codes that prescribe design and construction practices to be used when building in earthquake prone areas. Pediatric sedation takes place near the fault lines and sedation policies reflect the difficulty of working there.

Make no mistake about it, there is uncertainty about virtually every aspect of pediatric sedation: Who should do it? What drugs should be used? Where should it be done? When? How should the patient be recovered? – all these questions are contested, and some hotly. The workshop did not resolve the issues surrounding pediatric sedation. Instead it traced the fault lines, showing how the visible surface of polices and institutional care patterns are formed by forces buried within the structure of healthcare. This report describes an exploration of the deep geology of healthcare. It helps us understand where healthcare earthquakes originate.

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The significance of “Pride, Prejudice, and Pediatric Sedation” extends far beyond pediatrics. While we may read the report narrowly with a view towards pediatric sedation, the workshop and report together serve as a model of the kind of detailed study needed to make real progress on patient safety. It shows how we may come to grips with the “second stories” that underlie success and failure in healthcare. As the authors of this report point out, making progress on patient safety does not mean giving up pride and prejudice but rather understanding their sources and, most of all, their consequences.

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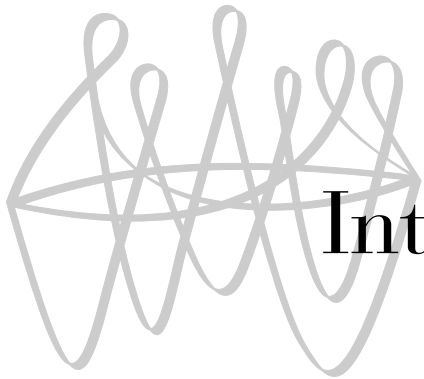
A great many people contributed to make the summit possible and successful. We would like to express our deepest appreciation and thanks to the many participants in the workshop who gave of their time, energy, and intellect to wrestle with the difficult questions that underlie safety in the complex and changing world of health care:

Stuart Lieblich, DMD/MD; Lia Lowrie, MD; Charlotte Bell, MD; Thomas Mancuso, MD; Shobha V. Malviya, MD; Richard Towbin, MD; Michael Girardi, MD; Charles J. Cote, M.D; Mary George, DMD; Ralph Epstein, DDS; Constance Houck, MD; George Bisset, MD; Mark Rockoff, MD; Myron Yaster, MD; Lynne Maxwell MD; David Polaner, MD; Baruch Krauss, MD.

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# Introduction

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**E**very year hundreds of thousands of children across the country are given sedation for diagnostic and therapeutic procedures in hospital settings and in physician or dental offices. The personnel that provide the sedation vary from briefly trained nursing personnel to experienced pediatric anesthesiologists. The sedative drugs used, techniques employed, and safety standards vary greatly from one location to another, and even within a given institution.<sup>1</sup> The care provided depends on the caregivers administering sedation, the time of day, and the area within the hospital that sedation is being provided. In essence, practitioners who are attempting to achieve the same result – that of a calm, generally still, child for a procedure – use widely varying techniques and medications to produce this outcome. Few areas of medical practice remain as non-standardized as pediatric sedation. Our challenge with this conference was to search beyond the preconceived notions, “turf battles”, and ignorance that exist among various specialists in order to explore the current state of this art in medicine.

Hospitals and dental practices struggle with the logistical concerns of how to provide an adequate service for all pediatric patients who require sedation/anesthesia. We firmly believe (based on our own experience and reports from around the United States) that with increasing education of parents and a generalized awareness of patients rights, that a paradigm shift is occurring in terms of what parents find acceptable in the care of their children. Requests for high quality sedation services have increased as the public becomes more aware of new pain management techniques for children. Unfortunately, sedation services are required in widely varying locations within an institution. In addition, pediatric sedation

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may be required at any time of the day or night. Expert sedation providers are not always available to provide this service given these demands. This mismatch of supply and demand for sedation care fosters such an eclectic approach resulting in a myriad of different sedation protocols and drug combinations being used in various hospitals and offices (even different departments in the same hospital).<sup>2</sup> Possibly most concerning is the lack of communication between various specialties that provide sedation for children. For example, when reviewing protocols for sedation in the emergency department, anesthesiologists may seek to restrict the use of certain medications (like ketamine) by pediatric emergency medicine physicians, without engaging in a constructive discussion with these physicians as to their needs and qualifications. Similarly, pediatric sedation research published in dental journals is almost never read or appreciated by radiologists, who are high users of sedation services.

As if to underscore this lack of “cross pollination”, advisory panels from various professional organizations have produced guidelines for sedation of pediatric patients that differ in key concepts and recommendations. An example of this is the fact that the current guidelines from the American Academy of Pediatrics, the American Academy of Pediatric Dentistry, and the American Society of Anesthesiologists do not even agree on definitions of the different levels of sedation that exist in children.<sup>3,4,5,6</sup>

With this background, the Dartmouth Summit on Pediatric Sedation was organized to help convene leaders in pediatric sedation research and policy development to facilitate a high level discussion of the challenges that face practitioners of pediatric sedation. We sought to recognize pediatric sedation as a single field of endeavor practiced by a wide variety of specialists. In addition to the logistical barriers of bringing together an outstanding group of sedation experts from various specialties, we understood that we would be inviting a clash of cultures. True “agreement” and firm “conclusions” would be elusive. Inevitably,

leaders who have made policy for their specialty field of practice bring with them strong prejudices and pride in their past accomplishments. We understood that wherever interests and policy are at odds, these egos would have to look beyond their own personal stature to help address the cross disciplinary safety and efficacy problems associated with current pediatric sedation practice. Ultimately, we can then direct future pediatric sedation policy and research in a more effective manner.

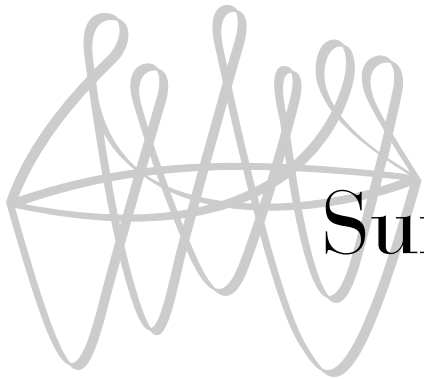
The conference was designed to allow a free flow of information between experts who normally would never have the opportunity to discuss sedation issues face to face. We wanted to provide a venue for this discussion that was free of the politically charged atmosphere that permeates committee meetings of national organizations such as the American Society of Anesthesiologists, American College of Emergency Physicians, American Academy of Pediatrics, etc. We sought to look beyond the superficial reports of disasters involving pediatric sedation. We endeavored to understand (in a detailed manner) the systems that have produced the current state of affairs in pediatric sedation practice. This conference espoused the precepts initially laid out in the workshop summary, “[A Tale of Two Stories: Contrasting Views of Patient Safety](#)” by Cook, Woods, and Miller.<sup>7</sup>

In order to begin the discussion of pediatric sedation we chose to open the Summit with a plenary session consisting of four lectures touching on a wide range of topics involving the current practice of pediatric sedation. These lectures were followed by an expert panel session. In this four-hour round table discussion, a series of typical sedation cases were presented to focus and provoke commentary by a panel of 20 invited experts and an audience of 100 observers. These cases were used as probes to allow each specialty expert to share his/her own perspective as to the most difficult issues facing this field of practice. These sessions were intended to begin the process of thinking globally about the salient issues associated with pediatric sedation care. They

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provided a launching pad for a conference that would ultimately provide participants with a new perspective of pediatric sedation, to begin to see this field as a single entity – a common interest – where differences in opinion succumb to the common goal of keeping children free of pain and fear while avoiding the risks always present when we depress consciousness.

The following report of the meeting is presented in summary form. In preparing this summary we sought out the major topics and themes and present them in an abbreviated format. The entire transcript of the meeting is available on the Web <http://an.hitchcock.org/PediSedation>. By posting this unique meeting's entire transcript on the Web, we hope to allow other clinical scientists the opportunity to review the dialog that the panel engaged in and draw their own conclusions. In essence, we are providing the “raw data” that we based this report upon to support peer review.



# Summary of Proceedings

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**A**fter the completion of the conference, the entire conference was transcribed and paraphrased (<http://an.hitchcock.org/PediSedation>). The resulting document is a rich source of information regarding the multiple interacting dimensions of pediatric sedation care systems. We have used this transcript as a resource that we excerpted and highlighted to produce summaries of both the morning lectures and the afternoon session along with editorial commentary.

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## Plenary Session Overview

**F**our plenary lectures provided an overview of pediatric sedation care issues.

Charles Cote, MD; *Sedation Errors, Lessons Learned*—a review of critical incident analysis applied to a set of sedation disasters.

Shobha Malviya, MD; *Pediatric Sedation for Y2*—a discussion of different JCAHO requirements and current sedation methods.

Thomas Mancuso, MD; *Unconscious Sedation*—an outline of the creation of sedation teams and a sedation suite.

Joseph Cravero, MD; *New Methods to Assess Safety and Efficacy of Pediatric Sedation Services*—a review of observational sedation research at the Children's Hospital at Dartmouth.

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## Topics Addressed by Plenary Speakers Regarding Pediatric Procedural Sedation

*“Every system is perfectly designed to get the results it gets.  
To understand the results, understand the system.”*

This initial section highlights and organizes aspects of each of the four lectures presented during the plenary session around six topics. In this way, material presented by multiple speakers on a single topic are coupled. This summary is not an effort to report exactly the words of the lectures, but rather offers a synopsis of some of key topics covered with editorial commentary.

- Topic 1: Current Safety and Efficacy of Pediatric Sedation
- Topic 2: The Role of Error in Negative Pediatric Sedation Outcomes
- Topic 3: Sedation Guidelines, Terminology, and Regulations
- Topic 4: Rationale for Providing a Specialized Sedation Service
- Topic 5: Evaluating Different Systems of Sedation Care for  
“Best Practice”
- Topic 6: Ethics of Using Force to Perform a Pediatric Procedure

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### **Topic 1: Current Safety and Efficacy of Pediatric Sedation**

Dr. Cote and Dr. Malviya both acknowledged that the true efficacy and safety of pediatric procedural sedation is unknown. However, there is reasonable evidence to support the contention that sedation failures are relatively common and that sedation deaths are relatively rare.<sup>8,2</sup> Inadequate sedation necessitating cancellation of a procedure or use of restraint in a screaming child has been reported to occur in <1% up to >30% of procedures depending on the providers, techniques and medications used.<sup>9,10</sup> In contrast, oversedation related critical events are rare. However, since millions of children receive sedation annually, injury from these rare sedation disasters is actually quite significant. The only published study of sedation critical incidents and deaths was reported by Cote et. al., and includes approximately 95 cases of death or neurologic injury caused by sedation spanning a 30 year period.<sup>2</sup> Although his goal in collecting and reviewing these cases was to gain insight into what goes wrong when sedation injury and death occurs, it is clear that his registry represents but a fraction of the deaths associated with pediatric procedural sedation. Indirect evidence of potentially fatal events is more available; Dr. Malviya presented data that hypoxemia (a marker of potentially dangerous respiratory depression) occurred in 0.4% of procedures.<sup>8</sup> Unfortunately, without a large mandatory reporting system, sedation safety will remain difficult to measure.

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## Topic 2: The Role of Error in Negative Pediatric Sedation Outcomes

If sedation related deaths are rare to the point of being hard to measure, why are so many clinicians concerned that pediatric procedural sedation care is unsafe? Cote answered this question when he presented the compelling stories of how and why children died as a consequence of the sedation care they received. In brief, the stories he uncovered suggest that the vast majority of the sedation deaths and severe injury were **avoidable**; and explains why the safety of current sedation practice is being challenged. The medical errors that were committed during the provision of safety should not have led to the harm children suffered.

### *Major Lesson from Critical Incidents—Rescue Strategies are Essential for Safety:*

The data presented by Dr. Cote takes the form of both testimonials about case disasters and demographic statistics about the children and the nature of the practice in which each patient was injured while undergoing sedation. Regardless of the nature of the data, lack of an effective rescue strategy (e.g., a failure to rescue) was a major factor in events associated with neurological injury and death. This factor easily explains the fact that 30 of 32 incidents reported from pediatric dental offices led to death or severe neurological injury. Not surprisingly, incidents that happened at home or in a car were more likely to result in a severe injury. Dr. Cote's research shows that 90% of critical events associated with sedation outside the hospital setting cause major morbidity and/or death. While critical incidents associated with sedation occur at the same frequency inside the hospital, only one third harmed the patient causing brain damage or death.

These data are hardly surprising. The conclusion that “failure to rescue” is a major contributor to bad outcomes for pediatric sedation seems obvious. None the less, this report strongly supports the contention that sedation systems with robust back up resources are safer. Sedation practitioners need to have the ability to recognize respiratory depression and they need to be able to begin some type of immediate treatment for this side effect of sedation. Perhaps, most importantly, there needs to be expert help readily available to manage cardio respiratory failure (e.g., a clinician skilled at positive pressure ventilation). This need must be kept in mind when designing sedation strategies. Sedation in an office setting cannot be performed exactly like that in a medical center because the venues simply are not the same. In fact, sedation in the office must be done with more expert providers and (preferably) reversible drugs since off-site airway providers will not be able to “rescue” within one to three minutes in an emergency situation (most 911 responses are at best five to ten minutes). In addition, the on-site clinicians will provide a safety net only if they have a plan for what will be done should respiratory arrest occur. To maintain necessary skills they will need to practice resuscitation at regular intervals (possibly using “simulated” codes, drills or time in the operating room with anesthetized patients).

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**Topic 3: Sedation Guidelines, Terminology, and Regulations**
*Sedation Guidelines and Terminology:*

Standardization of pre-sedation evaluation and monitoring during pediatric procedural sedation has been a goal for almost 15 years. This effort grew out of reports of disastrous outcomes of pediatric sedation primarily involving (but not completely limited to) dental offices during the 1970's and 80's. Current guidelines are available from the American Academy of Pediatrics (AAP) and American Academy of Pediatric Dentistry (AAPD) as well as other organizations.<sup>3,4,5,6,11,12</sup> These guidelines have generally been accepted as helpful in recommending: appropriate preoperative evaluation; fasting guidelines; appropriate consent; record keeping, and monitoring (machinery and personnel). Little data exists on whether adherence to these guidelines has actually changed outcomes for pediatric sedation and reports of serious morbidity and mortality continue in spite of their existence.

One major difficulty with sedation guidelines has been the use of distinct “levels of sedation” when recommending the nature of monitoring and personnel required. The guidelines for sedation that have been published from the AAP, AAPD and other organizations have emphasized the definition of these different levels of sedation. Experts from all fields generally agree that these are relatively artificial distinctions that offer questionable assistance in determining the need for specific monitoring and/or personnel. Several reasons for the limited usefulness of “levels of sedation” are: 1) The fact that young children almost never fit into the “conscious sedation” category and can “slip” from one level of sedation to another (regardless of the sedation drug used); 2) AAP guidelines in the past used the concept of “appropriate response to stimulation” to define moderate sedation. A nonspecific reflexive movement in response to stimulation could be misinterpreted as a purposeful response and result in incorrect categorization of a patient's state; 3) Use of the phrase “general anesthesia” in older versions of the guidelines led some providers to believe that these standards were only intended for anesthesiologists.

An effort to revise the current AAP guidelines will begin in the coming year. Leaders of various professional organizations will be working to make these guidelines consistent in terminology and content to the current state of our knowledge concerning sedation safety. Future research efforts should include evaluation of various monitors and provider competencies to determine the exact utility of various technologies and human resources.

*Sedation Regulations in the New Millennium:*

The Joint Commission has taken a keen interest in sedation practice within hospitals. New standards are in place as of Jan 1, 2001.<sup>12</sup> These new standards define four levels of sedation representing a continuum that spans from minimal sedation through anesthesia. (1. Minimal sedation [anxiolysis]; 2. Moderate sedation/analgesia [conscious sedation]; 3. Deep

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sedation/analgesia; 4. Anesthesia). Providers are required to show “competencies” to handle patients at each level of sedation and a credentialing process must be put in place to assure these skills are present and maintained. Specifically, the provider of moderate sedation must be able to meet the competencies for deep sedation, and those providing deep sedation must be able to manage anesthesia. The sedation provider must be credentialed at one level “deeper” than that which is being provided. As pediatric patients almost always require moderate to deep sedation, the required competencies are quite stringent and include the ability to: manage the airway; provide oxygenation and ventilation; and manage an unstable cardiovascular system.

These new standards also reinforce the directive that providers performing procedures cannot simultaneously be primarily responsible for monitoring sedation. In addition to pulse oximetry, a monitor of ventilation that indicates respiratory rate as well as the adequacy of ventilation is recommended. Finally there is a mandate to put in place a system for monitoring the outcomes of sedation so that trends can be followed for quality improvement purposes. Although these standards only apply to the hospital setting, they should be used in office practices where the risks of sedation are equivalent. In aggregate, the new standards require a level of practice that approximates or exceeds that which is recommended by the AAP and other organizations.

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**Topic 4: Rationale for Providing a Specialized Sedation Service**

*Expert vs. Conventional Sedation Services:*

The plenary speakers highlighted the fact that hospitals around the country are grappling with the question of how to deliver sedation in an era where requests are clearly outstripping our current capacity to provide care. A central theme involves the question of how to use experts – be they intensivists, emergency medicine physicians, or anesthesiologists. Some institutions have opted for a system where all pediatric sedation is relegated to airway/sedation experts while others have found this impossibly expensive and personnel intensive.<sup>13</sup> Human resource and personnel shortages and economic reality will require that non-experts in many locations will provide some sedation. The key to building efficient and safe sedation systems in the future will depend on optimal utilization of experts and technology to place them in areas where their effectiveness have the largest impact. Dr. Shobha Malviya and her co-workers in Michigan completed a study that compared the work of experts (anesthesiologists) to nursing personnel for MRI scans. Their study was not randomized or blinded, but several salient features of sedation are evident from their results.

- Potentially dangerous situations (oversedation producing hypoxia) occurred at a relatively infrequent rate of 0.4%. As discussed above, in a university hospital this may well be acceptable. In a location with little expert backup, one might question if an oversedation rate of 1 in 200 is tolerable.

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- Adverse events resulting from under-sedation were much less common with specialist (anesthesiologist) sedation care. Specifically, failed sedation and significant motion artifact on scans were much less common when experts were involved.
  - In terms of safety, the Malviya study lacked the numbers to give us information about true safety of one approach for sedation vs. another. The safety of any modality (e.g., IV sedation by a nurse vs. general anesthesia by an anesthesiologist) will depend on the skill of the operator and the setting in which the work is being done. Although the data is old, the risk of anesthesia in pediatric patients having minor surgery has been estimated as <1:50,000.<sup>14</sup> Many anesthesiologists challenge the notion that “anesthesia” is unsafe compared to “sedation.”
  - The onset time from delivering the sedative to beginning the scan is much faster and more predictable with a general anesthetic. The significance of this difference is mitigated in some radiology departments where special arrangements (e.g. induction rooms) are made for sedation.
  - Cost factors must be weighed carefully. The cost of providing a more expensive expert for sedation must be weighed against the benefit of fewer failed sedations (less expensive) and the superior image quality that may be gained when highly trained individuals are providing sedation.

Dr. Malviya presented other strategies being employed to deliver sedation care, and it is clear the debate regarding how to leverage the most skilled providers using the most potent and fast acting medications for sedation is ongoing. The idea of maximizing the use of experts by building “centralized sedation units” has sparked great controversy in pediatric sedation circles because the practice of inducing sedation and then moving a child was challenged as unsafe.<sup>13</sup> Part of the controversy is related to the fact that non-anesthesiologists (Lowrie’s model utilized pediatric intensivists) were overseeing the care. This idea is countered by the more labor intensive concept of the “mobile sedation team” that will travel anywhere in a hospital to provide sedation. Both of these paradigms represent efforts to optimize the use of experts; these strategies depart from the more traditional idea of using less trained individuals with older medications that are much longer acting and less efficacious (but perceived as safer) to accomplish the same purpose.

Dr. Cote’s work suggesting that “failure to rescue” was associated with significant negative sedation outcome has controversial implications for the hospital setting. There is no doubt that the lack of disastrous sedation events in many medical centers is not due to the brilliance of the sedation providers, but rather to the huge safety net that exists in that environment. One possible conclusion is that if front line sedation providers have excellent airway backup systems with response times of one to two minutes, negative outcomes can be reduced significantly. Should we give trained front line sedation providers with this type of back-up more potent agents to use such as propofol? Anesthesiologists and other airway “rescue” experts may soon be asked to provide guidance

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and support to radiologists (and other high volume users of sedation services) to a greater degree in the future than is occurring now. Improved efficacy and safety for pediatric sedation will only be realized when this expertise is leveraged against the ever increasing demands for sedation. However, it is essential not to generalize sedation regimens that seem safe in this “well backed-up” environment to other domains of practice.

Finally, when considering how to best utilize advanced pediatric sedation personnel and medications, we must consider late side effects (e.g. recovery profiles) of sedative medications that have a very long half lives. Further work by Malviya and colleagues indicates that as many as 89% of children have not returned to baseline activity for 24 hours after chloral hydrate or pentobarbital sedation.<sup>15</sup> In considering future studies of sedation systems, she advocated including outcome measures such as the status of the child after he/she leaves the hospital. In calculating the cost of sedation we must factor in the cost of a parent losing a day’s work because of a child who is not ready to return to school on the day after a procedure.

*Unconscious / Deep Sedation Provided by an Anesthesia Sedation Service:*

A growing trend in many children’s hospitals and medical centers across the country is the establishment of an anesthesia run sedation service specifically designed for painful pediatric procedures. The concept here is that “conscious sedation” is simply inadequate to control movement and stress in almost all young children undergoing painful procedures. The sedation service in this case provides general anesthesia for practitioners who want to schedule an elective procedure. These services are usually set up in an OR like environment but provide easier access to parents and fewer demands on staffing than an operating room (typically one to two less personnel than are used in an operating room). Once again this system represents an effort to maximize the use of highly trained individuals for the purpose of efficiently and safely accomplishing sedation.

These services are not standardized from one institution to another. As one would expect, the utility of this service is highly dependent on the surgeons, oncologists and other providers that utilize such a service. As Dr. Thomas Mancuso described in his presentation, in one hospital urologists may use such a service for minor surgeries (e.g., meatotomy) while in another hospital they may completely reject any option other than an operating room for the same procedure. He further described the key considerations for successful implementation of such a sedation service — including staffing, recovery space, age criteria, time parameters, preoperative visits, and equipment considerations. Once established, patients and the physicians performing the procedures generally appreciated this service for its effectiveness and efficiency. One of the major problems he encountered has been keeping up with demand for these sedation services once the team is established. Of note is the fact that providing such a sedation service has been budget neutral since the care is

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reimbursed under most insurance plans. Unfortunately, a full time anesthesia sedation service is obviously of limited usefulness outside of a children's hospital environment. Smaller hospitals may find this type of sedation service effective if set up on a one or two day a week schedule allowing booking of minor painful procedures to be limited to the days of operation. Adult and pediatric intensivists have established similar services.<sup>16</sup> In any of its incarnations, the sedation service represents a step forward in allowing individuals with the most training and the best tools to attack the problem of providing children with safe sedation for planned painful procedures.

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**Topic 5: Evaluating Different Systems of Sedation Care to Identify the “Best Practice”**

*A Human Factors Approach for Evaluating the Safety and Efficacy of Sedation Systems:*

Individual stories of sedation disasters are helpful in that they demonstrate that potentially dangerous mistakes in pediatric sedation may occur. Unfortunately these reports rarely lead to meaningful changes in sedation delivery. Dr. Cravero reviewed the need for a more robust understanding of the nature of sedation failures. He referenced the monograph, *A Tale of Two Stories, Contrasting Views of Patient Safety* (Cook, Woods, and Miller) which argues that meaningful changes will only come about when analysis of medical failure goes beyond the superficial “first” story to a deeper “second” story. He used this logic to suggest, “second story” analysis of pediatric sedation disasters will require an intimate knowledge of all the factors that influence pediatric sedation care activities (e.g., we must understand all of the components of the sedation care system and the complex interactions between the components before we can hope to improve safety and efficacy in this domain).

Understanding not only the failures of human operators, but also the vulnerabilities for failure that are present in the work domain (the tools used, working conditions, workforce and staffing, etc..) has led to innovative strategies to increase safety in the airline and nuclear power industries.<sup>17,18,19</sup> Cravero suggests that this deeper analysis of the systems that deliver pediatric sedation is needed as a first step for creating safer approaches to sedation care. Analyzing critical incidents in pediatric sedation will provide insight regarding the current tools, knowledge, and strategies that individual providers are using and the ways that they succeed and fail. In addition, we must completely understand the organizational context in which the work is performed. He reminds us that the superficial “first story” of medical error inevitably tends to blame the individual. Deeper knowledge is required to identify organization factors that may have provided the individual with inadequate resources to accomplish the job at hand. For example, are sedation providers really trained to handle a pediatric respiratory arrest or have they only been instructed to try to avoid this problem? What constitutes training to adequately manage pediatric airway emergencies? Have we armed providers with the skills and provided

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them back-up systems to handle unexpected apnea? If not how can we blame them for catastrophic outcomes?

In order to build safer and more effective sedation care systems in the future, a “Human Factors Approach” is advocated. With this approach, the “work domain” should be fully understood. The hazards facing providers should be characterized, the system should be modeled, remedies for problem areas should be suggested, and these remedies should be tested. The human factors approach was used to gain insights into why oversedation catastrophes occur and also highlighted problems with under sedation.<sup>20</sup> Sedation providers that are fearful of the respiratory depressant side effects of sedation medications will not use these medications to their fullest potential – instead tolerating a screaming patient because any attempt to further sedate the child is perceived as “unsafe”.

The investigators at Dartmouth Hitchcock Medical Center used a team of experts and pilot video data to further characterize pediatric sedation activities and they have proposed a model of pediatric sedation work. They then videotaped over one hundred separate sedations performed by providers with all types of backgrounds – from nurses to emergency medicine physicians. These tapes were then continuously graded to determine how well the providers were able to control parameters of over-sedation and under-sedation as described in their work model. This data was graphed over time and annotated with the “what,” “when,” “how,” and “why” a given sedation was performed.<sup>1</sup>

Evaluation of this graphical data indicated wide variation in the “fit” of sedation for various procedures. For example, two hours of sedation was routinely provided for CT scans that took less than five minutes. This knowledge facilitates re-evaluation of the strategies for providing sedation for various procedures – with potential for marked improvements in both efficacy and efficiency. The video data also revealed some concerning lapses in safety (marked and prolonged oxygen desaturation). Future work will involve recreating sedation overdose scenarios using a very sophisticated patient simulator and identifying specific hazards (accidents waiting to happen) and then proposing solutions to reduce risk (specific training of sedation providers, alternative monitoring arrays, etc.)

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**Topic 6: Ethics of Using Force to Perform a Pediatric Procedure**

Perhaps the most intriguing topic addressed in the plenary session was an ethical one. In considering the establishment of pediatric sedation systems, Dr. Mancuso encouraged us to consider the ethical context in which we provide these services. We must weigh the need to perform a procedure against a child’s wishes to be left untouched. We must consider whether the benefits of a medical test or therapy justify causing significant pain and stress for that child. Most importantly, if the knowledge and technology to perform sedation/analgesia for this procedure easily and painlessly exists,

can we justify merely restraining a terrified child for a painful procedure because of the cost?

In Dr. Mancuso's thesis, our society holds that a child is not autonomous – that is he/she is not at liberty to refuse needed treatment. This needs to change. He argues that as sedation professionals, we need recognize our obligation to make the experience of any procedure as tolerable as possible for each child. In giving sedation, we must strive to alter the experience of an uncomfortable or stressful situation, in which a given child may otherwise willfully want to resist. He offered a warning that cooperation by a child does not assure that the child's experience was stress free. For example, coercion and/or threats by providers or family may get a child to cooperate with a procedure. In contrast, pediatric sedation and distraction techniques are aimed at altering the behavior of the child in order to achieve a quiet and calm state for the procedure, but are far more laudable.

Dr. Mancuso concludes, if society ultimately considers physical restraint to accomplish a medical procedure a violation of a child's civil liberty, we will all become more committed to alternative solutions. The ethical obligation to provide sedation, which alters the experience of a threatening procedure for each child, has clear implications for designing sedation systems. We must be honest with parents and children about the nature of a given procedure and the possible options for altering perception of that procedure – be they emotional support, hypnosis, distraction techniques, anxiolytic/analgesic medications, or general anesthesia. Perhaps most importantly, the consideration of these ethical principles requires providers to consider alternative plans for sedation of each child. For example, in the case where well intentioned efforts to distract a child or provide minimal sedation fails to keep the child from becoming "out of control", a plan to provide more significant sedation should be in place. It is only through this type of complete planning that a system can avoid creating the psychological trauma that is all too common among children who have undergone one or more painful and/or stressful procedures.

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## Expert Panel Session Overview

With the plenary session as a background, the afternoon session then took up the more important challenge engaging a multidisciplinary group of sedation experts in a discussion of the salient issues pertaining to sedation care. The goal of this session was to extend and refine our understanding of the key issues in pediatric sedation care. To this end, an expert panel of sedation providers was assembled that included leaders in the fields of anesthesiology, emergency medicine, pediatric intensive care, radiology, oral surgery, dentistry, and dental anesthesiology. This panel of experts engaged in a productive discussion regarding the **“Key Issues in Pediatric Sedation Care.”** For approximately four hours, the panelists were invited to comment on “exemplar” sedation cases. These sedation cases were used to spark the expert panel discussion. The cases were based on actual pediatric sedation cases videotaped at the Children’s Hospital at Dartmouth. The cases were composites that we created by mixing and matching actual features from multiple individual cases. Using this technique, we believed realism was maintained while protecting the privacy of individual patients and care providers. This approach attempted to keep the expert panel discussion grounded in typical scenarios.

The invited sedation experts were:

Charlotte Bell, MD – Pediatric Anesthesiology

George Bisset, MD – Pediatric Radiology

Charles J. Cote, M.D – Pediatric Anesthesiology

Joseph Cravero, MD – Pediatric Critical Care and Anesthesiology

Ralph Epstein, DDS – Pediatric Dental Anesthesiology

Mary George, DMD – Pediatric Dentistry

Michael Girardi, MD – Pediatric Emergency Medicine

Constance Houck, MD – Pediatric Critical Care and Anesthesiology

Baruch Krauss, MD – Pediatric Emergency Medicine

Stuart Lieblich, DMD/MD – Oral Surgery

Lia Lowrie, MD – Pediatric Intensive Care

Shobha V. Malviya, MD – Pediatric Anesthesiology

Thomas Mancuso, MD – Pediatric Intensive Care and Anesthesiology

Lynne Maxwell MD – Pediatric Anesthesiology

David Polaner, MD – Pediatric Critical Care

Mark Rockoff, MD – Pediatric Anesthesiology

Richard Towbin, MD – Pediatric Radiology

Myron Yaster, MD – Pediatric Anesthesiology and Critical Care

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These experts were chosen specifically because they actively practice clinical care in their specialty fields and would, therefore, add practical information. Many of the experts have had leadership roles within their specialties that would allow insight into the policy making process for the professional organizations involved. We expected that these specialists would have multiple points-of-view regarding the key issues associated with the provision pediatric sedation. We hoped that both common ground and differences would be identified among the specialists that were dependent on each practitioner's scope of practice and perspective. We sought to facilitate learning from each other, despite our different practice settings and specialty training in pediatric sedation.

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## Major Themes Associated with the Safety and Efficacy of Pediatric Procedural Sedation

*“Good judgment comes from experience,  
Experience comes from bad judgment”*

To summarize the findings of the afternoon session, the comments made by the expert panelists with respect to the “exemplar” case being discussed were annotated in generic terms. Themes that emerged were used as a framework for aggregating comments. This summary represents a compilation of the **Major Themes Associated with the Safety and Efficacy of Pediatric Procedural Sedation** that were identified. Commentary from the panelists is identified in quotes. We did not focus on the individual, but rather referenced the specialty. We hope this review will invoke in those who read it the spirit of collaboration and insight experienced by those who attended and participated in this exciting session.

Theme 1: Goals of Sedation (Risks of Under-Sedation)

Theme 2: Sedation Care System Efficacy (Performance in Achieving Goals)

Theme 3: Risks of Sedation

Theme 4: Sedation Safety (Expertise in Managing Respiratory Depression)

Theme 5: Team Coordination and Communication in Sedation Care

Theme 6: Barriers to Sedation Safety

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### **Theme 1: Goals of Sedation (Risks of Under-sedation)**

*“A screaming thrashing child needing physical restraint decreases the quality of the test, and the pain/stress can harm the child...”*

The panel identified three basic goals that drive sedation care: 1) providing ideal operating conditions, 2) managing anxiety/stress, and 3) minimizing pain. In addition, the panel’s commentary strongly supported the notion that “under-sedation” negatively impacts on the outcome of the procedure and represents a significant source of harm for a child their parents. Commentary related to these goals is reviewed individually.

#### *1. Providing Ideal Operating/Testing Conditions.*

An important goal of sedation is to support the safe performance of a procedure – through positioning, restraint, voluntary cooperation, sleep,

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etc. The radiology experts emphasized that procedure requirements are not always considered fully: “The outcome we are interested in is that we gave a sedative and we successfully scanned the patient. The goal is not to bring radiology into the operating room, but to use sedation to control procedures.”

In essence, when conditions are not optimal, the procedure outcomes are compromised and children can suffer harm. For example, a moving child will create artifact on many imaging studies and this movement could increase the risk of misreading the films.<sup>21</sup> If the diagnosis of cancer is being entertained, a misread film could have grave consequences. This issue was common to all procedures regardless of the setting and sedation strategy. The emergency room physician attempting to suture a facial laceration, the ICU physician gaining IV access, the dentist performing a dental extraction, the oncologist performing a diagnostic LP, all reported on ways that position and immobility influenced procedural success.

The panel recognized the challenge of procedures that require cooperation from the child or in which the sedative medications may impact on the physiology of the test. Anesthesiology and radiology experts on the panel considered the voiding cystourethrogram (VCUG) test to be representative of these issues: Anesthesiologist, “VCUG is a particularly difficult sedation because the children have to actively (voluntarily) void?” Radiologist, “Sedation has been used without knowledge of its affect (positive or negative) on the study... sedation may relax bladder muscles, but we are testing for both passive reflux and active reflux. Does sedation change the staging of reflux? If you go up one grade you may recommend surgical intervention rather than observation. There could be a serious consequence...unnecessary surgery!” EEG studies in children are associated with similar issues.

## **2. Anxiety and Stress**

Anxiety and stress are common side effects of procedures. The panel was united in its belief that procedural anxiety should be managed. All specialties commented on this, “Children suffer due to the anxiety and anything I can do to lessen their suffering is of interest to me. I want each patient to have a good experience. We all want to minimize anxiety and pain in all children. The single most important issue is to make the child’s experience satisfactory!” Unmanaged stress and anxiety in children exposed to prolonged or repeated brief episodes of medical care can cause harm and must not be ignored. Even without pain, the panel recounted that physical restraint can traumatize a child into adulthood. Anesthesiologist, “In one study, investigators talked to adults (who had had ER procedures as children) and retrospectively asked them what they remembered about their procedures... Uniformly, they remembered being held down.” For the child with distraught parents, having a new painful procedure is especially stressful.

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Blocking memory without altering a child's stress or pain behavior was considered a complicated issue by the panel. There was disagreement among the panelists as to the impact of this situation on the child. The VCUG was used as example of this dilemma because this test is stressful (it involves placing a urinary catheter) and it requires voluntary effort from the child (voiding to empty the dye from the bladder while taking x-rays). Versed is commonly used for VCUG sedation because the child often does not remember even if they are screaming throughout the procedure if they receive Versed (midazolam). Emergency physician, "I can tolerate a child screaming in a papoose if I have Versed on board and I know he won't remember the incident." On the other hand, several panelists felt the child may still be suffering harm. This is because Versed only blocks explicit, not implicit memory. Implicit memory may be intact and the child may still be affected by a traumatic experience subconsciously.

Anesthesiologist, "There are two kinds of memory (implicit and explicit). The difference between them is this—if I told you (under anesthetics/sedatives that block memory)—"when I see you later you will scratch your nose." I then interview the patient an hour later and say, do you remember anything I talked to you about?" They will say, "no, not at all" (explicit memory blocked), but you observe them scratch their nose (implicit memory intact). Behavior changes post procedure in a child may be due to implicit memories.

Emergency medicine physician, "This question kind of eats at me in terms of being able to assess for myself whether the child is really suffering. Are they suffering at the moment and then they don't remember it? Does that lessen the suffering, etc.?" Sometimes it is hard to sort out if a child needs pain control or anxiety relief. An anesthesiologist pointed out that children choose anxiety relief over analgesia for procedures with high anxiety, but low pain.<sup>22</sup> However, this is an area of research that needs further investigation.

### **3. Pain**

The panel was in agreement that a "big procedure" is indeed a "small operation". The panel further recognized that under-treatment of procedural pain could directly harm a child and potentially lead to long-term sequelae. Anesthesiologist, "There are studies about circumcision without analgesia in the newborn period that show that sensitivity to pain later in life is heightened."<sup>23</sup> Untreated pain dramatically increases anxiety and causes suffering. Most of the issues discussed regarding anxiety also apply to pain and will not be restated.

### **4. Sedation Goals (Balancing Procedural Needs Against Side Effects)**

Clearly what makes a procedure a challenge is the trade off between the factors that optimize the outcome of the procedure against the potential negative impact of sedation on the child patient. In a way, restraint

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represents an intervention that is used for uncooperative children unable to “hold still”. However, a child attempting escape is expressing his/her anxiety and fear.

The panel identified that a balance must be struck between a) a child’s ability to cope and cooperate and b) the procedure’s potential to provoke stress and produce anxiety.

a) A child’s capacity to cope: The fact that the two to four-year-old range is probably the most difficult to deal with was expressed by individuals across specialties. The two-year-old child, for example, has minimal capacity to “hold still”, even for procedures that cause minimal anxiety and no pain (e.g., a six minute CT). Cognitive impairment and previous bad experiences are other factors that make a procedure more difficult. Mentally retarded children, although cognitively young, may be physically mature. While the notion that facemask sedation with nitrous oxide for school immunizations might seem preposterous at first, the panel recognized that there are considerations (e.g., consider a 16 year old, 200 lb, severely delayed patient) that may make this intervention reasonable. The dentist, dental anesthesiologist and the oral surgeon on the panel all noted that parents commonly make such requests on behalf of their developmentally delayed children while they are asleep (e.g., to give a school shot or draw blood work). Dentist, “We have people ask us all the time, can you give him or her nitrous?” and do something that is outside of the scope of dental practice... obviously, we cannot. Parents recognized that nitrous oxide allowed for local anesthetic injections and IV’s to be placed very smoothly in the dental office, and did not understand why their child had to be captured and held down in the pediatrician’s office for shots and blood tests.

Regarding “bad experiences”, the panel noted how children who have been sensitized by a previous procedure could become prone to anticipatory anxiety making a similar procedure difficult to execute in the future. Anesthesiologist, “We may be creating future needle phobias in our patients when we perform procedures with restraint and don’t manage the anxiety.” Other non-pharmacological interventions that can be used to achieve “stillness” were discussed including the use of parental presence, limited physical restraint, and distraction. The way in which parental presence may help or hurt physician attempts to balance the goals of sedation was discussed at length (see section on Team Coordination). Video, hypnosis, and distraction were all thought to be effective therapies deserving consideration to limit the stress of procedures.

b) A procedure’s capacity to stress: The procedure’s potential to overwhelm the resources of a child may be a crucial consideration. For example, even a teenager with excellent coping and pain tolerance is unlikely to endure a new diagnosis of cancer (which would include an IV,

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blood tests, a two hour MRI, a bone marrow biopsy, and a lumbar puncture) without having an experience akin to “surgery without anesthesia”. However, the members of the panel recognized that technological advances will impact on the need for sedation. Fast CT technology requires children to hold still for just seconds rather than minutes. Radiologist, “We now have all our pediatric CT scans performed on an ultra high-speed scanner called Light Speed. The number of kids we actually sedate now is one percent.”

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**Theme 2: Sedation Care System Efficacy (Performance in Achieving Goals)**

*“It’s the singer not the song, regarding the efficacy of a given sedation technique.”*

Regardless of the specific patient factors, the procedure, or the sedative drug and/or technique used, the panel repeatedly noted that overall sedation care system performance (e.g., achieving the goals or sedation) is heavily dependent on the expertise of the sedation provider. Optimal sedation (good conditions, no pain and no anxiety) occurred when provider competencies, strategy, tools and technology, and environmental conditions were matched to the child and procedure at hand. The following commentary pertains to clinician/provider factors, sedation tools and technological factors, and environmental factors that together generate the best sedation results.

*1. Clinician Expertise*

The different perspectives of the panelists led to the identification of several issues that help or hinder sedation care. Expert sedation providers use skill-based, rule-based, and knowledge-based activity to attempt to achieve the goals of sedation. Experts also possess a robust working knowledge of the drugs they use commonly. In addition, they have back-up plans and manage anticipated side effects.<sup>24</sup>

a) Selecting a good “Plan A” (support, distraction, drug, route, etc.): Panelists discussed the role of appropriate expectations regarding a technique’s potency and reliability when matching a technique to a given procedure. Those clinicians that gain experience from handling large procedure case loads have superior knowledge when selecting a “Plan A”. Repeatedly, panel members identified drugs and patient factors that led to good efficacy and few side effects. Pertaining to chloral hydrate, radiology experts claimed, “We only use it in children less than 18 months of age.” “We do about 45,000 exams (25% CTs) per year...we never use rectal chloral hydrate.” Emergency Medicine physicians did not consider nitrous oxide to have a role for fracture reductions, but make use of the drug regularly for suture removal and short procedures associated with minor levels of pain. When questioned about midazolam and amnesia, an experienced anesthesiologist warned, “You can never count on amnesia

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because as all of us in anesthesia know, there are case reports of people having memory even while they are completely unconscious.”

Panel discussion differentiated the textbook reported risks from the “real life” risks given the specifics of a clinical situation. Nuances in the use of sedative drugs were noted by providers who used them most. Anesthesiologist, “Propofol may impair airway reflexes, but in low doses the cough reflex is maintained.” Emergency physician, “Ketamine when mixed with morphine is an entirely different drug.” Radiologist, “It seems like I have been giving sedation a long time and although we make a big deal of aspiration risk (in academics) we just never see it clinically.” The emergency medicine physicians who use a lot of ketamine discriminated between hallucinations and diplopia. The issue of diplopia, I think is an interesting issue, there is a lot made about emergence phenomena with ketamine. When you examine the literature, kids under eight years of age don’t really have emergence phenomena. On the other hand, this child is really just at the cusp of reasoning and cognitive development where she sees two heads and that can be quite a frightening experience.

Experts noted that sedation guidelines often require a level of monitoring and support that actually makes effective sedation more difficult while not (necessarily) adding to safety. A radiologist noted, “We went through a period of using nasal cannula oxygen and DINAMAP blood pressure on kids having imaging studies with light sedation...we found we had to go up on the amount of sedation we used because of that blowing effect from the nasal cannula or mask that was disturbing them. We don’t use automated BP cuffs for the same reasons. You just can’t be blowing these things up on their arms without having to go to a heavier state of sedation.” All participants agreed that outcomes research is imperative if we are to develop effective guidelines in the future.

Predictability of technique is an important issue for practitioners. Given an array of choices the clinician is comfortable with, most clinicians choose the plan with the least uncertainty. Intensivist, “We use IV propofol for over 90% of our sedations because it is so reliable” Dental anesthesiologist, “We tend to use IV’s because we can titrate to the endpoints we are after.” Anesthesiologist, “We put in an IV because it allows the safest and most reliable sedation.” This issue may also explain why practitioners choose not to use a particular sedation drug or technique. Emergency physician, “Versed is associated with an adverse reaction...an agitated state (like an angry drunk) and that is why it is not one of my favorite drugs in all honesty...because it isn’t predictable.”

b) Anticipating and preempting side effects. Repeatedly, the panel discussion supported the idea that providers with the greatest experience used drug “cocktails” in which a side effects are minimized via pre-treatment. For example: Atropine is routinely added as a drying agent to

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counteract ketamine's salivary effects, benzodiazepines (only in older children) are used to mitigate delirium associated with ketamine. An emergency medicine physician noted, "Ketamine and Versed is a beautiful combination." Similarly, the use of preemptive anti-emetic was advocated by one radiologist, "Chloral hydrate is an emetic and when we give it, we usually give it with an anti-emetic, Vistaril." The timing of drug administration may be crucial to optimal usage and anticipating side effects. One panelist referred to giving sedation prior to transporting a child to radiology as poor planning, "We would never sedate a child on the pediatric floor because the best effect would be seen during transport."

Don't underestimate the finesse of the provider when discussing how individual technique can make a huge difference in the results. One of the radiologists used sedation in a baby by the oral route to illustrate this point, "I think there is a real art to giving chloral hydrate. You can't just squirt it into the mouth; I think there is a real art to kind of dribbling this drug along the side of the mouth. I have watched good nurses give it and babies usually don't sputter and spit as much as the child in the video did." One of the dentists discussed the injection of local anesthetics in the mouth similarly, "There are techniques we all have such as sneaking around from the side and tricks like that."

Many of the experts on the panel commented on non-pharmacological means of engaging, comforting, relaxing and distracting children that depend on the skill of the sedation provider. An anesthesiologist noted, "Hypnosis has this connotation of mumbo jumbo (making people do what they don't want to do), but hypnosis and trance are extremely effective adjuncts to anesthesia, analgesia, and sedation. I think our dental colleagues are not just using nitrous. They are using nitrous for part of the sedation and the Barney song as another part of the sedation. They are doing an incredibly good job with distraction techniques which is an effective sedative."

Much of this discussion demonstrated that the specialists sedating in different contexts developed different knowledge and expertise. This feeling was typified by an anesthesiologist who stated, "It is how you use the drug, not the drug itself." It is clear that all of us can learn from one another. Example: Anesthesiologist, "I have had a child develop nightmares after struggling through a procedure under nitrous oxide"; meanwhile a dentist who uses it daily in this application stated, "Titrating nitrous in slowly decreases the chance of this type of a reaction, and taking the mask off allows the child to realize that the effect goes away quickly...this is reassuring to the child." The dental experts on the panel who depend on injecting local anesthetics in children and need this injection to go smoothly have developed special expertise. The type of local anesthetic chosen in this case (carbocaine) is a little bit less painful for a child. Most of the local

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anesthetics that we use in adults include epinephrine to maintain the duration of action and reduce the toxicity, but the epinephrine does acidify the solution and makes it fairly uncomfortable when you inject it. The use of carbocaine or ropivacaine is important when treating children.

c) Knowing when to go to “Plan B”: the experts emphasized that the best laid plans do not always work as intended and one needs to know when to mobilize additional resources and try another approach. Therapies vary in potency for pain, stress, and movement control. Robust sedation care systems use a scaled approach involving plan A, plan B, plan C, etc. to manage uncertainty and patient variability. As explained by an emergency physician who struggles with where to perform a laceration repair, “Let’s consider a two year old with a complex and jagged facial laceration that needs repair. Immobility for this painful procedure is more important and difficult to achieve than in simple repairs...you may have to wait to go to the OR if things are not going just right.”

Repeatedly, the panel championed strategies that included backup options. An anesthesiologist noted, “You have to be prepared for all possible consequences... if this thinking is part of the system and the sedation we attempt fails, but we have other options (even if we have come to spend a little more time), eventually the procedure will be accomplished and the child won’t feel beaten or victimized.” In addition, the experts expressed the importance of knowing when to be patient vs. when to proceed (e.g., spending resources “up front” for a later “payback”). For example, topical anesthetics are timely to use but often result in a procedure being performed more quickly with better results. A dentist commented, “While I sing the Barney song I wait for the local anesthetic patch on the palate to take effect...this might take 15 minutes to work. However, once you have trust and cooperation things ultimately go much quicker and better.” A similar description came from an emergency physician, “For any of us who have gone through a situation where we are trying to hold down a kid during a procedure and everyone is traumatized (the patient is diaphoretic and screaming in your ear and you are trying to get this or that done). This situation ends up being much more traumatic and labor intensive than investing in sedation up front and shortening the time.”

While the value of patience was articulated, it was evident that experts recognize when waiting is futile. The panel considered the case of a child that had recently eaten and needs to have a bone fracture reduced. Both the anesthesiologists and emergency medicine physicians felt that although waiting for the stomach to be empty was one strategy to minimize aspiration risk, general anesthesia and control of the airway might be the most prudent. An experienced anesthesiologist pointed out, “Some at our institution would probably wait six hours if they could, or even overnight...however I would treat the child as if they had a full stomach even if they waited overnight. I tell the orthopedist, if you think

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it is an emergency, we can proceed now since I will treat them the same tomorrow.”

### ***2. Superior Technology Can Make a Difference:***

Tools and technology make a difference. Several of the panelists described how high volume services often can afford equipment that might be significantly superior to the average standard of care. The radiology departments at large centers can afford ultra fast CT, which dramatically reduces the need to use sedation in children having a CT. One of the radiologists commented on the use of state-of-the-art positioning devices, “For many of our diagnostic procedures (like fluoroscopic procedures), we routinely use restraining and positioning devices. We have OCTOSTOP boards...which are basically boards that use velcro straps to restrain the child as it moves on a rotisserie thing so we can get all of the positions that we need.” Similarly, nitrous oxide delivery systems used in dental offices are superior to the demand-valve units used in many ERs. An emergency medicine physician mentioned, “In the ER, the demand valve mask system used for nitrous makes you inspire the gas to create negative pressure. The kids under five just can’t cooperate.” The dental experts replied, “All of our nitrous machines are continuous flow with no demand valve.” Other examples were discussed. The most potent and predictable drugs often require controlled infusion pumps and additional specialized monitors to give them safely. Capnography is standard in anesthesia but uncommon in most other settings.

### ***3. Optimizing the Environmental Conditions:***

Experts on the panel commented on how manipulating the environment can make sedation more effective. Emergency physicians commented on the case of a young girl who was vomiting and hallucinating after ketamine sedation. Although ketamine can predispose to visual “dissociative” hallucinations and delirium, this child may have had an emergence reaction and nausea, but not so much due to the drug, rather this may be related to all the chaos around her. It was a brightly lit room, there were a lot of very excited people around and I think that is where you see nausea develop with ketamine...I think if you keep them still and calm in a dark area there would be fewer problems. Similarly, dentists using nitrous oxide sedation advocated an ideal environment as, “the room is quiet, non-medical looking, and has soft lighting”—a setting that is in stark contrast with a noisy, bright, scary emergency room, MRI scanner, or operating room. As further noted by an emergency physician, “We could also probably learn a lot from the dentists in terms of creating optimal environmental conditions. When you go to a good dentist’s office, the kid is looking up at a TV screen. We discovered in our hospital that a lot of the CT problems were fixed when they just put videos in there. If you look at the environments where most kids are sedated like in most emergency departments, they were not designed for kids as they are frightening environments!”

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#### 4. Parental Presence:

Experts in pediatric sedation have a plan for managing parents in a constructive way that is best for the patient (child). Radiologist, “Sometimes parental absence is best as parents can be a distraction when they are anxious.” Anesthesiologist/intensivist, “I like the concept of parental presence, but it doesn’t necessarily mean parental participation.” Another anesthesiologist commented, “With effective premedication, the parents are coming just to witness rather than support.”<sup>25</sup> Emergency medicine physician, “I have always let the parent observe procedures, even in acute trauma situations...especially if a child may die, we get the parent in the room ASAP. However we need to be cognizant that sometimes parents need to be excused, they don’t want to be in the room, but they will feel guilty if they leave. We need to give them permission to leave. We tell them we will take care of your child and you can wait in the waiting room. I never ask them to wait by the door because that is always the worst. They are outside the door and hearing things inside the room.”

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### Theme 3: Risks of Sedation

*“The side effects of the procedure can traumatize you; the side effects of the sedation can kill you!”*

Although sedative techniques and drugs can be associated with minor side effects (many of which can be managed preemptively by other treatments as mentioned above; e.g., giving a saliva reducer with ketamine), life-threatening hypoxia due to respiratory depression represents the primary hazard associated with sedation. The spectrum of sedative effects is such that categorization into discrete levels of “conscious sedation”, “deep sedation” and “general anesthesia” is misleading. In fact, all of the sedative drugs produce some level of depressed autonomic function. Sedatives induce a continuum of patient states, and respiratory depression is part of that continuum. Low doses of any sedative will have minimal effects, while an overdose of the same drug will not only blunt anxiety and pain, but also stop breathing.

The panel supported the contention that sedation related complications are of three basic types: a) under-use complications; b) over-use complications; and c) misuse complications. Under-use of sedation results in children suffering pain and stress as has been described. Over-use of sedation can cause obstructive or even central apnea that can lead to brain damaging hypoxia in minutes if not managed appropriately. Misuse of sedation involves errors in drug administration such as “drug swaps” (Fentanyl and Sufentanyl have been confused) or giving an overdose of any drug. Ultimately, the different consequences of under-use vs. misuse and over-use sedation problems results in a bias to avoid the life-threatening event and accept the morbidities of procedural pain and stress. That is, the sequelae of under-use are perceived as acceptable in

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order to avoid the horror of a significant over-use problem. This trade off is a key challenge sedation providers face.

Comments from the panel repeatedly came back to the theme of risk and benefit when selecting a sedation strategy. Potent sedative drugs and drug combinations are more effective, but much more likely to depress respiration. Anesthesiologist, “I see a big difference between sevoflurane and nitrous oxide in all kinds of ways. If you give nitrous with narcotics it can be a general anesthetic.” Some of the panelists felt that propofol is a drug with an onset, potency, and short duration that is well suited for many procedures. The radiologists clearly desired the virtue of propofol’s “profile” for short imaging procedures like CT scans, but were skeptical of its dangers when used in low doses. “I would love to do a dose response study of propofol to determine its safe, non-intubating, range.” Frustration with poor access to this ultra short-acting, extremely predictable drug may have accounted for statements like the one made by an emergency medicine physician, “Propofol is a politically active drug. There is reticence to allow people that are not anesthesiologists to use it. There are a lot of folklore warnings that make it difficult to use it in any setting if you are not an anesthesiologist.” However, these same experts acknowledged that propofol (and other potent sedative drugs) have a greater potential to do harm.

The anesthesiologists, intensivists, and emergency medicine physicians identified airway skills as a prerequisite for using propofol. Emergency physician, “I don’t think a radiologist is trained to manage the airway and propofol would be inappropriate for use in radiology unless you have someone trained to manage the airway.” Ketamine was viewed somewhat differently. Anesthesiologist, “I think ketamine has a very wide therapeutic index. It is pretty good and rarely stops anybody’s breathing. I think it its much safer than propofol.” Still, both ketamine and propofol can produce apnea or airway obstruction. According to one anesthesiologist, “I had a child sedated with ketamine completely obstruct in the operating room — things like this happen! If you are using ketamine, just to say ‘it is safe’ and not be prepared to treat laryngospasm (or respiratory obstruction)... you are really kidding yourself and putting the patient in quite a bit of danger.”

Depressed autonomic function can also lead to a loss of airway reflexes and thus poses an aspiration risk in the child with food in the stomach. A blunted cough reflex is part of the spectrum of respiratory depression associated with sedation. Emergency physician, “I consider oral benzodiazepine a minimal risk—when used as a sole agent even with a full stomach, I feel it is fairly safe.” Oral surgeon, “The combination of nitrous with benzodiazepines can lead to depression of airway reflexes. This is very different than nitrous used alone.”

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The panel endorsed the view that sedation related respiratory events are not preventable 100% of the time, but these events are manageable and should not cause harm. Non-anesthesiologist sedation providers are especially vulnerable to being unprepared for such rare events (they may never have to manage an airway disaster in their entire careers). But the fact remains, rare events do occur and if managed poorly they can be fatal. There have been cases of plumbing being switched between oxygen and nitrous.” Our patients need us not to simply “hope for the best” regarding sedation related respiratory depression. Finally, the panel noted that even when no sedative drugs are used, restraint used to achieve immobility can lead to impaired breathing. Anesthesiologist, “I reviewed a case where the child was smothered to death in a papoose board and received no sedation, but he was restrained so tightly he couldn’t breath.”

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**Theme 4: Sedation Safety (Expertise in Managing Respiratory Depression)**

*“You must be prepared to go to the next level... for deep sedation you need to be able to manage accidental general anesthesia”*

Just as expertise is a key factor in achieving the goals of sedation, expertise is an equally important factor in managing the risks of sedation. As was noted in the plenary session by Dr. Cote, “Failure to rescue is the common theme in predicting brain damage and death when a respiratory event occurs.” While the literature may label hypoxia, airway obstruction, laryngospasm, etc. as adverse events of variable clinical significance, the panel was in agreement regarding the significant negative outcomes (e.g., brain damage and/or death). In the cascade of events that progresses from critical incident to irreversible damage, the patient depends on the sedation provider to recognize the problem, identify the etiology and take appropriate action to resuscitate the patient and rescue them from harm.<sup>26</sup>

*1. Monitoring and Diagnosis of Respiratory Depression:*

Monitors of respiratory depression are critical for sedation care safety. Discussion of monitoring was centered on the early diagnosis of respiratory depression. “Depending on what you are using and to what level of sedation you bring the patient, that will mandate different types of monitoring and skills of practitioners taking care of the patient.” The time course by which apnea leads to hypoxia and brain injury is a matter of minutes making early detection and treatment critical. What constitutes appropriate monitoring may have represented the greatest divergence of opinion on the panel. Repeatedly, the panelists stated that the way they provide sedation is “safe” based on their personal experience and that “anesthesia grade” monitoring was excessive given the rarity of severe events. “I don’t know what it means to see transient oxygen desaturation in a child (they drop down to 88% and the exam is completed and they come back up to normal).” Pulse oximetry was clearly the primary monitor being used by the bulk of providers of sedation to identify

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respiratory depression. The value of pulse oximetry was not disputed, but several comments indicated a lack of appreciation that hypoxia is a relatively late indicator of respiratory depression.

Other panelists emphasized that diagnosing hypoventilation and apnea is not trivial (anesthesiologists have adopted capnography as an important monitor of ventilation because of this fact). The opinion on what constitutes appropriate preparation for sedation varied. Dentist, “We dentists have AMBU bags, bag valve masks, and things like that in the office...even though I don’t know of one case where nitrous alone has been a problem.” The American Dental Association currently is considering new guidelines for ventilatory monitoring which will include auscultation of breath sounds, respiratory excursion, and/or capnography. Electrical impedance monitoring is not routine during sedation, as EKG is not mandatory in all guidelines. It could be considered another mode of central apnea detection. However, impedance monitoring is not as accurate as capnography since gas detection is superior to chest wall motion detection. For example, upper airway obstruction, the most common cause of hypoxia during sedation would not be detected with impedance monitoring.

Those panelists who used more potent sedative medications that are associated with apnea were champions of capnography. Emergency medicine physician, “Should every slot in a new ER include capnography?” Pediatric Intensivist, “If they are going to sedate patients using propofol and things like that, absolutely!” Finally, monitoring a child when the chest and airway cannot be directly observed was generally agreed to be an absolute indication for capnography. For example, in the MRI scanner, where you can’t visually observe the patient at all, capnography is essential. An excellent Web site was mentioned regarding capnography and interpretation of the waveforms commonly seen.<sup>27</sup>

The required interval for post procedural sedation monitoring was questioned. The panel acknowledged that unreliable criteria are often used for determining when to discharge patients after sedation. For example, when children have received chloral hydrate, they may experience drug effects for over 24 hours, yet monitoring practices to recover the children routinely discharge them only two to six hours after the drug is given. The complete recovery actually occurs at home and is managed by the parents.

One approach is to copy post anesthesia recovery unit (PACU) methods for sedation recovery. Radiologist, “We recover the patient to satisfactory recovery. They are recovered with nurses monitoring as you would in a recovery room.” It was suggested that children receiving long acting drugs such as chloral hydrate require more careful recovery than patients having brief anesthesia. The advent of ultra short acting anesthetics like propofol

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used in the outpatient setting are eliminated from the body over minutes rather than hours allowing for the complete resolution of drug effects to be observed while still in the hospital. Indeed, slow off-set drug techniques used commonly in “inpatients” (e.g., spinal opiates for post op analgesia) are contra indicated in the outpatient setting, since the drug effect recovery will occur at home (an unmonitored setting). When residual effects of a drug produce respiratory depression after a patient has been discharged to their home, the results are disastrous. As one can imagine, differences in the ability to resuscitate respiratory depression in the hospital, office setting, and home vary dramatically. The panel was united in the opinion that both pre-medication at home and any amount of recovery from drug effects at home carry unacceptable risk.

### *2. Treating Respiratory Depressions:*

As noted previously, the spectrum of airway management skills varies greatly among providers currently giving sedation. Airway skills and the ability to positive pressure ventilate are the key factors impacting on outcome in the event respiratory depression is encountered. The competency gap between novice providers and experts in airway management is huge. While it is relatively easy to treat obstructive apnea by stimulating the patient, performing a chin lift, and by placing an oral or nasal airway, it is quite difficult to master positive pressure ventilation using a bag and mask apparatus. This topic will be covered more in the section on acquiring and maintaining skills.

### *3. Decision Making vs. “Running the Drill”:*

Expert airway providers on the panel advocated for precompiled (and practiced) plans for respiratory events. This is a logical approach when time pressure limits the utility of dynamic decision making (assessing a situation and then preparing/executing an action plan just in time). An anesthesiologist described a laryngospasm event: “A child developed a lot of secretions and became completely obstructed [and turned blue]...the patient was sitting up at the time, we laid the child down and quickly placed an IV, administered meds...and the situation was under control.”

The Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) programs developed by the American Heart Association represent good models for how precompiled responses can improve outcome in emergencies. The more they are practiced, the better resuscitation performance becomes. Similarly, the child suffering respiratory depression from sedation has a limited time for resuscitation to be effective. There are clear algorithms for how apnea should be managed but these processes must be rehearsed. Well children experiencing simple respiratory depression from sedation are imminently “rescueable”; any failure to rescue is a marker for a flawed sedation care system that has not trained providers adequately.

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#### *4. Acquiring and Maintaining the Skills to Diagnose and Treat Respiratory Depression:*

Unfortunately, many providers who regularly give sedation and manage only minor side effects (nausea) are not competent to resuscitate a child from respiratory arrest. Acquiring and maintaining these skills is difficult for individuals that do not practice airway management on a regular basis. Even pediatric emergency medicine physicians, who need to manage pediatric airway emergencies more frequently than radiologists and dentists, do not always have a lot of opportunity to maintain their airway skills. Anesthesiologist, “In the city of Baltimore, in the aftermath of an ambulance crew mismanaging a child’s airway, the question was asked... ‘How many ER physicians actually had to intubate or manage an infant’s airway in the last year? The answer was, close to zero... skills were taught at some point in their previous life—six to ten years before.’”

The panel agreed training is a major challenge. One of the panelists described the early findings of a course designed to credential practitioners for sedation. The findings validate the notion that we have done very little in our healthcare systems to ensure that sedation providers are competent and have a basic set of skills and knowledge. Anesthesiologist, “We make assumptions that people know things and can do certain things that are not based on any objective reality! We set up an eight hour course, six hours in the classroom plus two hours of lab time...the results have been pretty astonishing...many times the nurses knew more than the doctors who were supposedly supervising them. The other major discovery involved the things that we take for granted in terms of basic knowledge. For example, we had a 90% failure rate on our pre-test question about what pulse oximetry actually measures. We asked, ‘What does a pulse oximeter reading of 90 mean?’ ...much to our shock, people who take care of sedated patients didn’t know.”

The exact nature of the learning curve for airway management is unknown. Anesthesiologists that train residents suggested it takes a minimum of several months in the OR. Another of the panelists described a course for giving benzodiazepines according to the American Board of Anesthesiology guidelines, “Participants were required to complete a prescribed course of 60 hours and then an additional 20 hours of monitored cases.” The issue of experts knowing their limitations was raised in the context of training and maintaining core competencies in airway management. An ER physician voiced concern over this issue, “I don’t know if a radiologist should really be giving propofol... I think there is a certain time to draw a line in the sand and say—‘Look, this is out of my scope of practice’...it is OK to use certain agents and certain types of sedation, but other things are too invasive...we are just getting to the point now of using propofol in emergency departments because we have to prove our skills, and I think that is justifiable.”

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Panelists who supervise nurses that administer more potent agents espoused the most aggressive competency testing. In one institution, nurses are required to demonstrate competency with the ability to provide positive pressure ventilation. Intensivist, “Every three months... I need to see the nurses I am working with bag-mask ventilate a kid or at least a mannequin to make sure they are competent. “We are of the belief that it needs to be a daily event, especially the assessment and the knowledge of what you do when respiratory problems occur. To keep your skills up, you need to do that on a daily basis.” Regarding how to confirm provider competency, “My job as the sedation expert is to be absolutely sure that the sedation nurse I send down with the patient knows what to look for in terms of sedation side effects, what to give, what to react to. ...if he/she has not proven capable of reliable resuscitation, by bagging a kid in front of me and knowing how to call me, they are not allowed to be the primary sedation provider on a case.” Specialists on the panel urged collaboration as a means to expand competencies to manage airway issues more skillfully. Emergency medicine physician, “For anesthesiology to feel comfortable with emergency physicians using some of these paralytics, they invite us to go to the OR with them. I think that is a great way to do things.”

Credentialing was discussed as not always relating to competency as it should. Currently, credentialing is based on professional title rather than demonstrated competency in skills such as positive pressure ventilation using a bag and mask. An emergency medical physician commented, “If an anesthesiologist becomes an emergency physician, he/she would suddenly be restricted and not allowed to use certain anesthetic drugs. Credentialing in the hospital is based upon local politics and it has nothing to do with my training, really!”

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**Theme 5: Team  
Coordination and  
Communication in  
Sedation Care**

*“No one seemed to be on the same page...”*

If we consider a micro system the smallest definable set of people, tools and environmental resources needed to interact with a medical problem, then the provider team for a procedure and its sedation must be considered two halves of the whole. The complete “team” includes several different individuals with different roles: 1) the procedure operators which includes the MD ordering the test, the MD interpreting the test, and technicians/clinicians performing the test; 2) the sedation providers responsible for providing optimal conditions and managing side effects; 3) the pediatric patient and parents who can often impact on sedation outcome by using internal resources and cooperation to aid the procedure operators; and 4) the resuscitation team that will manage major complications of the procedure and/or sedation. This is similar to other areas of medical practice where as processes have become more complex,

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we have tended to break the medical problems into parts and use specialists who are able to maintain particular areas of expertise that generalists cannot.

It must be noted that teamwork is not always easy—significant effort must be put forth by the individuals communicating and coordinating their activities. Indeed, the primary mode of failure in care systems utilizing a team approach is due to failures in team communication and coordination. As an example, the radiologists on the panel commented on how anesthesiologists don't always appreciate how sedation might negatively impact a test. Miscommunication can occur between the procedure operator and the sedation provider, the sedation provider and the patient/parents. Team members that do not understand each other's roles and responsibilities often fail to have a common language and miscommunication is frequent. The highest risk for miscommunication is between the patient and the clinicians. A panelist recounted a child that overheard a radiology technician loudly ask the radiologist, "How thick do you want the brain slices?" The resulting misunderstanding clearly distressed the child. The panel recognized that the patient and parents often hear multiple versions of what the procedure and sedation entails and this impacts adversely on cooperation and satisfaction.

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**Theme 6: Barriers to Sedation Safety**

*"Seat belts have a cost, they consume time, energy and money, yet are rarely needed..."*

Systems research has suggested that in manufacturing, high quantity output, low cost, and high quality production represent competing interests. They are related such that optimization of any two parameters results in suboptimization of the third. In a service industry like medicine, quantity relates to the number of patients the system can care for in a given period of time. Access to care is one measure of a medical care system's capacity. The number of patients treated in a day might be another measure of throughput for a clinical service. Cost of care in medicine is often related to charges. However, true costs to generate a work product must be considered when determining the "cost effectiveness" of the resources (people, tools, and environment) we might assemble to provide medical care for a given health problem. Quality is especially difficult to measure in the healthcare industry. We want our patients to have the "best possible" outcomes for the problem they present and the care we provide. We in medicine recognize that a good outcome must be more than biological. Indeed, the bio-psycho-social model of health has become mainstream. While we would like to magically provide our patients' perfect outcomes with instantaneous access to care and at zero cost, we all know that this is impossible.<sup>28</sup>

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The panel discussed the specific ways that cost constraints and production pressures impact on pediatric sedation outcomes in terms of both efficacy and safety. There was consensus on the panel that the state-of-the-art pediatric sedation system would include expert airway providers using short-acting medications like propofol with advanced monitors and ideal environmental conditions. Most of the anesthesiologists that regularly use these drugs did not consider the average sedation case to be technically challenging. These observations beg the question, “Why is pediatric sedation commonly provided with relatively unpredictable, low potency, long acting drugs like oral chloral hydrate by non-airway experts in a suboptimal monitoring environment?” The panelists answered this question by citing the various barriers (economic, political, regulatory) that currently prevent us from providing the “best possible outcomes” to children having procedures.

#### *Economic Barriers*

Cost considerations were discussed at length. Sedation costs start when a procedure is scheduled and end after the procedure is complete, the patient has recovered from sedation, and all complications have been managed: 1) clinicians must perform a pre-procedure evaluation; 2) during the procedure, the sedation providers, the drugs, equipment, and the procedure team represent major costs; and 3) documentation, billing, phone calls, managing side effects, etc. are also costs of providing this care.

In support the need for caution in determining cost effectiveness, a panelist mentioned research on post procedural behavioral changes.<sup>29</sup> Anesthesiologist, “I think a lot of times when we are talking about cost effectiveness and accomplishing procedures quickly, we forget about the down side of a child being traumatized emotionally for days, weeks or even months after a procedure with poor sedation, and what economic effect that has on the parents and family structure? For kids that are coming for sedation a lot of times (LP’s, bone marrow biopsies) it is one in a series of traumatic events...and if they have to come back after they have been so traumatized by the first procedure, ...we are going to have to give general anesthesia the second time – what is the cost effectiveness of that?!”

When costs exceed reimbursement, a system must reduce cost to avoid operating at a financial loss. This “cost centered” priority has compromised outcomes. One of the anesthesiologist panelists commented on this as a reason anesthesiologists have not been very supportive in providing sedation care. “It is always a money losing proposition. In some cases you are talking a lot of money. We have a full-time anesthesiologist devoted to sedation and we are not getting anything close to what it costs us to put that anesthesiologist out in

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other parts of the hospital. I suspect there are a lot of other institutions that run into the same thing. I alluded to the CPT codes this morning for reimbursement. Insurance companies have historically only paid for sedation if the person who is doing the procedure is also the one providing the sedation, which is the opposite of what we are advising. What we need to do, as a medical community once we develop more information about the safety issues, is to go to the insurers and convince them of the value of having skilled people provide this service...convince them that not only does it improve the throughput in the radiology department,...instead of waiting an hour for chloral hydrate to work! You pay for skilled people to get the kids through there faster AND have a better, safer result. I think that is part of the sedation issue that it is very hard to address because the insurance industry just will not recognize those points.”

While detailed cost information for sedation care is limited, the panel was in agreement as to the value of expert clinicians skilled in the use of state-of-the-art techniques and the importance of procedures being done efficiently to avoid access problems. The three cost issues that were discussed by the panel in more depth are a) personnel costs; b) costs of delays and inefficiency; and c) the costs of a service that is under utilized.

a) Personnel costs. Who provides the sedation care is a major cost factor to driving the manner in which sedation care is delivered today. The differential in salaries between an RN and a expert physician sedation specialist is considerable. However, the differential in the ability to rescue a child suffering a respiratory arrest is just as considerable. Even if society accepted the costs of providing sedation experts with high level airway skills, the demand for sedation care exceeds the capacity of existing airway experts to provide that care. The panel remarked on the need to improve the base of sedation providers with adequate competencies to give sedation and manage respiratory depression. Training is costly and will take time.

As mentioned previously, there is a program developed for providers using benzodiazepines-based conscious sedation that follows the American Board of Anesthesiology (ABA) guidelines that is a prescribed course of 60 hours with an additional 20 monitored cases. Oral surgeons train within anesthesia sections and advocate that approach, “The people that are running educational programs – residencies and fellowships – need to be willing to take their residents out of their department and give them to the department of anesthesiology for a period of time (two to three months) to educate them in airway management.” However, having anesthesiologists assist in the training of all sedation providers in the operating room is not feasible. One anesthesiologist remarked, “As director of an anesthesia program in a very busy children’s hospital with 22 operating rooms... I can report that we couldn’t accept the people from

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all the non-anesthesia departments even if you freed up your people and wanted to send them. We currently have over 200 people a year, who are non-anesthesiologists, coming to our operating room and want to learn airway skills...there are emergency room fellows, pediatric ICU fellows, some cardiologists, transport nurses, medic flight nurses in Boston, respiratory therapists, etc.” Another anesthesiologist put it this way, “There is no way we can take every single clinician that should know how to manage an airway and have them intubate somebody. We would have to lay down and volunteer!”

One possible solution to this quandary involves the utilization of modern human simulators. Modern simulators are anatomically correct mannequins that use computers to model physiologic responses to pharmacological and mechanical interventions. Medical Education Technologies Inc. has developed a pediatric version (PediaSim) that the Children’s Hospital at Dartmouth has purchased and demonstrated at the Summit. PediaSim is a toddler simulator with pupils that react to light, lung breath sounds, exhaled breath that contains carbon dioxide, and responses to over 100 common drugs. This simulator can re-create thousands of common and rare critical events that clinicians must be able to manage. One panelist cited simulation to point out available technology that is being underutilized in training, “We are not taking advantage of the technology we have available in the year 2000. Surgeons are teaching laparoscopic techniques (and doing laparoscopic surgery in very risky areas of the abdomen) from thousands and thousands of miles away. The surgery department at Yale runs a program where they are doing laparoscopic surgery in Guatemala and half way around the world on television screens with an operator locally and a teacher at a distant location. Certainly distance learning and distance observation are things we could use. Training on simulators is something we should be doing... This is the year 2000 and there is technology available and it works well... On a relative cost effectiveness basis two days in a simulator is probably cheaper than six months in an operating room.” However, at a cost of about \$150,000, the cost effectiveness of simulators remains to be proven. Emergency medicine physician, “I saw a simulator here at the Summit that was very exciting, but it is expensive.”

Training and maintaining skills is especially difficult in settings where the need for pediatric sedation is rare and case volumes are low. This is a challenge facing community hospitals and academic centers alike. Anesthesiologist, “I get many phone calls from small hospitals saying, ‘what do we need to do?’ It is usually from a risk manager and the risk manager is the one putting in the requirements for an individual hospital. These questions are raised so they can bring themselves into line with what JCAHO requires, but the very practical aspect of this is what you just mentioned. A community practitioner might see a child every five months that has to be sedated, and they are not comfortable with it.” Another anesthesiologist on the panel commented, “I think some of the

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issues that are addressed to the local community hospitals are also relevant to the big tertiary care hospitals and it has to do with availability of people to assist with sedation. If you don't do much sedation it is tough to maintain your skills."

b) Costs from inefficiency. In all settings, production pressure was mentioned as a strategic factor that limited how sedation care is provided.<sup>30</sup> Many comments were directed to this reality. Radiologist, "I don't care if it is sedation or hypnotism, it doesn't matter to us. What we have to do is get our cases done in a timely way. When you are doing 50 cases a day, half of which need sedation, the methodology of operating rooms does not work. We can't afford having long delays for sedation given the time pressure of our schedule, we cannot afford the transport woes and issues, therefore, we do everything on site. Twenty minutes to time of action just doesn't cut it for us." Emergency Medicine Physician, "The use of IV ketamine in this situation gives me what I am looking for in the emergency department. We have incredible production pressures on us in the emergency departments across the country right now – we move people in (and we usually have too little resources and too many patients) so we want to move people out. The floppy infant syndrome you alluded to with the chloral hydrate is something we don't want to be stuck with. IV ketamine gives us an option to treat and release asap." Another Emergency physician, "I want to comment on staffing. We are not popular with our nurses when we consume their time. That can shut down an ED." Dentist, "We also have the ability to use EMLA cream, but to have a child come into my office and sit around for an hour with EMLA on their hand is impractical." Anesthesiologist, "We do not use hypnosis and these type of preparatory things because of time."

c) Cost of underutilized service. Providing a sedation service will have a fixed cost. In some low volume settings, the costs of providing that service will be prohibitive. For example, a high volume radiology sedation service used in Boston or Philadelphia children's hospitals will not necessarily be cost effective in a small children's hospital or community setting.

Safety systems designed to manage rare events are by nature under utilized, especially in the community setting. Pediatric intensivist, "One of my big points is that safety is very dependent on your volume, on your set up, and who your back-up resources are...I know I have three layers of back-up for the sedation providers I supervise, (who I know are competent in the first five minutes of emergency management) and I am going to be there long before five minutes are up. If I am not there or once I am there and I have trouble, I have an anesthesiologist who is going to back me up. That is a luxury that isn't possible in a community hospital. That luxury is not there and that is really when you have to start weighing what is safe to do. The setting and system really affects what you are able to do and what you are not able to do."

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### **2. Access Barriers.**

Limited access to the best resources causes clinicians to forgo the safest approach in lieu of a more expeditious one. Emergency physician, “We had a case with multiple lacerations of the face requiring an extensive repair and ketamine was used in the emergency room. The reason why it was done in the emergency room was that the OR was very busy and the surgeon did not want to wait for whatever indeterminate time would be taken until an OR was available.” Limited access was an especially relevant issue for all clinicians that do not typically practice in the OR. Dentist, “At least there is ‘access to care’ if you want access to the OR from the ER, but in dentistry we do not have ready access to the OR. This is why we are doing what we are doing in the office. A colleague might have a child that has abscessed teeth and needs quite a bit of work and if she has to wait three months to get into the OR, and the OR time she gets is 3:00 p.m. on a Friday..., is that good care for that child? These are problems [access to an operating room] that we have in a metropolitan area where we have major university hospitals two of them within three miles.”

### **3. Political Barriers.**

Politics and production pressures were discussed as common factors driving clinicians to unsafe practices. A community physician commented, “In a rural setting at a community hospital, the political and economic pressure on anesthesia services is incredible. You are being hired or recruited to help build patient volume at the same time you are looking back to your training to set standards which really no longer apply to the community setting. You have to set new standards for your institution at the risk of canceling cases. It is a “no win” situation and is a really tough position to be in. I think the community standard is really different and not the same. It is not better, it is not worse, it is just different.”

Another community practitioner agreed, “That is the point I think you see in the community. The focus is on the economic and political aspects of sedation work and not on the safety part. You can’t really blame the “sharp-end” operators because they are trying to do the best they can. The problem is you are fighting with the industry, your insurance, etc. which is really difficult. You can either just succumb to the system and accept it and hope you don’t get sued, but if you fight it, you can get labeled. I think people need to realize providers are not “dumb” in community practice, it is a really tough battle and individuals feel forced to perform sedations they either don’t want to do or cannot do.”

### **4. Regulatory Barriers.**

The multiple venues in which pediatric procedural sedation is provided have lead to subspecialty guidelines and standards that often don’t agree, resulting in confusion among practitioners. Several panelists voiced the need for a unified approach. Anesthesiologist, “I would like to see the

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safety systems built in such a way that we can get all of the different organizations – the emergency medicine physicians, the dentists, oral surgeons, the American Dental Association, the American Society of Anesthesiology, the American Academy of Pediatrics and whoever else is doing this stuff – to all be on the same wavelength and use the same definitions for sedation activity. When we have all different definitions for what we are doing, we can't compare what is truly being done to the patient. I think there are some serious misconceptions out there that need to be addressed and until those things are truly addressed for what they really are, nothing is going to change.”

The fact that regulations requiring expertise to manage sedation side effects (such as airway expertise for sedation overdose) can be prohibitive and result in the therapy being abandoned was cited. Anesthesiologist, “I have heard comments from a variety of physicians that they feel because the guidelines of various organizations have been put into effect that it is just easier to restrain a child than to sedate. I guess that is the flip side of what we are all about today. We want to make this process safe, but we also want to make it available in such a way that it is practical and doesn't cause people to move away from doing the right thing for children.”

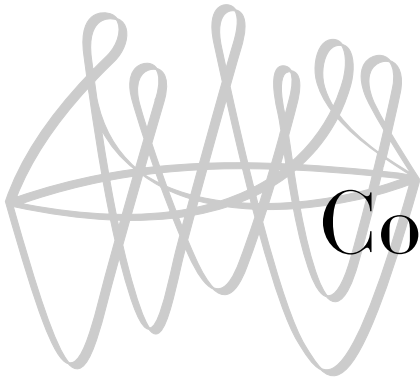
#### *5. Cultural and Psychosocial Barriers.*

Even when standards do exist, compliance is difficult when asking a clinician to change years of successful practice because a new standard of care has changed. The culture of medicine is not currently a culture of safety. Clinicians are taught that they are responsible and that they must be perfect. In addition, events that compromise patient safety are rare making it all too easy as a clinician to believe their current practice is safe simply because they have not personally experienced that complication. The medical community accepts the concept of Murphy's Law, “Whatever can go wrong, will go wrong.” Unfortunately, sedation providers are biased to optimize efficiency and skip safety measures. It is very difficult to convince clinicians of the need for safety measures when they believe the event won't happen to them.

An audience member commented, “I had a chance in Vermont to be involved in a committee that worked at creating standards for conscious sedation in community hospitals. The toughest part of this effort involved almost starting in a fistfight with the surgeon who wanted to continue using DPT. We decided DPT was something we were not going to use anymore and it was really hard to even agree on that. Then it was hard to get by the idea (some providers have) that if you give sedation by any means other than IV, you really do not need to monitor the patient because if it wasn't IV, how could anything happen? You must understand the way these institutions work – in a community hospital there can be five or six months that go by before you necessarily have to provide a sedation.” A pediatric dentist commented, “At the American Academy of Pediatric

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Dentistry... We were out there in the beginning with guidelines. Our guidelines have been changed frequently. They are changed almost every single year... to keep up with new monitoring and new ideas of what is safe. We have tried very, very hard. To our knowledge there have been no cases of morbidity and mortality by pediatric dentists who have followed our guidelines and we study every single case that comes through to see if the guidelines were followed. ...Still, people don't always comply... We are trying to figure out, how do you get people to do the right thing? This is a big problem. You can pass laws, you can pass guidelines and still how do you get people to do the right thing?"



# Conclusion

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**A**t the conclusion of the expert panel session, each of the expert panelists commented on the single most pressing issue, or high leverage change that they felt would advance our common mission to eliminate the suffering and harm associated with pediatric procedures and the sedation care provided. The common priorities stated were:

- We need to characterize existing sedation care strategies in a common way across specialties using observational research, tracking tools, registries, critical incident reporting systems, with data collected from multiple institutions across the country.
- We need to identify hazards and vulnerabilities proactively. Since many of the events that carry risk are rare (apnea, laryngospasm...) simulation represents a powerful tool for this research and can support efforts to test innovative solutions.
- We need to improve sedation provider training, team training and develop approaches for regionalizing care (internally and/or externally) in low volume settings. Educational research needs to be performed to develop methods for training a larger workforce of clinicians with the core competencies that constitute sedation expertise.
- We need to perform systems research that helps us understand how to optimally match the sedation resources available for pediatric sedation care with the procedural demands that exist within a health care system.
- We need to focus on a balance of outcomes that will represent optimal sedation care and a common set of measures for those outcomes. This will allow for research results to better generalize across practice settings facilitating “cross pollination”.
- We need to maintain a patient centered focus and understand the factors that influence a child’s procedure and sedation care experience.

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## Summary Statement

Modern medical capabilities to effectively treat pediatric procedural pain and stress far exceed current practice. This conference provided insights into the systems and barriers that are preventing state-of-the-art sedation care from being routinely used. This report supports a multidisciplinary effort to tackle these barriers. It is only through a coordinated approach that real progress can be made in this field.

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## References

- <sup>1</sup> Blike GB, Cravero JP, Nelson E. Same patients, same critical events –different systems of care, different outcomes: description of a human factors approach aimed at improving the efficacy and safety of sedation/analgesia care. *Quality Management in Health Care*, 2001, 10(1), 17-36.
- <sup>2</sup> Cote, 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):805-814.
- <sup>3</sup> Task Force on Sedation and Analgesia by Non-Anesthesiologists. Practice guidelines for sedation and analgesia by non-anesthesiologists. *Anesthesiology* 1996;84(2):459-470.
- <sup>4</sup> American College of Emergency Physicians. Clinical policy for procedural sedation and analgesia in the emergency department. *Ann Emerg Med* 1998;31:663-677.
- <sup>5</sup> American Academy of Pediatrics Committee on Drugs. Guidelines for monitoring and management of pediatric patients during and after sedation for diagnostic and therapeutic procedures. *Pediatrics* 1992;89:1110-1115.
- <sup>6</sup> Dentistry, American Academy of Pediatric. Guidelines for the elective use of pharmacologic conscious sedation and deep sedation in pediatric dental patients. *Pediatr Dent* 1997;19:48-52.
- <sup>7</sup> Cook, RI, Woods, DD, Miller, C. *A tale of two stories: Contrasting views of patient safety*. A report from a workshop on assembling the scientific basis for progress on patient safety. National Patient Safety Foundation at the AMA, 1998.
- <sup>8</sup> Malviya, S, Voepel-Lewis, T, Tait, AR. Adverse events and risk factors associated with the sedation of children by non-anesthesiologists. *Anesthesia and Analgesia* 1997;85:1207-1213.
- <sup>9</sup> Hopkins, KL, Davis, PC. *Sedation for pediatric imaging studies*. Neuroimaging clinics of North America 1999;9(1):1-10.
- <sup>10</sup> Karian, VE. Sedation for pediatric radiological procedures: analysis of potential causes of sedation failure and paradoxical reactions. *Pediatric Radiology* 1999;29(11):869-873.
- <sup>11</sup> Smith DF. *Sedation, anesthesia and the JCAHO* 2nd Edition. Opus Communications, Inc., 2001.
- <sup>12</sup> [www.JCAHO.com/standard/stds2001\\_mpfrm.html](http://www.JCAHO.com/standard/stds2001_mpfrm.html)
- <sup>13</sup> Lowrie, L, Weiss, AH, Lacombe, C. The pediatric sedation unit: a mechanism for pediatric sedation. *Pediatrics* 1998;102(3):E30.
- <sup>14</sup> Downes JJ, Raphaely RC. Anesthesia and intensive care. In Ravitch MM, Welch KJ, Benson CD, and others, editors: *Pediatric surgery* 3rd ed, Chicago, Year Book Medical Publishers, 1979.
- <sup>15</sup> Malviya, S, Voepel-Lewis, T, Prochaska, G, Tait, AR. Prolonged recovery and delayed side effects of sedation for diagnostic imaging studies in children. *Pediatrics* 2000;105(3):E24.

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- <sup>16</sup> Hertzog, JH, Campbell, JK. Propofol anesthesia for invasive procedures in ambulatory and hospitalized children: experience in the pediatric intensive care unit. *Pediatrics* 1990;103(3):E30.
- <sup>17</sup> Helmreich, RL. On error management: lessons learned from aviation. *BMJ* 2000; (320):781-785.
- <sup>18</sup> Ginnett, RC. Building a culture for team safety: By design and by default. Proceedings of the NTSB symposium on corporate culture and transportation safety 1997.
- <sup>19</sup> Reason, JT. *Managing the risks of organizational accidents*. Ashgate Publishing 1997.
- <sup>20</sup> Blike, GT, Cravero, JP, Lancaster, JC. A Descriptive Model of Pediatric Procedural Sedation Work Based on Video-Analysis. *Int Journ of Clinical Monitoring & Computing* 2001:(in press).
- <sup>21</sup> Malvia, S, Voepel-Lewis, Eldevik, OP, et. al.. Sedation and general anaesthesia in children underdoing MRI and CT: adverse events and outcomes. *Br J Anaesth.* 2000; 84(6):743-8.
- <sup>22</sup> Sandler ES, Weyman C, Conner K, Reilly K, Dickson N, Luzins J, McGorray S. Midazolam versus fentanyl as premedication for painful procedures in children with cancer. *Pediatrics.* 89(4 Pt 1):631-4, 1992 Apr.
- <sup>23</sup> Taddio A, Goldbach M, Ipp M, et. al., Effect of neonatal circumcision on pain responses during vaccination in boys. *Lancet* 1995; 345:291-292.
- <sup>24</sup> Wickens CD, Gordon SE, Liu Y, Decision making, in *An introduction to human factors engineering*. Addison-Wesley Educational Publishers, 1998.
- <sup>25</sup> Kain Z, Mayes LC, Wang SM, et. al., Parental presence and a sedative premedicant for children undergoing surgery: a hierarchical study. *Anesthesiology.* 2000; 92(4):939-46.
- <sup>26</sup> Gaba DM. *Human error in dynamic medical domains. Human error in medicine*. Editor Bogner M, Lawrence Erlbaum Associates, 1994; 197-224.
- <sup>27</sup> www.capnography.com
- <sup>28</sup> Medicine, Committee on Quality of Health Care in America, To err is human: Building a safer health system. In: L. Kohn, J. Corrigan and M. Donaldson (Eds.), *Institute of Medicine*, Vol. 17-25, National Academy Press, 1999, pp. 86-108.
- <sup>29</sup> Kain ZN. Postoperative maladaptive behavioral changes in children: incidence, risk factors and interventions. *Acta Anaesthesiologica Belgica.* 2000; 51(4):217-26.
- <sup>30</sup> Anesthesia Patient Safety Foundation Newsletter. Special Issue: Production Pressure. Patient Safety and Production Pressure. 2001; 16(1).