DHMC Dept. of Anesthesiology

“Specifications for High Reliability Pediatric Sedation System”

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INTRODUCTION

In previous work we developed a set of "best/safe" practices for sedation and analgesia care. These practices represent significant changes that are designed to dramatically reduce errors in pain management and thus improve the efficacy, safety, efficiency and overall reliability of sedation/analgesia care for all patients (pediatric and adult inpatients and ambulatory minor surgery/procedure patients) at Dartmouth Hitchcock Medical Center. This document outlines a plan for rigorously assessing the implementation strategy for these tools by measuring the level of adoption and impact. Ultimately, this provides a path for addressing the Institute of Medicine's charge to make "eliminating needless pain and suffering" a fundamental priority in the provision of reliable patient-centered care.

A secondary aim of this plan is to advance patient safety science by demonstrating the utility of a High Reliability Organizational (HRO) framework for packaging a set of best/safe practices for pain management in a manner that will be generic and re-usable for other patient safety interventions. This HRO framework seeks to simultaneously and incrementally change:

- The patient safety **culture** of an organization
- The **structures** and systems that represent infrastructure for safe practice
- The **training** paradigm to incorporate measures of competency
- The **organizational learning** network that facilitates practice chance across departmental, sectional and unit boundaries

A third aim of the plan is to test a human factors approach for developing an idealized sedation/analgesia micro-system. The safe/best practices being implemented in this plan were not identified though traditional trial and error, but rather engineered de-novo based upon an empirically derived patient state-feedback control model. This innovative approach addresses the rare event problem in patient safety that has hindered advancement with traditional epidemiological approaches. Model-driven design is a logical and proven strategy used in the NASA space program and modern motor vehicle crash-test facilities to design safety and error countermeasures. The use of high fidelity simulation in this plan to test rescue performance and to identify latent conditions needing corrective action needs further evaluation. The outcome measures being utilize will allow rigorous evaluation of the utility of this approach.

BACKGROUND

<u>Pain Management Failures are Prevalent and Multifactorial:</u>

During the provision of needed medical care, the gap between state-of-the-art capabilities to control pain and the "typical" levels of pain control provided is unacceptably large. [2] Modern medicine is winning the battle against many diseases. Unfortunately the treatments used to obtain this progress are often invasive, stressful and a source of significant suffering. Suboptimal pain control is extremely common

among hospitalized patients and ranges in severity from minor pain accompanying venipuncture to the major pain associated with interventions such as a chest tube placement into the thoracic cavity, wound debridement, bone marrow aspiration and changing vacuum dressings for deep wounds. In addition, the resources deployed to provide this care are highly variable. Because these procedures are often performed in an urgent manner and in a variety of locations, anesthesiologists, emergency medicine specialists, cardiologists, radiologists, generalists, nurses and (often) house officers are all asked to provide sedation. The medications used, depth of sedation provided, monitoring employed and degree of training for this task varies greatly from one specialist to another even when the goals for sedation are identical.

Sedation/analgesia failures:

Under-use errors--Despite evidence pain and anxiety management is being attempted (>60% of inpatients on any given day at the Dartmouth Hitchcock Medical Center (DHMC) are receiving pain medications or sedatives), under-treatment remains a major problem in our facility and throughout healthcare. Our own assessment of children undergoing invasive procedures found that 68% had prolonged episodes of screaming and/or thrashing that required physical restraint to accomplish the procedure. [3] Reported care for adults is not much better. [2,4] The magnitude of this problem led the IOM to explicitly emphasize that reliable patient-centered care must eliminate unnecessary pain and suffering.[1] Because this care is required in all areas of the hospital at multiple times of the day this goal has proven daunting [5] Specifically, available tools to manage pain better (more potent, targeted, short-acting medications and individuals qualified to deliver them) are not being widely leveraged. Standard educational programs have been unsuccessful in getting clinicians or patients to use new pain medications and sedatives more aggressively.[6,7]

Research performed at DHMC has been the first to describe one major provider factor driving the widespread under-treatment of pain - risk aversion. Sedation providers use less potent medications and techniques to avoid any possibility of the side effect of drug induced respiratory depression. Restated, healthcare providers accept significant pain in their patients because they fear the life threatening respiratory depression that is associated with more potent pain therapies.*

Over-use and mis-use errors--This “risk aversion” appears to be justified. The Joint Commission on Accreditation of Hospitals (JCAHO), the American Society of Anesthesiologists (ASA) and the Anesthesia Patient Safety Foundation (APSF) have all recognized the need for, and hazards of, sedation/analgesia.[8-10] Exact estimates of the risk associated with sedation/analgesia are lacking. However, ongoing quality assurance surveillance at DHMC revealed 32 primary respiratory events in a single year, 38% of which were associated with the use of opioids, benzodiazepines, or other

* *Pediatric Sedation: a Safety and Efficacy Problem for Children Requiring Diagnostic and Therapeutic Procedures in the Hospital Setting: a Human Factors Opportunity for Improvement* funded by the National Patient Safety Foundation 2000.

similar sedative/analgesic medications.[11] These data represent one respiratory arrest necessitating a "code blue" response per ~10,000 patient care days at our hospital.[§]

These seemingly rare events, in aggregate, represent a major source of avoidable patient harm. During the same time frame in which the specialty of Anesthesiology has demonstrated that even general anesthesia can be provided with a high degree of safety, moderate sedation for minor procedures performed by non-anesthesiologists carries greater risk. The current estimate of anesthesia-related mortality is one death per 200,000-400,000 anesthetics. In contrast, deaths related to sedation and local anesthesia for liposuction performed in an office setting by non-anesthesiologists have been reported to occur once in every 5,000 procedures.[12] This represents a 40 to 80-times greater risk of dying that is attributable to care system differences rather than to patient populations.

Research to identify "best/safe" practice for sedation/analgesia at DHMC:
We have conducted human factors research over a five year period to identify an ideal micro-system of resources to provide highly reliable yet safe sedation/analgesia care. This research addressed a gap in understanding the nature of sedation/analgesia failures and why existing guidelines had proven to have minimal impact towards improving this care.

Pediatric Population--We targeted this population because it was high risk and would allow us to quickly identify safety features that would generalize to all sedation/analgesia care settings. Of all patients receiving sedation, the pediatric population represents the highest risk, lowest error tolerance subgroup. Pediatric patients require sedation/analgesia more often than adults (e.g., you can not ask a 2 year old who is in pain to hold perfectly still, even for a 10 minute CT scan). In addition, sedation/analgesia for children must be "deeper" than that given adults in order to achieve ideal procedural conditions. Most importantly, because of the unique physiology of children, they are at higher risk for respiratory depression and oxygen desaturation. In a review of 110 sedation related deaths captured in a registry - but a fraction of all deaths associated with pediatric sedation - the overwhelming majority were preventable and due to operator error. Most of the deaths could be related to the known respiratory depressant side effects of the sedative medication used. [13]

Existing guidelines inadequate--Unfortunately, even clinicians adhering to current practice guidelines for pediatric procedural sedation appear to be at risk of causing iatrogenic injuries. One center implemented the American Association of Pediatrics (AAP) guidelines for pediatric sedation, and then prospectively followed 1140 children (age 2.96 + - 3.7 years) sedated for procedures by non-anesthesiologists using a quality assurance tool. Approximately 13% of the children received inadequate sedation. They also reported a 5.3% incidence of respiratory events including one in which a child stopped breathing. [14]

[§] A crude estimation based on 250,000 hospital beds nation-wide occupied 365 days per year would predict 3,750 such arrests associated with sedative medications nationally per annum.

Microsystems and human factors approach-- As we embarked on field observational research to better characterize sedation/analgesia care, several conceptual frameworks in the literature were considered. A "micro-system approach" is based on the work of quality improvement leaders Batalden and Nelson who have adapted Quinn's micro-system ideas to the medical domain. They have advocated conceptualizing the healthcare setting and working conditions as divided into clinical "micro-systems". [15,16] They define a micro-system in healthcare delivery as: A small group of people who work together on a regular basis to provide care to discrete subpopulations of patients. The micro-system has aims, linked processes, shared information environment and produces performance outcomes. They evolve over time and are often embedded in larger organizations. As a type of complex adaptive system, the members of the micro-system must: a) do the work; b) meet the staff needs; and c) maintain themselves as a clinical unit. Woods, Reason and other Human Factors pioneers have proposed a similar model regarding complex man-machine systems as cognitive systems. This schema of complex human technological systems[17,18] proposes expertise and failure (i.e., high quality outcomes) be expressed when a pyramid of resources are leveraged to manage a given clinical problem or demand. These two frameworks seem to represent convergence from independent scientific paths (quality and safety). [3]

Two major hypotheses were central to our broad objective of defining the best/safe practices associated with an ideal micro-systems: Hypothesis 1-Essential components in an ideal clinical micro-system are those that create robust "control loops" for managing the key problem states associated with a domain of care. Clinical micro-systems with components that constitute complete control loops will have the best quality and safety; Hypothesis 2- Essential processes and behaviors in an ideal clinical micro-system are those that support control loop performance through interactions and coordination of the components. In complex human technical systems where control is distributed across multiple caregivers, teaming is an essential process that supports communication and effective delivery of care. Clinical micro-systems with team building processes will have the best quality and safety.

Best/safe practices for sedation/analgesia care-- Empiric research was conducted using the guiding research hypotheses. A "Sedation Summit" conference was convened of experts in the field of pediatric sedation to gain a multidisciplinary perspective on the challenges of sedation/analgesia care.[19] Subsequently, observational research was performed that included over 350 hours of video of actual sedation care.[3,20] High fidelity simulation of respiratory arrests were then investigated and used as a standardized "crash-test" to assess rescue capabilities throughout the hospital where pain control is provided.[3,21,22] Finally, we created an outcomes database and consortium of over 30 hospitals to measure the impact of safe practice interventions. This research provided a firm foundation for a set of best/safe practices (see next section for details-Previous Studies Section C) embedded in an intervention—the CHaD PainFree Program. For over three years, these practices have been implemented in our Children's Hospital at Dartmouth (CHaD) PainFree Program. All metrics of sedation/analgesia care show continued improvement. The program has received national recognition for its innovative approach.[23-25] This program has dramatically

diminished pain and improved anxiety control for more than 3,000 children and resulted in happier patients, better quality tests and conditions for therapies, safer conditions with better back-up for rare high risk events, more consistent care and better access. We firmly believe that the methodologies pioneered in this area of practice have been validated and will translate directly into improvement in alternate patient populations. This program represents a proof of concept for the hospital-wide program we are proposing.

High Reliability Organizational (HRO) theory--The framework we have adopted for our implementation strategy is based on the four tenets of high reliability organizations that Gaba has aligned with the healthcare domain. [26] Gaba has defined these tenets as:

> **Safety culture**: The organization commits to safety as a primary priority (greater than or equal to production or mission accomplishment). This is transmitted palpably and concretely throughout the organization.
> **Optimal structures, systems, and procedures:** The organization adopts structures, systems, processes and procedures that facilitate safety and reliability as well as efficiency and production throughput.
> **Intensive training:** Safe and reliable operations depend critically on personnel who are highly skilled. Skill is only maintained through intensive and continuous training activities both during actual work and in special training sessions (particularly simulation). Training is conducted for individuals, single disciplines and multi-disciplinary teams and is ongoing and systematic. No one is too senior to participate in training. Training sessions are embedded in the work, not an ad hoc, sporadic or self-selected activity.
> **Organizational Learning:** The organization constantly attempts to learn from successes and failures, honing and adapting systems and procedures. This includes: a just reporting culture (low blame); incident reporting and analysis; interdisciplinary analysis of events; prospective safety analysis (e.g. FMEA and other prospective techniques); systematic capture and transmission of lessons learned; and identification and implementation of systems changes rather than individual training.

We believe ideal the clinical micro-system in our PainFree pediatric demonstration defined: a) optimal structures, systems and procedures; and b) the basis for an intensive training program using computer instruction and simulation. However, other components were not essential at the micro-system level for success. The hospital-wide replication involves a 20 to 30-fold increase in patient impact and will necessitate complex adaptation of the lessons learned to date. HRO theory provides the rationale for our strategic plan for the large scale implementation proposed (see Intervention Design and Methods below for details).

PRIOR WORK

Research to understand how to improve the efficacy and safety of sedation/analgesia has been underway at DHMC since 1999. [3,20-22] The following summaries describe five funded investigations that constitute the foundation for best/safe practice regarding sedation/analgesia care.

Study 1-Expert knowledge elicitation regarding sedation/analgesia care:

The Dartmouth Summit on Pediatric Sedation was convened to assess the state-of-the-art of pediatric sedation, to identify issues that impact on sedation outcome, and to generate a framework for understanding the critical factors associated with safe and effective sedation care. Nineteen recognized sedation experts from across the United States were invited to participate in this conference. Experts were chosen from various medical specialties including: Anesthesiology, Emergency Medicine, Pediatric Intensive Care, Radiology, Oral surgery, Dentistry and Dental Anesthesiology.

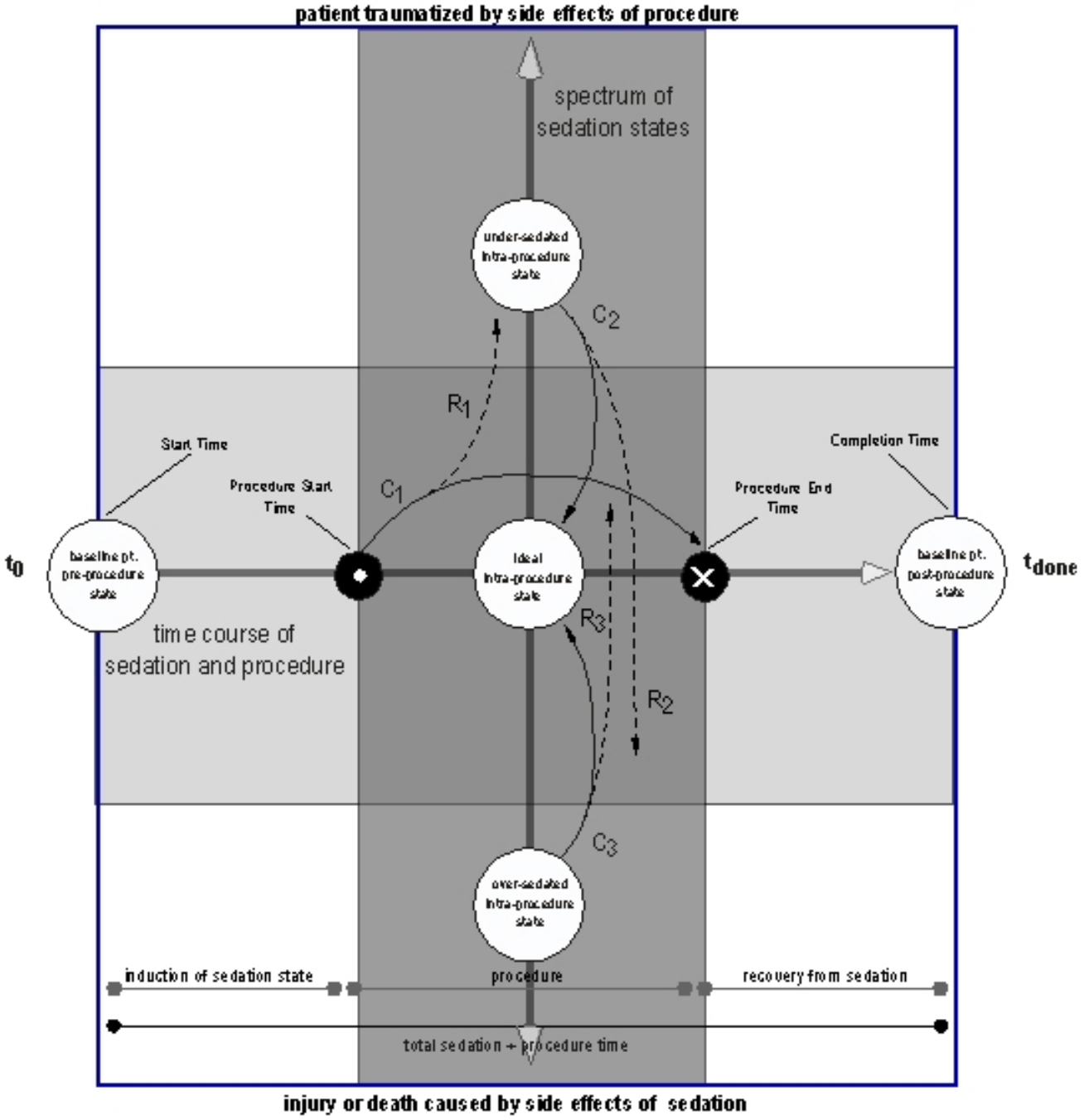
The invited sedation experts were:

1) Charlotte Bell, MD – Yale University, Pediatric Anesthesiology
2) George Bisset, MD – Duke University, Pediatric Radiology
3) George Blike, MD- Dartmouth Hitchcock Medical Center, Anesthesiology and Human Factors Science
4) Charles J. Cote, M.D – Memorial Children's Hospital Northwestern University, Pediatric Anesthesiology
5) Joseph Cravero, MD – Dartmouth Hitchcock Medical Center, Pediatric Critical Care and Anesthesiology
6) Ralph Epstein, DDS – Private Practice Long Island New York, Pediatric Dental Anesthesiology
7) Mary George, DMD – Private Practice Long Island New York, Pediatric Dentistry
8) Michael Girardi, MD – Pediatric Emergency Medicine
9) Constance Houck, MD – Boston Children's Hospital, Pediatric Critical Care and Anesthesiology
10) Baruch Krauss, MD – Boston Children's Hospital, Pediatric Emergency Medicine
11) Stuart Lieblich, DMD/MD - University of Connecticut, Oral Surgery
12) Lia Lowrie, MD – Rainbow Babies Children's Hospital, Pediatric Intensive Care
13) Shobha V. Malviya, MD – University of Michigan, Pediatric Anesthesiology
14) Thomas Mancuso, MD – Boston Children's Hospital, Pediatric Intensive Care and Anesthesiology
15) Lynne Maxwell MD – John's Hopkins University, Pediatric Anesthesiology
16) David Polaner, MD – University of Colorado, Children's Hospital Denver, Pediatric Critical Care
17) Mark Rockoff, MD – Boston Children's Hospital, Pediatric Anesthesiology
18) Richard Towbin, MD – Children's Hospital of Philadelphia, Pediatric Radiology
19) Myron Yaster, MD – Johns Hopkins University, Pediatric Anesthesiology and Critical Care

The summit included a structured panel discussion in which these experts commented on "exemplar" sedation cases. The cases were based on actual pediatric sedation cases videotaped at the Children's Hospital at Dartmouth. The same case was viewed differently by the different specialists because of the contextual differences in their domains of practice. Transcripts of this commentary formed the basis for analysis to gain a deeper multidisciplinary insight into the key factors underlying safe and effective practice. Consensus findings around goals, determinants of efficacy, sources of risk, drivers of safety, team communication and coordination factors and barriers to making systemic improvements were summarized in a report published by the National Patient Safety Foundation. [19]

Study 2-Empiric field observation as to the nature of sedation/analgesia care:
This NPSF-funded research consisted of field observation of 100 pediatric sedations at Dartmouth Hitchcock Medical Center. Adding to expert information resulting from the Dartmouth Summit, investigators used process-tracing and expert knowledge elicitation to analyze a cohort of 12 videos. These data were used to develop a model of sedation care using a state feedback control model. [3]

The resulting patient state control model pictured below depicts the range of patient states on the y-axis, over time on the x-axis. This range of states varies over the time of the sedation and the procedure which is represented by the vertical dark grey shaded area. The goal of safe sedation practice is for the patient to be maintained in the "safe zone" or "middle of the road", (that is, neither over- nor under-sedated) from the Start Time to Completion Time. This is depicted by the horizontal light grey shaded area. **Risk factors** that push a patient out of the ideal state (such as the performance of an invasive procedure or the administration of an overdose of medication) are represented by "**R**" arrows while the **control tasks** (consisting of detection, diagnosis, and treatment components) performed to reinstitute the ideal patient state are represented by the "**C**" arrows.



This control model was used to develop a continuous measure/metric of patient state: the Dartmouth Operative Conditions Scale (DOCS-Table 1). Previous sedation scales were only concerned with "level of sedation", and lacked the fidelity to define the actual state of the patient with respect to all of the important factors present during a procedure. There was no instrument available to allow a comparison of the effectiveness and safety of sedation provided by various providers and techniques. [27-31] In contrast, DOCS allows one to score video observational data regarding patient state continuously over the time course of a procedure. DOCS has been validated with

respect to construct validity, criterion validity and reproducibility. [20] In addition, information regarding the sedation care strategy was cross-correlated with the video record of the "outcome" of the care process. Ultimately this coding scheme allowed us to graph the control behavior of patient state throughout the sedation. From hundreds of hours of video data, we were able to identify intervals of good control (patient state was maintained in the goal zone and the child was still, comfortable and relaxed) and intervals of control failures (patient state observed consistent with pain, anxiety and dangerous movement). This detailed analysis of over 350 hours of video showed that under-treatment of pain and stress was very common (65% of the cases observed). Structured interviews were conducted to understand the control failures and errors that had been identified. For example, a care team used barbiturate for a painful procedure with the erroneous belief that the medication had analgesic properties. The child then was observed to react to the painful portion of the procedure with screaming and thrashing. Subgroup analysis was then performed in matched cases in which similar patients and procedures were associated with very different control outcomes (see Figure 1). Thus we could identify the resources and practices that support vs. undermine good control.

Table 1: The Dartmouth Operative Conditions Scale (DOCS)

Patient State	**Observed Behaviors**			
Pain/Stress	(0) eyes closed or calm expression	(1) grimace or frown	(2) crying, sobbing, screaming	
Movement	(0) still	(1) random little movement	(2) major purposeful movement	(3) thrashing, kicking, biting
Consciousness	(0) eyes open	(-1) ptosis, uncoordinated, "drowsy"	(-2) eyes closed	
Sedation SEs	(-1) SpO2<92%	(-1) noise with respiration	(-1) respiratory pauses >10seconds	(-1) BP<5th percentile

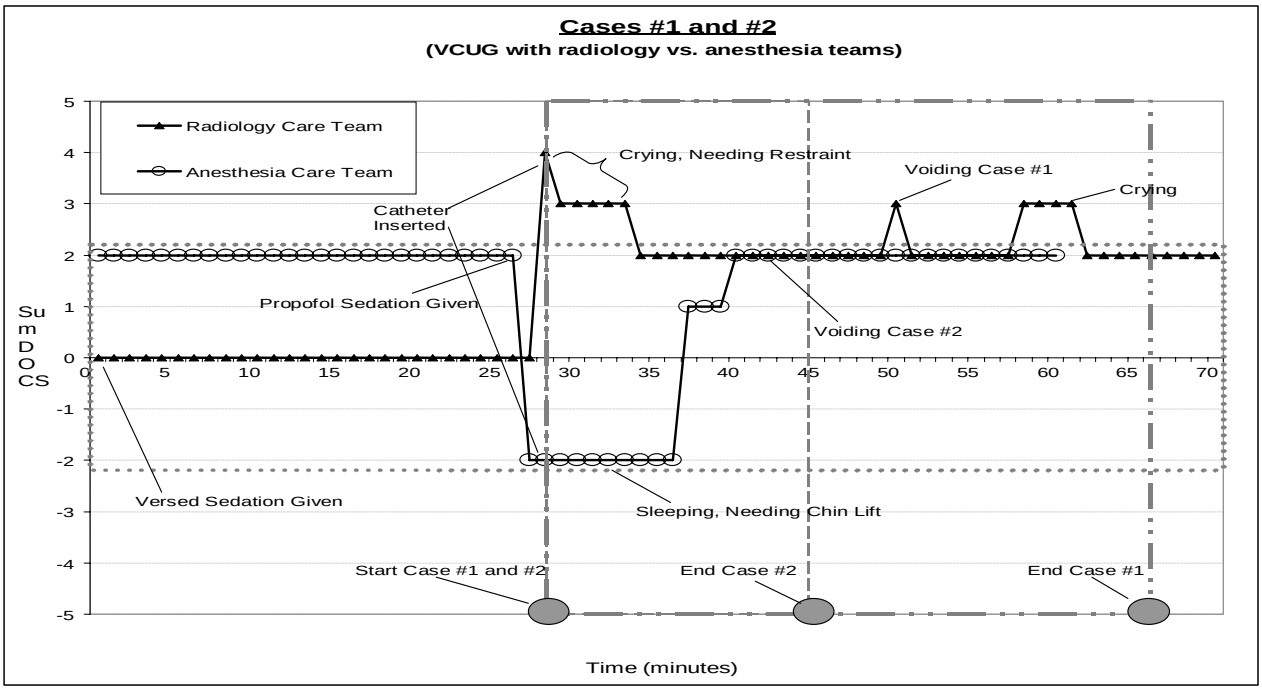


Figure 1: Same procedures performed on matched children with two different techniques

Study 3-Use of simulated critical incidents assess rescue capability:

Human errors that result in rare critical events at a low incidence during the course of routine medical care are difficult to study. Hundreds of studies involving sedation/analgesia have been published in the last 30 years that lack statistical power to address patient safety. Still authors of these papers almost always conclude that their techniques are “safe and effective” because they did not detect a critical event. Similarly, our observational video study of 100 patients lacked sufficient power to observe a sedation critical event and the rescue care associated with it.

To address this gap in our ability to assess the true safety of different approaches and sets of resources being used to provide sedation care, we used high fidelity simulation to generate rare events that are otherwise difficult to study. We then performed field experiments to provocatively test current sedation care settings for safety in terms of “rescue capability.” Research milestones consisted of: 1) development and validation of a simulated rare event; 2) use of this standardized event to test care systems in context; and 3) video analysis for deviations in observed care relative to best/safe practice. The scenario developed consisted of a standard reproducible event with physiology that degraded over time if no appropriate interventions occurred, and improved when treated effectively. We then performed “crash-testing” in actual care domains. The simulated event was videotaped and data-files of the simulator’s physiology captured. The quality of each team's performance was assessed using the simulator data files to calculate

"time out of range" measures for the critical variables and behaviors were analyzed using qualitative methods for deviations from "ideal care".

This provocative test readily allowed rescue performance in different sedation care settings such as the Emergency Room and in the Radiology department to be compared with best/safe practice. [21] Ten simulated sessions were conducted both under ideal conditions and in actual care-settings. An unexpected finding was that personnel deemed competent and safe on the basis of meeting our hospital training requirements for airway management had significant performance deviations when compared to best/safe practice in an objective manner. Video analysis consisted of scoring observed rescue performance for deviations from a set of best/safe system structures and practices. The simulator data log was used to quantify episodes of hypoventilation, apnea, hypoxia and cardiovascular collapse. The range of deviations between different units was quite large. Deviations in the Post-Anesthesia Care Unit totaled 1 out of 26 measured variables while there were ~10 deviations each for an Emergency Department bay and one of the CT scanner locations. Hypoxia and hypotension lasted only 90 seconds in the benchmark pediatric sedation unit, but was 3 and 4 minutes in the Emergency and Radiology settings respectively.

Contributory factor analysis used the approach described by Vincent et. al. This qualitative method uncovers failure opportunities across the full spectrum of resources supporting sedation care—from the blunt-end (system resources) to the sharp-end (provider interface factors) of the system. [32,33] We have demonstrated that this methodology allows rescue performance to be measured, latent conditions identified and corrective actions taken to impact the margin of safety for sedation/analgesia care.

Study 4-High Reliability Sedation/Analgesia Demonstration:

The empiric research we performed was used to design a high reliability sedation/analgesia care micro-system. The design consisted of specifying the components that support sedation, analgesia and movement control and respiratory depression control (i.e., rescue). The resource specification included the people, tools and environmental components that afford control (a.k.a., an affordance map, Tables 2A, 2B and 2C).

The PainFree Program at Children's Hospital at Dartmouth implemented these best/safe practices. Several aspects of the implementation are worth noting:

- ***A robust team with clear roles and responsibilities*** consisting of an analgesia expert, an IV expert, an expert in child anxiety and coping with hospitalization, an expert in laboratory testing and equipment, and a scheduling expert to coordinate teams of clinicians (PainFree team = anesthesiologist, a former critical care neonatal nurse, a child life specialist (CLS), licensed nurse technician and scheduling coordinator.)
- ***Centralized coordination of sedation/analgesia resources*** in which a single individual links sedation team to procedures required. This individual also needed special training to execute a set of clinical questions that is a simple triage

system for identifying high risk patients who need additional advanced preparation.

- ***Education in 100% of patients prior to procedure*** with secondary triage of medical conditions has allowed patients to be better prepared for what will happen and their role in achieving a safe effective outcome. In addition, the sedation team identifies patients warranting advanced strategic planning and special resources (100% RN phone consultation, 100% Child Life Specialist phone consultation prior to procedure).
- ***State of the art equipment/medication delivery systems.*** Given the diverse settings in which sedation/analgesia is required, these tools need to be highly portable, miniaturized and durable. Critical equipment consists of capnography, respirometry, pulse oximetry, an inhalational anesthesia delivery system, ultrasound to assist in difficult IV access, iontophoretic local anesthetic delivery systems and syringe pumps that can handle small syringes for premature infants and large syringes for obese 17 year olds.
- ***The rescue team for this care activity must be formalized.*** Simulator-based drills are vital for the rescue team to practice resuscitation of sedation/analgesia rare events. Also this methodology allows deficits in the rescue systems to be identified and then corrected.
- ***Measurement and continuous improvement*** to create a high reliability unit with a culture of patient safety. This feedback is essential for optimizing the attainment of sedation/analgesia goals and reduction in risks in the face of production pressure and other demands that tend to erode the margin of safety.
- ***Ongoing reduction in variability in practice*** allows innovation in this care domain where best practice has not yet been identified. However, when data supports one technique as superior, this best practice is made the standard of care.

Table 2A: Best/safe practice specifications for sedation/analgesia

C2 Undertreatment Errors

CONTROL LOOP COMPONENTS	PROBLEM STATE	STRUCTURES ASSOCIATED WITH CONTROL	
Detection	**Pain**	Direct observation	
		EKG	
		BP	
	Anxiety	Direct observation	
		EKG	
		BP	
	Dangerous Movement	Direct observation	
		Test results	
Diagnosis	**Pain**	RN w/ moderate sedation training	
		Anesthesiologist, CRNA	
	Anxiety	Child Life Specialist	
		Parents	
	Dangerous Movement	Procedure operator	
Treatment	**Pain**	Local anesthesia	Lidocaine/insulin needles
			EMLA
			Numbey
		Non-opioids	Tylenol oral, rectal
			NSAIDs
		Opioids	Fentanyl
			Remifentanyl
		Inhalational	Nitrous
			Sevoflurane
			Isoflurane
	Anxiety	Parental presence	Clear role
		Desensitization (education)	Procedure specific
		Distraction	DVD/goggles
		Choice	A vs. B
		Nitrous Oxide	Face-mask training
		Benzo	Versed/IM/oral/IV
	Dangerous Movement	Mechanical	Arm boards
			Papoose/Velcro
		Airway	Oral/nasal/LMA
		Muscle relaxants	Rocuronium, Vecuronium

Table 2B: Best/safe practice specifications for rescue

C3-Over and Mis-treatment errors

CONTROL LOOP COMPONENTS	PROBLEM STATE	STRUCTURES ASSOCIATED WITH CONTROL		
Detection	**Obstructive or Central Apnea**	Direct observation		
		EtC02		
		Cont. auscultation		
	Hypoxia	Sp02		
		Cont. tone/beep		
		Alarm for Sp02		
	Hypoperfusion	Sp02 pleth		
		Sp02 HR		
		EKG HR		
		EKG trace		
		NIBP		
	Deep Sedation/GA	Verbal		
		Pain		
Diagnosis	**Obstructive or Central Apnea**	RN w/ capnograph		
	Hypoxia	RN w/ pulse oximeter		
	Hypoperfusion	RN with non-invasive blood pressure monitor		
	Deep Sedation/GA	RN w/ moderate sedation training		
Treatment	**Obstructive or Central Apnea**	RN	w/ oral airway	
			w/ suction/yankauer	
	Positive Pressure Ventilation	RN call for help		Back-up available
				Access mechanism
		Respiratory Therapy/Anesthesia Provider		Bag
				Mask
				O2 source
				Oral airway
				LMA
	Definitive Airway	Anesthesiologist		Laryngoscope
				ETT
				Stylet
	Deep Sedation/GA	RN w/ reversal drugs		Narcan
				Flumazenil

Table 2C: Measured competencies for rescue

COMPETENCIES

Video-markers of best/safe practices for managing respiratory depression			Scoring Criteria (seconds)		
			Good	*Adequate*	*Poor*
Phase I	*Monitoring*	Apnea diagnosed (no chest movement)	0-30	31-60	>60
	Mobalizing help	PPV call (from time apnea detected)	0-30	31-60	>60
	Basic Airway Tx	Supplemental O2 (from time apnea detected)	0-15	16-60	>60
		Jaw Lift (from time apnea detected)	0-15	16-30	>30
		Oral Airway (from time jaw lift)	0-15	16-30	>30
		Bag/Mask Ready (from time requested)	0-15	16-30	>30
Phase II	*Advanced Airway Tx*	PPV expert arrives (from time called)	0-120	120-240	>240
		Expert BMV (PPV attempts from when arrived)	0-15	16-30	>30
		Two Person (from when one person failed)	0-15	16-30	>30
		Intubation (from when two person failed)	0-60	61-120	>120
		Failed intubation "call for back-up" (from when failed)	0-15	16-30	>30
		Succinyl Choline (from when laryngospasm dx)	0-60	61-120	>120
	PALS	Atropine (HR<60)	0-60	61-120	>120
		Epinephrine (Atropine, HR<60)	0-60	61-120	>120
		Compressions (no pulse)	0-15	16-60	>60

These critical practices have resulted in highly customized sedation/analgesia care. The capacity to provide multiple modalities of sedation/analgesia with rational triggers for switching modalities has resulted in sedation wider range of sedation solutions. Previously all patients scheduled for CT scans would receive oral chloral hydrate even if an IV was in place (and regardless of the indication for the examination). Subsequent to

the inception of the PainFree program, many sedation options are entertained including simply swaddling neonates for comfort and sleep, distraction with video goggles and DVD movies for older children, brief inhalational anesthesia for IV placement in those who can not cooperate or propofol for those requiring deep sedation and optimal movement control.

This Program has received national recognition, winning the VHA Leadership Award for most innovative clinical program, the international award for Ronald McDonald Charities, and has been featured in the national press. [23-25] The program was highlighted in the *JCAHO Journal on Quality and Safety* in a series describing the implementation of high reliability clinical micro-systems. [34] Drs. Cravero and Blike were invited to write a review article on pediatric sedation for *Anesthesia and Analgesia*, the official journal of the *Society of Pediatric Anesthesiology*. [35] Most recently, the unit is to be video-taped for an educational series on clinical micro-systems supported by the American Hospital Association. Research and implementation results have been invited for presentation at the American Society of Anesthesiologists Annual Meeting, the American Academy of Pediatrics Annual Meeting, NPSF congress, the Institute for Healthcare Improvement patient safety collaborative, the Quality Congress for Neonatology and at the AHRQ patient safety conference.

Study 5-Multi-center Outcomes Registry:

This NPSF-funded project has involved the creation of a research consortium of hospitals throughout the US and Canada that have agreed to share information on pediatric sedation for diagnostic and therapeutic procedures. The goal of the consortium is to explore outcomes and techniques for pediatric sedation, ultimately establishing sites with "best practices" and exporting these practices to other sites in the consortium. The mission statement and other informational materials for this consortium can be located at www.pediatricsedationrc.org. The data being collected by the group includes demographic information on the patients sedated, comorbid conditions that are present in these patients, types of providers delivering sedation care, the medications used for these encounters and the important outcomes from this work, including significant adverse events and conditions present during procedures. All of the information is collected through a web-based data collection tool that has been developed by the funded researchers in conjunction with the Dartmouth Bioinformatics Group. A demonstration of the web-based data collection tool is available at https://tempto.dartmouth.edu/psrctest/enter.

At this time there are 31 institutions participating in this project. To date we have had yearly meetings of all participants to discuss and plan the data collection and research questions to be answered with this data. The first organizational meeting took place in Chicago, IL in 2003. The following year our organizational meeting was arranged in conjunction with a conference on pediatric sedation organized by Dr. Cravero in cooperation with the Children's Hospital - Denver. The conference was titled "The First International Conference on Pediatric Sedation." It included five lectures by leading pediatric sedation investigators and afternoon break-out sessions involving specific topics on pediatric sedation for subspecialists. A roundtable discussion of "hot topics"

took place at noon. Information on all of the meetings that have taken place for this group and a summary of the lectures given can be found at www.pediatricsedationrc.org.

Data collection by the PSRC is ongoing. Reports are generated quarterly for each site at which data collection is actively taking place. These reports allow any participating institution to carefully follow its own quality assurance data while simultaneously comparing performance to that of the entire consortium.

The ultimate aim of the consortium is to use the data collected to determine sites with outstanding data and to model these as sites of "best practice." Subsequent analysis of the processes in place at these sites will allow the group to put in place practices that are associated with excellent safety records and superb efficacy and efficiency at locations where sedation practice does not meet these high standards. This group is on target to collect between 15,000 and 20,000 sedation encounters within the first year of its existence.

INTERVENTION DESIGN AND METHODS

As stated in the introduction our goal is to advance the margin of safety for using more potent sedation and analgesia to reduce the pain and suffering associated with modern medical care in the hospital setting. Success will be reflected in superior analgesia with fewer associated complications. Our strategy is to implement the best/safe practices described in Tables 2A-C for creating high reliability and minimizing errors in sedation/analgesia care; error reduction will include that due to undertreatment, overtreatement and mistreatment. [1]

Safety Culture:

We agree with the IOM contention that patients should not have to suffer while receiving needed medical care. DHMC is strategically positioned to execute this proposed Pain-Free Hospital initiative. To begin, this program is aligned with DHMC's mission (to provide high quality health care and comfort to the ill, to prevent illness among the well and to advance health care through education, research, community service and the improvement of clinical practice). In addition, DHMC has in place numerous components of a culture of safety, as defined by AHRQ and NQF. These include the presence of a non-punitive reporting culture and system for reporting patient safety events and near-misses; the adoption and support of a designated Office of Patient Safety with Medical Director; presence of targeted patient safety initiatives in each annual budget and operating plan; weekly forums for senior leaders to discuss patient safety issues; and engagement at the most senior level in understanding, leading, and promoting efforts to create safer care for DHMC patients.

Several cultural assets have allowed such innovation at DHMC to flourish. The unique relationship among the Medical School, professional physician and nursing staff, hospital and community promotes collaboration and a true melding of the academic,

educational and public health missions. DHMC is a supportive place to work with exceptional staff satisfaction and retention.[36] and has been named the “Best Place to Work” in New Hampshire in 2004. (Business New Hampshire Magazine) Another critical asset is The Center for the Evaluative Clinical Sciences (CECS) at Dartmouth Medical School. The CECS is a world-renowned outcomes evaluation center dedicated to the science of clinical practice and performance. [37] This center and its leaders are to be credited with integrating evidence-based medical thinking into the culture of DHMC.

Specific actions include:

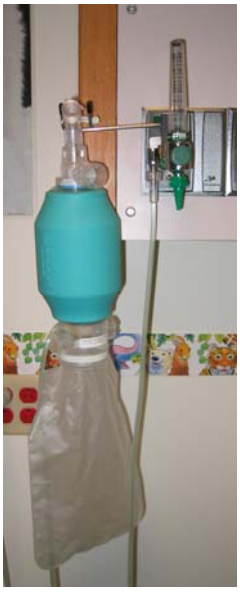
i. A hospital-wide “stand-down” regarding errors in managing pain and promoting The Pain-Free Hospital initiative designed to counter this threat to patient safety. The senior leaders of the program will initiate an intensive campaign to send the message that the status quo is unacceptable and that there is great opportunity for improvement. Intranet resources will be used to verify that >75% of personnel have received information on the magnitude of the problem, the safe practices proposed to improve care and the strategy for implementation.
ii. A series of intensive presentations will be made to the Board of Trustees, Board of Governors, Sectional Chiefs, Senior Managers and all unit leaders, under QA protection with explicit examples and feedback of pain management failures at DHMC.
iii. Rescue failures and unit based data will be presented monthly to highlight baseline performance and performance targets to senior managers, section chiefs and unit leaders for subsequent presentation to front-line clinicians.

<u>Optimal systems, structures, policies and procedures:</u>
The structural changes described in Section C.4 and Tables 2A-C will be implemented in all care settings in which opioid medications and sedatives are delivered. We have identified over 100 locations that will need to be upgraded to optimally support the provision of sedation/analgesia and rescue of sedation-related events. The structures support problem state recognition, diagnosis and treatment. Most of these standards have been included in the web-based course:

i. **Standardized monitoring** for all patients who are sedated across the continuum of minimal, moderate and deep levels, regardless of location, setting or procedure. Moderate levels of sedation will be supported with EKG pulse oximetry with a variable pitch audible tone and a default alarm. Telemetry pulse oximetry will be used selectively to create a safety net for over-treatment event detection that will trigger the rescue system. End tidal CO2 monitoring will be supported as the standard for procedural sedation in all endoscopies, interventional radiology procedures and minor surgeries.
ii. **Standardized rescue equipment** for initial management of obstructive apnea and secondary management of central apnea and the need for positive pressure ventilation will be deployed institution-wide. Unit-based Plexiglas airway boxes have been developed to hold equipment needed for initial airway support. This equipment will be supplied with an oxygen delivery system that automatically provides high flow when the bag is lifted to be used. All equipment will be

supplied with its packaging removed allowing pre-sedation checks of equipment functionality and increased usability. Infection control review has determined this is an acceptable practice with no significant infection risk. Secondary airway management equipment will be supplied in all critical care units and as a separate module on all code-carts. This will be a change from current practice in that an exchange system will be used and a smaller number of items included. The reliability of providing these mission-critical components will be monitored with audits.

Figure 2: SOBA MDI (**S**uction **O**xygen **B**ag-mask **A**irways **M**onitors **D**rugs **I**v-access) as shown below as will be the standard equipment immediately available throughout our hospital in any location where sedation or analgesia is delivered.

iii. **Standardized training** will be deployed and associated with privileging. Those individuals who have not taken the training will not be allowed to perform the practice. This has already been done with the existing online course www.dhmcsedation.com

iv. **A STAT airway rapid response team** will be implemented with alphanumeric paging that will be available 24/7. This system with be tested daily using simulated events to assure a <2 minute response time. The current paging system and response team is not optimized to manage respiratory depression. Three wireless internet phones (that function over our hospital's computer network) will be available to the rescue team members. These phones will allow immediate communication and enable the sedation team to gather data and advise initial bedside providers on interventions while traveling throughout the hospital to manage these critical events.

v. **Outcomes measures of efficacy and safety** will be captured hospital-wide using existing pharmacy data collection routines and CPR registry data. Patient

satisfaction will be captured using existing satisfaction survey tools regarding pain management. A web-based database tool for recording patient demographics, procedure characteristics, medications given and outcomes will be used hospital-wide and managed by the Dartmouth Bioinformatics group. [see Evaluation Metrics for more detail]

vi. **A communication network** will be used to inform front-line clinicians on outcome measures and targets with weekly updates as to changes and the impact on outcome measures and process measures.

D.2.c Intensive Training:

Overview of training-- Safe practices for high reliability sedation/analgesia care have been embedded into two training modules. One module is computer-based and the other uses high fidelity simulation. The content in these courses is comprehensive and represents an excellent first step towards the intensive training that will be deployed and maintained to create a Pain-Free Hospital. This course focuses on using a smaller number of newer pharmacologic medications in a more potent and targeted fashion. For example, midazolam and fentanyl are emphasized for their rapid onset, which facilitates titration with small increments and limits the tendency for dose stacking. In addition, the sedation planning portion of the training emphasizes four high risk patient conditions and the different strategies that should be used for each. The high risk scenarios are patients with chronic pain on high dose opioids, obese patients with obstructive sleep apnea, patients with anxiety disorders on chronic benzodiazepines and medically unstable patients with cardiac disease and/or COPD who are at risk for hypoventilation and hypoxia. These same patients are used in the hands-on simulation -based training and help to reinforce rescue principles.

Computer-based Instruction-- Existing resources at DHMC have been committed to developing a web-based sedation/analgesia course for providers privileged to give moderate sedation. Both adult and pediatric versions of this curriculum have been developed and deployed (www.dhmcsedation.com). This course is being used presently by other organizations. This plan will leverage the expertise of educators at DHMC, who are world leaders in computer-based instruction. Outcome measures will be used to further validate that curricular goals are met in an efficient fashion. Our hospital has invested in information technology infrastructure. We have already been successful in deploying multimedia, interactive, computer based instruction to all types of learners who provide sedation/analgesia at DHMC.

Specific **enhancements to the web based portion** of our intensive training program for safe, effective sedation and analgesia planned in this plan are:

i. A significant increase in the number of interactive components so that learning is active rather than passive. These components will incorporate a variety of interactive strategies such as:
    a. Replacing some of the passive didactic material with matching, fill-in-the-blank, pick lists,or true/false exercises with immediate learner feedback about correct answers and the rationale for the answer.

b. Roll over dialog boxes for further explanation of some material (including definitions of terms).
c. Interactive diagrams with pop-up information.

ii. Video-clips, photos, audio-clips, and or diagrams of :
a. equipment used during sedation or rescue from adverse situations
b. conditions that increase sedation risk (obstructive sleep apnea, COPD, chronic pain, anxiety disorders and cognitive pathology that impairs cooperation)

ii. Interactive cases where the learner gathers pre-sedation history and physical examination information, formulates a sedation plan, and a rescue plan.
iii. Simulated cases using the AnesSoft sedation trainer that learners will execute and then receive feedback on their performance. Site-license will allow for this use per Company President, Howard Schwid MD.
iv. A computer simulation to allow execution of the rescue algorithm we are endorsing that emphasizes patient state determination, verbal stimulation, jaw thrust, oral airway and subsequent activation of the rescue team for conditions of deep sedation or general anesthesia.
v. Hot links to the DHMC sedation policy and sedation forms.
vi. Short (5-7 question) quizzes to be reviewed at the end of each content section with immediate learner feedback about correct answers and the rationale for the answer.
vii. Hot links to national standards and guidelines regarding sedation will be regularly maintained to assure they are current (AAP, ASA, ACEP, ENA, and other significant sedation references).

High Fidelity Human Simulation-- The hands-on portion of the training uses high realism simulation to manage challenging patients and to detect, diagnose and treat multiple presentations of respiratory depression (the primary simulator, which cost ~$150,000, talks, has pupils that react to light, breathes spontaneously, exhales carbon dioxide, has pulses, etc.). We will utilize four human patient simulators already on site and available for this effort. This experience-based sedation rescue training engages learners with multiple “I will remember that for the rest of my life” lessons, while never putting a patient at risk.

This simulator training augments the computer-based didactic modules. The key personnel in this plan have experience with simulation-based experiential learning at DHMC. High fidelity simulation is currently being used for: skills training, to accelerate learning in nursing students, rule-based protocol execution in rare events and advanced team training (the focus on behavioral strategies to support crisis resource management). We are committed to using high fidelity simulation to demonstrate provider competency regarding pre-sedation risk assessment, sedation planning, monitoring of patient state and consistent rescue of patients with respiratory depression. A two hour course has been developed and trialed in 10 sessions (~2 physicians and ~3 nurses per session) in settings that provide procedural sedation/analgesia. Again, this course represents an excellent starting point, but this plan will support logical enhancements and broader deployment.

DHMC currently has METI simulators (adult and child), Laerdalh simulators (2 adults and a neonate on order), and a Noelle obstetric simulator. The standardized event for pediatric sedation that has been used to identify latent conditions in our rescue capabilities will be converted to the adult, neonatal and obstetric simulators for use in these settings in the hospital.

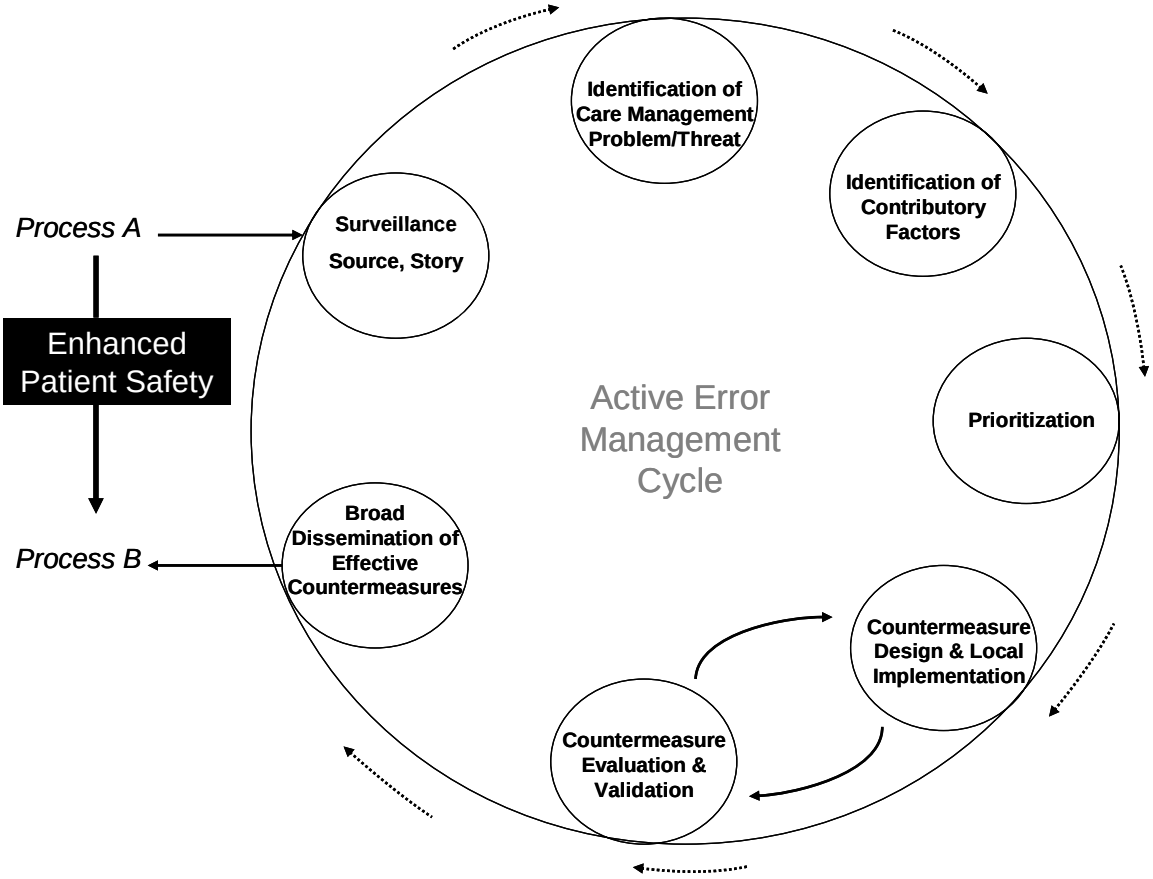
Specific enhancements to the high fidelity simulation portion of our intensive training program for safe, effective sedation and analgesia that are planned in this plan are:

i. To convert the prototype course software scenarios to function on all of the other simulation platforms (METI simulator software will need to modified or developed for the adult model, the Laerdahl platform, the OB simulator and the neonate)
ii. To use the simulated test environment in our hospital's actual Clinical Information System electronic record so that students will use actual systems to assess relevant patient information, in the simulation course.
iii. To develop a computer database tool that instructors will use to track clinicians and score performance to verify that components of the training have been repeated and practiced until minimums have been met.

Organizational Learning:

The DHMC office of patient safety has developed and disseminated a standardized approach to incrementally improving patient safety and facilitating cross-learning. This approach is termed Active Error Management, and consists of: standardized surveillance for threats to patient safety; identification of contributory factors; identification of phenotypes of failure as "care management problems"; prioritization of problem lists; development of countermeasures based on systemic contributory factors; iterative design of countermeasures and validation with local tests; and finally, broad implementation of validated countermeasures to all settings within the organization in which the same threat is relevant.

This process has led to experience with the concepts of latent system failure and robust identification of systemic problems followed by concrete action to counter threats. Current policy regarding moderate sedation is being regularly reviewed and revised to drive changes in procedures and practice at the unit level. In addition, appropriate violations in policy have a forum for review in which the policy can be up-dated and kept relevant. We are realistically positioned to have individual units understand the threats associated with safe, effective sedation/analgesia that were identified in our high risk pediatric population and to implement countermeasures to increase the margin of safety in all of the other settings in which the same threats exist. In addition, departments, sections and inpatient units are all aware of the rationale for provocative testing with simulated rare events to identify holes in our rescue systems supporting aggressive sedation/analgesia. The proposed hospital-wide intervention is only possible because of the preparatory work that has occurred on the unit level.



EVALUATING IMPACT AND ADOPTION OF THE PAIN-FREE HOSPITAL INTERVENTION:

We will implement an evaluation plan to assess both the adoption and outcomes of the intervention. Because outcomes matter most, we propose using retrospective, broad scope, available, unobtrusive measures as well as prospective, narrow scope outcome measures.

Expected Outcomes

We anticipate the organization-wide program will achieve the same outcomes that we have seen in the demonstration program. Implementation of best/safe practices for sedation/analgesia across DHMC will potentially impact all patients in pain (estimated at over 50,000 patient care days of hospitalization and over 18,000 outpatient procedural encounters). This level of clinical excellence will include:

- *More potent and effective pain/sedation management*

- *Improved safety from the life-threatening side effects of sedatives and pain medications*
- *Improved conditions (for diagnostic or therapeutic procedures)*
- *Improved patient experience*
- *Improved efficiency and access to procedures*

Evaluation Metrics

Our evaluation strategy is comprehensive and is embedded into existing work processes. The Dartmouth BioInformatics Group, the DHMC Department of Clinical Quality Resources and Dartmouth's Center for the Evaluative Clinical Sciences are able to support measuring and analyzing the outcomes data residing in existing systems. In addition, we anticipate being able to form an advisory group in quality and safety measurement to provide a critical review of the evaluation metrics.

Data will be reported as is appropriate to provide timely feedback on the impact of the sedation/analgesia interventions either weekly, monthly, or quarterly. The outcome and process measures are listed individually with example data from the month of November 2004 showing our self-assessment baseline performance against benchmark levels of performance.

1. Potency of pain and anxiety treatment-- The DHMC pharmacy currently captures electronic data on all controlled substances (opioids, benzodiazepines, sedative/hypnotics, anesthetics, etc.). These data can be used to calculate the "Morphine Equivalent Dose" and "Valium Equivalent Dose" normalized to medical care activity (such as patient days treated). The benchmark unit treats children who are primarily having imaging studies which are not painful; however, deep sedation is used and as would be expected, nearly five times the Valium equivalent is used per patient compared to hospital inpatients at large.

	Total IV morphine equiv	Total IV diazepam equiv	IV morphine per patient day treated	IV diazepam per patient day treated
DHMC inpatients and minor surgery outpatients	362,843mg	142178mg	39.8mg	15.6mg
Benchmark unit	218mg	4,473mg	4.0mg	82.8mg

2. Preventable severe pain/suffering adverse events-- Since patient comments on the patient satisfaction survey regarding severe pain are highly reported, we will seek to determine the rate of such comments. The patient complaints hotline, the Quantros occurence reporting system and the Risk Management systems will be polled monthly. All instances of reported severe pain will prompt a chart review by a sedation expert. The preventability (meaning that available medications and techniques were NOT used and NOT contraindicated) will be rated on a 6 point

scale (0=state-of-the-art care; 6=extreme deviation from the standard of care). This methodology is an accepted approach.[38]

Patient complaints in which pain was a component November 2004:
DHMC = 8 adverse events; 1 preventable
Benchmark unit = 0 adverse events

3. Patient experience -- Using two patient satisfaction tools (Press-Ganey and the modified DHMC outpatient procedure survey) we will be able to track quantitative and qualitative changes in the degree of pain and suffering experienced by patients on a subjective basis.

Patient experience of pain management November 2004:
DHMC = 60; Poor/very poor 19%
Benchmark unit = 79; Poor/very poor 3 %

4. Mortalities due to sedation/analgesia--These data will be obtained during the retrospective chart review of all sedation-related adverse events described above. Specifically, death and brain injury will be captured.

Mortalities associated with sedative/pain medications November 2004:
DHMC = 0 deaths or brain injuries
Benchmark unit = 0 deaths or brain injuries

5. Preventable sedation adverse events-- All sedation-related adverse events will be captured either in the National CPR Registry in which DHMC participates, the sedation/analgesia database to be implemented in this plan or the web-based occurrence reporting system currently in use at DHMC. We are currently following the National CPR Registry inclusion and exclusion criteria (see web-site for details). All events will also be reviewed as described above for "preventability." This review will include the detection methods used and rescue response.

Acute respiratory arrest associated with pain medications November 2004:
DHMC = 1 adverse events; 1 preventable
Benchmark unit = 0 adverse events

Medication errors associated with sedative/pain medications November 2004:
DHMC = 11 adverse events; 10 preventable
Benchmark unit = 0 adverse events

6. Procedure/therapeutic conditions and outcomes-- The web-based pediatric sedation/analgesia outcomes database will require minor modifications to be applicable for the adult population.[28] The data-fields will take approximately 1-2 minutes to complete and will yield information on patient risk factors, the sedation technique used and the results achieved including patient state during the procedure.

At present this data is available for the benchmark unit, but not for the hospital

7. Variability in rescue resources and response-- We have used simulated respiratory arrests, coupled with debriefing, to uncover a myriad of system vulnerabilities that can be corrected one by one. This novel approach is the first to use the human simulator as a "crash-test" dummy for sedation/analgesia rescue capabilities. Just as a crash test allows one to differentiate which car and airbag better protects the passenger in a vehicle, we have used a standard simulated event to test actual sedation settings for their capability to protect the simulated patient from harm. [22] Most importantly, these repeated drills over time begin to instill greater confidence in our organization's rescue capabilities from these rare events. It is imperative that the safety net we create is real and functions 24/7.

Rescue performance data will be obtained from video recorded during simulated drills, simulator data logs and debriefing notes.[21,22] This program is anticipated to increase use of pulse oximetry and ventilation monitoring (using end-tidal carbon dioxide) because these tools are emphasized in the rescue training. The data will track individual units' performance over time, the goal being to achieve benchmark performance on all units.

November 2004 data (units in which moderate sedation/analgesia were audited for compliance with 26 component structures to be implemented as best/safe practices):

Total patient care locations reviewed = 149
Total number of deviations from ideal = 1258
Average deviations per patient care location = 8.4 (range 1 to 14 deviations out of 26 items checked)
Benchmark unit number of deviations = 1

Sedation Simulation drills are not being performed across DHMC at this time. Funded research allowed us to develop the standardized testing methodology and data analysis. These drills have only been performed ten times. Most recent benchmark unit performance January 2004 (end of NICHD funded research interval, was:

Video-markers of "ideal" obstructive and central apnea "behaviors"			Gold Standard	Test Sedation Unit	Scoring Criteria (seconds)		
					Good	Adequate	Poor
Phase I	Monitoring	Apnea diagnosed (no chest movement)	18	38	0-30	31-60	>60
	Mobalizing help	PPV call (from time apnea detected)	0	11	0-30	31-60	>60
	Basic Airway Tx	Supplemental O2 (from time apnea detected)	3	0	0-15	16-60	>60
		Jaw Lift (from time apnea detected)	5	15	0-15	16-30	>30
		Oral Airway (from time jaw lift)	15	52	0-15	16-30	>30
		Bag/Mask Ready (from time requested)	3	13	0-15	16-30	>30
Aggregate time to complete Phase I tasks			**44**	**129**			
Phase II	Advanced Airway Tx	PPV expert arrives (from time called)	0	182	0-120	120-240	>240
		Expert BMV (PPV attempts from when arrived)	7	>30	0-15	16-30	>30
		Two Person (from when one person failed)	0	>30	0-15	16-30	>30
		Intubation (from when two person failed)	NA	115	0-60	61-120	>120
		Failed intubation "call for back-up" (from when failed)	NA	NA	0-15	16-30	>30
		Succinyl Choline (from when laryngospasm dx)	NA	NA	0-60	61-120	>120
	PALS	Atropine (HR<60)	NA	NA	0-60	61-120	>120
		Epinephrine (Atropine, HR<60)	NA	NA	0-60	61-120	>120
		Compressions (no pulse)	NA	NA	0-15	16-60	>60
Aggregate time to complete Phase II tasks			**16**	**297**			
Time out of range: SpO2<60%			**0**	**90**			

Benchmark unit rescue performance 90 seconds of hypoxia, no hypotension, no bradycardia.

8. Efficiency and access-- An indirect marker of the efficiency of sedation care for adults will be the number of cases performed in a given day and the average wait time for a given procedure that requires sedation – i.e. selected Gastroenterology procedures. Administrative databases will be used to generate a report of procedure-based care provided to include the throughput for sedation cases, and average wait-time for that care. These data will be available only after hospital-wide data collection tool is deployed.

Benchmark performance pre and post intervention for two procedures in which data is available:

MRI time allotted pre Pediatric Sedation Unit (1999) =2hrs
Time allotted post Sedation Unit (2004) = 1hr

VCUG time allotted with Pediatric Sedation Unit (1999 and currently) = 3hrs
Time allotted post Sedation Unit (2004) = 1hr

Efficiency increased 50% and 30% in two Benchmark intervention groups studied

Statistical Analysis

The primary outcome measure of sedation/analgesia efficacy will be Morphine equivalents and Diazapam equivalents normalized to a standard number of patient care hours or days of hospital treatment. These data will be tracked weekly as an aggregate of the entire hospital inpatient and outpatient activity. It will also be tracked by individual care units. When available, administrative data will be used to risk adjust for variances in patient acuity over time. These time series data will be analyzed for control limits and presented as control charts. Benchmark levels of sedation analgesia will be those levels utilized in the operating theater by anesthesiologists. As the potency of sedation/analgesia increases over time towards benchmark levels, one can be assured that superior pain control was provided. While between-hospital patients populations may vary significantly, variability of within-hospital patient populations week to week should be limited. The primary outcome measure for sedation/analgesia safety will be injury and death rates associated with these medications. These data will be tracked as complications per a standard number of morphine and diazepam equivalents of sedation/analgesia provided.

"TOOL KIT" FOR SAFE PRACTICE IMPLEMENTATION:

As our organization has pursued the six components of quality outlined by the Institute of Medicine Quality Chasm Report, we have invested in infrastructure for quality and safety work. This plan addresses a problem that unites all clinicians and will allow us to extend the platform we are pursuing for one of the key components of high reliability, that of organizational learning. Anticipated gains and specific components of a toolkit that will result from this plan will be generic and applicable for future safe practice implementations, both at DHMC and in other healthcare organizations. The components of the Toolkit are organized according to the four tenets of the HRO interventions as listed below.

1. Safety culture:
    a. Will include: A description of the methods for conducting a hospital-side "stand-down" regarding errors in managing pain and example presentations for communicating pain management failure modes to key audiences of leaders and clinicians.
2. Optimal systems, structures, policies and procedures:
    a. Tools used in the DHMC Active Error Management Program that support the conduct of standardized surveillance of threats to patient safety; identification of contributory factors; identification of phenotypical care management problems; prioritization and development of countermeasures.
    b. A flow sheet to support standardized monitoring for all patients receiving sedation/analgesia regardless of setting.

c. An annotated list of standardized rescue equipment for initial management of obstructive apnea and secondary management of central apnea and the need for positive pressure ventilation.
d. A description of the membership and process of engagement of a STAT airway rapid response team
e. Data definitions, collection and analysis methods for patient satisfaction and outcome measures used to assess the effectiveness of these interventions.

3. Training tools:
    a. A copy of the web-based training module deployed to all clinicians responsible for administering and/or monitoring adults undergoing sedation.
    b. A simulation scenario used to provoke latent failures in use of sedation/analgesia with adults.

4. Organizational Learning:
    a. Measurement and feedback tools: Measurement and feedback are critical tools for driving changes in clinical practice. Some of the measures in this plan are novel as real-time measures. The margin of safety measures, preventable adverse events measures and provocative test results, for example are uniquely designed for patient safety work.
    b. Tools for communicating performance data regarding progress toward safer sedation/analgesia care.
    c. We will need to move our intervention throughout our hospital. Safety interventions often need to the customized to the context in which the intervention is being used.

LIMITATIONS AND POSSIBLE SOLUTIONS

This plan is limited by the very broad nature of the sedation/analgesia needs and the high levels of uncertainty present due to normal patient variability. Sedation work is performed in so many locations involving such a wide variety of providers it is logistically very complex.

Potential problems include:

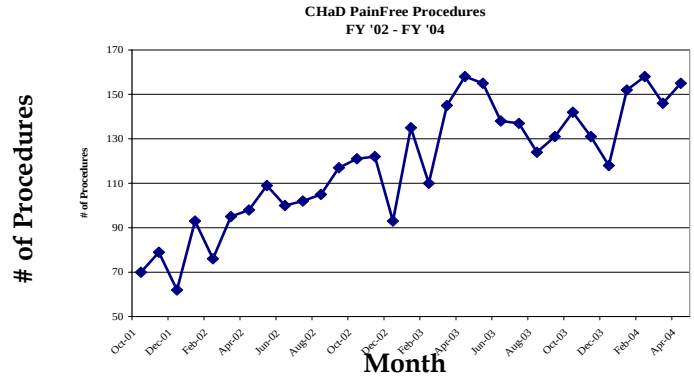
A. Motivational issues regarding sedation/analgesia care***:*** Consideration of “under treatment of pain” not as a safety problem, but a quality problem that is less urgent and of lower priority. This is a subtle, but important issue. Error in human performance can be categorized as overuse, underuse and misuse of a tool or technique. Errors of omission and errors of commission are not separated or given differential value. Unfortunately, many clinicians fail to see the magnitude of this problem because they focus on the rare overdose events—which do not seem prevalent enough to consider pain management failures a major safety problem. This bias will need to be overcome.

Driven by a commitment to provide patient-centered care, DHMC has a proven track record for the rapid implementation of truly innovative programs. For example, a program to reduce pain and increase safety in young children requiring procedures was brought from concept to implementation in the course of a single year. The problem of provider complacency with the status quo was addressed in our pediatric demonstration project by videotaping and feeding back current practice and alternative best practice segments. Many clinicians needed to be confronted with the reality of seeing a 5year old child held down and having a catheter inserted forcibly vs. under propofol sedation to appreciate the more sterile data we provided.

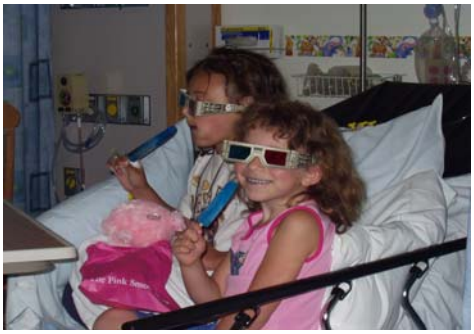
B. Financial barriers: Innovation carries financial risks. Creating high reliability sedation/analgesia care will be costly. The estimated costs of achieving benchmark performance will be over one million dollars in equipment and personnel. Based on our experience with improving pediatric sedation/analgesia care, we believe we can overcome this barrier because:

- *The Pain-Free Hospital is compatible with the organization's strategic priorities* **-** service excellence, technical excellence and cost excellence (via operating improvements in the areas of capacity and productivity). In April 2004, the senior leadership of DHMC unanimously approved the strategic plan for the continuation and expansion of the CHaD PainFree Program, after which the proposed Pain-Free Hospital program is modeled.[39]
- *The Pain-Free Hospital provides opportunities for revenue enhancement and cost reduction* (via enhanced efficiency and increased volumes). Based on the financial performance of the CHaD PainFree demonstration program *we fully expect The Pain-Free Hospital to be sustained long term by remaining budget neutral.* Program costs will be met by hospital technical revenue and efficiency gains leading to additional patient volumes and improved access. Since the program will be self-sustaining, it will be automatically incorporated as a standard budgetary item within a specified department in the same manner as the current pediatric PainFree model.
- *As the program earns recognition, it is anticipated that self-referrals will increase DHMC market share,* providing for continuing growth in inpatient and outpatient volumes. We have seen patients and their families will drive further for the superior care offered by our pediatric PainFree unit.

The CHaD PainFree Program has proven financially self-sustaining and in fact generated a moderate positive net income. Success has been associated with increasing demand for CHaD PainFree Program services. At the end of the first year, this program nearly met the second year goal by providing care for 1087 procedures. This year we will support procedural sedation/analgesia for over 1600 children.



Growth in Volume per Month of Children Treated in PainFree Unit



Watching "Spy Kids 3d" after multiple dental extractions

C. Recruitment of personnel: The timely recruitment of additional anesthesia and nursing providers, given a national shortage, could prove difficult. DHMC is a supportive place to work with exceptional staff satisfaction and retention.[36] The nursing department at DHMC has recently been awarded Magnet Status for its excellence in care and career development. The department of Anesthesiology is highly competitive due to an excellent national reputation as well. In addition, this plan will utilize proven leadership. The same team responsible for successfully implementing the demonstration PainFree program will lead this effort to extend that program.

D. 24 hours per day/7 days per week/ 365 days per year coverage: Another challenge will be to provide truly comprehensive coverage with a "rapid response" to manage pain. This goal has not been realized in the pediatric demonstration. However, we have been able to honor >85% of urgent add-on requests on the same day of the request. This capacity to manage urgent care reliably on the same day as requested has led to a reduction in off-hour requests for sedation/analgesia support. The reality may be that true 24/7 coverage is not practical. Still, this plan will deploy the intensive training to a broader base of clinicians and with the goal of establishing a large network of critical care nurses proficient in moderate sedation, and a smaller group for deep sedation needs.[40]

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