Microsystems in Health Care

Microsystems in Health Care: Part 6. Designing Patient Safety

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P revious articles in the Microsystems in Health Care series have summarized recent research findings,¹ explored the generation of a rich information environment in microsystems to support highquality care,² discussed specific approaches to planning services³ and patient care⁴ in microsystems, and described the work of leading microsystems.⁵ This article explores safety within the context of clinical microsystems. In 1999 the Institute of Medicine (IOM) report *To Err Is Human* estimated that 44,000 to 98,000 people die each year from medical errors.⁶ Although the topics of safety, medical errors, and patient harm have been on some agendas for decades,⁷⁻¹² the release of the IOM report brought national attention to the subject.¹³⁻¹⁷

Clinical microsystems provide a conceptual and practical framework for thinking about the organization and delivery of care. The purpose of this article is to explore patient safety from a microsystems perspective as well as from an injury epidemiological perspective and to address the tensions that exist between the conceptual theory and the daily practical applications, such as how we embed safety into a microsystem's developmental journey and how we promote system resilience, given the many transitions of care (gaps and handoffs) between various microsystems.

The article begins by presenting a hypothetical scenario (Figure 1, p 402) that we have used to teach health professionals how to apply what is known about systems safety to the microsystem concept. Several safety principles (Table 1, p 403) can be elicited from the scenario, and

Article-at-a-Glance

Background: This article explores patient safety from a microsystems perspective and from an injury epidemiological perspective and shows how to embed safety into a microsystem's operations.

Microsystems patient safety scenario: Allison, a 5-yearold preschooler with a history of "wheezy colds," and her mother interacted with several microsystems as they navigated the health care system. At various points, the system failed to address Allison's needs. The Haddon matrix provides a useful framework for analyzing medical failures in patient safety, setting the stage for developing countermeasures.

Case study: The case study shows the types of failures that can occur in complex medical care settings such as those associated with pediatric procedural sedation. Six patient safety principles, such as "design systems to identify, prevent, absorb, and mitigate errors," can be applied in a clinical setting. In response to this particular case, its subsequent analysis, and the application of microsystems thinking, the anesthesiology department of the Children's Hospital at Dartmouth developed the PainFree Program to provide optimal safety for sedated patients.

Conclusion: Safety is a property of a microsystem and it can be achieved only through thoughtful and systematic application of a broad array of process, equipment, organization, supervision, training, simulation, and teamwork changes.

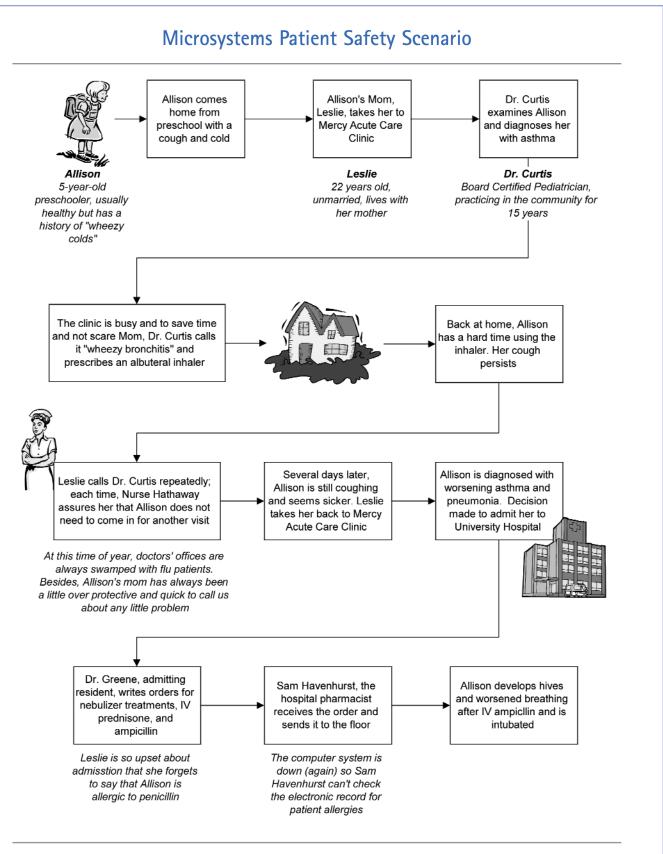


Table 1. Principles for Safety Within Clinical Microsystems

Principle 1. Errors are human nature and will happen because humans are not infallible.

Errors are not synonymous with negligence. Medicine's ethos of infallibility leads wrongly to a culture that sees mistakes as an individual problem or weakness and remedies them with blame and punishment instead of looking for the multiple contributing factors, which can be solved only by improving systems.

Principle 2. The microsystem is the key unit of analysis and training.

We can train microsystem staff to include safety principles in their daily work through rehearsing scenarios, simulation, and role playing. The goal is for the microsystem to behave like a robust high-reliability organization—an organization that is preoccupied with the possibility for failure or chronic unease about safety breaches.¹

Principle 3. Design systems to identify, prevent, absorb, and mitigate errors.

Identify errors by establishing effective sustainable reporting systems that encourage and support transparency and freedom from punitive actions and empower workers to feel comfortable to speak up, even if speaking up means that they will challenge the authority gradient. Design work, technology, and work practices to uncover, mitigate, or attenuate the consequence of error. There are many ways to reduce the impact of errors by simplifying and standardizing the systems and processes people use. For example, tools such as checklists, flow sheets, and ticklers to reduce reliance on memory all address deficiencies in vigilance and memory. Improve access to information and information technology. Systems should be designed to absorb a certain amount of error without harm to patients. Key buffers might include, for example, time lapses (built-in delays to verify information before proceeding), redundancy, and forcing functions.

Principle 4. Create a culture of safety.

A safety culture is one that recognizes that the cornerstone to making health care safer is a transparent climate that supports reporting errors, near misses, and adverse events and recognizes these events as opportunities for learning and improving.^{2,3} Embrace and celebrate storytelling by patients and clinicians to clarify where safety is made and breached and to provide opportunities for learning.

Principle 5. Talk to and listen to patients.

Patients have much to say about safety. When a patient is harmed by health care, all details of the event pertaining to the patient should be disclosed to the patient and/or his or her family. Elements suggested for disclosure include:

- A prompt and compassionate explanation of what is understood about what happened and the probable effects;
- Assurance that a full analysis will take place to reduce the likelihood of a similar event happening to another patient;
- Follow-up based on the analysis; and
- An apology.

Principle 6. Integrate practices from human factors engineering into microsystem functioning.

Design patient-centered health care environments that are based on human factors principles. Design for human cognitive failings and the impact of performance-shaping factors such as fatigue, poor lighting, and noisy settings.

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these principles are further explored in the "PainFree" case study from the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. This case study illustrates how these principles are applied in a clinical setting.

Finally, we link important characteristics of high-performing microsystems to specific design concepts and actions that can enhance patient safety in microsystems. These characteristics were introduced in Part 1 of this series and were refined in Part 2, on the basis of further reflection and analysis.

Microsystem Patient Safety Scenario

Figure 1 illustrates a hypothetical scenario that we [J.J.M., P.B.] have used to connect patient safety principles with clinical microsystems thinking. In this scenario, the patient is Allison, a 5-year-old preschooler with a history of "wheezy colds." As we follow the scenario, it is clear that Allison and her mother interact with several microsystems as they navigate the health care system in an attempt to address Allison's illness—the hypothetical community-based pediatric clinic (Mercy Acute Care Clinic) and the university hospital, which includes several overlapping microsystems.

While working through the scenario, the reader finds illustrated many obvious points where the system "failed" to address Allison's needs. What are the ways to think about these system failures? Many tools are available for analyzing medical errors, such as morbidity and mortality conferences, root cause analysis, and Failure Mode and Effects Analysis. Although it is tempting to rely on one or two tools in an attempt to simplify the complexity involved in understanding errors and patient harm, the challenge for most of us—before we start the search for the root cause—is to start with a broader look that will help us place the error in context. One method that we have found to be useful builds on William Haddon's overarching framework on injury epidemiology.¹⁸

As the first director of the National Highway Safety Bureau (1966–1969), Haddon was interested in the broad issues of injury that result from the transfer of energy in such ways that inanimate or animate objects are damaged. Haddon identified 10 strategies for reducing losses:

1. Prevent the marshaling of the energy;

2. Reduce the amount of energy marshaled;

3. Prevent the release of the energy;

4. Modify the rate or spatial distribution of release of the energy;

5. Separate in time and space the energy being released and the susceptible structure;

6. Use a physical barrier to separate the energy and the susceptible structure;

7. Modify the contact surface or structure with which people can come in contact;

8. Strengthen the structure that might be damaged by the energy transfer;

9. When injury does occur, rapidly detect it and counter its continuation and extension; and

10. When injury does occur, take all necessary reparative and rehabilitative steps.

All these strategies have a logical sequence that is related to preinjury, injury, and postinjury.

The Haddon matrix is a 3×3 matrix in which factors related to an automobile injury (human, vehicle, and environment) head the columns, and phases of the event (pre-injury, injury, and postinjury) head the rows. Figure 2 (p 405) shows a Haddon matrix that has been completed to analyze an auto accident.¹⁸ The matrix focuses the analysis on the interrelationship between the factors (in this matrix version, the human, vehicle, and environment) and the three phases (pre-event, event, and postevent). A mix of countermeasures derived from Haddon's strategies are necessary to minimize loss. Furthermore, the countermeasures can be designed for each phase-pre-event, event, and postevent. This approach confirms what we know about adverse events in complex environments: It takes a variety of strategies to prevent and/or mitigate harm. Understanding injury in its larger context helps us recognize the basic fragility of systems and the important work of mitigating the inherent hazards by increasing the resilience of the system.¹⁹

Building on injury epidemiology, we can also use the Haddon matrix to think about analyzing medical injuries.²⁰ To translate this tool from injury epidemiology to patient safety, we have revised the matrix to include phases labeled "pre-event," "event," and "post-event" instead of "preinjury," "injury," and "postinjury." We have revised the factors to include health care professional, patient/family, and system and environment instead of human, vehicle, and environment. Note that we have added *system* to refer to the processes and systems that are in place for the microsystem. *Environment* refers to the context within which the microsystem exists. The addition of *system* recognizes the significant contribution that systems make toward harm and error in the microsystem. Figure 3 (p 406) shows a completed matrix using Allison's scenario.

The next step in learning from errors and adverse events is to develop countermeasures to address the issues in each cell of the matrix.

A Case Study: Dartmouth-Hitchcock PainFree Program

JH is a 4-year-old white girl with a history of multiple congenital abnormalities. Most notably, she has had developmental delays, unusual facial appearance, and absence of the corpus collosum. She does not have an identifiable syndrome. At home on the day before admission, her

	Factors						
		Human	Vehicle	Environment			
	Preinjury	Alcohol intoxication	Braking capacity of motor vehicles	Visibility of hazards			
1 1100CD	Injury	Resistance to energy insults	Sharp or pointed edges and surfaces	Flammable building materials			
	Postinjury	Hemorrhage	Rapidity of energy reduction	Emergency medical response			

Haddon Matrix Used to Analyze Auto Accident

Figure 2. A Haddon matrix focuses the analysis of an auto accident on the interrelationship between the factors (human, vehicle, and environment) and the three phases (preinjury, injury, and postinjury).

mother noticed the onset of three generalized seizures, each seizure lasting 10 minutes and terminating on its own. JH was admitted for further evaluation and a magnetic resonance imaging (MRI) scan. Because the MRI scanner had a full schedule for the day and the technicians did not want to inconvenience the elective patients, JH was scheduled to be scanned at 7:00 PM on the evening of admission. Sedation was to be delivered by the pediatric house officer because the anesthesia team that worked on the elective cases during the day was not available at night.

The primary sedation provider was a first-year resident. He had been advised by his senior resident to give a combination of midazolam hydrochloride and fentanyl for the sedation and to titrate to effect. The patient actually proved quite irritable and was difficult to sedate. She seemed to have a paradoxical reaction to the 2 mg of midazolam, which was titrated in more than 30 minutes (for she became irritable and was crying and inconsolable). Fentanyl titration was then started. During the course of the next 30 minutes, the child received 4 mcg/kg of fentanyl. She became sleepy and was placed in the MRI scanner. Four minutes after the scan was started, O_2 saturation levels were noted to be 75%, and the child was pulled out of the scanner when it was noted that she was apneic. A code blue was called, and the pediatric code team responded. A significant (4-minute) delay

occurred while a discussion ensued over whether the patient should be taken out of the scanner area during this code because of equipment considerations or if she should be taken care of in the scanner. Eventually JH was moved out of the scanner area and fully resuscitated, and reversal medications were administered. She recovered without difficulty and was scanned 2 days later, with an anesthesia team (physician anesthesiologist and resident) administering the sedation.

Discussion

The case study is illustrative of the type of failures that can occur in complex medical care settings such as those

associated with pediatric procedural sedation. A gap was evident between the state-of-the-art resources available for the work and the systems to ensure that the best people, tools, and environmental conditions were used. The first goal for the two leaders of redesign in the anesthesiology department [G.T.B., J.P.C.] in understanding this event was to characterize the "problem space" sedation providers contend with by using a human factors approach to videotape and evaluate sedations as they were performed by a variety of providers (nurses and physicians) in a variety of settings (radiology, pediatric cardiology, pediatric oncology, pediatric anesthesiology).^{21–23}

In response to this particular case, its subsequent analysis, and the application of microsystems thinking, the anesthesiology department of the Children's Hospital at Dartmouth developed the PainFree Program. The PainFree Program became operational in October 2001, with a combination of charitable funds and clinical revenue, and it currently services approximately 1,300 patients annually. The staff now includes a registered nurse (RN), a patient care technician, a dedicated anesthesiologist, and a secretary. Resident and certified RN anesthetist (CRNA) staffing is variable and on an asavailable basis. All children requiring sedation for diagnostic or therapeutic procedures are designated to come through this program. Preprocedural education, admission, sedation, and recovery services are the responsibility

Completed Patient Safety Matrix

		Factors	
	Health Care Professional	Patient/Family	System & Environment
Pre-event	Physician decision about diagnosis	Child with history of wheezy colds	Busy primary care clinic University hospital
Event	Intravenous (IV) ampicillin	Allergy to penicillin	Computer systems down
Post-event	Intubation	Hives, difficulty breathing	Hospital—team response to allergic reaction

Figure 3. The Haddon matrix can be adapted for analysis of medical injuries, as shown in this matrix, which was completed using Allison's scenario.

of the PainFree Program staff and are designed specifically to meet the needs of sedation patients. All sedation is provided by pediatric anesthesiologists in conjunction with nurse anesthetists and residents. Pediatric residents participate on the service as a month-long sedation/pain management rotation during their first year. Child life specialists—health care professionals with specialized training and certification in reducing child and family stress associated with health care experiences-are consulted on all patients, and primary pediatric providers are solicited for input on the management of patients. When appropriate, children receive their tests and procedures with distraction techniques as the only intervention. When required, general anesthesia with endotracheal intubation is provided. All intermediate levels of sedation are also provided, depending on the requirements of the procedure to be done. A shared decision making model has been adopted; in it parents and patients themselves are informed of the nature of the intervention to be undertaken and options for management.

The PainFree Program is intended to provide optimal safety for sedated patients. It reflects the recognition that errors in medication delivery and sedation will occur, but there is a focus on the ability of the team to recover from these events. The advantages of the PainFree Program over the previous system lie in the fact that the providers with the optimal ability to resuscitate patients after errors in sedation delivery (pediatric anesthesiologists who possess the most expertise and experience in delivering medications for sedation) are now at the point of delivery of sedation itself. The nursing staff and technicians are similarly fully oriented on sedation recovery criteria and management, as this is the only care they provide at this time.

Although the orientation and training provided by the PainFree Program led to a deeper understanding of sedation practices by its staff, it was widely recognized that one cannot assume

safety in the absence of critical events. Said another way, there is a risk of "operational complacency" when an organization is successful.²⁴

To convey the lessons learned from the comprehensive reorganization involved in the design of the PainFree Program, considering how the patient from the case study would be treated today,

■ the staff has adopted the motto "do today's work today". This means that they work emergency cases into each day's schedule through a flexible staffing system with the anesthesiology department.

■ an anesthesiologist with expertise in pediatric care uses the newest and shortest-acting sedative agents available to allow rapid emergence from sedation.

■ pediatric sedation is now a centralized process that uses anesthesia providers and postanesthesia nursing staff. The PainFree Program is an intentionally designed clinical microsystem built to do the work of pediatric sedation for procedures and examinations. Rather than design the provision of surgical anesthesia by "fitting the work" into the anesthesiology department's structure, the department has made the pediatric population that is in need of care the driver of the design of the microsystem.

in the case of a respiratory event, the anesthesiologist is present to manage the airway when a patient is suffering a sedation complication by using proven equipment and techniques that he or she practices every day.

On the basis of the authors' experience with multiple microsystems across diverse settings and understanding and interpretation of the patient safety literature, we offer six safety principles that may be used as a framework within which to adapt patient safety concepts into clinical microsystems (Table 1).

Conclusion

A discussion of patient safety within clinical microsystems would not be complete without acknowledging how characteristics of high-performing microsystems can be used to help shape a microsystem's response to the challenge of embedding safety into the daily work of caring for patients. Table 2 (p 408) lists 10 important characteristics of high-performing microsystems and provides some specific actions that can be further explored in actual clinical microsystems. The list of actions is not intended to be exhaustive but rather represent a place to start and an organizing framework for applying patient safety concepts to microsystems.

As the PainFree Program illustrates, safety is a dynamic property of microsystems. It can best be achieved through thoughtful and systematic application of a broad array of process, equipment, organization, supervision, training, simulation, and teamwork changes.

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Table 2. Linkage of Microsystem Characteristics to Patient Safety and What This Might Mean for Safety*				
Microsystem characteristic	What this might mean for patient safety			
1. Leadership	Define the safety vision of the organization			
	Identify the existing constraints within the organization			
	 Allocate resources for plan development, implementation, and ongoing monitoring and evaluation 			
	Build in microsystems participation and input to plan development			
	Align organizational quality and safety goals			
	Provide updates to board of trustees			
2. Organizational support	Work with clinical microsystems to identify patient safety issues and make relevant local changes			
	Put the necessary resources and tools into the hands of individuals without making it superficial			
3. Staff focus	Assess current safety culture			
	Identify the gap between current culture and safety vision			
	Plan cultural interventions			
	Conduct periodic assessments of culture			
4. Education and training	Develop patient safety curriculum			
	Provide training and education of key clinical and management leadership			
	Develop a corps of people with patient safety skills who can work across microsytems as a resource			
5. Interdependence of the	Build PDSA into debriefings			
care team	Use daily huddles for after action reviews and celebrate identifying errors			
6. Patient focus	Establish patient and family partnerships			
	Support disclosure and truth around medical error			
7. Community and market focus	Analyze safety issues in community and partner with external groups to reduce risk to population			
8. Performance results	Develop key safety measures			
	Create the "business case" for safety			
9. Process improvement	Identify patient safety priorities based on assessment of key safety measures			
	Address the work that will be required at the microsystem level			
	Establish patient safety "demonstration sites"			
	Transfer the learning			
10. Information and	Enhance error reporting system			
information technology	Build safety concepts into information flow (eg, checklists, reminder systems)			

* PDSA, plan-do-study-act.