The Evolution of Neonatal Patient Safety

Nicole K. Yamada, MD, MS*, Louis P. Halamek, MD

KEYWORDS

• Neonate • Patient safety • Human factors • Systems engineering • Simulation
• Debriefing

KEY POINTS

- Neonatal patients are particularly vulnerable to medical errors due to their unique fragility and the complexity of their care.
- The synergy between human factors science and patient safety has led to a fundamental shift in health care away from blaming individual health care professionals and instead acknowledging that adverse events occur because of system failures.
- Integrating human factors principles into simulation, debriefing, and quality improvement initiatives will strengthen the quality and resilience of the process improvements and systems changes that are developed.

INTRODUCTION

Patient safety is defined by the Agency for Healthcare Research and Quality as "freedom from accidental or preventable injuries produced by medical care."[1] The modern focus on patient safety was ignited by the 1999 publication "To Err Is Human: Building a Safer Health System" by the Institute of Medicine (IOM).[2] Since then, improving patient safety has become a major goal within all areas of health care, and the integration of patient safety as a component of improving quality in patient care was the focus of the complementary IOM book "Crossing the Quality Chasm: A New Healthy System for the 21st Century."[3] In the decades since these publications, the understanding of patient safety and mechanisms for improvement have evolved under the influence of human factors science and principles, and so these concepts are woven throughout this article. We will review the history of safety frameworks in health care, discuss how simulation and debriefing dovetail with efforts to improve care in the actual clinical environment, and describe the role of recording and analyzing safety data for better-understanding patient safety. Finally, we will look into the future of patient safety as it continues to evolve in the context of neonatal care.

Division of Neonatal and Developmental Medicine, Department of Pediatrics, Stanford University, 453 Quarry Road, MC 5660, Palo Alto, CA 94304, USA
* Corresponding author.
E-mail address: nkyamada@stanford.edu

Clin Perinatol 50 (2023) 421–434
https://doi.org/10.1016/j.clp.2023.01.005 perinatology.theclinics.com
0095-5108/23/

DEFINITIONS AND CONCEPTS

To understand patient safety, we must first define the foundational terms to understand the types of problems that can be detected during clinical care: adverse events, active errors, latent errors, and near misses. *Adverse events* in health care are defined as any injury caused by medical care.[4] An adverse event does not indicate that an error or failure has occurred; it describes only that an undesirable clinical outcome has resulted from some aspect of medical diagnosis or therapy. *Active errors* are actions committed by the health care professionals who directly care for patients, occurring at the point of contact between a human and some component of the health care environment, that leads to an undesirable outcome.[5] *Latent errors* refer to failures that reside in the design of some component of an environment that set the stage for active errors to occur.[6] Latent errors may exist undetected for long periods before the right set of conditions occur that allow them to manifest and result in patient harm. Finally, *near misses* are also known as “close calls” and are defined as events or situations that did not produce patient injury due to the unintentional benefit of chance.[7]

Historically, health care has primarily focused on adverse events (ie, the situations in which patient harm occurred) and active errors, while devoting fewer resources to understanding latent errors or near misses as well.[8] This approach is known as Safety-I. Many health care professionals are familiar with a Safety-I approach through techniques such as root cause analysis or models for error such as the “Swiss Cheese Model,” which explains negative outcomes as the result of a combination of active errors and latent errors.[9] In a Safety-I approach, things are presumed to go wrong because of specific and identifiable failures or malfunctions of the equipment, people, procedures, or system in which they operate.[10] In Safety-I, efforts at improving patient safety are focused on understanding why an adverse event occurred and managing those factors to keep adverse event rates as low as possible. Yet the scope of the Safety-I concept is limited, because many adverse patient safety events are relatively uncommon, constraining the overall relevance of the results of such analyses. In addition, the Safety-I tactics as employed in health care tend to focus on the actions of individual health care professionals, failing to consider the multitude of additional contextual factors present in any complex system that potentially influence the delivery of care. This emphasis on linear relationships between human error and patient harm has for the most part failed to produce significant improvements in patient care.

Patient care delivery is not linear; in fact, it is inherently variable from patient to patient and environment to environment. The Safety-I perspective misses a significant opportunity to learn from circumstances in which, despite such variability, humans and systems perform correctly. The Safety-II perspective is based on this principle and emphasizes understanding successful interventions–rather than only individual or system failures–to enable things to go right more often and under varying circumstances.[10] In other words, successful safety management is about understanding how systems effectively respond to stressors and how the system can be configured for best performance, and then actively seeking to design the system to achieve that.[11] By doing so, the Safety-II approach takes a proactive and more comprehensive approach to examining human and system performance.[12,13]

An appreciation for the complexity of health care systems has also led to the development of several models for patient safety in health care. The Systems Engineering Initiative for Patient Safety (SEIPS) model is one of the most commonly used and was developed by Carayon and colleagues[14] out of the understanding that “Most errors and inefficiencies in patient care arise not from the solitary actions of individuals but from conflicting, incomplete, or suboptimal systems of which they are a part and with which they interact." SEIPS 1.0 describes a work system where a person performs tasks using tools and technologies within an environment under certain organizational conditions. The work completed influences clinical processes, and these processes impact patient care. SEIPS 2.0 expands this initial approach by adding the concepts of configuration, engagement, and adaptation as significant influences existing beyond the original (limited) internal environment. It emphasizes outcomes affecting not just patients but also health care professionals and organizations.[15] Most recently, SEIPS 3.0 included patient experience over time as patients move through their health care journey, encountering numerous health care professionals in a multitude of clinical and non-clinical settings.[16] These types of constructs provide a framework against which to assess various aspects of patient safety in the health care ecosystem.

CURRENT STATE

Neonatal patients present unique physiology and are cared for in consistently complex systems that present constant challenges to patient safety. Safety in neonatology spans issues ranging from the identification of a fetus that is compromised in some manner, to resuscitation at birth, to ongoing care in the neonatal intensive care unit (NICU), through discharge home. Neonates have immature organ development, and most neonates in the NICU have superimposed serious illnesses. These infants are likely to be exposed to multiple medications, invasive procedures, and extended hospitalizations.[17] During a NICU hospitalization, there are several critical transitions in care, including admission, discharge, shift-to-shift handoffs between multiple levels of health care professionals, within-hospital transfers, and changes in clinical status. In an audit of 95 NICUs in the Vermont Oxford Network Critical Transitions collaborative, 43% of infants experienced ≥1 critical transition during the week before the audit.[18] The fragility of neonatal patients means they are particularly vulnerable to errors, and even minor errors can lead to devastating short-term and long-term consequences.[17]

As an illustrative example, consider for a moment only those neonates requiring resuscitation at birth. These neonates experience a compromise in their oxygen delivery during labor, may have congenital anomalies, or are born prematurely. Every year in the United States, approximately 1 in 10 of all newborns (400,000 neonates) require resuscitation, a time-pressured activity requiring teams of health care professionals to carry out invasive procedures in a specific sequence of steps in a relatively constrained volume of space (**Fig. 1**).[19] Unfortunately, error rates in excess of 50% during neonatal resuscitation have been reported.[20–23]

One can see that neonatal resuscitation does not involve merely a patient and those health care professionals providing care. Through a human factors lens, neonatal resuscitation is best described as a complex system comprised of multiple complex subsystems. The components of this complex system include but are not limited to the physical environment, medical devices, supplies, patient, family, health care professionals, and hospital culture–and within each exists multiple potential points of intervention for improving patient safety (**Fig. 2**).

As work in patient safety has evolved over the last two decades, one of the most important advancements in the field has been the application of complex system thinking to understanding and addressing patient safety threats. Simulation, debriefing, and continuous collection and review of objective performance measures are key to improving and sustaining patient safety in any field.

Fig. 1. Neonatal resuscitation in a constrained space.

Simulation

Simulation is an ideal methodology to support the shift from an individual to a systems approach for improving patient safety. The historical model of medical education focuses on education of the individual student or trainee to study and master a body of content knowledge and technical skills. However, individual study is not sufficient to learn or practice the behavioral skills that are necessary to work in a team (including

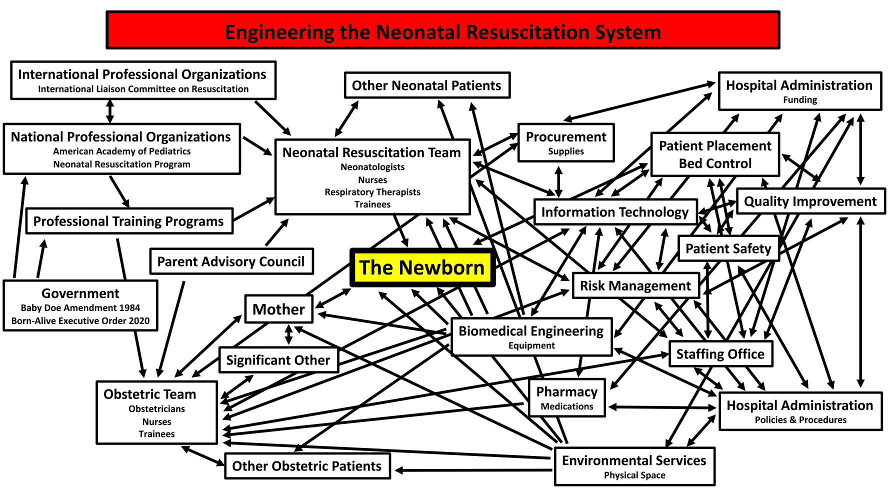

Fig. 2. Neonatal resuscitation system.

communication, task delegation, and leadership) and which are paramount to safe and effective patient care in complex work environments.[24,25]

Simulation-based training is defined as a methodology for learning in which participants are:

1. Immersed in an environment filled with realistic visual, auditory, and tactile cues
2. Required to integrate multiple skill sets while working with colleagues, equipment, and supplies just as in the real world, and
3. Provided the opportunity to reflect on their performance.

The goal of simulation-based training is to evoke the same responses during training as would be elicited in the real environment, thus allowing participants to understand their strengths and how to replicate them as well as their weaknesses and how to avoid them. Simulation-based training is the standard for skill acquisition and maintenance in multiple industries when human or system failure creates a high risk of death or severe injury.[25]

Health care professionals in neonatology are likely most familiar with the use of simulation for neonatal resuscitation training, as simulation has been formally integrated into the Neonatal Resuscitation Program curriculum since 2010.[26] In addition to resuscitation training, however, simulated clinical events conducted in the actual patient care environment (ie, in situ *simulation*) have the additional benefit of the ability to probe elements of that physical environment and the larger system in which care is delivered. The term "simulation" in this context involves more than a simple walkthrough; rather, it represents a true-to-life portrayal of patient care. In situ simulation allows direct observation of work in the real clinical environment, with all component personnel, culture, equipment, supplies, physical features, and care protocols. This type of observation is key to understanding "work as done" (the real everyday challenges and complexities of work) and how, where, and why variations occur from the idealized conception of "work as imagined" (what is expected to happen in ideal circumstances).[27] As such, in situ simulation has been used to probe new NICU environments for latent errors before opening them for the care of actual patients and is a valuable tool for optimizing patient safety.[28,29]

Debriefing

Debriefing is a key tool for analyzing complex systems and improving individual and team performance within them. Debriefing is most associated with its use following simulation for the purposes of enhancing and solidifying the learning that takes place through simulation-based training.[25] However, debriefings can be conducted after any patient care event–whether real or simulated. A debriefing is a discussion about events that have already occurred. In a debriefing, information flows

a. Between the leader(s) of the debriefing and the team being debriefed, as well as
b. Among the members of the team themselves.

The person or persons leading a debriefing may or may not have been involved in the event that is being discussed.

There are essentially two types of debriefings: *technical performance debriefings* that are used to assess human and system performance and *critical incident stress debriefings* conducted to provide emotional or psychological support to humans involved in an event.[22] Technical performance debriefings are used to evaluate human and system performance, and therefore, can provide direct connections to patient safety. The goal of technical performance debriefings is to establish a factual mental model of what occurred during the preceding event, develop a proper understanding of the situation, and determine whether responses during the event were appropriate and executed in accordance with established policies and/or guidelines.[25] The outcome analysis that occurs through technical performance debriefing is a key part of the learning that occurs after both simulated and real clinical events and can contribute to patient safety by identifying performance strengths or gaps in any element of individual, team, or system performance.

A successful debriefing need not rely on complicated and expensive technology nor take excessive time. Critical to a valuable debriefing is the use of a standardized method of addressing what occurred (or did not occur, but should have) during a particular event, with an understanding of the take-home points when considering safe and effective health care.

- Health care is delivered within the context of a complex system comprised of many interrelated subsystems.
- Investigation into patient safety requires examination of both human and system performance.
- It is critically important to understand the circumstances associated with:
  - Weaknesses/errors and develop tactics to avoid those, and
  - Strengths/exemplar performances and develop strategies to replicate those.

These take-home points underlie the debriefing method espoused at the Center for Advanced Pediatric and Perinatal Education at Stanford (**Boxes 1** and **2**).

Recording and Reporting Data

As in all quality improvement efforts, data are needed to provide an understanding of the system. These data can also be used to inform the design of simulations and enhance the context of the debriefings so that these tools can effectively inform changes that may be made to improve patient safety. Process, outcome, and balancing measures to understand how systems impact patient safety can be obtained from multiple data sources that combine both retrospective and prospective data collection including

- Incident reports
- Medical record review
- Morbidity and mortality case review
- Direct observation of clinical activities in real-time
- Analyses of audiovisual recordings of individual and team performance during real clinical events and simulated clinical events

Review of incident reports and medical records are among the most common potential sources of safety data. However, these records are rarely sufficiently comprehensive, detailed, and objective enough to ensure that all important data are present and accurate. *Case reviews* are based on both subjective and objective sources of data but they too have similar limitations. In addition, neither of these data sources allow for a complete understanding of the system dynamics.

More robust sources of data are those that allow detailed analysis of all aspects of clinical care and allow for an understanding of how components of the complex system interact. As described previously, *observation of clinical work in real-time* facilitates an understanding of the differences between "work as imagined" and "work as done." Specific tools can be used to understand sub-components of this work and provide structure and objectivity to recorded data. Examples of such tools include flow disruption analysis and teamwork scales. Flow disruptions are events where a process deviates from the optimal state as identified by a trained observer. They signify instances where the task demands are greater than the ability of the people

Box 1
Center for Advanced Pediatric and Perinatal Education guiding principles for debriefing

Guiding Principles for Effective Human and System Performance Debriefings

1. Leaders should set a professional, business-like, matter-of-fact tone for the debriefing and maintain that tone whether the performance of the team members was exemplary or highly flawed.
2. The role of the leader in a debriefing is to facilitate, rather than dominate, discussion among team members.
3. Debriefings should be focused on:
   a. The actions of individual team members
   b. How those actions contributed to the performance of the team
   c. How team performance influenced patient outcome
   d. Developing strategies for
      i. Replicating actions that facilitate successful human and system performance
      ii. Avoiding actions that are ineffective or harmful

and the system to meet them, often necessitating deviations from planned or accepted procedures.[30] Teamwork scales such as the Oxford Non-Technical Skills (NOTECHS) scale act to assess behavioral skills.[31,32]

Analysis of audiovisual recordings of individual and team performance during actual clinical events limits the negative effects of memory, recall, and hindsight bias that are frequently seen when reviewing notes in the medical record and may negate some of the potential Hawthorne effect that may occur when conducting observations in real-time. It is challenging for health care professionals to possess sufficient situation awareness during patient care to observe all aspects of that care and accurately recall the actions taken and words spoken when they are performed and said. It is even more challenging for them to then accurately document all of their interventions, the time each intervention was initiated and completed, and the patient's response, especially when these actions are carried out during time-pressured care such as resuscitation or intensive care. Many written records of clinical events are limited by time pressure, lack of situation awareness, and/or recall bias, and therefore, cannot be construed to be fully accurate or complete.[33,34] An audiovisual record is the only way to obtain a completely accurate chronology of events.

The use of video to record clinical activities in neonatology is feasible[35–37] and useful in improving performance.[38,39] Some authors have even reviewed recordings of neonatal resuscitations with parents to help them understand what happened to their child and provide them with screenshots or videos as keepsakes, especially in the event of patient death.[40] Before initiating any recording (audio, video, or combined) of real patient care events, neonatologists must review the legal implications of doing so with their hospital risk managers so that they may proceed in a manner that both protects patient and staff confidentiality and provides a mechanism for discussing any deviations from the standard of care with parents and remediating any weaknesses in human and system performance. Similarly, any ethical concerns should be discussed and resolved with coworkers and appropriate bodies (eg, ethics committee).[41–43] Despite real and perceived challenges to recording clinical events in neonatology, we believe that an audiovisual record provides the most accurate account of human and system performance and recommend its use to improve neonatal patient safety in the delivery room and NICU.[44]

NEONATAL PATIENT SAFETY IN EVOLUTION

The future of patient safety will require a continued shift toward thorough integration of human factors science into health care. The fields of human factors and patient safety

Box 2
Center for Advanced Pediatric and Perinatal Education specific tactics for debriefing

Specific Tactics for Effective Human and System Performance Debriefings

Debriefing Basics

1. Preparing the team: Clearly communicate expectations.
2. Initiating debriefings: “What happened in 10 words or less?”
3. Sequencing debriefings: Chronological order is easiest to follow.
4. Pacing debriefings: Maintain awareness of time remaining for debriefing.
5. Terminating debriefings: “Any final questions/comments?”

Facilitating Discussion

6. Asking questions, avoiding statements: Target a question-to-statement ratio of 3:1.
7. Using silence: Wait approximately 10–15 s for a response.

Encouraging Self-Assessment

8. De-emphasizing debriefer viewpoint: Limit the use of first-person pronouns.
9. Avoiding qualitative statements: Draw performance assessment from team members.
10. Minimizing personal anecdotes: Emphasize team member (not debriefer) experiences.
11. Eschewing hindsight bias: Debrief as if experiencing the event for the first time.

Asking Questions

12. Formulating pertinent questions: Create lists of debriefing points from four sources
    a. Primary: expected events during the scenario or learning objectives upon which the scenario is based
    b. Secondary: unexpected events during the scenario
    c. Tertiary: concerns raised during the debriefing
    d. Quaternary: hypothetical situations
13. Listening for “red flags”: Recognize phrases that indicate a need to drill down.
14. Drilling down to root causes: Use a series of four questions
    a. What happened/what did you notice (at that point in the scenario)?
    b. What circumstances led to that?
    c. What happened to the patient as a result?
    d. What can be done to:
       i. Facilitate the recurrence of that positive event?
       ii. Prevent that negative event from happening again?

Maintaining Focus

15. Deconstructing defensiveness: Limit use of second-person pronouns.
16. Dealing with emotion: It is not necessary to assume all team members need to ventilate.
17. Deciding when to intervene: Interject only when necessary
    a. Inability to recognize performance gaps
    b. Talking over one another
    c. Lack of gravitas
    d. Inappropriate laughter
    e. Harsh criticism

Special Debriefing Circumstances

18. Debriefing with video: Scroll to segments of interest and pause playback for discussion.
19. Debriefing novices and experts: Employ the same strategies regardless of experience.
20. Debriefing real clinical events: Formal process is required.

have both existed since the middle of the twentieth century, but the last two decades have marked the greatest growth and development of synergy between these two fields. Human factors experts know well that the cultural emphasis on the work, knowledge, and individuals that exists in health care fosters a tendency to blame individual persons for adverse events. Only in the last 20 years has health care begun to shift away from this blame-and-retrain approach and toward acknowledging that adverse events instead occur as a result of system failures.[11,45] This has allowed human error to be viewed as a symptom of system failure, and thus turned the focus to building systems and processes that support limitations in human capabilities and prevent errors or mitigate their impact.[46,47]

One example of a future development to improve neonatal patient safety is the creation of a national neonatal safety management system (SMS). Individual NICUs typically have some type of safety committee and system for reporting safety events; many NICUs are also members of a regional and/or national collaborative that shares deidentified safety data among members. A national neonatal SMS would be much more comprehensive in scope than any patient safety system that currently exists in health care. A national neonatal SMS would provide a methodical approach to achieving safety, be modeled after that in use by commercial aviation,[48] and be comprised of four major safety components:

- Policy (organizational methods, processes, and structure)
- Risk management (define and manage acceptable risks)
- Assurance (assess effectiveness of current initiatives)
- Promotion (efforts to create a culture of safety)

A national neonatal SMS would allow NICUs to centrally report safety data as well as view comprehensive reports of that data from NICUs across the country. The neonatal safety database could include frequently measured adverse events from quality improvement work such as medication errors, unplanned extubations, and hospital-acquired infections. It would support the learning around less commonly reported (but critically important) adverse events such as diagnostic errors, detailing both the events and strategies and tactics to reduce the risk of their recurrence.[49] It would also log near misses, which are seldom identified and rarely formally reported. Problems with patient care technologies would be a component of this searchable database, allowing rapid identification of device failures or misguided applications and subsequent recall of said devices or, if necessary, alterations in operating procedures. These data could be reported from events occurring not only during real clinical care but also simulated scenarios. Data could be filtered to allow comparisons between similarly sized, geographically located, or resourced NICUs. It can also allow for the identification and dissemination of the most common problems encountered, similar to what the Federal Aviation Administration tracks in terms of factors that cause aviation accidents (**Box 3**).[50]

Another concept for the future is the development of perinatal operations centers. Tremendous advances in safety, efficiency, and effectiveness have resulted from the development of operations centers in high-risk industries such as mass transit, commercial aviation, aerospace, nuclear power, and the military. Although it is true that “hospital command centers” have come online in various US locations, these

Box 3
Aviation accident cause factors

10 Most Frequent Cause Factors for General Aviation Accidents that Involve the Pilot-In-Command

1. Inadequate preflight preparation and/or planning.
2. Failure to obtain and/or maintain flying speed.
3. Failure to maintain direction control.
4. Improper level off.
5. Failure to see and avoid objects or obstructions.
6. Mismanagement of fuel.
7. Improper inflight decisions or planning.
8. Misjudgment of distance and speed.
9. Selection of unsuitable terrain.
10. Improper operation of flight controls.

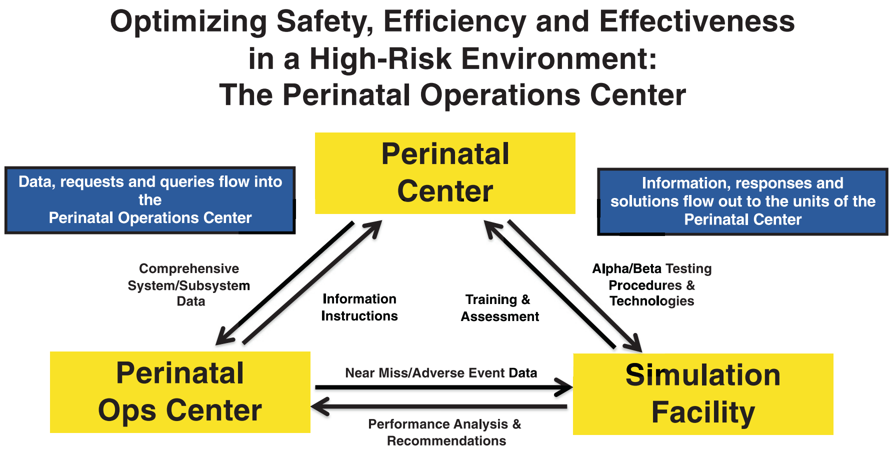

Fig. 3. The perinatal operations center.

centers typically miss their full potential, instead serving only to reinforce existing reactive, inefficient, and unsafe processes while focusing on the function of a single subsystem (typically patient placement and bed management). Current facilities tend to focus on technology (eg, placing multiple computer displays on a desk or a wall) but provide less emphasis on functionality. This outcome can be avoided by re-engineering hospital operations by delineating the components of this complex system, defining the interactions among those components, and crafting performance-based mission rules to guide operations. Because a busy regional perinatal center is a microcosm of a large hospital system, a perinatal operations center could generate unique insights about the interactions between subsystems of these larger health care systems and how those interactions may present opportunities to achieve improvements in the safety, efficiency, and effectiveness of clinical care. Functions of a perinatal operations center could include tracking high-risk pregnancies and maternal and neonatal transports, predicting the probability of delivery and the severity of neonatal disease, simplifying neonatal care coordination within the hospital, supporting local reporting of neonatal patient safety events at the hospital, and facilitating communication between referring physicians in community hospitals and physicians at referral centers. Simulation could be integrated to recreate near misses or adverse events; the lessons learned and system modifications identified during the performance analysis and debriefings of those simulations could be fed back through the operations center to improve the processes through which patient care is delivered (Fig. 3).

SUMMARY

The attention on patient safety in health care has been unquestionable for decades, but the mechanisms by which to improve patient safety continue to evolve. Human factors science teaches us that patient safety is not achieved by disciplining or training mistakes out of individual health care professionals, but rather by designing systems, protocols, and work environments that acknowledge human vulnerability and capitalize on the capabilities of the human beings working within them. The integration of human factors principles into patient safety work is increasingly understood to

add value to the redesigning of processes, equipment, and systems for safer care. Incorporating human factors knowledge into well-known methodologies such as simulation, debriefing, and quality improvement initiatives based on reported data will strengthen the quality and resilience of the solutions and systems changes that are developed. The future of patient safety in neonatology–and all of health care–will depend on continued efforts to engineer and re-engineer systems that best support the humans who are at the interface of delivering safe patient care.

Best practices

What is the current practice?

- Patient care is comprised of a complex system with numerous components including but not limited to the physical environment, medical devices, supplies, patient, family, health care professionals, and hospital culture.
- Focus on the contribution of an individual health care professional to any adverse event limits the scope of patient safety analyses.

What changes in current practice are likely to improve outcomes?

- Broadening perspectives on patient safety to include the following will enhance the quality of quality improvement efforts:
  - Use objective data from audiovisual recordings of real clinical care and simulated clinical events.
  - Examine the role of system components.
  - Look beyond adverse events. Scrutinize near misses as well as successes in safe patient care.

Major Recommendations:

- Incorporation of human factors science principles will strengthen the quality and resilience of the processes, equipment, and systems implemented for safe patient care.

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DISCLOSURE

The authors have nothing to disclose.

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