Human Factors Engineering and Patient Safety
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Human factors engineering (HFE) is a potentially misunderstood science that is identified as a critical component of sustained improvement in patient safety [1,2]. HFE is linked to patient safety improvement through team training, accident investigation, and the design of safe devices [3–5]. Each of these examples of HFE in health care, however, reflects specific applications of the much broader science represented by HFE: the science of improving human performance. Thus, an understanding of the full science of human factors is necessary to capitalize fully on its benefits to improving patient safety.

Unfortunately, an understanding of HFE itself is inadequate to address the needs of children who receive health care. The science of human factors and ergonomics traditionally has sought to enhance the performance of individuals, including those who have functional limitations [6]. There is little written, however, on the application of human factors as it relates to children [7]. The few notable exceptions are studies related to school furniture [8–13], children interacting with information technology [14–17], and childhood injuries [18,19]. In pediatric health care, the few notable exceptions to the lack of HFE include studies of the ergonomics of intubation in children [20], ergonomics aspects of total parenteral nutrition [21], and ergonomic studies of pediatric surgery [22]. Nonetheless, a review of leading

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textbooks of human factors finds no references to pediatrics or children in their respective indices [23,24], a shortcoming addressed in an upcoming textbook [25]. This article seeks to introduce the science of HFE with explicit consideration of pediatrics and patient safety.

**A case illustration of human factors engineering and pediatric patient safety**

A hypothetic pediatric hospital has identified a recurrent problem with mistakes in the programming of infusion pumps and subsequent errors in dosing of medications, which at times have been life threatening. Repeated efforts through educational in-service training of nurses have not achieved lasting improvement. Additionally, adoption of standard concentrations also has not eliminated the problem of pump programming errors. In light of the ongoing risk to patients, the hospital has selected and introduced smart-pump technology with the goal of eliminating programming errors.

One month into the implementation of the new pump technology, a review of reported adverse events and near misses reveals a range of errors related to the use of smart-pump technology. These include wrong dosing within the pump alarm limits, a greater than 100-times overdose related to incorrect entering of the medication concentration, use of wrong medications for a given patient, and reports of the infusions becoming dislodged by young patients, despite expressing design concerns to the vendor regarding the potential of manipulation by patients.

These adverse events have led to a series of questions, including:

1. How could any of these events occur with the use of safer technology?
2. Is the introduced infusion technology really safer?
3. Did the hospital select the correct safe pump?
4. How did the hospital fail (if at all) with training?
5. How did the vendor fail (if at all) with usability testing of the device?

The short answer to all these questions is that there is a lack of understanding of what is involved in the design of safe systems of health care. Specifically, there are two important considerations: first, understanding HFE, and second, the role of the clinical context in determining human performance (the role of systems). The failure to understand these considerations may lead to failed implementations of safety solutions (technology related and nontechnology solutions), misuse of resources for patient safety, and unintended patient harm.

**Human factors engineering and health care**

Within health care, HFE (also known as human factors or ergonomics) has become synonymous with such concepts as team training and crew resource management, usability testing, root cause analysis, and failure modes and effects analysis. These actually are specific tools or applications of HFE, which, in the absence of correct understanding of the science behind the
tool, risks misapplications and leads to incorrect analysis and flawed conclusions. Just as medical students are expected to learn the medical science behind diagnosis and therapeutics before they are credentialed for patient care, so it is critical to have an understanding of human factors science before attempting the diagnosis and therapeutics of patient safety problems.

HFE is a science and a practice discipline. As a science, it discovers and applies information about human abilities and limitations and other characteristics to the design of tools, machines, systems, tasks, jobs, and environments for productive, safe, comfortable, and effective human use. In practice, human factors engineers use the science to design products, equipment, facilities, procedures, and environments and to fit the people who live and work in or with those systems. The goal is to fit systems to people, not the other way around.

The discipline of human factors grew out of work during World War II where the focus was on optimizing performance and safety of man-machine systems by improving controls, displays, and skill acquisition. HFE now is studied and applied in all industries, including health care, medical devices, defense, agriculture, mining, recreation, transportation, aerospace, manufacturing, and service. HFE can be used to identify and understand the human performance requirements and design systems to meet the needs of any situations in which humans have to perform. Currently, there are many resources devoted to clinical and academic work in this area (Table 1). The discipline also has developed several design guidelines and standards, all

<table>
<thead>
<tr>
<th>Human factors resource</th>
<th>Additional specifications</th>
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<tbody>
<tr>
<td>Education</td>
<td>More than 65 graduate and undergraduate programs in the United States</td>
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<tr>
<td>United States professional society</td>
<td>Human Factors and Ergonomics Society (<a href="http://www.hfes.org">www.hfes.org</a>), with more than 4500 members</td>
</tr>
<tr>
<td>International professional society</td>
<td>International Ergonomics Association (<a href="http://www.iea.cc">www.iea.cc</a>), with 42 federated societies and educational programs in 35 countries</td>
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<tr>
<td>Specialty areas</td>
<td>Include aerospace systems, aging, cognitive engineering and decision making, communications, computer systems, environmental design, health care, human performance modeling, industrial ergonomics, macroergonomics, perception and performance, product design, safety, and training</td>
</tr>
<tr>
<td>Professional certifications</td>
<td>Examples include Certified Professional Ergonomist and Certified Human Factors Professional (<a href="http://www.bcpe.org">www.bcpe.org</a>)</td>
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relevant to health care. There are human factors standards incorporated into several American National Standards Institute and International Organization for Standardization standards (including standards on general ergonomics, controls and displays, mental workload, machinery safety, office work, and manual handling. Specific to health care, for example, human factors methods and guidelines are incorporated into the design of medical devices through joint standards with the Association for the Advancement of Medical Instrumentation that are used by the United States Food and Drug Administration. Specific design guidelines for computer workstations, laboratory equipment, microscope workstations, floors, ramps, stairs, instrument displays, electronic displays, keyboards, mice, tablets, computer interface controls, hand tools, pipettes, shift work, repetitive work, inspection tasks, lifting, pushing, pulling, and lighting all can be found readily [26].

Yet, despite the maturity of the field and its diffusion into every industry throughout the world, it is relatively unknown inside health care delivery. The converse is not true; human factors engineers have been working on health care delivery problems for decades, including publishing on human factors and medication safety nearly 50 years ago [28]. Then, as now, HFE was focused on designing systems to support performance, safety, and comfort while reducing fatigue, errors, and injuries.

Sanders and McCormick [27] identified six features of human factors that distinguish it from other applied disciplines:

1. A belief in the idea that technologies (eg, computerized physician order entry), tools (eg, scalpels), and machines (eg, ventilators) are built to serve people and, therefore, must be built with users in mind
2. An understanding that individual differences in physical (eg, hand size, height, weight, and dexterity) and cognitive (eg, memory and learning) capabilities and limitations exist and a further understanding that designs must accommodate these differences
3. Knowledge that the design of all things, including technologies, environments, and processes, influence human behavior and well-being
4. Emphasis on evaluation and on empiric data during the design process
5. Use of the scientific method and objective data to test hypotheses and generate data about human behavior and performance
6. A systems orientation and recognition that technologies, cultures, procedures, processes, environments, and people do not exist in isolation and that effective design must take into account the implication of their interactions

These features are in many ways in opposition to traditional thinking in health care that emphasizes trying to make individuals (eg, nurses, physicians, and pharmacists) fit the work system through an emphasis on education, in-service training, and procedures. But, just as HFE has made substantial contributions to improved performance and safety in other fields, its principles and methods should be implemented in health care.
The idea that systems, such as hospitals, clinics, patient rooms, and pharmacies, must be designed to support human performance and safety is a complex proposition. In short, it means understanding what a system really is, identifying the range of performance needs, understanding how the interactions of elements in a system affect performance, and then designing to accommodate the performance requirements. Consider the case illustration discussed previously. From an HFE perspective and, thus, also a clinician performance and patient safety perspective, a short list of performance requirements for effective pump use and short list of system elements that might have an impact on that performance are listed in Table 2.

The traditional notion of “train the nurse to program the pump correctly” is overly simplistic and, worse, dangerous. Instead, there are

<table>
<thead>
<tr>
<th>Nurse performance</th>
<th>System elements that have an impact on performance</th>
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<tbody>
<tr>
<td><strong>Program the pump</strong></td>
<td></td>
</tr>
<tr>
<td>- Push the correct buttons without hitting other buttons</td>
<td>- Will the spacing of the buttons accommodate the hand and finger size of most users?</td>
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<tr>
<td>- Know the correct buttons have been pressed</td>
<td>- Was the training conducted according to scientific training principles?</td>
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<tr>
<td>- Force required to activate a button</td>
<td>- Do policies or unit culture reward nurses in any way for rushing or require them to rush?</td>
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<tr>
<td>- Knowledge of what to program</td>
<td>- Are buttons designed for the right amount of activation force?</td>
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<tr>
<td><strong>Load syringe</strong></td>
<td></td>
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<tr>
<td>- Correct positioning of the syringe</td>
<td>- Is the loading mechanism designed to facilitate correct placement?</td>
</tr>
<tr>
<td>- Force to position the syringe</td>
<td>- Is the force required for activation correct?</td>
</tr>
<tr>
<td><strong>Verify pump correctly programmed</strong></td>
<td>- Do the lighting in the room, the type of display, and angle of display cause glare?</td>
</tr>
<tr>
<td>- Ability to sense, perceive, and make sense of any feedback about programming</td>
<td>- Are the fonts used the most readable?</td>
</tr>
<tr>
<td><strong>Verify syringe correctly loaded</strong></td>
<td>- Are the letters in the display far enough apart to facilitate easy reading?</td>
</tr>
<tr>
<td>- Ability to sense, perceive, and make sense of any feedback about loading</td>
<td>- Is the arrangement of information in the display such that it can be understood easily?</td>
</tr>
<tr>
<td><strong>Verify correct medication is in the syringe</strong></td>
<td>- Is the position of the pump and display such that nurses can read the display for locations in patient rooms that they work in?</td>
</tr>
<tr>
<td>- Ability to sense, perceive, and make sense of any feedback about the medication in the syringe</td>
<td>- Are there simple visual indicators that a pump is loaded correctly?</td>
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Table 2
Performance requirements and system elements impacting safety of pump usage
performance requirements related to visual performance, manual dexterity, sensation, perception, decision making, data interpretation, and so forth. If these performance requirements are not designed into the pump itself, the physical environment, and the processes involved, then it can be anticipated that nurses will fail at programming and, thus, patient lives be put at risk—not because the nurses are not trying their best and not because they did not pay attention during in-service training periods but because design of the entire clinical environment—pump—process—nurse system did not consider the performance needs of the nurses. That means that even if devices, such as a pump, have undergone usability testing at a manufacturing or vendor site, the results of the testing may have no relevance to primary care nurses because they work in a unique environment (lighting, pump arrangement, and pump placement relative to patient care), with unique policies (whether or not and when to verify or monitor pump information), within a unique culture (emphasis on speed or belief that the pump “solves” all problems), and with its own interfacing technologies. All of these contextual factors influence performance, as described in Table 2.

One model that illustrates HFE thinking as it applies to health care is the University of Wisconsin–Madison Systems Engineering Initiative for Patient Safety (UW SEIPS) model [29] and its recent adaptation to explaining the relationships between the work system (eg, clinical context), clinician performance on clinical processes, and patient safety (Fig. 1) [30]. The UW SEIPS model extends Donabedian’s classic structure-process-outcomes [31,32] model to explain HFE in health care. In this HFE model, the structure (or systems) includes (1) technologies and equipment; (2) the organization, along with its structure, culture, and polices; (3) tasks, (4) environment, including noise, lighting, and physical layout; and (5) the people, including health care professionals, patients, and other staff. The adaptation by Karsh and colleagues [30], as shown in Fig. 1, simply provides additional detail. On the left side of the figure is the structure, shown as a series of nested hierarchies. For example, even though nurses in the illustration work in patient rooms, those rooms are nested in units, units in hospitals, hospitals in health systems, and health systems in a wider external environment that includes local, state, and federal laws and regulations; the community at large; market forces; and so forth. At each level of the hierarchy are people, tools and technologies, policies and cultures, tasks, and environments, and those system elements at each level can influence the performance of people at all levels, such as nurses programming the pumps. In the middle are the processes or types of performance that clinicians may need and on the right are the outcomes, short and long term.

The model proposes that the extent to which the technologies, organization, environment, and tasks are designed to fit the people in the system have an impact on the ability of the people in the system to carry out their processes, such as care tasks. That is, the design of the system determines whether or not the people in the system can achieve the desired levels of
physical (eg, patient transfer and manipulation or surgical tasks), cognitive (eg, memory or learning), and behavioral performance. In turn, the execution of processes, as determined by the system design, has an impact on staff (eg, satisfaction and turnover), patient (eg, better health), and organizational (eg, profitability) outcomes. As such, this model makes clear that the design of any health care delivery system is the ultimate determinant of outcome. Focusing on pediatrics, HFE principles suggest that to achieve desired outcomes, the system must be built to accommodate the people in the system—patients and providers—simultaneously.

But, HFE also is a systems engineering discipline, which means that design for patients and providers does not occur in a vacuum. Any health care delivery system must be designed to support patients, provider performance, and business needs, such as profitability and positive public relations image, and satisfy external environment requirements, such as compliance with Joint Commission on Accreditation of Healthcare Organizations and Medicare regulations.

There is evidence from outside of health care that designing systems to support employee performance can help achieve safety goals, financial goals [33–35], and quality goals [36]. There are justifiable reasons to believe the same can be true in health care. Consider that if systems are designed to support the performance needs of providers, the likelihood of achieving the
Patient goals of safer and more effective care is increased precisely because provider performance needs are met. Similarly, if providers can do their jobs more effectively and efficiently, the organization likely will benefit because of safer care (less risk for malpractice suits), safer employees (less risk for workers’ compensation claims), and more satisfied employees (less risk for turnover and related hiring and training costs). Certainly this also would help achieve safety regulatory goals.

Human factors and patient safety considerations applied to pediatric care

One of the domains of quality identified by the Institute of Medicine’s *Crossing the Quality Chasm* [37] is patient-centered health care. Consistent with this perspective, the study of pediatrics is premised on understanding the range of normal or healthy development as a prerequisite for caring for ill children. From the time of birth, children undergo dynamic changes in physiology, physical characteristics, and cognitive and language development. This article explores aspects of pediatric care from a human factors perspective using a framework that is consistent with the principles of patient-centered care and pediatrics. A potential risk for using a patient-centered focus, however, is a loss of the interconnectedness of the other system elements and the importance of the context of care. For instance, the relation between specific characteristics of pediatric patients and their implications for the performance of pediatric providers can be viewed as two sides of a coin. Yet, even the mental model of a coin is inadequate in that the interactions of environment, tools and technology, and the organization all interact with patients and providers to ultimately determine performance. Thus, readers are cautioned not to look at the following elements as separate components to be viewed in a vacuum but instead as part of the complex system of health care. Fortunately, the HFE focus on human-centered design is analogous to the call for patient-centered care and provides potential solutions for grappling with these complex issues.

Pediatric physical characteristics and patient safety implications

Children undergo dramatic changes in number of physical characteristics, including weight, length, and head mass. For instance, infants are small with a disproportionately large head mass, which may account for 15% of its total body mass. In contrast, an adult’s head typically accounts for 3% of its total body mass [38]. At the same time, the rate of physical growth and development is not constant. Although newborns gain an average of 30 grams of weight per day and 3.5 centimeters of length per month, this growth begins to slow at approximately 3 months of age [39]. Growth continues with additional periodic accelerations, most notably in adolescence. The change in physical characteristics of children also is evidenced by changes in skin:
infants and small children have relatively thin epidermal skin layers and little subcutaneous fat tissue, making them more susceptible to heat and fluid loss or thermal injury [40].

Each of these changes in physical characteristics creates safety issues for children. The disproportionately large head mass makes it easier for children to lose their balance and sustain a brain injury. Relatively narrow airways with proportionately higher resistance provide increased risk for obstruction from foreign bodies, edema, or even secretions. The changes in physical size allow children to become entrapped easily in spaces that otherwise might pose no risk to adults. The relative susceptibility to thermal injury can result in burns to children in circumstances that might cause merely discomfort to adults.

These physical characteristics pose challenges to health care providers. The large head mass creates added need for appropriate neck and head support when handling pediatric patients. Further, the head size, particularly in infants, may require additional planning and positioning when managing a child’s airway. Traumatic manipulation of an airway during resuscitation can create significant swelling and even scarring, which is more problematic than in adult patients. The relative lack of subcutaneous tissue in infants and small children creates an increased risk for hypothermia if providers do not provide adequate warming. Small blood vessels may pose difficulties for securing vascular access, and the small bodies and organs create additional challenges for other surgical and therapeutic interventions.

Perhaps the greatest risk to the safety of pediatric patients and the performance of their providers is the lack of a constant weight, with normal ranges changing with age. As a result, the correct dosing of medication is weight based, creating a range of barriers to effective performance. One problem is treating a single weight as if it is a constant value rather that accounting for changes that may occur even daily, particularly in neonates and infants. Additional factors that may have an adverse impact on pediatric medication prescriptions include decimal place errors and computational errors. Misplacement of a decimal by one place in either direction can lead to a 10-fold under- or overdose; pediatric resident physicians are found to be prone to making computational errors when prescribing medications [41,42].

In each of these examples, the unique characteristics of children have an impact on the performance of their health care providers. An understanding of these characteristics with specific thought to optimizing performance in this context is critical to providing safe and effective care. Neither patients and their characterizations nor providers and their performance, however, operate independently of the other system components. As a result, characteristics specific to children have further implications. For instance, the physical environment in which pediatric patients are cared for should accommodate the range of patient needs and, ideally, optimize the performance of providers. This could mean providing cribs that prevent entrapment of small children while allowing for height adjustment to assist with placement of intravenous catheters by providers of a range of heights.
Neonates may require additional consideration for maintaining temperature regulation while allowing access to providers for care. Lighting is another environmental consideration that ideally should meet the needs of patients and providers in the shared context.

Beyond environment, there are technologies and tools that are needed by patients based on their characteristics that at the same time influence the performance of providers. One example is the use of intravenous catheters that readily can be inserted into small veins of infants while protecting providers from the risk of needle sticks. If the design of a 24-gauge catheter is intended to protect providers yet prevents the effective placement because of the inability to see the flashback of blood, then it is inherently flawed. Conversely, a catheter that facilitates placement yet increases risk to providers also is problematic. Technology should be viewed no differently from devices; ideally, it should facilitate providers by accomplishing specific tasks to provide care to pediatric patients who have unique characteristics, all in the larger context of an environment in an organization with policies, resources, and culture. Thus, an organization that entertains computer provider order entry technology but does not facilitate weight-based dosing to pediatric patients or barcode technology that does not accommodate for the challenge of wristbands on small wrists [43] neither meets patient needs nor optimizes the performance of providers.

Pediatric physiologic characteristics and patient safety implications

In the same way that children’s physical characteristics vary and thus influence provider performance, pediatric physiologic characteristics have a similar potential impact. One of the most dramatic illustrations of physiologic characteristics is the change in vital signs that occurs throughout pediatric growth and development. A normal newborn’s heart rate ranges from 120 to 160 beats per minute, whereas teenagers have heart rates that range from 60 to 100 [44]. Similarly, the normal ranges of respiratory rates and blood pressure values vary with changes in age. Even the elevations in temperature that are viewed as a significant sign of infection vary between infants and older children. From a patient-centered perspective, these changes have significant implications for the other systems elements that likely have consequences for children’s outcomes.

Foremost, providers caring for children must know the normal ranges of vital signs for a given pediatric patient. Although this knowledge may be second nature for providers who care for children routinely, for trainees or providers who only occasionally care for children, any deficiencies in this fundamental knowledge may result in the inability to recognize an abnormality with an increased risk for preventable harm.

Although providers may have the appropriate knowledge to allow for performing medical care based on these patient-specific characteristics, the larger
context of the system in which care is to be provided may provide barriers to performance. Independent of any written policy, an organization may have a culture in which provider knowledge and competencies do not meet patient needs as evidenced by allowing providers who are not trained or credentialed in pediatric care to care for children. Monitoring technology is another system element that needs to be designed, implemented, and used in a manner that addresses pediatric patient characteristics while optimizing performance. Monitors that generate either false-positive alarms because of motion artifact or false-negative alarms because of being set wide to accommodate variation in the normal ranges desensitize providers or do not alert them to real threats to patients. Even the decision to select a given monitoring technology may be influenced by organization factors (contracting relations) or environmental factors (space considerations and networking capabilities) rather than by the unique requirements of a pediatric institution.

Pediatric cognitive characteristics and patient safety implications

Pediatric patients also reflect a range of cognitive abilities based on stage of development, environmental factors, and innate abilities. Like physical and physiologic characteristics, the cognitive abilities of children provide important considerations for assuring safe health care. Developmentally, children learn awareness of self, and then move through stages of “magical thinking” characterized by egocentrism to more concrete thought mechanisms, with a final state of more formal logic and abstract thinking. The development of formal thinking, however, which includes logical evaluation, consideration of abstract processes, and application of principles, is not a forgone conclusion, as evidenced by some adults. Normal speech development occurs in relation to cognitive development with the recognition of sound beginning within the first month of life and the generation of cooing noises occurring by 4 months of age [45].

Just considering the range of normal cognitive development, there are many pediatric considerations that have an impact on a health care system and vice versa. Central to cognitive (and physical) growth is the dependency of children on adults for a range of health-related factors, including the ability to fill a prescription or follow-up with medical recommendations. Instead, children are far less likely to recognize an errant medication and can object much less effectively to health care providers. The lack of abstract thinking also has implications for compliance with health care regimens, resulting in preventable harm. Young children may resist medication administration, in particular oral medications, and the ability to reason with children arguably is limited. Finally, the limitations of cognition and communication result in the inability of children to convey what is medically wrong with them.

For providers, the cognitive development, coupled with dependency on adults, creates potential barriers to compliance. Additionally, the speech
and cognitive development creates an added risk for delayed diagnosis or even misdiagnosis. Processes meant to ensure safety, such as medication reconciliation and patient verification, become more complex in the face of nonverbal children or children limited by virtue of their developmental stage. Thus, pediatric providers are faced with developing safety strategies beyond those needed in routine adult care.

The varying cognitive and language development has implications for organizations and their environments. Patients who are developmentally unable to use patient call systems may require being kept within a range of visibility of providers. Similarly, policies designed to have patients assist in marking their surgical site also need to be reframed in the context of assuring the safety of pediatric patients.

**Pediatric motor characteristics and patient safety implications**

Finally, dramatic gross motor changes occur in children during the first year of life. These include the ability to roll over at approximately 4 to 6 months of age, the ability to crawl at 8 to 9 months of age, and the ability to walk at approximately 1 year of age. The constant and often surprising changes in mobility have implications for accidental injury and exposure to things previously believed inaccessible to children. Beyond a year of life, children’s ability to ambulate improves along a learning curve. It is not unusual for children to run at 16 months of age; however, this running often is associated with many falls. Fine motor changes parallel the gross motor changes, with children moving from crude grasping at 3 months, to reaching for objects and transferring objects between hands at 4 to 6 months, to a finger-thumb pincer grasp between 8 and 9 months.

Gross motor skills also may have an impact on pediatric provider performance and, thus, patient safety, especially in the context of cognitive and language limitations. Children may not understand the need for catheters and either remove devices or inflict self-harm with them. As a result, physical restraints may be needed to prevent injury. The restraint devices themselves, however, may cause injury if not sized and monitored properly. The restraints may cover patient wristbands or prevent access to intravenous catheters, impairing the safe delivery of medications. Children are at risk for entanglement in hospital bed rails or fluid or oxygen tubing. Similarly, small children may roll and fall from beds or examination tables, resulting in preventable injuries. Finally, mobile children in hospitals or offices that are not child proofed are at great risk for physical injury.

**Summary**

The pediatric population is characterized by many features that are different from those of adults and, by their nature, dynamic during the
pediatric age range. These pediatric-specific issues result in added potential risks for harm during medical care. The increased risk for harm may be the direct consequence of the patient-specific factors on the performance of providers or indirectly through lack of a health care system that addresses these patient-specific factors and the performance of providers.

Basic and applied human factors research has resulted in improvements in the performance of healthy adults and those adults who have functional limitations. Thus, the many risks to patient safety in the pediatric population may be viewed as an opportunity for the human factors and ergonomics community and pediatric providers. Future work should focus on systematically understanding the human factors needs of children with the goal of redesigning systems of health care to optimize the safety of children and the performance of their care providers.

References


