Chapter 10
Systems Design, Modeling, and Simulation in Medicine

Hannes Prescher, Allan J. Hamilton and Jerzy W. Rozenblit

Abstract Health care is changing at a very rapid pace. So does its attendant complexity and ever increasing reliance on high technology support. Technical medicine, where sophisticated, technology-based methods are used in education of healthcare professionals and in treatment of patients, is becoming a recognized discipline. Such methods require a new generation of engineers, scientists, systems designers, and physicians to integrate medical and technical domains. With this in mind, this chapter provides an overview of modeling and simulation technologies as applied to healthcare. A historical perspective is given followed by the discussion of how simulation helps in gaining professional competency and how it improves healthcare outcomes. Systems for support of medical training and clinical practice are discussed from both engineering and clinical perspectives. Challenges and opportunities for further development of complex simulation-based medical trainers are presented as well.

Keywords Future developments in medical simulation · History of simulation-based medical education · Simulation for clinical training · Simulation for healthcare · Simulation to evaluate healthcare outcomes · Simulation to improve healthcare outcomes · Simulation-based medical education

10.1 Introduction

Modeling and Simulation (M&S) is a mature scientific and engineering discipline, where rigorous, theory-based foundations (Zeigler 1976) gained considerable footing. The field spans a broad spectrum of contexts, e.g., mathematics, natural systems in physics (computational physics), astrophysics, chemistry and biology, economics, psychology, social science, engineering, and now, healthcare. In the last

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decade or so, we have witnessed burgeoning interest in and demand for simulation-based education and training in healthcare fields (Rozenblit and Sametinger 2015). The motivation and rationale are clear: through the use of simulation in medical training, a safer patient experience will result by preventing medical errors and by improving outcomes. The benefits of such an approach are manifold: (a) healthcare providers can practice procedures, techniques and responses to various scenarios without any risk to patients. Such exercises are infinitely repeatable, (b) training and education can occur in true-to-life environments, with facilities and technology identical to those used in various medical settings, (c) all learners—expert physicians to high school students—can benefit from simulated experiences, and (d) training can support the development of a wide variety of skills without the risk to patients and sacrifice of animals.

In this chapter, we give an overview of the history and current uses of simulation in healthcare. We also address the methodological challenges for development of techniques, validation, and design of features that can leverage from the rigorous science of modeling.

10.2 History of Simulation-Based Medical Education (SBME) and Its Current Use in Undergraduate Medical Education (UME)

The use of simulation in medical education traces its roots to the origins of modern medicine. In the 17th century, mannequins, referred to at the time as phantoms, were used to teach obstetrical skills. Cadavers have long been used along with clay and wax models to teach human anatomy (Owen 2012). Several developments in the middle of the 20th century, both technological and ideological, transformed medical simulation into its current form (Bradley 2006).

10.2.1 Simulation Environments

The first was the technological improvement of part-task trainers. In 1960, Asmund Laerdal launched “Resusci-Anne,” a part-task trainer for teaching cardiopulmonary resuscitation (CPR) to emergency medical technicians (Cooper and Taqueti 2004). The trainer revolutionized resuscitation training through widespread availability of a low-cost, effective training model (Lind 2007; Grenvik and Schaefer 2004). Other, more technologically advanced part-task trainers followed (Issenberg 2005). The most notable of these was the Harvey mannequin, a cardiopulmonary patient simulator launched in 1968 at the University of Miami that was designed to mimic the basic cardiac functions of the human body (Gordon 1974; Gordon et al. 1980). Using a series of cams and levers to create heart movement and a 4-track tape recording for sound, the trainer allowed students to practice cardiac auscultation skills. In so doing, it became the first trainer to provide a standardized method of testing bedside cardiovascular examination skills (Cooper and Taqueti 2004).

The second development was the introduction in the late 1960s of Sim One, the first computer-driven high-fidelity patient simulator capable of reproducing physiological functions of the entire patient (Abrahamson et al. 1969, 2004). The mannequin was controlled by a hybrid digital and analog computer and was designed for anesthesiologists to practice endotracheal intubation. However, Sim One failed to achieve acceptance as a training model, due in part to its divergence from the widely accepted apprenticeship model of medical education at the time (Bradley 2006). Advances in the 1980s of mathematical models of human physiology along with marked acceleration in computing power led to the development of the high-fidelity patient simulators widely used today (Owen 2012).

Building on the concept of screen-based simulators capable of running on a desktop computer, a new human patient simulator, the Comprehensive Anesthesia Simulation Environment (CASE), was designed at Stanford University and combined commercially available waveform generators on a desktop computer with a commercially available mannequin (Cooper and Taqueti 2004; Gaba and DeAnda 1988). This mannequin, whose vital signs could be adjusted to create different clinical events, was placed in a real operating room and was used with the express intent to improve patient safety under anesthesia through team-based training (Gaba et al. 2001). A training curriculum was designed based on the aviation model of crew resource management and thus emerged a program of performance assessment of both technical and behavioral skills in medical education (Grenvik and Schaefer 2004).

The third and most significant development was the movement in the late 20th century of medical education reform (Bradley 2006). For over a century, the undergraduate medical curriculum rested primarily on intense didactic learning coupled with an apprenticeship model of clinical observation. This led to information overload at the expense of learning clinical and team-based skills and produced medical students that were ill equipped to face the demands of an increasingly complex healthcare system (General Medical Council 1993; Cartwright et al. 2005; Feher et al. 1991). At the same time, a landmark Institute of Medicine report *To Err is Human* exposed institutional deficiencies in patient safety and created an ethical imperative to promote the training of complex technical and behavioral skills in a setting that does not compromise patient care (Kohn et al. 2002; Ziv et al. 2003, 2005). These forces combined to promote the widespread adoption of SBME.

The last decade has seen advances in simulation technologies that continue to improve the fidelity of simulation environments (Bradley 2006; Cooper and Taqueti 2004). Today, the scope of medical simulation modalities available ranges from low-tech models used to practice simple physical maneuvers or procedures to realistic computer-driven patient simulators that simulate the anatomy and physiology of real patients and provide learners with an immersive environment in which to practice complex, high-risk clinical situations in a team-based setting.

Screen-based computer simulators have been developed to train and assess clinical decision-making (Schwid et al. 2001; Bonnetain et al. 2010). Complex task trainers including virtual reality simulators provide fully immersive, high-fidelity visual, audio, and touch cues along with actual tools integrated with computers to replicate a clinical setting (Cook et al. 2010). These complex simulators allow students to develop technical skills in ultrasound, bronchoscopy, laparoscopic surgery, arthroscopy, and cardiology (Khanduja et al. 2016; Konge et al. 2011; Beyer-Berjot et al. 2016). Despite the recent advances in simulation technologies, the most common simulation modality used in UME continues to be the standardized patient —actors trained to role-play patients for training history taking, physical examination and communication skills (Keifenheim et al. 2015).

Standardized patients have played an integral part in the most established simulation exercise in UME, namely the Objective Structured Clinical Examination (OSCE) (Newble 2004). First described in 1979, the OSCE was designed to assess the clinical competency of medical students by using clinical scenarios with patient actors to test communication and professionalism, history taking, physical examination, and clinical reasoning skills (Harden and Gleeson 1979). These simulated patient encounters have become a required part of the United States Medical Licensing Examination (USMLE) and a strong emphasis is therefore placed on practicing these encounters. While standardized patients are useful in learning basic clinical skills, they do not challenge the learners to train in the types of interdisciplinary teams required to provide efficient care coordination (Patricio et al. 2013). They also do not allow learners to perform invasive procedures and often fail to provide accurate diagnostic cues.

Other simulation modalities have gained appeal as their utility has become clear. In a survey conducted by the Association of American Medical Colleges (AAMC) in 2011 on the use of medical simulation in medical education, 95% of respondents reported using full-scale mannequins, while 93% reported using partial task trainers to train students in clinical skills, clinical medicine and physical diagnosis (Passiment et al. 2011). Using the six core competencies set by the Accreditation Council for Graduate Medical Education (ACGME) of medical knowledge, patient care, interpersonal communication skills, professionalism, practice-based learning, and system-based practice—competencies that undergraduate medical students are expected to satisfy—86% of respondents reported using some form of simulation to train students in these competencies. However, only 46% of this training was done in multidisciplinary, interprofessional teams (Cook et al. 2010). Likewise, there was large inconsistency in the types of partial task trainers used with most medical schools only providing basic trainers for suturing, IV access, and airway management.

10.2.2 University Education

Undergraduate SBME is supported by a strong theoretical foundation. Proponents of SBME emphasize the ability for repetitive practice of procedural skills in a safe, controlled environment, and the ability to personalize the training to the needs of individual learners and capture clinical variation to standardize medical training (Moorthy et al. 2005). It provides the opportunity to give immediate feedback to learners, and creates an environment for competency-based mastery-learning based on defined outcomes (Deutsch et al. 2016). A systematic review and meta-analysis of 609 studies was conducted to assess the effectiveness of technology-enhanced simulation for health professions education (Cook et al. 2012). It revealed that, in comparison with no intervention, technology-enhanced simulation is associated with large effects for outcomes of knowledge, skills, and behaviors and moderate effects for patient-related outcomes. When compared to other instructional methods (i.e., lectures, small group discussions), technology-enhanced simulation was associated with small to moderate positive effects on learning outcomes.

The authors noted significant inconsistencies in effect size between studies but were able to isolate several components of simulation interventions that were consistently associated with significantly higher outcomes. Higher feedback and learning time, group work and lower cognitive load all contributed to higher effect size in simulation versus the comparison intervention (Cook et al. 2013a). Similarly, interventions using a mastery-learning model that requires learners to achieve a benchmark of skills before proceeding to higher level exercises were associated with significantly better outcomes, as were those with curricular integration (Cook et al. 2011; McGaghie et al. 2011a, b).

These studies suggest that the merits of simulation may vary for different educational objectives. Designing undergraduate medical curricula to align educational objectives with instructional modalities, therefore, will be critical to maximize the effectiveness of the intervention and justify the financial investment. The literature does provide empirical evidence for the importance of creating an integrated, longitudinal simulation program that is aligned with physiology, pathology and pharmacology topics learned in the didactic setting (Gorman et al. 2015; Gordon et al. 2006; Rosen et al. 2009). Using this model, SBME provides an opportunity for active, team-based collaborative learning that promotes transfer of basic clinical knowledge to treat real clinical problems. Simulated patient encounters, whether in a virtual reality environment with avatars or using a computerized high-fidelity mannequin should challenge learners to apply their knowledge in a simulated clinical setting with the type of emotional engagement and stress encountered in the real clinical setting (Hunt et al. 2007).

As medical schools reshape their curricula to incorporate simulation training, it will be important to continue to study the impact of elements of instructional design (i.e., learning time, repetition, feedback) versus the effect of modality (i.e., simulation tools) on learning outcomes to maximize the efficiency of resource utilization. Figure 10.1 depicts the key stakeholders in healthcare simulation and summarizes its benefits.

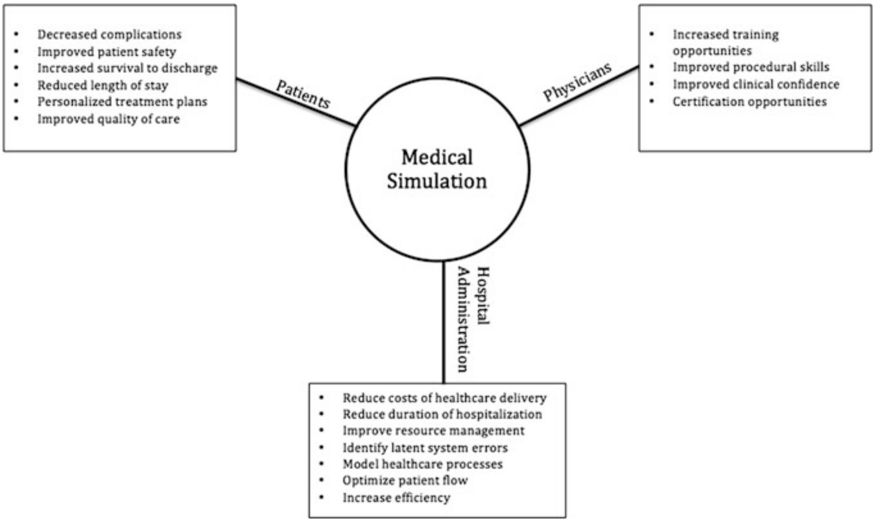

Fig. 10.1 Healthcare simulation stakeholders and benefits

10.3 Use of Simulation for Clinical Training and Acquisition of Procedural Competency

The traditional model for procedural training in medicine was established by William S. Halsted in 1890 when he transformed graduate medical education by creating the first surgical residency program at John Hopkins University (Kotsis and Chung 2013). Based on the principle of graduated responsibility, Halsted used the adage "see one, do one, teach one" as a pedagogical framework for acquiring procedural competency. This system of learning remained unchanged for over a century. Reductions in resident duty hours instituted by the Accreditation Council for Graduate Medical Education (ACGME) in 2003 along with a national movement to improve patient safety finally led to a paradigm shift (Rodriguez-Paz et al. 2009). At the same time, simulation-based medical education (SBME) emerged as an alternative training model that enabled learners to safely acquire procedural competency without causing harm to patients. A new pedagogical framework was proposed that integrates both the cognitive and psychomotor phases of learning with deliberate practice and emphasizes formative and summative assessment with defined benchmarks for skill acquisition (Sawyer et al. 2015).

Using simulation for procedural training has gained acceptance in many graduate medical education programs. The ACGME requires simulation-based training opportunities for trainees in anesthesiology, general surgery and internal medicine and accepts it as a method of training, assessment and evaluation in emergency medicine, ophthalmology, otolaryngology, radiology, and urology (Deutsch et al. 2016). The American Board of Surgery requires successful completion of competency-based skills training in simulation to achieve eligibility for board certification and the American Board of Anesthesiology and the American Board of Internal Medicine permit the use of simulation for maintenance of certification in required procedural skills (Deutsch et al. 2016).

As acceptance of simulation-based training has grown within an increasingly complex healthcare system, a new generation of engineers, scientists, systems designers and physicians has been challenged to develop new technologically complex training models to replicate partial and complete organ systems for practicing procedural skills. Using a variety of synthetic materials (i.e., plastics, silicones etc.), biomaterials and fluids, bioengineers and clinical researchers have developed a vast collection of life-like, anatomically accurate procedural trainers. Medical trainees now routinely use artificial arms to practice peripheral IV and arterial line placement. Models have been designed to practice, amongst other procedures, endotracheal intubation, cricothyrotomy, lumbar puncture, thoracentesis, thoracostomy as well as central line and urethral catheter placement (Nestel et al. 2011).

Surgery is perhaps the medical specialty most reliant on psychomotor and visuospatial skills and routinely performs procedures that pose significant risks of patient morbidity. This makes it uniquely suited for simulation training and it has been the specialty, along with Anesthesiology, that has been historically most invested in it. Surgical trainees have long used silicone pads to practice basic suturing and knot-tying techniques and various-sized silicone tubing to practice open and microsurgical anastomosis of blood vessels (Badash et al. 2016). In an effort to standardize basic surgical skills training, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) in 2004 launched Fundamentals of Laparoscopic Surgery (FLS), a formal simulation-based education program for teaching the basic skills of laparoscopic surgery (Zendejas et al. 2016). Using a series of manual tasks within a simple box trainer to simulate the surgical working space, learners were able to train in the critical skills of depth perception, spatial orientation, and manual dexterity that form the foundation for safely performing laparoscopic surgery (Scott 2006). The educational program is based on the principles of mastery-learning; trainees are required to complete the series of tasks within validated time and performance benchmarks to prove procedural competency (Schout et al. 2010).

Further technological advances in surgical simulation have seen the emergence of computer-driven computational models of whole organ systems to create virtual reality trainers (Aggarwal et al. 2007). These simulators allow users to interact with a virtual image using a physical interface that is identical to the actual instrument used in the clinical procedure (Deutsch et al. 2016). For instance, in a virtual cholecystectomy, the user holds instruments shaped like a retractor, clip-applier and scissor to manipulate, ligate and cut the appropriate virtual anatomy (Schijven et al. 2005). The simulators provide haptic feedback to learners to give the tactile sensation of actually performing the procedure. They are also sensitive to the forces applied to virtual anatomic structures by the user and can simulate surgical complications such as bleeding. Similar simulators exist for practicing bronchoscopy, arthroscopy, cardiac catheterization and other complex procedures (Gallagher and Cates 2004).

The unique nature of virtual reality trainers lies in their ability to actively engage the learners' senses and provide the most immersive learning experience available (Alaker et al. 2016). Adult learning theory in medicine dictates that multisensory engagement in a learning activity is essential for effective learning and retention of skills (Kneebone 2005; Rutherford-Hemming 2012). The degree of immersion in current virtual reality procedural trainers operates on a spectrum from simple interactive gaming platforms (e.g., mobile and desktop applications) to comprehensive 3D surgical environments. Despite proven effectiveness in facilitating basic surgical skill acquisition, virtual reality technology in medicine remains in its infancy (Larsen et al. 2012). Recent advances in CAD and 3D printing technologies promise to expand our ability to create patient-specific 3D models in a virtual simulation environment to aid surgeons in evaluating and simulating pre-operative treatment options.

As medical education evolves towards a personalized, competency-based training system, the role of assessment will continue to grow (Michelson and Manning 2008). In order to define procedural competency and prove mastery of a skill in a simulated environment, training programs have developed and validated procedure-specific assessment tools. These tools include global rating scales and checklists (Ilgen et al. 2015; Riojas et al. 2011). Other assessment tools, including FLS in surgery training, use objective variables such as task completion time, the quality of a finished product (e.g., accuracy of stitch placement in a suturing task) or procedural errors as measures of proficiency (Feldman et al. 2004). Newer computer-based trainers are able to provide a performance score based on the users' economy of instrument movement and overall efficiency in completing a task (Chang et al. 2016). However, a recent systematic review of validity evidence of commonly used assessment tools reports that the methodological and reporting quality of validity testing is inconsistent and often inadequate (Cook et al. 2013b). If the role of simulation is to continue to grow and influence decisions regarding trainee preparedness, remediation and credentialing, assessment tools will need to be subjected to rigorous validation testing to support the interpretation of scores.

A great body of evidence has emerged over the last decade in simulation research in support of the effectiveness of various simulated learning platforms (Cook et al. 2013a). Studies have shown that deliberate practice in a simulation environment can improve procedural skills compared to traditional methods of training. However, a major challenge in simulation training and a persistent point of contention among clinicians is providing evidence that skills acquired on a simulated model transfer to the clinical setting. For instance, does achieving proficiency in surgical skills in a box trainer translate to acceptable skill levels in the operating room? Studies across specialties using a diverse set of simulation platforms to learn a large variety of procedures have provided evidence that practicing a procedure using a mastery-learning model leads to superior performance of that procedure in a clinical setting (Huang et al. 2016; Brydges et al. 2015; McGaghie et al. 2010). Furthermore, it has been shown that repeated practice of procedural skills facilitates the retention of skills over time (Shewokis et al. 2016; Opoku-Anane et al. 2015; Sant'Ana et al. 2016).

Restrictions in resident duty hours were implemented by the ACGME to improve resident fatigue and burnout and increase patient safety. However, in the process it has also inadvertently decreased the learning opportunities of residents especially in clinical procedures. Increased clinical demands of faculty in a profit-driven healthcare system have also limited the time available for formal instruction and mentorship during patient care. In this setting, SBME offers a viable alternative training model that is congruent with efforts to improve patient safety by providing the opportunity for deliberate practice on procedural simulators without compromising resident duty hours.

10.4 Use of Simulation to Evaluate and Improve Healthcare Outcomes

Healthcare organizations are complex ecosystems composed of integrated networks of human teams supported by technological systems. These organizations are challenged by political, social and economic forces to improve the value of healthcare delivery by providing safer, higher quality care at lower costs (McGinnis et al. 2013). Complicating this effort are inefficiencies in the *individual*, *team* and *systemic* processes that contribute to the delivery of care. Research has consistently shown that failures in healthcare processes are multi-factorial in nature and occur because of unpredictable combinations of component failures (Kohn et al. 2002; Marshall et al. 2016). Simulation can be used as (a) dynamic prototyping platforms to better understand how *individual*, *team* and *system processes* interact, (b) methodology to assess collective performance to optimize healthcare outcomes (Deutsch et al. 2016; Isern and Moreno 2016); and (c) a tool to evaluate human performance factors and the impact of new methods or technologies.

Improving *individual* performance in healthcare organizations has been the main focus of simulation-based medical education (SBME) to date. Careful review of patient safety and quality control management databases revealed that iatrogenic human error in clinical procedures is a common source of patient morbidity and mortality (Kohn et al. 2002; Hripcsak et al. 2003). SBME programs were developed to improve individual performance in common procedural skills. Outcome studies were subsequently designed to assess the impact of the simulation intervention through pre/post analysis of procedural complications, patient survival to discharge and duration of hospitalization (Zendejas et al. 2013; Griswold-Theodorson et al. 2015; McGaghie et al. 2011a, b).

According to the Center for Disease Control (CDC), in 2009 an estimated 18,000 central line-associated bloodstream infections (CLABSIs) occurred among patients hospitalized in intensive care units (ICU) in the United States, each carrying an attributable mortality risk of 12–25% in addition to millions in excess healthcare costs (Centers for Disease Control and Prevention 2011; Klevens et al. 2007). In an effort to reduce the complication rates, a team at Northwestern University developed a simulation-based mastery-learning program for central venous catheter (CVC) placement (Barsuk et al. 2009a). Following the implementation of its simulation-based training program, the team reported an 85% reduction in CLABSIs (Barsuk et al. 2009b). Residents trained in the program experienced fewer complications including fewer needle passes, arterial punctures, catheter adjustments and higher success rates in CVC insertions in the medical ICU compared with traditionally trained residents (Barsuk et al. 2009c). The study was replicated at a second institution, where a 74% reduction in CLABSI rates was reported (Barsuk et al. 2014). The researchers further demonstrated that the improved patient outcomes resulted in significant medical care cost savings with a 7–1 return on investment (Cohen et al. 2010). In a separate study, training of critical care nurses in sterile technique using a simulation-based training program resulted in a reduction in the rate of CLABSIs of 85% in an ICU setting (Gerolemou et al. 2014).

Similar outcomes studies have been conducted in surgical simulation training (Seymour 2008). Training on a virtual reality (VR) simulator has been shown to significantly improve the performance of surgical residents in actual cholecystectomies in the operating room (Ahlberg et al. 2007; Beyer et al. 2011). In addition, residents trained on a VR colonoscopy simulator similarly performed significantly better on real patients and experienced fewer procedural complications than the control group (Park et al. 2007; Sedlack and Kolars 2004; Cohen et al. 2006). Training Ophthalmology residents in a structured surgical curriculum in cataract surgery resulted in a significant reduction in the sentinel complication rate, as defined by posterior lens capsule tear, and vitreous loss during actual surgery, from 7.17 to 3.77% (Rogers et al. 2009). Experiential simulation training in thoracentesis resulted in a decrease from 8.6 to 1.1% in the rate of pneumothorax (Duncan et al. 2009).

Strategic SBME interventions have also been designed to improve the performance of healthcare *teams* in response to evidence that poor communication among team members is a common source of avoidable medical errors. Studies in obstetrics and gynecology have demonstrated that implementation of a hospital-wide multidisciplinary simulation-based teamwork training can significantly decrease the adverse outcomes index (Phipps et al. 2012; Riley et al. 2011). In addition, targeted teamwork training in births complicated by shoulder dystocia decreased birth complication rates of brachial plexus injury and neonatal hypoxic ischemic encephalopathy and increased the APGAR scores of neonates at 5 min after birth (Draycott et al. 2008).

Simulation-based teamwork training in the actual clinical setting has also been shown to improve early trauma care and increase patient survival in cardiopulmonary resuscitation codes (Morey et al. 2002; Steinemann et al. 2011; Capella et al. 2010). Human factors experts argue that conducting simulations in the actual unit where patient care is delivered probes for overt and latent problems in the way the clinical environment influences human performance (Deutsch et al. 2016).

This can therefore be a particularly useful method to identify *system* factors that can impact patient outcomes. However, full-scale simulations in actual clinical spaces can be challenging on several levels and can be disruptive to patient.

Simulation methodology can also be applied at the system level to improve unit efficiency. Dynamic simulation modeling (DSM) is an alternative simulation platform that can be used to create computer-based representations of real healthcare processes to explore their interaction in a modeled clinical setting. The individual healthcare processes are variables that can be adjusted to see how particular changes affect the system outcomes predicted by the model (Deutsch et al. 2016; Isern and Moreno 2016; Pennathur et al. 2010). A common DSM method used in modeling healthcare systems is discrete event simulation (DES), which models the operation of a system as a discrete sequence of events in time. It is of particular value in studying resource management in a clinical setting to achieve a desired outcome, for instance to reduce the wait time for patients in the emergency room (Day et al. 2012). In this scenario, a DES model was constructed using as adjustable time-sensitive variables, triage and registration time, availability of ED beds, rooms, labs and radiology services, nurses and physicians. The model predicted that wait time was most dependent on the availability of ED beds, nurses, physicians and labs and radiology resources. Researchers subsequently adjusted these variables to identify the time-limiting resource and determined that increasing physician and mid-lever provider coverage at triage significantly reduced ED length of stay. Shorter length of stay has been directly associated with reduction in in-hospital complications and improved patient outcomes (Rotter et al. 2012).

Similar computational models have been used by healthcare managers and administrators to estimate bed capacity in an intensive care unit (ICU) setting (Zhu et al. 2012; Ferraro et al. 2015), predict staffing needs based on patient mix, patient acuity and resource costs (DeRienzo et al. 2016; Hoot et al. 2008) and optimize patient care in the cardiac ICU (Day et al. 2015). Optimizing the use of available resources allows for the delivery of more efficient, higher quality care at a lower cost.

Model parameters can be captured from a rapidly growing dataset of clinical information that includes electronic health records (EHRs), clinical research data and quality improvement data (Isern and Moreno 2016). Advances in computing have led in the past decade to the emergence of so-called "big data" as a tool for understanding health system dynamics and informing decisions about patient care delivery. Such data analysis has been defined in the bioinformatics literature as "information assets characterized by such a high *volume*, *velocity*, and *variety* as to require specific technological and analytical methods for its transformation into value" (De Mauro et al. 2015). DSM can function as the analytical method to evaluate and analyze large database to aid in the interpretation of its clinical significance and test hypotheses about the impact on patient outcomes of potential healthcare interventions (Huang et al. 2015).

A team of health economists, software engineers, data miners, business analysts, and clinicians demonstrated this system design process by integrating health informatics, activity-based costing and dynamic simulation modeling to create Network Tools for Intervention Modeling with Intelligent Simulation (NETIMIS) (Johnson et al. 2016). This tool functions as a DES model that captures the flow of individual entities (patients) through discrete events in a simulated process. The utility of the tool was demonstrated through a simulation of potential care pathways of patients presenting to the ED with sepsis. Potential care pathways included admission to critical care, admission to the ward, and discharge home, among others. The model was designed to assess the potential cost savings and reduction in adverse patient outcomes with implementation of a hypothetical point-of care testing device for early detection of severe sepsis. The sensitivity of the device in detecting early symptoms of sepsis determined initiation of respective care pathways. Patient data in the model was derived from EHRs and provided an accurate clinical model of symptoms exhibited by patients with sepsis. The tool was pre-populated with reference sets of activity-based costs so that simulated actions by healthcare providers within the model reflect current health economic cost models. The NETIMIS model demonstrates the ability of computer simulations to assess interventions within modeled clinical environments to evaluate and predict healthcare outcomes.

On a population-based level, DSM has been used synergistically with informatics to analyze chronic diseases such as diabetes, HIV/AIDS, cancer and heart disease to identify patient factors that predict their progression (Gallagher and Cates 2004; Gaba 2004). Data derived from such models have then been applied to inform decisions for patient-specific treatments (Cooper et al. 2002). For instance, physicians have used simulation models to compare various treatment options in adjuvant breast cancer therapy based on predicted outcomes and cost (Isern and Moreno 2016). Computational modeling has also found applications in predictive analytics; researchers were able to use a patient-specific DSM of epileptogenic cortexes in patients suffering from intractable, medically refractory epilepsy to determine which patients are likely to benefit from surgery (Sinha et al. 2016).

Patients interact with individual healthcare providers and healthcare teams in a rapidly changing and increasingly complex care delivery system. New knowledge, available treatments, equipment, technology, and business models constantly redefine the standard of care and challenge the optimization of care delivery. Creating an integrated, dynamic simulation architecture can help healthcare stakeholders analyze the intrinsic complexity and diversity of healthcare delivery systems and develop solutions for improving the performance of *individual*, *team-based* and *system* processes to ultimately optimize healthcare outcomes. The summary of outcomes categorized with respect to individual, team training, and systems optimization is shown in Fig. 10.2.

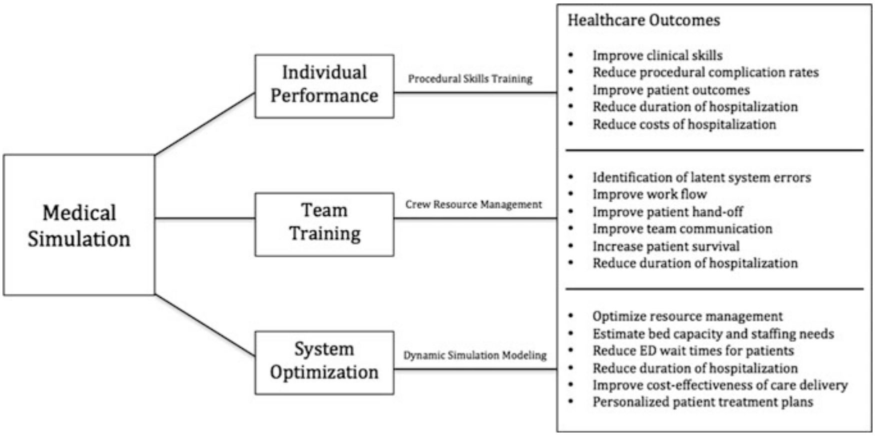

Fig. 10.2 Summary of healthcare outcomes

10.5 Design, Modeling Challenges and Opportunities

From a methodological perspective, simulation models in medicine can be classified as *simulation scenarios* and *simulation systems* (Rozenblit and Sametinger 2015). A scenario is a set of steps and actions that replicate a specific medical procedure which may be as simple as phlebotomy (making a puncture in a vain with a needle) or as complex as multiple-organ failure emergency treatment. As described above, in such cases, various actions taken by the trainees are carried out in a simulated setting, by either using actors as patients or computer-based systems and devices that emulate human anatomy and physiology. In the *systems* category, we employ models which are part of the training scenarios, and ones that are embedded in various medical devices and equipment used in actual clinical practice.

Simulation-based training cycle can be abstractly represented as shown in Fig. 10.3. Trainees are students, fellows, residents, EMS personnel, etc., who use various medical implements to carry out a training exercise/procedure. As discussed in Sects. 2–4, they can practice on low-end trainers or highly complex simulators. The low-end trainers *do not* incorporate in them the process and steps to be followed in order to perform a certain procedure—in this case, the step are typically quite simple. They are described by the supervisor or simply given through a description of the task to be completed. The high-end trainers “drive and guide” the users through a series of procedural steps. Such simulators provide feedback on how well users perform. This is done through the set of metrics. The training cycle continues until a satisfactory performance level has been achieved.

Either group, that is simulation-based training process models, and simulation systems, presents different challenges for validation, assurance of robustness, and security but also a set of exciting opportunities for leveraging from high technology in simulation-based training.

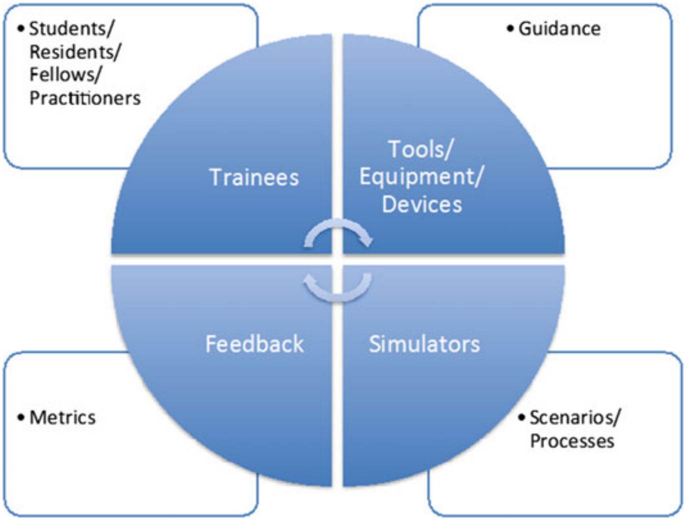

Fig. 10.3 A conceptual, simulation-based training cycle

Such training requires not only the requisite physical equipment that is used in medical procedures, but also *correct/valid* models that are the foundation for emulating the symptoms and responses to "virtual treatment". For instance, in a scenario of anaphylactic shock—a life-threatening allergic response—the model should present typical symptoms such as swelling, a weak and rapid pulse, lowered blood pressure, skin reactions, etc. The treatment by injection of epinephrine and its outcome should be reflected by the reversal of such symptoms. This is key to proper understanding of the case and learning how to appropriately treat it (Rozenblit and Sametinger 2015).

Therefore, proper validation and verification (i.e., assurance that the simulator faithfully executes the underlying models) of the trainers must be carried out prior to their deployment. In addition, as trainers become more and more sophisticated and incorporate discrete, continuous, and hybrid dynamic models, mechatronic (i.e., electronic and mechanical) devices, immersive, virtual reality environments, and very complex control software, integration of all such subsystems are non-trivial. In essence, despite the growth of new technologies for hardware and software design, networked computation, sensing, and control, the following challenges remain:

- How to tackle the complexity of the systems, which requires long design cycles, verification, and certification (if such is needed).
- How to develop unifying formalisms for specification and exploration of design options of such complex systems before that are physically built and deployed.
- How to ensure flexibility in modification and re-configuration of training systems.
- How to ensure robustness and security of medical simulation systems and devices.

In regard to the last concern, embedding models, or more specifically their realizations in the form of computational processes encoded as software and hardware, in actual medical devices presents an extraordinary set of safety, security, and reliability challenges. Such models effectively "run" complex implantable devices and are a key component in medical imaging or robotic surgeries. Consider, for example, computer assisted surgery (CAS). CAS enhances the capabilities of surgeons performing surgery (for instance, using the DaVinci surgical robot (Gettman et al. 2004) but it requires models of ultimate reliability and robustness. Indeed, it is easy to imagine the dire consequences of improper translation of the surgeon's hand's movements into a maneuver of the DaVinci's robotic arm's end-effector. This highlights the urgent need for research into assuring absolute robustness of such life-critical computing systems.

Additionally, given the recent exponential rise in cybersecurity threats and attack, security measures should be implemented to guarantee confidentiality, integrity, and availability of simulation systems. In medical simulators, confidential information includes the performance of residents during training. The integrity of information becomes critical when medical reasoning is based on this information. In simulation, modified parameters may lead to discrepancies between the simulated and the real world, thus, yielding to medical errors and declined outcomes in real patient scenarios later on (Sametinger and Rozenblit 2016).

In training scenarios with simulators there is no direct impact on real patients. However, maliciously modified simulators can have various negative consequences. For example, surgery residents may automate surgical skills based on parameters that do not exist in the real world, resulting in a negative training effect and increasing the potential for error and negative outcomes. Besides training, simulation can be used in surgery for pre-surgical planning, and for guiding or performing surgical interventions. Therefore, it is critical that the integrity and security of such models are ensured as any compromise may result in negative outcomes.

Opportunities for further research in simulation modeling for healthcare

The challenges listed above have already spurred research in realms such as space and aeronautics, industrial plants, or autonomous vehicles. Further application of the theory-based methods and techniques from the following (related) fields, to medical simulation is envisioned.

1. Design and modeling for high-autonomy systems: the intent here is to provide trainees as much assistance as possible throughout the training process so that sophisticated trainers can take on the role of a "master" in the classic "master/apprentice" model. To design such systems, modelers must integrate sensing and control features that monitor and adapt to users' performance in order to provide the "right" kind of guidance, that it assistance that is functionally correct and measured in a manner that leads to better outcomes. Design of such highly autonomous systems will clearly have features offered by artificial intelligence and machine learning.

2. Artificial Intelligence: due to the advances in computational techniques and underlying HW/SW technologies, AI is currently experiencing strong resurgence. Speech recognition, reasoning, natural language processing, planning, fuzzy logic, and heuristics all offer an exiting potential for building high-end medical simulators.

Machine Learning (ML): as pointed out in Sect. 1.3, big data, predictive analytics is already being used extensively for modeling in healthcare. In the procedural, training context, ML is envisioned as a tool to provide a user-tailored training experience, where adaptation to individual trainees will take place based on their initial skill level and degree of progress they make throughout the learning process.

10.6 Future Developments in Medical Simulation

In 2004, David M. Gaba, one of the pioneers of simulation in healthcare at Stanford University, provided a future vision of simulation in which he proposes "full integration of its applications into the routine structures and practices of healthcare" (Gaba 2004). To date, medical education continues to operate largely under an apprenticeship model of training, originally developed by Halstead in the 1920s (Evans and Schenarts 2016). Over the last decade, simulation has gained wide acceptance in graduate medical education (GME) programs as a way to train and certify physicians in particularly in procedural skills. However, the full integration of simulation into clinical education, training, and outcomes assessment has yet to occur.

One of the challenges of embracing simulation as a robust educational methodology is that its benefits only emerge after long-term implementation. Improvements in patient safety and reductions in healthcare spending, long held as the hallmark benefits of simulation training, are difficult to measure, especially when one attempts to translate those benefits into hard financial data. Without an irrefutable clinical or financial evidence base, most healthcare organizations remain reluctant to make large and significant institutional investment in simulation. This is all the more difficult as new technologies in medical simulation, like immersive virtual reality and holographic displays, for example, can be very expensive purchases until they gain a wider commercial market. Moreover, academic Medicine, like many institutional cultures can often be resistant to change. Many physicians continue to argue that training in a simulation environment cannot achieve the degree of immersion provided by actual patient care. However, several market forces are likely to force a change in the medical education model and lead to further expansion of simulation use in the future.

Reducing the cost of healthcare is likely to be the primary driving force for the wider expansion of simulation use. Medical errors and poor patient outcomes continue to be a primary cost burden for healthcare organizations in the form of wasted resources and increased length of hospital stays. Administrators and policymakers look to simulation to provide a systematic training to educate, train and assess personnel, teams and systems to provide safe clinical care. In order to improve patient safety, risk managers, insurers, and government and non-government regulatory and accrediting bodies are likely to demand a robust simulation architecture be in place (Evans and Schenarts 2016). Furthermore, reductions in work hours have led to unbalanced clinical exposure and experiences among training healthcare trainees. Simulation provides a systematic and reliable way for healthcare organizations to standardize clinical training and to train providers to specific benchmarks of competency.

As changes are made to training curricula to expand use of simulation, new informatics technology support systems must be established. Learner management systems (LMS) are playing an increasing role in tracking the progress of learners towards competency-based training goals. Tracking a learner's performance both in the simulation lab as well as the clinical setting allows for more efficient integration and smarter training. It provides educators with critical information of how best to tailor a learner's training curriculum to address specific deficiencies in clinical performance. Linking simulation training to known clinical weaknesses with high potential for error maximizes the clinical impact of the training. Using clinical performance data will inform training and allow healthcare providers to continuously refine their skills through simulation tools that will be a natural extension of the real clinical environment.

New technological support systems will facilitate the process of integration. In order to make training more realistic, use of hybrid simulators that combine standardized patients (SP) with virtual reality adjuncts are likely to grow. For example, an SP may wear an ultrasoundable skin model to enhance the diagnostic learning experience. Similarly, a simulated trauma patient may wear a synthetic chest tube model to allow learners to perform invasive procedures when clinically indicated. These VR adjuncts are flexible and adjustable allowing educators to modify the learning experience and simulate the full breadth of actual clinical encounters.

Virtual reality training environments, as a technological domain, are likely to have greater applications in simulation training (Badash et al. 2015). The degree of immersion (i.e., the sense of realism experienced by learners involved in a training task or setting) in the virtual clinical environment will steadily grow. At some time in the future, learners will be able to log into an interactive virtual environment that is a replica of the actual clinical environment. As avatars, they will interact with virtual patients and other providers as they would in the real world. Improvements in haptics technologies will eventually allow them to perform physical exams and procedural interventions on virtual patients.

Surgical simulators have made the greatest advances in this area. Using medical imaging and computer-aided design technologies, researchers have developed patient-specific VR simulators to allow surgeons to plan and practice complex procedures in a virtual environment (Vakharia et al. 2016; Makiyama et al. 2012). Moreover, 3D rapid prototyping has allowed researchers to produce accurate renditions of patient-specific anatomic variations (Endo et al. 2014). In neurosurgery, 3D printed models of patient-specific aneurysms have allowed surgeons to plan the trajectory of approach and to test different aneurysm clips for size and shape

(Kimura et al. 2009; Ryan et al. 2016). As these technologies continue to grow and the interface between the virtual and the real world continues to dissolve, surgeons will be able to harness the benefits to become more efficient and skillful in the operating room. Improving the realism of these virtual training environments will also revolutionize licensing examinations for board certification. Instead of verbally describing the steps of a surgical procedure during oral board proceedings, surgeons will be adjudged by their actual performance on virtual trainers. The ability of VR trainers to provide a standardized assessment makes this particularly effective. This type of assessment method will approach the systematic use of simulation in the aviation industry, where flight simulators have been used extensively for the purpose of certification.

In an effort to improve efficiency and reduce costs in healthcare delivery, healthcare organizations are likely to expand the use of computational modeling. To make the best use of available resources, complex simulation models will be applied to every healthcare process. Hospital inventory, staffing, scheduling, and delivery of services will be determined by models that seek to optimize patient care and satisfaction while limiting costs. Furthermore, every proposed change to the system will undergo extensive testing in a simulated environment prior to implementation. Advances in computational speed and growth of available databases will allow system engineers to construct more accurate and complete models of healthcare organizations. This will allow researchers to better isolate the impact of individual components on the operation or behavior of the system and implement changes accordingly to increase overall efficiency.

Finally, the field of health economics will make greater use of computational models to improve the delivery of individualized healthcare in clinical practice. Simulations of disease progression based on patient's individual disease states compared to a large cohort of similar patients will be used routinely to drive clinical decisions regarding care (Zafari et al. 2016). Simulation models will be used to evaluate the potential value of new products or services, as for instance telemonitoring for heart failure patients (Kolominsky-Rabas et al. 2016) or team-based care for hypertension (Dehmer et al. 2016). Prospective health outcomes will be modeled against the economic impact to create a smarter, more efficient way to deliver high-quality healthcare.

The use of simulation as a means of training healthcare providers and improving the efficiency of healthcare organizations has a big potential to grow. Progress over the last two decades has shown the great potential of simulation but more systematic, long-term implementation must be achieved to realize its true benefits—that is to create a sustainable healthcare system that produces safer, higher quality care at lower costs.

Review Questions

1. Who are the key stakeholders in medical, simulation-based training?
2. How does simulation improve professional competency?

3. How does simulation improve healthcare outcomes?
4. What are the categories of models and simulators used in healthcare training?
5. What are the technical challenges and impediments that modelers face in designing complex healthcare simulators.

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