Simulation in Medicine: Addressing Patient Safety and Improving the Interface Between Healthcare Providers and Medical Technology

Elizabeth A. Hunt, MD, MPH; Kristen L. Nelson, MD; Nicole A. Shilkofski, MD

Medicine, as an industry in which human lives depend on the skill and performance of operators, must create and maintain a culture of safety, in addition to promoting the design of systems to mitigate errors. The use of medical simulation as a mechanism for training healthcare professionals in a safe environment is expanding rapidly. An important component of systems that ensure the safety of patients in the hospital setting is the interface between humans and technology in the hospital. The objective of this paper is to review: (1) the definition and a brief history of medical simulation, (2) examples of how current medical simulation centers are using simulation to address patient safety, and (3) examples of how simulation can be used to enhance patient safety through improvement of the interface between healthcare practitioners and medical technology. Medical simulation and human factors engineering can be used to examine and enhance the interface between healthcare practitioners and medical technology, with the potential to make a significant contribution to patient safety.

(Biomedical Instrumentation & Technology 2006; 40:399–404).

In 1999, the disturbingly high frequency of life-threatening and lethal medical complications was brought to public attention by the Institute of Medicine's publication *To Err is Human: Building a Safer Health System*.[1] This report estimated that medical error may be anywhere from the fifth to the eighth leading cause of death in the United States.[1] The Institute recommended, among other initiatives, to establish interdisciplinary team training programs that incorporate efficient training methods, such as simulation, in an effort to improve patient safety and to address this iatrogenic epidemic within health care.[1]

An important component of systems that ensure the safety of patients in the hospital setting is the interface between humans and technology in the hospital setting. Many medical errors involve the misuse of technology in a variety of manners.[2] The objective of this paper is to review (1) the definition and a brief history of medical simulation, (2) examples of how current medical simulation centers are using simulation to address patient safety, and (3) examples of how simulation can be used to improve patient safety through improvement of the interface between health care practitioners and medical technology.

Simulation Definition and Brief History

Simulation implies a replication of potential real-life experiences in an environment similar to one in which these events actually might occur. Simulation provides a safe environment that encourages experiential learning and reflective thought; it attempts to "bridge the gap between 'knowing' and 'doing'" by providing opportunities for practitioners to practice newly learned skills.[3] Simulation has long been used as a tool for training and testing in nonmedical industries such as aviation and military divisions.[4]

The application of simulation to medicine began in the 1960s with the creation of Resusci Anne by the Laerdal Company.[5] The initial impetus to devise a

From Johns Hopkins School of Medicine, Department of Anesthesiology and Critical Care Medicine (EAH, KLN, NAS), Baltimore, MD; Johns Hopkins Simulation Center (EAH, KLN, NAS), Baltimore, MD; and Johns Hopkins School of Medicine, Department of Pediatrics (NAS), Baltimore, MD.

Address correspondence and reprint requests to Dr Hunt, Johns Hopkins School of Medicine, Department of Anesthesiology and Critical Care Medicine, 600 N Wolfe St, Blalock 904, Baltimore, MD 21287 (e-mail: ehunt@jhmi.edu).

patient model grew from the work of Dr Peter Safar. In 1958, Dr Safar published his work demonstrating the effectiveness of mouth-to-mouth ventilation in providing both effective oxygenation and carbon dioxide elimination on sedated and paralyzed human volunteers.[6] He presented his findings at a conference in Norway in the early 1960s, where the connection to Asmund Laerdal was made. Laerdal was a Norwegian toy manufacturer at the time, and in response to the findings of Dr Safar, Laerdal promptly created a full-size training mannequin for mouth-to-mouth ventilation. The airway of this mannequin could be obstructed and required appropriate manipulation in order to deliver the technique of mouth-to-mouth ventilation described by Dr Safar.[7]

Almost simultaneously, the work of Kouwenhoven, Knickerbocker, and Jude was published, revealing that external chest compressions in a pulseless patient could provide adequate blood flow.[8] Laerdal then created a spring mechanism in the chest wall of the mannequin to permit the simulation of chest compressions. With these accomplishments, the ability to use simulation to teach the now familiar ABCs of cardiopulmonary resuscitation (A for airway, B for breathing, and C for circulation) was created and Resusci Anne became known around the world.[7] The introduction of this mannequin and the ability to test the resuscitation skills of healthcare providers changed forever the training environment in medicine.

The pioneering work of an engineer, Dr Stephen Abrahamson, and a physician, Dr Judson Denson, in the late 1960s was a starting point for the development of computer-controlled modern simulators. Their mannequin, known as Sim One, was controlled by a hybrid digital and analog computer and had many high-fidelity features.[5] It was utilized in studies of proficiency levels among anesthesiology residents in which it was demonstrated that residents using the simulator reached professional levels of performance in fewer elapsed days and in a smaller number of trials in the operating room than did residents who did not have training on the simulator.[9] Since that time, the development of "higher-fidelity" mannequins and virtual reality simulators in the mid-1990s has greatly expanded the experience of the medical profession.[5,7,10]

With today's computer-driven models, a healthcare provider can feel a pulse, deliver medications, and deliver shocks, with the simulator responding appropriately to the providers' actions. If an inappropriate medication is administered, the simulator can be programmed to respond as a human would. The difference here is that a human is not harmed and the personnel being evaluated with this simulation technique learn a valuable lesson. In addition to computerized human patient simulators, there are other important approaches and tools being used in simulation, such as virtual reality simulators, partial task simulators, computerized microsimulators, and standardized patients.

The most important outcome of this rapidly expanding field of medical simulation is the potential for improvement in patient safety. The current models and structures in our healthcare system do not work as effectively as they should, as evidenced by near-daily reports of medical errors, many of which potentially could be prevented by the application of simulation models.[1] The training of healthcare practitioners and support staff today emphasizes basic science education, with clinical training left to a mentoring environment; you learn by watching what others have done before you. If mistakes were made, they can be copied. What simulation allows healthcare personnel to do is learn how to handle crisis situations properly, allow them to ask questions, and try again and again, all without harming anyone.

Simulation Centers

In the near future, the healthcare industry should envision a system that is optimized for patient safety and quality. Simulation is a key component of this vision. In 2004, it was estimated that there were more than 1,000 simulation centers worldwide.[11] Simulation centers vary in their structure and management, but generally have shared goals.

Simulation centers are designed to provide a centralized location for training healthcare providers in a manner that improves both the educational experience and the safety of patients. The courses that are offered and the equipment that is used will vary depending on the student population. For example, a center that is used by students in training programs for surgical technologists or dental hygienists will vary from one whose students are anesthesiologists or emergency medicine physicians. Centers should attempt to equip their facilities with the exact models of medical equipment that are used in their clinical areas, to ensure that employees are practicing important procedures and management skills on the actual equipment that they will use in their day-to-day practice. Because timely feedback and evaluation of a student's performance in simulation is so essential to a rewarding experience, simulation centers must have state-of-the-art audiovisual and information technology systems. Several centers have led the charge in improving patient safety via the use of medical simulation. A few of those centers and their programs are discussed below.

At Stanford Medical School–affiliated Veterans' Affairs Palo Alto Health Care System, David Gaba and colleagues pioneered work in the use of mannequin simulators to investigate human performance in anesthesia.[12] They created a training curriculum, Anesthesia Crisis Resource Management (ACRM), based on an aviation model of crew resource management. The ACRM curriculum teaches responses to critical events and incorporates debriefings that use videotapes of simulation scenarios.[12] The aims of the curriculum are (1) to enhance participants' stock of precompiled plans for dealing with situations that could occur in their practice, (2) to provide exercises that encourage use of meta-cognition, situation awareness, and avoidance of fixation error, and (3) to provide exercises focused on leadership, communication, teamwork, and workload management.[13] One of many programs at Stanford focuses on using simulation as a new paradigm to teach neonatal resuscitation in a simulated delivery room environment.[14]

The Center for Medical Simulation in Cambridge, MA, has been operational since 1993. Its stated mission is to improve patient safety and the process of patient care and to reduce the financial and social burden of adverse outcomes by using simulation for education, training, and research to improve performance and teamwork of clinicians.[15] As such, it was one of the first centers to utilize simulation technology for educational applications, including anesthesia crisis resource management, teaching modules for crisis management in radiology, and preresidency emergency readiness training for medical students.[16–18]

The University of Pittsburgh's Peter M. Winter Institute for Simulation, Education, and Research (WISER) was established in 1994 and has grown enormously. In the academic year 2003–2004, approximately 8,000 healthcare professionals were trained using human patient simulators.[19] The center uses simulation to educate medical students, resident and attending physicians, nurses, respiratory therapists, and emergency medical technicians. For resident and fellow physicians, simulation is used to teach difficult airway management, fiberoptic bronchoscopy, and a yearly Anesthesia Crisis Leadership Training course. In addition, there are courses focused on pediatric crisis management, code team training, and a course to improve the management of obstetric critical events.[19,20]

Johns Hopkins School of Medicine has used a variety of simulation modalities to improve patient care and safety. There is a very active, standardized patient program to teach medical students clinical skills and another to teach healthcare teams how to communicate bad news to families during end-of-life scenarios. The gynecology, obstetrics, and biomedical engineering departments have collaborated to create a simulator to allow obstetricians to study the safest way to avoid brachial plexus injuries during difficult deliveries of infants with shoulder dystocia.[21] The Johns Hopkins Children's Center uses simulation during monthly mock codes to assess the preparedness of the Pediatric Rapid Response Team. A fundamental component of the realism in these simulations is to have doctors and nursing staff participating and learning together during the mock codes, with emphasis on the team approach to management of the scenario. Analysis of mock codes at Johns Hopkins includes an assessment of delays in important resuscitative maneuvers and has led to a categorization of the types of errors made during arrest scenarios.[22] These data have been used to alter the composition of the team and to focus resuscitation education of residents and nurses on identified deficiencies.

The Sydney Medical Simulation Centre (SMSC) at Royal North Shore Hospital in Sydney, Australia, represents the first center of its type in Australia. The philosophy of the SMSC is "patient safety through quality learning."[23] The SMSC's teaching faculty includes professionals in multiple disciplines, including anesthesia, emergency medicine, psychology, intensive care, and biomedical science. The focus of the SMSC is in multiple arenas, but includes "human factors" training that includes training in skills that are acknowledged to underpin effective decision making and communication in emergency scenarios. These human factors include fatigue, unfamiliarity with equipment, environment or situation, and stress-related memory failure.[23] The SMSC is one of the only simulation centers in the world that conducts simulation assessments on behalf of a medical licensing board, the New South Wales Medical Board. Simulation is used in this context as a tool for remediation and training in practitioners who are referred by the medical board due to concerns about clinical competence or performance, with the ultimate goal of improvement in safety and outcomes for patients in real life.[24]

Simulation to Improve the Interface Between Healthcare Practitioners and Technology

As stated above, simulation has the potential to improve the quality and safety of healthcare delivered to patients through a variety of mechanisms. The United States Food and Drug Administration (FDA) has delineated methods to improve patient safety through examination of the interface between healthcare practitioners and technology.[2] The FDA has specifically promoted "safety in medical device use" through their Human Factors Program. They define *human factors* as the "study of how people use technology" and state that "human factors engineering helps improve human performance and reduce the risks associated with use error."[25] They go on to state that "the validity of use testing depends on the extent to which realistic or simulated environments are used during the testing."[2] Such testing typically is conducted either in clinical situations of normal use or in laboratory situations that do not sufficiently mimic the real world. Simulation, especially in formats using high realism, has great potential as a vehicle to test new technologies and systems under critical situations, examining the reactions of operators in ways that cannot be achieved in the real setting. The lessons learned should be methodically documented and utilized to guide the design of medical devices before they reach the market for sale. Below, we present other examples of how simulation centers and hospitals have used simulation to enhance how healthcare practitioners use medical technology and utilize human factors engineering to improve patient safety.

Virtual Reality Training for Medical Procedures

In addition to the use of human patient simulators, another simulation modality has been introduced to decrease the learning curve of medical practitioners and to increase patient safety. Virtual reality (VR) simulators are used to train medical practitioners in colonoscopy, bronchoscopy, laparoscopic surgery, and cardiac catheterization.[5] In randomized, double-blinded studies, VR has been associated with decreased intraoperative errors and faster rate of completion of laparoscopic cholecystectomy among VR-trained surgical residents *vs* traditionally trained residents.[26,27] Recently, the FDA made a landmark decision to include VR training as a necessity for physicians who will perform placement of newly approved carotid stents.[28] The effect of VR simulation training on the ability of a physician to safely place these carotid stents is being studied in an ongoing trial.[28] With evidence mounting regarding their effectiveness, it seems likely there will be an increase in the use of VR simulators for training and for assessment of competency in medical procedures.

Purchasing Process

Every day, hospital administrators order new medical equipment that will be used directly in the care of the patient. The process by which products are chosen is not always clear or standardized.[29] In addition to cost, it is essential that patient safety and usability be considered.[30] Simulation can be used to test various products in a setting similar to how they will be used in the hospital. Any additional testing of products in a simulated environment should be standardized (*i.e.* each product should be tested using the same clinical scenario, users, assessment tool, and scale), in order to increase the validity of comparisons.[29] As noted earlier, it is preferable that such testing be performed before products reach the market. However, users will still benefit from using simulation to compare products that are already on the market, as part of the process by which they choose the products that best suit their local needs. The testing should look at both ease of use and safety under high stress situations.[2]

In-service for New or Infrequently Used Equipment

Once a new product has been purchased, it will need to be introduced into the clinical environment. This is generally done through in-service training, which also is used to maintain proficiency in the use of infrequently used equipment. Simulation can be a valuable tool during in-service training. Traditionally, healthcare practitioners take part in a hands-on exercise that has been designed to teach them to use the new equipment. However, this exercise generally is used as a teaching tool and does not assess proficiency. A simulation exercise can allow the person to use the equipment in a manner similar to what they will be doing in their own work environment. This method enables both the practitioner and the teacher to assess proficiency in the use of the equipment. This also allows the teacher to observe patterns of errors made by the various practitioners. These patterns can be used in future teaching sessions and are valuable information for the company that designed the product.[31]

Forensic Testing of Adverse Events

Any time a medical error has occurred, it is essential that we learn from our mistakes. In addition, we must encourage the reporting and investigation of "near-miss" events (*i.e.* events where a mistake or the impact of the mistake was caught prior to affecting the patient). After any medical error is made, it may be valuable to re-enact the entire situation in a simulated setting in order to determine what factors contributed to the mistake. These factors may include poor medical judgment, but are even more likely to uncover other problems such as communication errors, poorly designed equipment, and improperly used equipment.[32]

Diagnostic Tool

Simulation can be a powerful tool to diagnose deficiencies in hospital response systems and in understanding problems related to the use of medical technology.[33] Through utilization of simulated medical emergencies (*i.e.* mock codes), the University of Pittsburgh recognized that the existence of different models of defibrillators throughout their hospital was associated with confusion by the users and a potential delay in therapy during life-threatening emergencies. They now advocate for standardization of equipment.[34] This is an example where the device was not failing, but the device use was less than ideal. Evidence suggests that "the frequency and consequences of hazards resulting from medical device use might far exceed those arising from device failures."[2]

Train Biomedical Equipment Technicians to Test Equipment, to Recognize and Repair Equipment Failures

Simulation can be used to teach biomedical equipment technicians (BMETs) the skills needed to manage medical equipment more effectively. An important responsibility of the BMET is to perform thorough examinations of medical equipment both prior to actual use in the clinical setting and during periodically scheduled rechecks. Commonly, engineers learn to examine equipment by observing a more experienced engineer perform an actual test of clinical equipment. The problem with this approach is that most equipment will pass the tests, thus giving little experience in identifying defects. Berge *et al* reported altering an actual anesthetic machine internally so that 20 different preset defects could be triggered by a mobile control unit.[35] This would enable an instructor to demonstrate all known possible defects and for the trainee to practice until they could recognize and fix the defects. A potentially powerful application of this approach would be to perform competency assessments of the BMETs. For example, an instructor observes a BMET perform an equipment check and observes whether they are able (1) to identify a planned defect and (2) to repair the defect appropriately.

Conclusion

Medicine, as an industry in which human lives depend on the skill and performance of operators, must create and maintain a culture of safety, in addition to designing systems to mitigate errors. The use of medical simulation as a mechanism for training health care professionals in a safe environment is expanding rapidly. Medical simulation and human factors engineering can be used to examine and to enhance the interface between healthcare practitioners and medical technology, with the potential to make a significant contribution to patient safety. ■

References

1. **Kohn LT, Corrigan JM, Molla SD.** *To Err is Human: Building a Safer Health System.* 1st ed. Washington, DC: National Academy Press; 2000.
2. **Kaye R, Crowley J.** Guidance for industry and FDA premarket and design control reviewers—medical device use–safety: incorporating human factors engineering into risk management. Available at: http://www.fda.gov/cdrh/humfac/1497.html. Accessed August 16, 2005.
3. **Flanagan B, Nestel D, Joseph M.** Making patient safety the focus: crisis resource management in the undergraduate curriculum. *Med Educ.* 2004;38:56–66.
4. **Gaba DM.** The future vision of simulation in health care. *Qual Saf Health Care.* 2004;13(suppl 1):i2–i10.
5. **Cooper JB, Taqueti VR.** A brief history of the development of mannequin simulators for clinical education and training. *Qual Saf Health Care.* 2004;13(suppl 1):i11–i18.
6. **Safar P, McMahon M.** Mouth-to-airway emergency artificial respiration. *JAMA.* 1958;166:1459–1460.
7. **Grenvik A, Schaefer J.** From Resusci-Anne to Sim-Man: the evolution of simulators in medicine. *Crit Care Med.* 2004;32:S56–S57.
8. **Kouwenhoven WB, Jude JR, Knickerbocker GG.** Closed-chest cardiac massage. *JAMA.* 1960;173:1064–1067.
9. **Abrahamson S, Denson JS, Wolf RM.** Effectiveness of a simulator in training anesthesiology residents. *J Med Educ.* 1969;44:515–519.
10. **Gaba DM.** A brief history of mannequin-based simulation and application. In: Dunn WF, ed. *Simulators in Critical Care and Beyond.* 1st ed. Des Plaines, IL: Society of Critical Care Medicine; 2004:7–14.

11. **Grenvik A, Schaefer JJ III, DeVita MA, Rogers P.** New aspects on critical care medicine training. *Curr Opin Crit Care.* 2004;10:233–237.
12. **Stanford School of Medicine and Veterans' Affairs, Palo Alto Healthcare System Simulation Center.** Anesthesia crisis resource management (ACRM). Available at: http://anesthesia.stanford.edu/VASimulator/acrm.htm. Accessed September 21, 2005.
13. **Gaba DM, Howard SK, Fish KJ, Smith BE, Sowb YA.** Simulation-based training in anesthesia crisis resource management: a decade of experience. *Simul Gaming.* 2001; 32:175–193.
14. **Halamek LP, Kaegi DM, Gaba DM, *et al.*** Time for a new paradigm in pediatric medical education: teaching neonatal resuscitation in a simulated delivery room environment. *Pediatrics.* 2000;106:E45.
15. **Harvard Medical School Center for Medical Simulation.** About the Center for Medical Simulation. Available at: www.harvardmedsim.org/. Accessed September 21, 2005.
16. **Holzman RS, Cooper JB, Gaba DM, Philip JH, Small SD, Feinstein D.** Anesthesia crisis resource management: real-life simulation training in operating room crises. *J Clin Anesth*. 1995;7:675–687.
17. **Sica GT, Barron DM, Blum R, Frenna TH, Raemer DB.** Computerized realistic simulation: a teaching module for crisis management in radiology. *AJR Am J Roentgenol.* 1999;172:301–304.
18. **Gordon JA.** The human patient simulator: acceptance and efficacy as a teaching tool for students. The medical readiness trainer team. *Acad Med.* 2000;75:522.
19. **Peter M Winter Institute for Simulation, Education and Research (WISER).** WISER Simulation Center at the University of Pittsburgh. Available at: www.wiser.pitt.edu. Accessed September 21, 2005.
20. **Schaefer JJ III, Grenvik A.** Simulation-based training at the University of Pittsburgh. *Ann Acad Med Singapore.* 2001;30:274–280.
21. **Gurewitsch ED, Kim EJ, Yang JH, Outland KE, McDonald MK, Allen RH.** Comparing McRoberts' and Rubin's maneuvers for initial management of shoulder dystocia: an objective evaluation. *Am J Obstet Gynecol.* 2005;192:153–160.
22. **Hunt EA.** Simulation of pediatric cardiopulmonary arrests: a report of mock codes performed over a 40-month period focused on assessing delays in important resuscitation maneuvers and types of errors. Available at: http://www.anestech.org/media/Publications/IMMS_2004/Hunt.pdf. Accessed September 21, 2005.
23. **Sydney Medical Simulation Centre (SMSC).** About the SMSC. Available at: http://www.nsh.nsw.gov.au/services/SMSC/. Accessed September 21, 2005.
24. **Cregan P, Watterson L.** High stakes assessment using simulation—an Australian experience. *Stud Health Technol Inform.* 2005;111:99–104.
25. **US Food and Drug Administration, Department of Health and Human Services, Center for Devices and Radiological Health.** FDA's human factors program—promoting safety in medical device use. Available at: http://www.fda.gov/cdrh/humanfactors/whatis.html. Accessed September 21, 2005.
26. **Grantcharov TP, Kristiansen VB, Bendix J, Bardram L, Rosenberg J, Funch-Jensen P.** Randomized clinical trial of virtual reality simulation for laparoscopic skills training. *Br J Surg.* 2004;91:146–150.
27. **Seymour NE, Gallagher AG, Roman SA, *et al.*** Virtual reality training improves operating room performance: results of a randomized, double-blinded study. *Ann Surg*. 2002;236:458–463; discussion 463–464.
28. **Gallagher AG, Cates CU.** Approval of virtual reality training for carotid stenting: what this means for procedural-based medicine. *JAMA*. 2004;292:3024–3026.
29. **Keselman A, Patel VL, Johnson TR, Zhang J.** Institutional decision-making to select patient care devices: identifying venues to promote patient safety. *J Biomed Inform*. 2003;36:31–44.
30. **Cooper JB.** The role of simulation in patient safety. In: Dunn WF, ed. *Simulators in Critical Care and Beyond.* 1st ed. Des Plaines, IL: Society of Critical Care Medicine; 2004:20–24.
31. **Lin L, Vicente KJ, Doyle DJ.** Patient safety, potential adverse drug events, and medical device design: a human factors engineering approach. *J Biomed Inform.* 2001; 34:274–284.
32. **Knickerbocker GG.** The evaluation of resuscitation and critical care equipment: a user's quality assurance service. *Crit Care Med.* 1981;9:401–402.
33. **Zhang J, Johnson TR, Patel VL, Paige DL, Kubose T.** Using usability heuristics to evaluate patient safety of medical devices. *J Biomed Inform.* 2003;36:23–30.
34. **DeVita MA, Schaefer J, Lutz J, Dongilli T, Wang H.** Improving medical crisis team performance. *Crit Care Med*. 2004;32:S61–S65.
35. **Berge JA, Gramstad L, Jensen O.** A training simulator for detecting equipment failure in the anaesthetic machine. *Eur J Anaesthesiol.* 1993;10:19–24.