# **5 The Role of Simulation in Improving Patient Safety**

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#### **Simulation Pearls**

- 1. The role of pediatric simulation in improving patient safety is evolving and has tremendous potential.
- 2. Simulation is increasingly being used to evaluate systems and processes in both a retrospective and prospective fashion.
- 3. Simulation is a powerful bridge between existing safety initiatives and frontline providers.
- 4. The integration of simulation into ongoing patient safety, risk reduction, and quality initiatives has great potential to demonstrate the return on investment of simulation and to improve patient outcomes.

## **Background**

Pediatric simulation practitioners often conduct their work to improve proximal outcomes such as provider skills and teamwork. In addition, simulation can be used within the broader context of the practice and improvement of patient safety as it allows for an individual-provider and/or teambased and/or systems-based approach to patient safety. Simulation activities can be focused on a single individual (knowledge, skills, and attitudes), individuals interacting with other individuals (teamwork, communication), and

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individuals interacting with systems (in situ simulation). Collaborations between simulation practitioners and safety scientists from other disciplines such as systems/industrial engineering, human factors, health-outcomes research, and the behavioral sciences are critical to future innovations in our field. The application of theory and processes from these domains has great potential to maximize the impact of simulation on improving the safety behaviors of healthcare providers/teams, technologies/devices, and the performance of the system itself.

Pediatric-specific reviews on the role of simulation in patient safety have been published and largely discuss microsystem applications of simulation including routine training for emergencies, training for teamwork, testing new procedures for safety, evaluating competence, testing device usability, investigating human performance, and providing skills training outside of the production environment [[1,](#page-8-0) [2](#page-8-1)]. A number of recent publications point to the value of simulation in improving the safety of pediatric patients through translational outcomes [\[3](#page-8-2)[–7](#page-8-3)]. Many pediatric institutions are at the cutting edge of innovation in the development of a systems-based approach to patient safety with simulationbased activities integrated into their quality, risk, and safety initiatives (see Table [5.1](#page-1-0) for examples).

This chapter will begin with patient safety terminology; discuss the role of simulation to enhance patient safety at the provider, team, and systems level; outline the importance of systems and simulation integration in a robust patient safety program; and conclude with future directions for simulation and patient safety.

# **Definitions**

The elements of patient safety and how it is practiced are the subject of multiple perspectives and domains, and it is important that common language be applied to the various characteristics and activities of patient safety. It is only by

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assuring that there are similar concepts relative to the language and terms used in describing patient safety that programs can move forward with some confidence in work that utilizes simulation as a means to develop and enhance patient safety. Therefore, the first requirements are to define and develop common understanding of basic terms and concepts in patient safety.

**Patient safety** refers to *"freedom from accidental or preventable injuries produced by medical care"* [[8\]](#page-8-4). Thus, practices or interventions that improve patient safety are those that reduce the occurrence of preventable adverse events. Patient safety is often described as a characteristic or something that an organization possesses or achieves. Moreover, the usual definitions of patient safety describe it in terms of what patient safety is not (i.e., the events that constitute an absence of patient safety) [[9\]](#page-8-5). More realistically, patient safety is dynamic; it is something that an organization and most importantly the people in the organization think about and practice [\[10](#page-8-6)]. When an organization believes it has achieved *safety*, the organization may have *lost it*.

A number of frameworks exist to describe **patient safety domains**. Donabedian provided one of the earliest frameworks to describe quality of care that included three domains: (1) structure of care, (2) process of care, and (3) outcomes of care [[11](#page-8-7)]. In this model, **structure** includes those things external to the patient: the environment, organizational and human resources, and the regulations and policies affecting patient care. The **process** includes what actually occurred in the care of the patient and includes the patients' and providers' activities. One might think of it as the actual work

performed in caring for the patient. Finally, the **outcome** describes the effect of the care on the individual patient as well as the population as a whole  $[11]$ .

More recent safety frameworks provide more detail, specifically describing the patient, healthcare providers, and system factors that affect patient safety. For example, the Systems Engineering Initiative for Patient Safety (SEIPS) model describes patient safety in terms of the interactions, relationships, and influences of various system components, including the individuals that are part of the system  $[12]$  $[12]$  (see Fig. [5.1\)](#page-2-0). This more sophisticated and multifactorial model allows for a more nuanced view of the various elements that affect patient care.

The terms *quality* and *safety* in healthcare are sometimes confused or used interchangeably. In order to clarify this confusion, the Institute of Medicine describes six elements of high-quality patient care. High-quality care is safe, effective, efficient, patient-centered, timely, and equitable [[13\]](#page-8-9). In this model, safety is described as only one element of quality healthcare. An alternative way to think about the relationship between safety and quality is to envision safety as the floor or threshold of care and quality as the ceiling or goal [\[14](#page-8-10)]. Healthcare may be safe but not meet the other six targets for quality of care established by the Institute of Medicine. However, safe care is a requisite element of high-quality healthcare.

**High-reliability organizations (HROs)** manage to conduct operations in high-risk environments in a remarkably safe fashion. HROs are defined as organizations that operate in high-risk environments or are engaged in high-risk

<span id="page-2-0"></span>**Fig. 5.1** Systems Engineering Initiative for Patient Safety model of work system and patient safety. (Reproduced with permission from [12] (BMJ Publishing Group))



activities but suffer fewer than expected adverse events. Some examples of industries with HROs include commercial aviation, military (aircraft carriers), and nuclear power. HROs have five specific characteristics that have been described: (1) reluctance to simplify, (2) sensitivity to operations, (3) deference to expertise, (4) preoccupation with failure, and (5) commitment to resilience [[15\]](#page-8-11). In recent years, a number of healthcare organizations have attempted to develop an HRO culture and practice HRO behaviors. Of interest, many of the types of organizations that are exemplars of an HRO utilize simulation and/or regular training as a tool to develop and maintain an HRO culture and HRO behaviors [\[16](#page-8-12)]. For example, licensed civilian nuclear power plants in the USA require their operators to participate in ongoing simulation-based training approximately 25% of the time that they are working. The Nuclear Regulatory Commission sets standards for the fidelity of the nuclear simulators, the types of training, and scenarios that should occur as well as standards for simulation instructors [\[17](#page-8-13)].

#### **Simulation-Based Patient Safety Activities at the Provider Level**

At the core of patient safety are healthcare providers equipped with the knowledge and skills necessary to safely diagnose and treat patients and their varied, often complex, medical concerns. This applies to both trainees and frontline providers in all healthcare fields—medicine, nursing, pharmacy, respiratory therapy, etc. Herein lies one of the fundamental tensions in healthcare provider education—providing trainees the opportunities to learn while at the same time providing safe care to patients. Since its introduction into healthcare, simulation has been used successfully to improve providers' knowledge, skills, behaviors, and attitudes. A large systematic review reported that simulation-based training was associated with large effects for outcomes of confidence, knowledge, skills, attitudes, and behaviors [\[18](#page-8-14)]. A review conducted specifically in pediatrics noted large effects on knowledge, skills, and behaviors in 57 studies [\[19](#page-8-15)]. Further discussion of this evidence can be found in this book, Chaps. 7 ("Assessment"), 13 ("Simulation along the healthcare education continuum"), and 15 ("Interprofessional Education"). Through simulation, the apprenticeship paradigm of *"do one, see one, teach one"* is giving way to a thoughtful competency-based approach with graded levels of supervision and independence or entrustment assigned to the trainee based (in part) on performance in a simulated setting. These efforts will continue to ensure that providers at all levels and in all disciplines work in an environment in which they can develop and maintain their skills while keeping patients safe.

With the increasing focus on competency and the rapid pace at which new equipment, technologies, procedures, and processes are incorporated into healthcare, simulation can provide a means by which providers can continually train, practice, and be assessed in an ongoing manner. In some institutions, healthcare providers are being required to demonstrate competency with new equipment, technology, and processes in order to receive and/or maintain clinical privileges. At a national level, anesthesia leads the medical field and has included simulation as part of the maintenance of professional certification of physicians through the American Board of Anesthesiology since 2010. All physicians seeking recertification are required to participate in 6 h of simulations and structured debriefs and to identify areas of improvement in their own practices [[20,](#page-9-5) [21](#page-9-6)]. Since 2009, residents completing surgical residencies in the USA have been required to successfully complete a Fundamentals of Laparoscopic Surgery course. While other specialty boards (e.g., family medicine) utilize computerbased simulations, no other medical boards require fullbody or haptic-type simulations for initial certification or recertification [[21](#page-9-6)]. Currently, simulation is not part of the pediatric board examination process; however, many institutions have started to implement simulation as a requirement at the local level (examples in Table [5.1\)](#page-1-0). The application of simulation for summative assessment has been limited by the availability of robust assessment tools that are sufficiently valid to inform these high-stakes decisions (see also Chap. 7 "Assessment").

Recent studies have taken the important step of translating improvements in knowledge and skill into improved patient outcomes. A systematic review noted 50 studies reporting patient outcomes and that simulation was associated with small to moderate benefits on patient outcomes [\[22](#page-9-7)]. In fields outside of pediatrics, significant effects have been noted for central-line placement [\[23](#page-9-8)], obstetrical-neonatal outcomes [[4\]](#page-8-16), and laproscopic surgery [[24\]](#page-9-9). Unfortunately, of the 50 studies included in this review, only 4 were in pediatrics [[22\]](#page-9-7). One such pediatric study showed improved cardiopulmonary arrest survival rates for pediatric patients following the implementation of simulation-based *mock code* resident resuscitation training [\[3](#page-8-2)]. Additional pediatric studies have demonstrated a positive effect of simulation on acquisition of procedural skills (see also Chap. 11).

Simulation also has a role in advancing providers' adherence to established patient safety tools, such as the use of care bundles. For example, evidence-based practice to decrease central-line infections have been well studied with the result being an effective bundle of practices that, when performed together, have a significant impact on the rate of central-line-associated bloodstream infections. What was

unclear was the best way to ensure that staff were trained and followed the recommended procedures. A simulationbased intervention reduced central-line infections by 74% compared with a unit in which residents were not required to undergo training [\[25](#page-9-10)]. Additionally, this intervention was noted to be highly cost-effective with a net annual savings of US\$700,000 per US\$100,000 allocated [\[26](#page-9-11)]. Unfortunately, cost-benefit analyses are infrequent and incomplete in most simulation studies [\[27](#page-9-12)].

## **Simulation-Based Patient Safety Activities at the Team Level**

The role of teamwork and communication in improving patient safety is well established, with studies demonstrating deficiencies in these domains contributing to an estimated 70% of medical errors [[28\]](#page-9-13). Interprofessional simulation provides a training ground for teams to practice and improve their teamwork and communication skills. Numerous studies have incorporated simulation-based teamwork training modules and identified improvement in teamwork behaviors. [\[29](#page-9-14)[–34](#page-9-15)]. An example of a well-developed and widely disseminated team-training program is the Agency for Healthcare Research and Quality (AHRQ) TeamSTEPPS program [\[35](#page-9-16)]. Compared to a didactic-only TeamSTEPPS program, a simulation-based TeamSTEPPS program was associated with 37% decrease in adverse outcomes. [\[29](#page-9-14)]. Likewise, a systematic review noted that in nine studies, simulationbased crisis resource management training translated to improved patient outcomes and decreased mortality [\[36](#page-9-17)].

Simulation affords the opportunity to embed key behaviors in high-risk clinical endeavors. For example, the concept of a shared mental model was introduced and practiced in simulation-based training in a pediatric emergency department. This term is common to safety science and refers to the team members being "on the same page" [[37\]](#page-9-18). In practice, sharing a mental model involves four elements: "this is what I think is going on," "this is what we have done," "this is what we need to do," and "does anyone have any other ideas" or "what am I missing." We encourage team leaders to share a mental model in the first 3–5 min of any crisis situation and to update it frequently. Alternatively, any team member can ask for the mental model or that the mental model be updated when the situation is not progressing as expected or the situation is confusing. The introduction of this concept was viewed as so helpful by emergency nurses in one study that they incorporated it as a required item in a resuscitation flow sheet. If the team leader had not shared a mental model in the first 3–5 min of caring for a patient, the nursing team leader would request it [[6\]](#page-8-17).

Handoffs between providers are another example of key safety behaviors ripe for simulation-based process improvement and research [[38\]](#page-9-19). One institution incorporated simulation-based handoff training into teamwork and communication training following a serious event investigation that identified lack of handoff standardization as a root cause of the serious event. Observations after the training demonstrated an increase in the communication of crucial information between nurses during handoffs [\[39](#page-9-20)]. Another group used simulated patient cases to study patient handoffs as a first step in creating an effective, standardized handoff process [\[40](#page-9-21)].

#### **Simulation-Based Patient Safety Activities at the System Level**

The preceding paragraphs focus on the potential to improve providers' and team performance in order to reduce patient harm. Newer approaches to patient safety involve a systemsbased approach with the view that errors or safety threats reflect the risks and hazards that providers and patients face in the context of a poorly designed system [\[41](#page-9-22), [42\]](#page-9-23). Instead of focusing on individual failings, this approach identifies the components of the system that contribute to harm and involves the implementation of systemic changes that minimize the likelihood of these events. A robust simulation-based patient safety program involves identification of system threats using both retrospective reviews of adverse events and near misses as well as prospective efforts to identify and mitigate risk before an actual patient incident occurs (examples are provided in Table [5.1\)](#page-1-0).

## **Retrospective Approach to Safety at the System Level**

Simulation can be used to retrospectively examine why an error occurred (e.g., simulation-informed root cause analysis (RCA)). Simulation of adverse outcomes (SAO) has been used in the surgical arena as a method of conducting investigations of the causality of adverse surgical outcomes [[43,](#page-9-0) [44](#page-9-1)]. This process involved conducting each simulation up to seven times (with debriefings) to identify sources of errors in order to augment traditional RCA processes. The addition of simulation and re-creation of adverse events identified an increased number of systems issues compared to a traditional RCA. The debriefings allowed for a greater understanding of *why* and *how* decisions leading to the adverse event were made. By re-creating the adverse event, it became possible to understand what the individual team members were seeing and hearing that made the actions seem logical at the time of the event. These types of simulations can also identify periods of heavy workload, possible task fixation, and loss of situation awareness.

## **Prospective Approach to Safety at the System Level**

Prospective risk reduction applies methods developed in the engineering community (e.g., human factors or ergonomics, systems engineering, probabilistic risk assessment, cognitive task analysis) and used in other HROs combined with simulation techniques to optimize the safety of the system. A good example was the use of simulation during implementation of a new electronic medical record. When Yale-New Haven Children's Hospital implemented a new electronic medical record, simulation was used for provider training. The program collaborated with human factors engineers and informatics experts to provide feedback on the usability of the system in the clinical environment from providers during in situ simulations prior to formal implementation in the clinical environment. One specific example from this work was a group of simulations that provided information on the implications of nurses working with a new electronic medical record while concurrently caring for a severely injured trauma patient in the actual clinical environment. This work identified that it was difficult for the documenting nurse to see the vital signs on the monitor while working on the electronic record. The documenting nurse also reported multiple challenges with the usability of the graphic user interface. This work resulted in a requirement for an additional nurse in trauma resuscitations due to the increased workload during the first months of implementation (Marc Auerbach, written communication, October 2014).

Another familiar use of simulation to prospectively improve safety is through the use of in situ simulation to identify potential latent safety threats (LSTs). LSTs have been defined as systems-based threats to patient safety that can materialize at any time and are previously unrecognized by healthcare providers [[45\]](#page-9-24). In situ simulation in a pediatric emergency department (ED) proved a practical method for the detection of LSTs as well as reinforcing team training [\[46–](#page-9-25)[49\]](#page-9-26). In its most effective form, in situ simulation can become a routine expectation of staff that positively influences operations and the safety climate in high risk-clinical settings [[6\]](#page-8-17). In situ simulation can also be used to monitor the impact of other risk reduction strategies (new processes and procedures) through on-demand measurement and is discussed in more detail in Chap. 12 (examples are provided in Table 12.1). The authors encourage simulation practitioners to collaborate with content experts as they

embark on these types of systems-level simulation-based initiatives.

#### **Simulation for Improving the Safety of New Processes**

Incorporating simulation into process development offers an opportunity to *road test* the process and revise it before clinical implementation. In one institution, a new process for response to critical airways was developed and tested using simulation [\[50](#page-9-3)]. Six simulations were conducted at baseline, and six simulations were conducted to test the new critical airway response. While two of the six simulated patients "died" in the original airway response system, no simulated patients "died" in the new airway response system. In addition, there was a significant decrease in the otolaryngologist's response time to the emergency department. In another experience, five iterative simulations were used in the development of a massive bleeding emergency protocol. The final protocol was more pragmatic and reliable for staff and resulted in marked reductions in laboratory turnaround times for crucial bleeding labs (Kimberly Stone, written communication, October 2014).

### **Simulation to Improve the Safety of New Environments**

Simulation has been used to test the staffing model and safety of a new pediatric ED  $[5]$  $[5]$ , a new general ED  $[6]$  $[6]$ , and a children's hospital's obstetrical unit [\[51](#page-9-4)]. In the case of the new pediatric ED, in situ simulation prior to clinical occupancy resulted in changes to team members' roles and responsibilities as well as identifying latent threats in the new clinical space. Several hospitals have successfully utilized in situ simulation prior to opening new hospital units to identify and mitigate LSTs identified before caring for patients as documented in Table [5.1](#page-1-0) [[51\]](#page-9-4).

#### **Systems Integration: Simulation–Patient Safety–Quality**

Simulation programs can maximize their impact on safety through systems integration. Systems integration is defined by the Society for Simulation in Healthcare (SSH) as "consistent, planned, collaborative, integrated and iterative application of simulation-based assessment and teaching activities with systems engineering and risk management principles to achieve excellent bedside clinical care, enhanced patient safety, and improved metrics across the healthcare system" [\[52](#page-9-27)]. An institution's simulation activities should be

Patient safety initiative	Simulation value added
Quality improvement—event reporting	Simulation-based in situ events reported in system
Quality improvement—PDSA	Simulation integrated into PDSA
Risk management (incident or safety reports including) those that do not meet the criteria for a serious safety event)	Simulation to re-create patient safety events for RCA or to re-create potential adverse events or near misses that do not meet the criteria of a serious safety event
Guidelines/committees	Testing new processes/policies/procedures
Human resources	Simulation in interview process
Biomedical engineering	Testing/training for new products
Systems engineering	Studying/improving flow of patients
Architecture/facilities	Testing new spaces/redesigning existing spaces
Performance improvement	Lean, Six Sigma integrated with simulations

<span id="page-6-0"></span>**Table 5.2** Opportunities to integrate simulation within existing patient safety initiatives

*PDSA* plan, do, study, act, *RCA* root cause analysis, *FMEA* failure mode effects analysis

integrated into ongoing safety programs. Examples of opportunities for integration are listed in Table [5.2](#page-6-0). This integration should result in regular bi-directional flow of information between these groups. For example, the goals and objectives of simulation-based exercises are created based on perceived risk, adverse events, and near misses identified from realpatient databases. Subsequently, the simulations and debriefings inform the analysis of how to reduce risk. Optimally, simulations and debriefings identify and bring attention to risks that may not have been otherwise recognized and help organizations to anticipate and mitigate harm to patients. In Fig. [5.2](#page-7-0), we provide an example of how simulation can be integrated into ongoing patient safety activities after a serious event (see also Chap. 6 "Systems Integration").

In an integrated system, simulation-based activities are a part of everyday activities of an institution that is expected by staff as part of their daily work. Additionally, in some established programs, errors or threats identified in simulation are reported in the hospital event reporting system in the same manner that a real patient event is reported (e.g., Yale-New Haven Children's Hospital, Seattle Children's Hospital). This provides a clear reporting structure, allows for prioritization and tracking of actionable findings, and applies the accepted quality and safety nomenclature to simulation-based events (near miss, serious safety event, etc.). Formal reporting of simulation-identified threats also removes the responsibility of the mitigation of identified risks from the simulation team as, typically, the simulation team or program will not have the ability to influence the multiple factors often involved in systems issues. The risk is when providers participate in simulations, but do not believe that feedback from those sessions will be heard or lead to change, they come to believe that the organization is building safety only on the backs of the increased vigilance of providers rather than by addressing system issues[[45\]](#page-9-24). An effective simulation *culture* exists when there is *buy-in* from the highest level of leadership

(top-down) and from the frontline providers (bottom-up) across multiple disciplines.

## **Barriers/Challenges to Simulation in Patient Safety**

In order to fully realize the potential of simulation to improve the practice of patient safety, it will be critical to develop tools that are able to link simulation practices to improvement in patient outcomes. It will also be necessary to leverage the expertise of those working in various fields of safety sciences in domains external to healthcare. Terry Fairbanks, human factors expert and emergency physician, has stated that when airlines wanted to become safer, they did not ask pilots and flight attendants how to become safer, they involved engineers, cognitive psychologists, and human factors experts (Terry Fairbanks, written communication, June 2013).

The cost of implementing simulation in terms of provider time, instructor time, and equipment/resources can be balanced through savings related to improved quality of care, avoidance of adverse events, reduction in malpractice and liability insurance, and decreased litigation costs. Additional study is needed to understand the cost avoidance associated with simulation-based safety activities.

#### **Future Directions**

Though simulation has historically been utilized to assess individual and team competencies, in recent years simulation is increasingly being used to assess system competencies and to evaluate new facilities, new teams, and new processes [\[5](#page-8-18), [6,](#page-8-17) [50](#page-9-3), [51](#page-9-4)]. Historically, healthcare providers have not embraced expertise that originated outside of healthcare;

<span id="page-7-0"></span>**Fig. 5.2** Example of simulation integration into patient safety. *IV* intravenous, *IO* intraosseous, *RN* registered nurse, *RCA* root cause analysis, *EMR* electronic medical record



however, increasingly, there is a recognition of relevant expertise in fields outside of healthcare and a willingness to incorporate this expertise in healthcare simulation and safety work. This includes recognition of the value of human factors, cognitive task analysis, and engineering (cognitive, industrial, and systems) in addressing some of the major issues facing healthcare today.

In recent years, resident work hours in the USA have been reduced. Though the hours and length of shifts for residents have substantially decreased from the typical number of

hours worked by residents a decade ago, there has not been a corresponding increase in the length of postgraduate medical training [\[53](#page-9-28), [54\]](#page-9-29). It is well described that expertise in any domain is related to the hours spent in deliberate practice and coaching [[55\]](#page-9-30). A significant issue for those in medical education is how to assure competence with a decreased number of hours devoted to training and an ever-increasing knowledge base. The question of whether simulation can accelerate the development of expertise is beginning to be explored but is yet unanswered [[56\]](#page-10-3). It is clear that simulation-based

deliberate practice in laparoscopic surgery or central line placement results in improved performance in an actual clinical environment [[22–](#page-9-7)[26\]](#page-9-11). However, it is less clear that non-procedural expertise, for example, recognition of the patient with sepsis, is sensitive to simulation-based training. To understand the effect of simulation on the development of this type of medical expertise will require collaboration with experts in the development of expertise, naturalistic decision-making, and cognitive bias and de-biasing.

Another area of safety that is suitable for simulation is the exploration of the adaptive capacity of systems and teams relative to unexpected disturbances. This is related to the safety science of resilience engineering. While resilience engineering is employed in other industries, it has only recently surfaced in healthcare. Often, resilience engineering is concerned with retrospective evaluation of systems that have failed or succeeded spectacularly such as the space shuttle Columbia and Challenger disasters [\[57](#page-10-4)]. Though still theoretical, simulation offers a prospective way to evaluate systems' adaptive responses, tolerance for disturbance, and ability to recover from disruptions to the system. In healthcare, this could mean evaluation of existing and proposed systems relative to normal function and the ability to adapt to and recover from unexpected events in healthcare. Simulation also offers a method to evaluate the effect of proposed changes in the system relative to adaptive capacity and the brittleness of a system in the face of changing resources, for example, staffing, team configuration, and institution of an electronic health record.

In the future, as a simulation community, we will need to demonstrate that integrated simulation-based patient safety programs lead to measurable improvements in the healthcare that is delivered, a financial return on investment, and improved health outcomes.

#### **Conclusions**

Simulation is a natural partner for ongoing patient safety activities at the individual, team, and systems levels of organizations. A growing number of simulation-based training programs are linking their program improvements in knowledge, skills, and teamwork to patient outcomes. Increasingly, simulation is being used at the systems level to identify and mitigate patient safety risks. Simulation can facilitate the discovery of error-producing conditions before those conditions affect patients and a deeper understanding of these conditions when they have affected patients. Safety science and simulation experts will need to integrate and coordinate their activities within existing and new programs in order to achieve maximum patient safety.

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