

Title of Project: Society for Pediatric Sedation Consensus Meeting: Great Expectations—
Defining Quality in Pediatric Sedation

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SPS CONSENSUS MEETING:

GREAT EXPECTATIONS — DEFINING QUALITY IN PEDIATRIC SEDATION

STRUCTURED ABSTRACT

Purpose: Recognizing the inconsistencies in sedation practices, the Society for Pediatric Sedation convened this meeting to begin the process of defining quality as it relates to the field of pediatric sedation. The objectives of the conference were as follows.

1. Define the Institute of Medicine's (IOM) six aims of quality as related to pediatric sedation.
2. Identify key outcome metrics for each aim in improving quality.
3. Outline next steps to develop quality measures for each aim.

Scope: Millions of procedures are performed each year on children. Caring for children, even for routine procedures, can be challenging. Children may not have the ability to follow commands, tolerate painful stimuli or even lie still for a diagnostic study. Therefore, pharmacologic sedation with medications designed to blunt the awareness of the patient and provide relief of pain and anxiety is necessary.

Methods: A multidisciplinary group of sedation providers and quality methodology experts met in November 2011. Through two days of didactics, small workgroups, and consensus discussions the attendees met the objectives of exploring quality in pediatric sedation around the Institute of Medicine's (IOM) six aims of quality: Safe, Effective, Patient Centered, Timely, Efficient, and Equitable.

Results: The conference findings outlined in this document address the Agency for Healthcare Research and Quality's (AHRQ) mission of improving quality healthcare for all Americans, especially for underrepresented groups such as children. The conference outlines a key next step in defining and achieving quality in pediatric procedural sedation.

Key Words: pediatrics, sedation, child, procedure, quality

PURPOSE

The Society for Pediatric Sedation Consensus Meeting: Defining Quality in Pediatric Sedation was held to promote the process of standardizing sedation practice through quality. The objectives for the conference include:

1. Define the Institute of Medicine's (IOM) six aims of quality as related to pediatric sedation.¹
2. Identify key outcome metrics for each aim in improving quality.
3. Outline next steps to develop quality measures for each aim.

SCOPE

In 2006 alone, according to AHRQ's Healthcare Cost Utilization Project, over 3 million procedures were performed on hospitalized children.² These numbers do not include the additional millions of children who underwent procedures in outpatient or office settings.

Caring for children, even for routine procedures, can be challenging. Children may not have the ability to follow commands, tolerate painful stimuli, or even lie still for a diagnostic study. Physical restraint has been commonly used in pediatrics but may be associated with psychological or physical trauma for the child and suboptimal procedure or diagnostic test results. Therefore, for millions of children every year, pharmacologic sedation with medications designed to alter level of consciousness and provide relief of pain is necessary.

Sedation is not without risk, and the choice of medicine utilized comes with wide variation in time to onset, duration, time to offset, and safety profiles. In addition to pharmacologic factor variation, the sedation provider must weigh many patient and procedure characteristics in determining the appropriate sedation for a patient, including age, the required procedure, medical conditions, the physical environment in which the procedure will be performed, and level of pain control desired. Every case brings a unique set of factors and challenges for the sedation provider.

This range of patient- and situation-specific factors makes evaluation of quality care for each case difficult. Basic quality measures and definitions do not exist for this burgeoning pediatric procedural sedation process. This lack of measures does not allow comparison for the many differences in provider types, medications utilized, monitoring parameters, discharge practices and access. Hence, we are left with wide variation in pediatric practice.

Recognizing the need to further the discussion of quality in this emerging field of pediatric sedation, the Society for Pediatric Sedation convened this meeting of multidisciplinary experts to define quality, identify quality metrics, and prioritize future research initiatives to reduce this variability and improve the quality of sedation care for all children.

METHODS

Planning Committee and Process

The following is a list of the planning committee team members and their conference role(s)

- J. Michael Connors, M.D., Principal Investigator, general session facilitator, "Patient Centered" small group leader
- George Blike, M.D., general session presenter
- Joseph P. Cravero, M.D., opening session presenter, "Effective" small group leader
- Susanne I. Kost, M.D., "Efficiency" small group leader
- Deborah LaViolette, R.N., "Timely" small group leader
- Lia Lowrie, M.D., "Safe" small group leader
- Patricia D. Scherrer, M.D., "Equitable" small group leader
- Joye Stewart, Conference Coordinator
- Marlene Miller, M.D., general session presenter

- Stephen Lawless, M.D., general session presenter
- Julie Morath, R.N., Quality Advisor

Through weekly conference calls facilitated by Dr. Connors, the planning committee jointly finalized each element of the conference. The team designed a conference to be attended by a diverse group of participants assigned to a specific small group focused on one of the six IOM aims of quality. **Addendum 1**

Conference Participants

The planning committee, which included the small group leaders, identified persons and created small groups based on individual expertise and skills, ensuring multidisciplinary representation, and ability to build consensus. The list of participants is included in **Addendum 2**.

Pre-Conference Participation

Prior to the commencement of the conference, each small group communicated via email and/or conference call to ensure that everyone understood the goals and objectives of their particular group and the overall meeting. Also, each participant was asked to complete a brief pre-conference survey. The survey was utilized to assist the planning committee in refining the overall plan for the conference and ensured that all participants had an opportunity to comment on all areas of quality. The surveys were collected and common themes were identified, reported to entire group, and are included in the individual breakout group reporting sessions below.

RESULTS

Conference Proceedings - For simplicity, and to avoid confusion, we will report the conference proceedings based on each of the six aims in its entirety.

Safety

IOM Definition - *Avoiding harm to patients from the care that is intended to help them.*

Background: The provision of procedural sedation is accompanied by risk to the patient and deaths related to procedural sedation events continue to occur.^{3,4}

At the same time as national standards for patient assessment were developed, sedation monitoring and recommended recovery assessments were devised. Many centers reported small (no more than 2000 sedation events) case series of sedation processes and reported these processes to be “safe.”^{5,6} These processes differed widely in terms of patient selection, procedure type, monitoring performed, medications used, and recovery schema. Adverse events were not uniformly defined and wide ranges of occurrence of adverse events were described as “safe.” Consensus of what constitutes “safety” has not emerged.

Pre-Conference Survey: The themes identified from the survey included:

1. How to define safety in terms of definitions of what constitutes an adverse event?

- a. Does it have to reach the patient to count?
 - b. If the patient experiences a brief monitored event but no lasting effects, is the event adverse?
 - c. Does the magnitude of a monitored response change constitute an adverse event at a particular level?
2. How do we define effective rescue?
 3. How can we predict risk of adverse outcome for an individual patient undergoing different kinds of procedures?
 4. Does level of sedation truly predict risk?

Breakout Session Discussions: Group consensus arrived at focusing on risk assessment as the next step in moving providing quality improvement support to the community of pediatric procedural sedation providers as a whole. The Safety Group thought that the Pediatric Sedation Research Consortium (PSRC) database work had already gotten fairly far along in defining important adverse events and had already appropriately moved the discussion toward rescue skills required rather than simply monitoring rates of any particular event.⁷ The safety group thought it would be important to start to help organizations provide competency training metrics for patient rescue from adverse events but could not arrive at a good mechanism for doing so. Providing more risk assessment tools to the individual procedural sedation providers seemed likely to be directly beneficial to individual patients; also, the group could envision that tool development could actually be completed with data from the PSRC database.

The safety group also discussed studying obesity as a specific procedural sedation risk factor, particularly as it might relate to obstructive sleep apnea. One individual in particular has a proposed screening tool available and ready for study in a large population. The safety group decided that perhaps study of obesity and/or sleep apnea could be a model for deriving a risk assessment tool; however, because the community of providers of procedural sedation is expanding so rapidly and is so diverse, a more general risk assessment tool including obesity was a more pressing need.

The safety group is envisioning a tool similar to the ASA score that provides a rating of a particular patient's risk for experiencing need for rescue during procedural sedation. Variables might include elements of a patient's medical history and physical exam, specifics of the procedure planned and medication types chosen, and level of sedation planned.

It was envisioned that an emergency room provider or dentist or pediatrician who might only intermittently need to provide sedation care for children might wish to apply this "score" to predict risk for an event occurring for which rescue care may or may not be available.

Outcomes

Definition of Safe Procedural Sedation: Avoiding physical or psychological harm related to the procedures children must undergo.

Initial goal of safe procedural sedation: No deaths associated with pediatric procedural sedation.

Outcome Measure: Collecting and comparing data on significant safety events associated with pediatric procedural sedation.

Next steps: The safety group felt that the Pediatric Sedation Research Consortium database work has already gotten fairly far along in defining important adverse events. This database is approaching the numbers needed to begin to define benchmarks for comparison and further defining safety. The safety group also considered that work already done in the field of anesthesiology has clearly defined the rescue skills necessary for safe sedation. The group felt that focusing on patient assessment to predict risk during procedural sedation to be the area most in need of study.

The safety group is envisioning a tool similar to the ASA score that provides a rating of a particular patient's risk for experiencing need for rescue during procedural sedation. Variables might include elements of a patient's medical history and physical exam, specifics of the procedure planned and medication types chosen, and level of sedation planned. It was envisioned that an emergency room provider or dentist or pediatrician who might only intermittently need to provide sedation care for children might wish to apply this "score" to predict risk for an event occurring for which rescue care may or may not be available. This validated risk assessment tool will allow assignment of right patient to right rescue skills in the right venue.

Effectiveness

IOM Definition: providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit.

Background: Background and Pre-conference themes

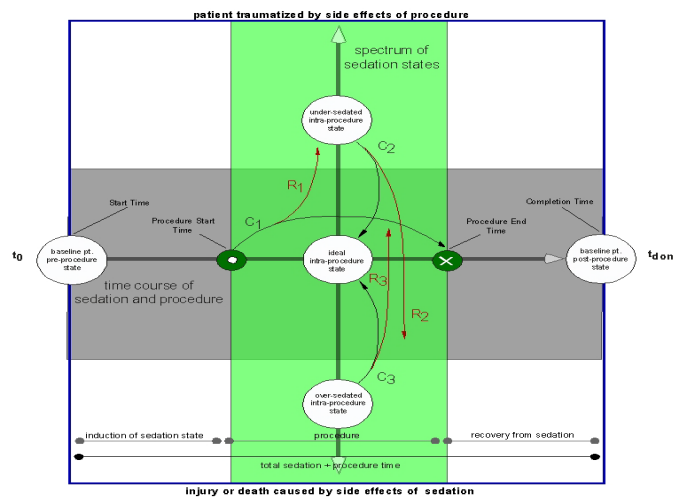
Defining "effectiveness" in pediatric sedation care is a fundamental issue in order to allow for improvement in this area of patient care. There are numerous studies in the collected medical literature that report outcomes involving pediatric sedation. In almost every instance, however, "successful" or "effective" sedation is defined simply as the ability to complete a procedure along with the lack of any permanent (or temporary) injury to the patient. Unfortunately, these reports rarely include data on the patient condition during the procedure or how well the sedation "timing" fits the procedure duration.

In defining "effectiveness" of care in the domain of pediatric sedation, several issues need to be considered. Most importantly, we should understand the patient "state" during the procedure. The state description should include information about pain or stress experienced any movement, the level of sedation, and any side effects during the procedural sedation.

The concept has been suggested in the past that a detailed consideration of the process of pediatric sedation should begin with the creation of a working model of pediatric sedation

(Figure 1).⁸ In this deconstructed consideration of the sedation, a patient is taken from the pre-sedation state t_0 and guided through the procedure to the post-procedure state t_{done} . Various factors (R_1, R_2) represent procedural effects, such as pain or anxiety, threaten to take the patient out of an ideal “state” during the procedure. Control tasks (C_1, C_2) are interventions by the sedation providers that will return the patient to the ideal state. Ideal effectiveness could be defined as the techniques that keep a patient in the ideal state with a minimum of time spent sedated outside of the procedure duration.

Figure 1. Working Model of Pediatric Sedation



Effectiveness measures, if developed with these concepts, could fundamentally change the approach taken in reporting outcomes in this field. Optimally, future reports in this field would include a standard description of the care that would allow comparisons of effectiveness in this field that are simply not possible at this time.

The pre-conference survey outlined these common themes:

1. Many sedation studies cite “effective” care. What does that mean and how do we define
 - a. Procedure completed
 - b. If a child is still or crying or thrashing throughout the procedure – is that effective?
 - c. If a child is asleep long after procedure complete – is that effective?
2. What effectiveness measures do we have and do they include:
 - a. State of patient during procedure
 - b. Procedure results
 - c. Any lasting psychological effects
 - d. Appropriate sedation level for procedure
 - e. Side effects
 - f. Recovery

Breakout Session Discussions: “Effectiveness” with respect to sedation provision is difficult to define. As a group, we found the above definition not easily applied to issues relating to procedural sedation. In our first session, we agreed that, in dissecting this definition, we are still left with the problem of determining what defines “success.” Several questions immediately were raised by this consideration. Is sedation success defined by accomplishing the procedure that you set out to complete? Is it the absence of severe injury or adverse events in conjunction with the sedation that was provided? Does a successful sedation require providing appropriate “conditions” for a procedure – meaning appropriate movement control and the absence of stress or anxiety in our patients?

Based on a preconference survey, background and with significant discussion the group agreed that the best overall definition of sedation effectiveness was offered by Bhatt and coworkers:⁹

Definition of efficacy: The creation of conditions necessary to safely facilitate the completion of a procedure through attenuation of pain, anxiety, and movement with amnesia or decreased awareness. All of the following criteria must be present for a sedation to be considered efficacious:

1. The patient does not have unpleasant recall of the procedure.
2. The patient did not experience sedation-related adverse events resulting in abandonment of the procedure or a permanent complication or an unplanned admission to the hospital or prolonged ED observation.
3. The patient did not actively resist or require physical restraint for completion of the procedure. The need for minimal redirection of movements should not be considered as active resistance or physical restraint.

There was a discussion that ensued in which members of the group agreed that “amnesia” is not required – but that the lack of unpleasant recall should include those children who are coached through a procedure and may recall some aspects of the procedure but whose memories are not (in fact) unpleasant.

Next, we discussed what measures of effectiveness, if any, currently exist. Most studies recognize the successful completion of a test or procedure as “effective.” We discussed that perhaps “effectiveness” could be based on the quality of the studies accomplished under a given sedation, the timing of the sedation (including time to obtain sedation), the time required to accomplish the procedure, and the late effects of the sedation. The issue was raised that perhaps there was a need for a new scale that would codify the patient “state” during the procedure. It was noted that the “state” required for different procedures would be different from one procedure to another. We concluded that the lowest “bar” would be the idea that either the sedation allowed the procedure to be completed or not. On the other hand, there could be other “degrees” of sedation effectiveness. In today’s

environment, true “effectiveness” requires more than just accomplishing the procedure; rather, a sedation “event” should be compared to the “ideal” sedation.

We also discussed the fact that, in the studies that have included some assessment of the patient state during a procedure, various measurement tools have been employed. Several sedation monitoring scales are available for use during sedation activity. Unfortunately, most have been designed for sedation depth monitoring in the ICU environment and require stimulation of the patient in order to test the level of sedation. The University of Michigan Sedation Score (UMSS) (Table 1) has been used most frequently in pediatric sedation studies to document sedation levels during procedures.¹⁰ As with other scales, it requires stimulation to detect levels of sedation and is therefore of limited usefulness during procedures where movement would seriously affect the outcome (i.e., MRI scans).

Table 1. University of Michigan Sedation Score

Level State

0 = Awake/Alert

1 = Minimally Sedated: Tired/sleepy, appropriate response to verbal conversation and/or sounds.

2 = Moderately Sedated: Somnolent/sleeping, easily aroused with light tactile stimulation.

3 = Deeply Sedated: Deep sleep, arousable only with significant physical stimulation.

4 = Unarousable

During this session, Dr. Cravero further described a specific project that he and coworkers undertook at Dartmouth Hitchcock Medical Center, which was also part of the “background” presented previously.

Though most of the group agreed that the concepts imbedded in the DOCS score were valid, the score was actually intended to be used in conjunction with videotaping of sedation encounters and is a bit complex to be used routinely.

As a result of these facts/issues, it is not an “answer” to the need for better analysis of sedation effectiveness in the broadest sense.

Figure 2. D.O.C.S. (Dartmouth Operative Conditions Scale)

CONDITIONS	RA RATING
Pain/Stress	0=Eyes- Calm Expression 1=Grimace; Frown; Tears 2= Crying; Sobbing; Screaming
Movement	0=Still 1=Random minor movement 2=Major Purposeful Movement 3=Thrashing; Kicking; Biting
Level of Consciousness	0=Eyes Open -1=Ptosis; Dysarthria; No Motor Tone -2=Eyes Closed
Respiratory Side Effects	-1=Pulse Ox <92 -1=Respiratory Noise (Snoring) -1=Pauses-Apnea -1=Bradycardia < 5 th Percentile -1=BP < 5 th Percentile

We agreed as a group that, in order to improve the practice of sedation for children, we need a method for comparing “effectiveness” between different providers or care systems. The current definition of success that exists in the literature concerning sedation – primarily revolving around the successful completion of the procedure in the absence injury to the patient – is inadequate. The group agreed that the use of a standardized scale that would allow providers to compare the effectiveness of their care for various procedures would be incredibly useful to improving the understanding of the effectiveness of sedation generally.

We also discussed at length additional factors that can and should influence effectiveness of pediatric sedation, including the following: a) *Creation of multidimensional sedation services for children* that have a standard training and credentialing process, appropriate monitoring and equipment, and a provider who make sedation a focus of their practice and participate in ongoing quality improvement activities. b) *Use of potent sedatives* unquestionably leads to more effective sedation. As such it is problematic to deny certain providers or systems access to these medications.

Everyone in the group agreed that access to more potent medications would result in a smaller therapeutic index and more risk, but this should be managed by improved training and back-up systems for the sedation providers.

Outcomes

Definition of effective procedural sedation: The creation of conditions necessary to safely facilitate the completion of a procedure through attenuation of pain, anxiety, and movement with amnesia or decreased awareness. All of the following criteria must be present for a sedation to be considered efficacious:

1. The patient does not have unpleasant recall of the procedure.
2. The patient did not experience sedation-related adverse events resulting in abandonment of the procedure or a permanent complication or an unplanned admission to the hospital or prolonged ED observation.
3. The patient did not actively resist or require physical restraint for completion of the procedure. The need for minimal redirection of movements should not be considered as active resistance or physical restraint.

Outcome Measure: We agreed as a group that, in order to improve the practice of sedation for children, we need a measure of “effectiveness” that currently does not exist.

Next steps: The group agreed that the use of a standardized scale that would allow providers to compare the effectiveness of their care for various procedures would be incredibly useful to improving the understanding of the effectiveness of sedation generally. This validated scale would measure and codify sedation “state” of a given patient during a procedure. Ideally, this scale should be easy to use on a day-to-day basis and should be easily replicated. The group, through discussion, proposed this scale.

Proposed scale for evaluating sedation effectiveness:

- 5-Uncontrolled kicking and screaming
- 4-Crying requiring minimal restraint
- 3-Expression of pain or anxiety on face
- 2-Quiet and not moving during procedure
- 1-Apnea, requiring airway intervention, etc.

The development and validation of an “effectiveness scale” will challenge the fundamental nature of how we evaluated success vs. failure in pediatric sedation practice. Moving from simply completing a procedure to the state of the child during the procedure will allow a much better method of comparing and contrasting sedation techniques and approaches.

Patient- and Family-Centered Care

IOM Definition: providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions

Background: Patient- and family-centered care is an approach to the planning and delivery of healthcare that seeks a partnership between patients, families, and healthcare providers. How to approach diagnostic and therapeutic procedures for pediatric patients that may involve pain, discomfort, or anxiety from the perspective of patient and family centered care has not been well studied. The preponderance of studies related to family presence focus on resuscitation and/or procedures but do not include the many key factors outlined by the Picker Institute's eight principles relating to patient sedation.¹¹

There are published works relating to pediatric patient- and family-centered care for emergency department care; however, even those works are limited citing the need for more studies to look at how family-centered care impacts outcomes, cost, and overall care.^{12,13} By gaining consensus on the key quality measures of a procedure, which include family-centered care, we can begin to study and identify the gaps in current care.

The pre-conference survey outlined a variety of the different aspects of patient and family centered care, including listening, dialogue, offering and explaining choices, ensuring pain is addressed, identifying and managing any anxieties (including anxiety related to prior experiences), providing a safe and successful procedure, considering family presence, and coordinating and streamlining care.

Breakout Sessions: The first breakout session allowed the group to discuss the pre-conference survey results with our own thoughts and experiences around patient- and family-centered care. Our first task was to identify a list of factors that we felt are part and parcel to family-centered care and key areas of variation in this care.

This list of factors included the many components that allow families and patient expectations to be aligned with the care providers. Key pieces of these components include listening, dialogue, offering and explaining choices, ensuring pain is addressed, identifying and managing any anxieties (including anxiety related to prior experiences), providing a safe and successful procedure, considering family presence, and coordinating and streamlining care.

Overall, we unanimously felt the following: 1. Families and patients have a role and should be included as part of the team that will provide the care needed. 2. Family-centered care is centered on excellent communication and assisting families with medical decision making through education.

From these goals, we next identified the barriers to successfully providing patient- and family-centered care. The barriers included variability between proceduralists and procedures, lacking a definition for family centered care as it relates to procedures, variability in approach to procedures confuses families, families often confusing providers with variability in requesting or refusing sedation, difficulties around educating families related to risk/benefits and gaining understanding, the complexity when multiple procedures are involved, and a lack of measure for quality improvement.

We discussed how to begin to conceptualize an improvement effort for the key issues that need to be addressed initially. Our discussion quickly focused on the fact that no

tool exists that measures patient- and family-centered care. We all have subjective measures and various satisfaction tools in our institutions; however, none have a focus on the key components of patient- and family-centered care. From this discussion, it was also clear that measuring satisfaction of patient or family was not the same as measuring the many factors we identified as critical to patient- and family-centered care.

Our ultimate goal would be to create a tool that could assess patient's experience, similar to the Iowa Anesthesia Scale, but likely more practical to assess the family's experience.¹⁴ Once a tool is developed, measurements can be made, and then improvements could be made and assessed as to how best impact patient- and family-centered care.

However, we also recognized that, with or without a tool, one must build the foundation for patient- and family-centered care within your institution. The key components of this foundation that need to be evaluated include:

1. Do you have hospital "buy-in" for the concepts of patient family centered care?
2. What clinical processes are in place and are they patient/family centered?
3. What policies are in place and how do they include/exclude families?
4. What communication processes are in place? Do you have central communication for families to ask questions and understand directions?
5. How is the hospital physical environment including space, signage, etc..?
6. Are the staff child and family friendly?

Outcomes

Definition of patient- and family-centered procedural sedation: Families and patients have a vital role and should be included as part of the team that will provide the care needed.

Outcome Measures: As a group, we decided that no measure currently exists and we need a way to measure objectively that patient- and family-centered care is delivered. This measure should include these key aspects, what the group called the "4 P's," which encompass the basis for patient- and family-centered care.

1. Providing information
2. Preparing child and family
3. Participation in decision making and plan
4. Post-discharge follow up

Next Steps: Developing a tool that can be developed to measure the key elements of patient- and family- centered care. This tool, envisioned by the group as a follow-up questionnaire, would allow us to measure, intervene, and re-measure the impact of outcomes. This tool could assist in measuring the impacts of changes in many areas around patient care, including:

1. Process – patient flow, scheduling, screening
2. Policy – family presence, time out/consent
3. Communication – instructions, directions, consent

4. Environment – location
5. Clinical care – topical anesthetics, child life

Timeliness

IOM Definition: Reducing waits and sometimes harmful delays for both those who receive and those who give care.

Background: Timeliness is an aspect of quality care that has been studied more in service industries than in healthcare.¹⁵ Taking into account all the different services and locations that interact to provide a procedural sedation, it is very important to optimize the factors that impact its timeliness. Procedures vary in length, location, complexity, and how urgently they are needed. These factors plus limited staffing, regulatory issues, and ever increasing demands are a continual challenge for sedation providers. The need to provide sedation in a timely and organized manner is paramount to providing quality sedation.¹⁶⁻¹⁸

Pre-Conference Survey: The issues raised in this survey in regard to timeliness helped guide the small group discussions by providing talking points and structure. Some of the issues that were brought out were:

1. Timely provision of care is constrained by adequate sedation providers, procedure providers, space, personnel and resources.
2. Patients and families must be instructed to be on time and prepped for procedure.
3. Scheduling must allow adequate time for all pre-procedure aspects to be done.
4. System must be in place to accommodate elective as well as urgent and emergent cases.
5. Find way to avoid cancellations and delays.
6. Reducing waits and delays for both those who receive and those who give care.
7. Appropriate triage and screening to ensure right patient, provider, and time.
8. Access to medicines that can be “quick on/quick off” to optimize turnaround time.

Breakout Sessions The biggest factors impacting timeliness were discussed and thought to be scheduling, pre-screening, physical space, and the logistics of getting everyone in the correct place at the correct time. Optimal timeliness for the sedation service was felt to be dependent on appropriate scheduling, prescreening, and physical space for preparation, procedure, and recovery.

The group then discussed how to define timeliness in a way that could be usefully measured. The timeframes discussed for useful measurement were:

- Order received to procedure scheduled
- Patient arrival to procedure start
- Scheduled start time to actual start time
- Procedure completion to discharge criteria met

We next discussed ways to capture the important aspects of timeliness in a measurable form. We discussed looking at metrics, such as next available appointment, but felt that this metric was not sedation specific, because too many factors outside the control of the

sedation service impacted this timeframe. Another metric discussed was finding the national standards for the different timeframes that are often measured. The time the patient checks in to the sedation area to when they are ready for the sedation to start would be a meaningful span to measure.

The other key discussion was the importance of pre-procedural screening to get the patient to the correct place with the correct sedation provider in the timeliest manner. Our group decided to incorporate the pre-screening component into our plan to impact change.

Outcomes

Definition of timeliness for procedural sedation: Ensuring that a patient receives the right procedure, with the proper sedation, in the proper setting at the appropriate time.

Outcome measures: Timeliness has a broad definition as it can be broken down into measures that include the time the order for a procedure is made until that time until the procedure is initiated. No current measures are currently recognized as standard measures, but examples of timeliness measures discussed for useful measurement were:

- Order received to procedure scheduled
- Patient arrival to procedure start
- Scheduled start time to actual start time.

Next Steps: The next steps of this group are to further define the key measures that could be utilized to establish some key benchmark measures of timeliness. Comparing these benchmarks could allow the identification of best practice models and extrapolation to other services.

One such area that is ripe for initial study, generated from discussion from our group, was to incorporate the pre-screening component into our plan to impact change. The group felt that a pre-screening structure needed to be developed, studied, and possibly standardized. This system would be envisioned to ensure that patients are medically screened, scheduled with the appropriate provider, and educated (all of family) prior to the procedure. The impact of this process on the measures described previously could be examined.

Efficiency

IOM Definition- avoiding waste includes waste of equipment, supplies, ideas, and energy.

Background: The growing demand for pediatric sedation challenges the resources of many facilities. These resource challenges, if unmet, can lead to disparate and inconsistent care.¹⁹ To meet demand and maximize resource utilization, the approach to procedures and diagnostic tests must become more efficient. An efficient sedation practice would maximize throughput of patients without compromising safety or effectiveness.²⁰ Establishing efficient sedation practices that maximize throughput of patients without compromising any other aspect of quality is needed.

Pre-Conference Survey

Themes around the topic of sedation efficiency that emerged from the survey included:

1. Lack of a “gold standard” for sedation efficiency; no one best practice regarding provider type or medication used for a given procedure has been defined
2. The need to maximize screening efficiency to better predict which patients will require sedation and level of sedation that they may require
3. Weighing benefits of individual patient efficiency (patient satisfaction) against the practicalities of staffing and system efficiencies; many systems struggle with efficient scheduling
4. Inefficiencies in re-creation of electronic medical record (EMR) sedation documentation software for individual institutions, and the advantages that such EMR systems could provide in research into best practices
5. Advantages and disadvantages of centralized sedation units versus travelling provider teams
6. The need to standardize definitions and include cost-benefit analysis in comparative sedation research

Breakout Session Discussion: The group felt that many improvements have been made in terms of sedation efficiency (along with the other elements of quality) over the past 20 years, including better guidelines and safety practices around the country, better pharmacologic agents, a broader spectrum of providers (beyond anesthesiologists alone), and improved monitoring technology. The advent of the EMR in many places, both for scheduling and record keeping, was touted as an important advance in improving efficiency, with huge untapped potential for further improvements.

The areas in need of improvement centered on a perceived lack of communication among healthcare providers. The problem of lack of coordination of care in patients who require multiple studies was recognized.

Finally, the variety of approaches to similar events (lack of standardization) was noted as a weakness in current practice. As the first session concluded, we established our group definition of efficient sedation practice with relative unanimity, as follows: efficient pediatric procedural sedation is maximizing the number of successful safe sedation events using the fewest resources in the least amount of time.

We moved on to discuss a measurable project. After much discussion, we revised our initial definition of efficient procedural sedation from “maximizing the number of successful safe sedation events using the fewest resources in the least amount of time” to “maximizing capacity to provide quality sedation care while optimizing costs.” We felt that the revised definition provided a more consolidated, unified outcome with fewer elements to measure, in recognition of the idea that time itself is a resource.

With the new definition in mind, we propose that sedation efficiency could be measured (and thus studied and compared) according to the formula of “episodes of quality sedation care divided by the number of FTE hour dollars required to provide that care.” The structure of interest in terms of sedation efficiency is that of an organized sedation service, including sedation providers, support staff, schedulers, and perhaps liaisons to other services (“customers” of the service). All these human factors can be measured in terms of FTE hours, and a cost can be assigned to those FTE hours.

Finally, the outcome of our efficiency model is the result of the efficiency equation. Efficiency could be increased within a given sedation system by either increasing the number of (quality) sedation events or decreasing the FTE hour costs.

Outcomes

Definition of efficiency in procedural sedation is maximizing capacity to provide quality sedation care while optimizing costs.

Outcome Measures: We propose that sedation efficiency could be measured (and thus studied and compared) according to the formula of “episodes of quality sedation care divided by the number of FTE hour dollars required to provide that care.”

Next steps: Until such time as we have the “tools” in this document to define quality, we would begin with collection of data to compare and contrast this model of efficiency within and across institutions. Efficiency could be increased within a given sedation system by either increasing the number of (quality) sedation events or decreasing the FTE hour costs.

Equitable care

IOM Definition - “providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socioeconomic status (SES).”

Background: Despite ongoing improvements in technology and education, disparities persist in the provision of medical care to children in the United States. Geographic and socioeconomic constraints continue to limit children’s access to pediatric emergency and subspecialty care.^{21,22} Race, ethnicity, culture, and SES may also impact the care delivered and received. As one of its six aims, the IOM has stated that healthcare should be equitable and that the quality of care delivered should not be affected by race, age, gender, ethnicity, income, geographic location, or any other demographic detail. Very little research or policy has addressed equity of care regarding pediatric procedural sedation.

Pre-conference survey: Based on the responses related to equitable care we received from the pre-conference survey, we synthesized the following questions for consideration during the conference sessions:

1. Do geographic limitations to access of subspecialty pediatric providers change the procedural sedation care a child receives in a rural hospital or clinic?
2. If so, are these variations in care clinically significant?
3. What factors are involved in these differences in care – provider education, staffing resources, reimbursement for the provision of this care?
4. How do we address these differences?
5. Do children experience disparities in their procedural sedation care based on their race, ethnicity, or culture?
6. How do we adequately define and measure these disparities?
7. What are the barriers to equitable care, and how do we begin to ameliorate them?

Breakout session: Using the base definition of equitable care from the Institute of Medicine, our group focused from there to a specific goal for pediatric sedation care – for children to receive the best quality care available regardless of race, ethnicity, socioeconomic standing, geographical location, location within a single hospital, or organization or between care centers.

We felt that it was laudable that we were even holding a discussion regarding equity of sedation care, as this aim is often relegated to a lower status than topics such as efficacy or safety. This discussion offers evidence that we as sedation providers are re-committing ourselves to providing the best care possible to all children by offering equal weight and importance to this aim.

We identified three key sources of variation in the equity of care currently being provided:

1. Disparities in procedural sedation system care of children based on race, ethnicity, language, SES, from their ability to access care based on their language/SES to their ability to be scheduled for a particular procedure based on their SES/insurance coverage to their interactions with the healthcare system (interpreters, obtaining consent, etc.), to the procedural sedation regimen and care they then receive. Examples included differences in procedural analgesia based on race in emergency department and postoperative care literature, and differences in pre-sedation screening and consent process, based on language and access to interpreter services.
2. Geographic limitations to equal quality sedation care. Depending on distance from tertiary care center and ability to access that center, care for a given diagnosis may be vastly different.
3. Inequities in the procedural sedation care provided within the same institution or between institutions. Should a child's ability to receive adequate procedural sedation depend on the time of day or the day of the week? Should a child receive a different level of sedation for the same procedure based on which team is performing the procedure or the sedation? Should a child receive a different level of procedural sedation, or a regimen with a different level of efficacy/safety for the same procedure, just based on the hospital to which they present for care?

Next, we began to think about establishing metrics for measuring these areas of variation and discrepancies from what we would see as true equity in pediatric procedural sedation

care. We quickly identified that one of the biggest limitations we have is simply a lack of pre-existing infrastructure to evaluate discrepancies compared to well-established databases to evaluate sedation safety, for example. We spent much of this session discussing concrete ideas for further study of each of the areas of variation in the equity of care. Potential topics for study included evaluation of disparities based on ethnicity and/or preferred language in analgesic administration rates for children cared for in the same emergency department, evaluation of differences in sedative/analgesics provided and perceived efficacy between community and children's hospital emergency departments, and evaluation of variability in access to and quality of sedation services within a single institution depending on when (time of day, day of week) those services are needed. In particular, we all agreed that repeating the survey performed by Dr. Baruch Krauss back in 1998 of sedative/analgesic use in rural versus urban/children's hospital settings would be particularly germane to evaluating the impact of geographic location.²³

Finally, we used the third session to organize potential structure and process steps to achieve our equity in pediatric sedation care. We also focused on two major intermediate outcomes as sources for preliminary investigation and research.

In our presentation of these topics to the plenary group, the conference attendees identified with the huge variability in sedation practice that occurs between institutions of care and even within the same institution. We discussed the challenges of balancing complete equity of care across the board with the limitations in delivering that level of care at every institution. We all agreed that it would be critically important to define and measure discrepancies in care across multiple levels and systems, evaluating multiple factors but that we need to identify specific topics to begin our investigation.

The process for providing equitable pediatric procedural sedation care should include:

- A standardized approach to patient scheduling, preparation, and care that is not impacted by patient age, gender, ethnicity, language, socioeconomic status, or geographic location
- A minimum standard of pediatric procedural sedation and analgesia provision for any hospital that provides care to children
- A minimum standard of care within institutions that will be based upon the effectiveness tool developed by the effectiveness subgroup
- Universal pediatric procedural sedation education.

Outcomes

Definition of Equitable pediatric procedural sedation: The quality of pediatric procedural sedation care will not be affected by patient age, gender, ethnicity, language, socioeconomic status, or geographic location.

Outcome Measures: Outcome measures are broad and have not been defined or measured relative to “equitable” procedural sedation. One of the biggest current limitations is a lack of pre-existing infrastructure to evaluate discrepancies compared to well-established databases to evaluate sedation safety, for example. We identified key areas in which outcomes can and should be measured.

Next steps: As first steps to evaluate the equity of currently offered pediatric procedural sedation care, we would propose to evaluate the following:

1. Rate of administration of sedative/analgesics for painful procedures in children stratified by patient age, gender, ethnicity, language, socioeconomic status, and/or geographic location in pediatric emergency departments, with possible procedures for study including laceration repairs and abscess incision/drainages
2. Rate of administration of sedative/analgesics to children based on geographic location, replicating to a significant extent a 1998 survey comparing community and pediatric emergency department sedation patterns.

Summary

Following the conference, all participants were asked to complete an online survey. The survey was responded to by 88% of the invited participants and is summarized below with the percentage of respondents who agreed or strongly agreed with each statement.

- 93%: The conference was well organized and goals were clearly outlined.
- 97%: The lectures helped me learn more about quality and quality improvement processes
- 93%: I learned quality improvement processes that I can apply toward pediatric sedation.
- 97%: The format of the conference was a good mechanism to accomplish the stated goals.
- 97%: I felt able to provide input and felt my opinion was considered.
- 97%: I feel the atmosphere was collaborative and the group was able to reach consensus.
- 93%: The conference outcomes addressed and furthered discussion of quality in pediatric sedation.
- 93%: The venue (location of hotel, conference facilities) was conducive to a working group meeting.
- 93%: The conference outcomes, if achieved as outlined, will enhance the delivery of pediatric sedation.
- 100%: Based on my overall experience, I would be interested in participating again in a similar conference.

In conclusion, the planning committee feels that this conference represents a substantial step forward for the emerging field of pediatric procedural sedation. We state this because we feel strongly that this field cannot advance without unanimity on how we truly define “quality” pediatric procedural sedation. This conference is perhaps the first step, and a very positive one,

to begin to develop definitions and identify the need for outcome measures. The Society for Pediatric Sedation is excited to lead the multidisciplinary and collaborative efforts of this meeting and to move forward with the “next steps” outlined in this document. The Society will explore additional grant funding and continue to invite a multidisciplinary approach to further advance quality in the emerging field of pediatric sedation.

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Society for Pediatric Sedation Consensus Conference: Defining Quality in Pediatric Sedation

Conference Agenda At A Glance

Four Points by Sheraton BWI Airport, Baltimore, Maryland

November 13-15, 2011

Monday, November 14

8:30am-8:45am	Welcome and Introductions
8:45am-9:30am	<u>Relating the Institute of Medicine's Six Aims of Quality to Pediatric Sedation</u> J. Michael Connors, MD Dr. Connors will provide a brief overview of the Institute of Medicine's Six Aims of Quality and report on the key areas of variations identified by the pre-conference survey and prioritization exercise from opening evening.
9:30am-10:15am	<u>Pride, Prejudice and 10 Years of Progress</u> Joseph P. Cravero, MD As one of the founding members of the Society for Pediatric Sedation (SPS) and the PI for an AHRQ grant awarded in 1999 which led to the founding of SPS, Dr. Cravero will share the current quantitative data and research which exists related to quality and pediatric sedation.
10:30am-11:30am	<u>Components of Quality and Quality Improvement</u> George Blike, MD It is imperative that the participants of each of the six simultaneous small group conference sessions have a shared understanding of the components of quality and the quality improvement process and purpose. Dr. Blike will provide a one-hour overview of the topic.
11:45am-1:00pm	<u>Breakout Sessions/Lunch</u> Meeting participants will break into the six small conference groups to identify 3 key areas of variation/problem in need of quality improvement for their topic area.

- 1:00pm-2:00pm Sharing Quality Priorities
- J. Michael Connors, MD
- In a general session, a representative from each of the six small groups will share the definition of quality from which their team will base the remainder of their conference discussion. Dr. Connors will facilitate a question and answer period to provide feedback to small groups.
- 2:00pm-3:00pm Moving from Defining Quality Concerns to Improving and Measuring
- Marlene Miller, MD
- To support the next small group breakout sessions, Dr. Miller, Vice Chair of Quality and Safety at John Hopkins Children's Hospital, will provide perspectives on how to move from a list of quality concerns to conceptualizing an improvement effort and the embedded quality measures.
- 3:15pm-4:15pm Breakout Sessions: Sedation Quality Metrics
- Within the six small groups session leaders will facilitate discussion around key questions: Of our three identified areas: Which is the most important now? Which are we able to measure? How do we measure each aspect of quality? What do we need to further the establishment of metrics?
- 4:30pm-5:30pm Sharing Quality Metrics: Reports from Six Groups
- J. Michael Connors, MD
- A representative from each of the six groups will share with the larger group the outcome of their discussion around the two session questions: How do we measure each aspect of quality? What do we need to further the establishment of metrics? Dr. Connors will facilitate questions and feedback directed to small groups regarding their quality metrics discussion outcomes.

Tuesday, November 14

- 8:00am-8:30am Day One Summary/Agenda for Day Two
- J. Michael Connors, MD
- Dr. Connors will review the work accomplished in Day One and set agenda for Day Two.

8:30am-9:30am	<u>Moving from Defining Quality to Improving Quality</u> Stephen T. Lawless, MD, MBA Dr. Lawless will facilitate discussions surrounding the translation of these quality metrics into meaningful tools toward improving quality in pediatric sedation from a research, educational and procedural perspectives.
9:45am-10:45am	<u>Opportunities in Quality Research: Learning from other models/changing the paradigm</u> George Blike, MD Dr. Blike will provide an overview of recent quality research studies and outcomes that are relevant to the work of the conference participants.
10:45am-11:45am	<u>Breakout Sessions: Determining Next Steps and Research Initiatives</u>
11:45am-12:45pm	<u>Sharing Future Directions</u> J. Michael Connors, MD Small groups will reconvene to discuss next steps needed surrounding their IOM aim to: disseminate their conference findings, share the definition for quality around their aim, and recommend research needed to establish or measure the quality metrics.
12:45pm-1:15pm	<u>Final Wrap-up</u> J. Michael Connors, MD A representative from each of the six groups will share with the larger group the outcome of their discussion and identification of areas for quality improvement and research.
1:15pm	Box Lunch and Departure

SPS Consensus Meeting Participants

Key: Names in **bold** = session facilitators and members of planning committee

Efficiency in Pediatric Procedural Sedation

1. **Susanne Kost**, MD, FAAP, FACEP
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2. Mark Buckmaster, MD
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4. Nabile Safdar, MD
Assistant Professor, Radiology and Pediatrics; George Washington University Director, Imaging Informatics and Musculoskeletal Imaging, Bioengineering Initiative, Principal Investigator, Sheikh Zayed Institute for Pediatric Surgical Innovation, Children's National Medical Center
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5. Jana Stockwell, MD, FAAP, FCCM
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6. Robert M. (Bo) Kennedy, MD
Professor, Department of Pediatrics, St. Louis Children's Hospital, Washington University School of Medicine
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7. Carrie Makin, RN, BSN
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Pediatric Sedation: Safety Before, During and After

8. **Lia Lowrie**, MD, EMR
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9. David Banks, MD
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10. Morton Rosenberg, DDS
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11. David Gozal, MD (unable to attend- flight delay)
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12. Charles J. Cote, MD
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14. James Hertzog, MD
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Timely Provision of Pediatric Procedural Sedation

15. **Deborah LaViolette**, RN
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20. David Werner, MD, FAAP
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Patient and Family Centered Care Approach to Procedures

21. **J. Michael Connors, MD**
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22. Kris Frey, CCLS
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23. Kirk Lalwani, MD, FRCA, MCR
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24. Gregory Hollman, MD
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25. Paula Fite, PhD
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Effectiveness of Sedation Care

28. **Joseph Cravero, MD**
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31. Marc Leder, MD
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32. Michael Mallory, MD, MPH
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33. Lynne G. Maxwell, MD, FAAP
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34. Mark Roback, MD
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Equitable Pediatric Procedural Sedation Care

35. **Patricia Scherrer**, MD
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36. Cheryl Gooden, MD
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37. Jeffrey Linzer Sr., MD, FAAP, FACEP
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39. Cheri Landers, MD, FAAP, FCCM
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41. Steve Wilson, DMD, MA, PhD
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General Session Leaders

42. **George Blike**, MD
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43. Marlene Miller, MD
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44. Steven T. Lawless, MD, MBA
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