Medical Simulation

the new tool for training and skill assessment

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ABSTRACT Medical simulation is a new method to facilitate skill training and assessment. Simulation has achieved a high degree of sophistication in aviation and other fields. However, the complexity of health care, the numerous stakeholders, and the lack of central control of medical education have been barriers to the development and broad implementation of medical simulation. Acceptance by the medical community is growing, with the publication of scientific validation studies, the development of economic models and funding, and the integration of simulation into existing curricula and training programs. The major forces for implementing simulation will most likely come from the medical device industry and from institutions with mandates to improve the quality of health care and enhance patient safety. Certification boards are expected to increase their utilization of simulation technology to objectively assess proficiency of skills relevant to physicians and the health care system. Medical simulation has made the transition from an experimental technology to the clinical world, and the next five to 10 years may be viewed as the golden age of medical simulation.

What is medical simulation? Is it a relatively inexpensive computer game that allows you to practice placing a stent in a coronary artery without getting penalty points? Or is it like a multi-million-dollar flight simulator, a tool that recreates the medical procedure room in full detail and function-

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ality? Medical simulation can mimic both examples. It is a broad term that encompasses a variety of technologies that enable medical personnel to practice and improve their performance in real life. Medical simulation takes many forms, since the process of medical care can involve many tasks that require simple to complex cognitive and technical actions, with predictable and unpredictable consequences.

As interventional cardiologists, we see medical simulation as a means to teach and assess procedure skills under realistic settings that provide the learners a safe and educational experience in all facets of patient care, including pre-procedure evaluation, decision-making, visual and motor performance of multiple steps involved in performing a procedure, and the recognition and management of complications. The patient, medical imaging, medical devices, medications, and flow of events must all be realistic enough that the process truly replaces the bulk of initial learning using real patients. A final key element of a sophisticated medical simulation is authoritative and timely feedback to the learner, so that the lessons learned are correct and the reinforcement is provided to hasten achievement of clinical proficiency (for a review of medical simulation, see Gaba 2004).

Medical simulation is a major innovation; its anticipated future impact on health care can now be described as profound. The tipping point has occurred: most participants in the complex medical culture have directly or indirectly endorsed simulation, have started to useit, or are actively studying how they can benefit from simulation. Some of the more notable trends and specific milestones that have been achieved in the United States include the development of numerous simulators, the FDA's approval of simulation training as part of a new medical device approval, and the widespread use by major medical device companies of medical simulation as part of both initial clinical trials and the commercial rollout of new products. Finally, board certification organizations are actively evaluating medical simulation as a tool to assess proficiency in procedure performance.

The rapidity and extent of implementation of simulation in the medical culture remains difficult to predict. The interested parties in medical simulation are each wrestling with understanding the diverse technology that is part of simulation, the business models and financial aspects of implementation, and how medical simulation fits into a huge and complex medical education and regulatory environment. Medical schools, device manufactures, professional societies, regulatory agencies, managed care, Medicare, insurers, hospitals, and medical board examiners all are players in this rolling implementation of simulation as a new methodology and an agent for culture change.

Three major factors in modern medicine have propelled simulation into the agendas of all major health care parties: the public and institutional demand to improve the quality and safety of patient care; the crisis in medical education; and the acceleration of innovation in care with new knowledge, diagnostics, devices, and drugs that providers must master and apply to a patient population who may hear about a new treatment before the practicing physician.

This review will present the rationales for a new paradigm in training and testing, some specific applications of medical simulation, a survey of the growing number of validation studies, and a prediction about future opportunities and challenges for simulation.

Rationales

Quality of Care and Patient Safety

Medical care in the United States has steadily and rapidly improved, but the gaps in quality of care, the mistakes and errors, and the harm to some patients via poorly performing individuals, teams, and systems are all now acknowledged. Imperfections will always exist, but medicine has a clear mandate to improve as articulated in the major analyses published by the Institute of Medicine, *To Err Is Human: Building a Safer Health System* and *Crossing the Quality Chasm* (IOM 2000, 2001). Ultimately the providers, how they are trained, and how their performance is assessed emerge as central agents to improve medicine. *To Err Is Human* presents simulation-based training as one tool to improve quality of care and reduce errors.

The Death of the Traditional Apprenticeship Model

Medical education is in crisis, with organized medical education undergoing a major transformation in how students and established providers are trained and how the intended results of training—proficiency and competency—are measured. Embedding trainees in a variety of care settings has been a fundamental mechanism of medical training. Some refer to this as the Halsted model; medical culture refers to it as "See one, do one, teach one." Clinical care and training occur simultaneously, with supervision and mentoring provided by faculty from both academic medical centers and medical practices.

This apprentice model has been successful in the past, but it is now in need of major revision. The inherent problems of this model are important to understand in order to see the attraction of medical simulation. First, training on patients is contrary to prioritization of patient safety, but the uncoupling of clinical training from patient care is tenable only if there are alternative means of achieving a minimal level of proficiency. Training on patients is also expensive, since medical care is expensive. Finally, trainees' work hours have been limited by Accreditation Council for Graduate Medical Education mandates to prevent sleep-deprived house officers from being overworked and exposing patients to poor care (ACGME 2007). Since the changes in working hours were not accompanied by an increase in the number of years of training, physicians must now be trained more efficiently.

The Move to Proficiency-Based Training

The evaluation of trainees during and at the completion of a stage of their medical career is a critical component of a system to produce and maintain high-quality providers. Good assessment tools must measure actual performance, provide feedback to allow improvement, and be sufficiently practical to be applied to thousands of people at multiple times during their training and their careers. The validation of educational effectiveness and of measurement tools has become an important topic with the emergence of new tools such as medical simulation. The new era of evidence-based education now complements the era of evidence-based medicine. The BEME Collaboration is an organization of individuals and institutions that are committed to the promotion of *b*est *e*vidence *m*edical *e*ducation and that brings expertise together to evaluate these new tools (BEME Collaboration 2006). They have performed a systematic review of simulator features leading to effective learning (Issenberg et al. 2005). The ACGME Outcome Project also provides specific criteria for assessment tools (ACGME 2007). They define the key issues in skills assessment, including its purpose (formative or summative), alignment with specialty-specific training objectives (blueprinting), and standard setting (minimum acceptable versus benchmarking relative to others). Proficiency-based medical education requires tools for training and assessing skills at all levels and has become another factor driving the development and implementation of medical simulation. The requirements for simulation may be quite different when it is used as a summative assessment tool to document performance at a minimal acceptable level or in high-stakes testing such as board certification, versus when it is used during an ACGME training program as a formative tool with blueprinting and as a reliable tool to direct a training program and promote learning.

Acquisition of New and Complex Skills

Innovative therapeutic procedures have resulted in dramatic improvements in the quality of medicine. These procedures frequently involve novel psychomotor and visual-spatial skill sets, using devices with unique operational techniques and new visual-guidance approaches. As Gallagher and Cates (2004) have written: “The skills required for the practice of modern procedure based medicine are frequently so difficult to learn that traditional training is no longer acceptable, and learning on patients is increasingly suboptimal.” The trainees are often experienced clinicians in busy practices. These new procedures cannot be taught in a day, but they also may not require a full year in special fellowships. The initial clinical research trials often involve a limited number of operators, which means that the pool of potential trainers may be limited.

The numerous new procedures and novel devices, and the complexity of required manipulation, present new challenges for the continuing medical education system that is less organized and regulated than formal postgraduate medical education. The reliance on proctored cases is often impractical, expensive, non-standardized, and potentially places the patients at increased risk. The U.S. medical system has been poor at centralizing these procedures to major medical centers, where expertise and experience can by maximized. Rather, the current system and economic incentives promote dissemination among low-volume physicians at low-volume hospitals, often with suboptimal outcomes. Once again, training efficiently, not utilizing patients, allowing an objective assessment of proficiency, and the ability to do follow-up training and skill assessment are attributes of a fully developed, valid simulation-based program of the near future.

Team Training

Concern for improving the quality of medical care and the safety of patients has led to an enhanced appreciation of the performance of a team rather than that of a solitary provider. The aviation industry learned long ago that crew resource management was important to understanding and correcting the miscommunications, and that a lack of crew coordination led to aviation accidents (Gaba et al. 2001). Failures in medical care are often based on similar system and team dysfunction, providing an avenue for implementation of team training to improve safety and performance.

The vast scope of medical training can be appreciated when it is realized that training continues throughout a medical career, that there is an acceleration of new techniques to be trained for, and that training involves physicians, nurses, and other members of the team. Training requires a major commitment of time and resources.

Learning Theories

Kneebone (2005) explores the theoretical grounding of medical simulation and describes four key areas of simulation-based learning: gaining technical proficiency (psychomotor skills and learning theory, the importance of repeated practice and regular reinforcement); the place of expert assistance (a Vygotskian interpretation of tutor support, where assistance is tailored to each learner's needs); learning within a professional context (situated learning and contemporary apprenticeship theory); and the affective component of learning (the effect of emotion on learning). These theoretical underpinnings of simulation-based learning have important consequences for the effective design and implementation of simulation technologies.

Dreyfus Model of Skill Acquisition

According to the Dreyfus model, individual pass through five states of proficiency. These stages are (1) novice, which emphasizes established rules; (2) advanced beginner, which incorporates rules into specific situations; (3) competency, which incorporates rules into selected contexts and emphasizes accountability; (4) proficiency, which emphasizes accountability and intuition; and

(5) mastery, which involves the immediate assessment of a given situation (Eder-Van Hook 2005).

Deliberate Practice and Expert Performance

Medical examinations for board certification aim to identify those who do or do not have a minimal level of knowledge and proficiency to be labeled competent to practice. Little attention has been given to the identification of true experts or masters, other than awards that may be given based on achievements that may reflect other attributes than mastery in a clinical sense.

Research on the thought processes and memory skills, as well as on the methods of training involved in superior performance in a variety of nonmedical areas, including sports, music, and chess, is now being applied to medical education. For example, Ericsson (2004) has begun to apply some of these principles to expert performance in medicine and the potential role for simulation training. One key concept emerging from nonmedical domains has been the role of deliberate practice in allowing individuals to attain expert performance. However, a challenge to applying this methodology to medicine for the purpose of training and identifying experts is the definition and task-specific criteria for expert performance. The limitations of using clinical outcomes to measure provider performance are well known and do not allow construction of a practice-based method with the combined training-feedback loop. Simulation-based training coupled with skill assessment appears as a potential means to apply deliberate practice to help individuals and teams achieve expert performance.

Human Factors and Situation Awareness

Human factors research has developed better measurements of individual and team performance. Situation awareness (SA) is an especially useful concept in considering simulation of medical procedures. Wright, Taekman, and Endsley (2004) describe SA as a task process involving three levels: perception, comprehension, and projection of future states. SA leads to decision making and action. Thus, SA can be viewed as the link between cognition and the technical aspects of procedure performance. This construct of SA gives a structure for simulator design, metrics, and the assessment of combined cognitive-technical performance.

SA may be especially useful in medical team training using simulation. Due in large part to the separate historical and cultural aspects of physician and nursing education, medical teams are rarely trained as a team. However, cross-training has been used successfully to increase the SA of teams in the military (Bolstad, Costello, and Endsley 2006), and it is applicable to the common practice of interdisciplinary training in medical procedure areas.

Practical Advantages of Simulation

Both learning theories and skill acquisition models suggest that simulation has a variety of intriguing opportunities and advantages. Simulation-based learning may allow attainment of a minimum level of competency before the transition to real patients. The use of simulation for error avoidance and for learning how to treat adverse events is inherently more efficient, standardized, and ethically acceptable than learning these painful lessons on patients. Simulation also allows one to "do" early in the process of learning, the pinnacle of the Anderson model: learners can experience elements of the end-product of training at an earlier phase than if learning was restricted by patient selection and safety considerations. Finally, simulation allows practice, an activity known to increase skill levels in other domains. The practice can be focused, it can be tailored to the individual, and it can provide the ability to try different approaches in a risk-free environment. With the appropriate implementation and facilities, techniques can be practiced over and over with material capable of helping the trainee master a task before he or she moves up to the next level of proficiency or to a more complex technique. A major advantage of the apprenticeship approach to medical training has been its hands-on nature, which not only motivates the learner but has a significant effect on retention of knowledge and experience. Simulation is also a hands-on endeavor, and the effectiveness of simulation-based learning to retention of knowledge is superior to passive learning models.

Simulation provides a solution to the conflict between trainee education and service functions and thus has a place for learner-centered training. Training programs should be redesigned with medical simulation as a central tool. Simulation not only allows for a more concentrated and purely educational experience to be embedded in a training program, but it can correct for case-mix inequalities during training. In addition, simulation-based training and skill assessment allows comparison across programs or even countries. Objective, immediate, and transparent feedback can help shape the trainee's progress—an improvement over the hit-and-miss, subjective, and often delayed feedback that occurs in the typical clinical training environment.

Simulation Technology

The diversity of simulation technology, as well as its purpose, the participants, and specific function, are well outlined in an article by Gaba (2004). He breaks down the structure of the simulator itself into a spectrum that includes role playing, partial task trainer, computerized patient simulator, all the way up to a full-blown, immersive virtual-reality work environment.

The realism or fidelity (exactness of duplication) of a simulation is a much-discussed feature of simulators. Adequate realism—such that the trainee suspends disbelief and truly engages in the task—is important for educational effectiveness, but a virtual environment is not really necessary for effective task training. The issue of fidelity is secondary to the issue of what is being taught and what is being measured. Furthermore, cognitive-technical skills and individual-team interactions are goals requiring different designs. Complete immersive simulators are not needed to practice simple hand-eye coordination or perception/action aspects of a procedure. On the other hand, the design elements of haptics, graphics and visualization, tissue modeling, device-tissue interactions, and real-time integration need to be created for specific training tasks. For example, the simulation of most percutaneous cardiac procedures requires much more than a "catheter-in-the-box" approach. Finally, familiarity with techniques must be factored into the equation. It may be that as trainees become more indoctrinated in the world of simulation training, they can be more readily trained using low-fidelity simulators.

The majority of simulation applications require feedback to the trainee and therefore need to be metrics-based. Metrics can be automated with feedback provided in real time (Gaba 2004). Alternative approaches, such as debriefing, mentor feedback, and video reviews, also can be used. Furthermore, feedback can occur in a benchmarking context or as a formative assessment with specific elements of performance broken out from global outcomes.

Implementation of Medical Simulation

Medical simulation should be integrated with a curriculum that is comprehensive and tailored to the specific training setting. Integration of simulation into the workflow of the traditional apprenticeship model remains to be completed. For graduate medical training, the use of simulators can be useful in the assessment of the six core competencies as outlined by ACGME and the American Board of Medical Specialties. Simulation would also be expected to become one of the assessment tools used by ACGME training programs, perhaps starting with procedure proficiency.

Variation by Country

Variations in the use of medical simulation reflect differences in the health care systems of different countries. For example, in the United States there is no national system for standardization or for implementation of medical simulation in undergraduate, graduate, or CME applications. Rather, some medical schools, hospitals, and educational entrepreneurs have developed simulation centers utilizing simulation. The medical device industry has used simulation for training on new products. Professional societies in anesthesiology, cardiology, and other disciplines have gone from demonstrative technology fairs to implementation of simulation in national meetings and other CME activities. It is expected that national standardization of curriculum and postgraduate training standards will eventually bring more universal availability of medical simulation.

By contrast, the European Union has a major goal of standardizing training and certification across the multiple countries with a wide spectrum of health care systems that previously had developed independently. The National Health System in the United Kingdom provides a natural means to develop a hub-and-spoke model of training centers, but it is also capable of mandating simulation-based training. These efforts should produce a substantial experience in the strengths and weaknesses of this implementation strategy. The European Society of Cardiology will meet in early 2007 to establish policy and an implementation strategy for medical simulation. One hurdle will be how to modify training and correct testing for cultural bias and translation problems.

Finally, as a small and relatively isolated country, Israel has established a more centralized approach, with coordination of multidiscipline activities, multi-vendors, and a vigorous evaluation program (Ziv et al. 2006).

Validation

Perhaps the most pressing issue for some institutions and groups making decisions regarding medical simulation is validation. The face validity of simulation as a method does not address the more pressing issues of having confidence that a large investment in specific simulation technology will improve medical care, or that basing board certification in interventional cardiology in part on the results of a simulation-based exam will lead to a greater competence in clinical care.

Validation for training often carries a broader meaning, including the educational effectiveness of training. Intrinsic to the objective of medical training is to demonstrate that a training method impacts on patient outcomes. The first step in this process is demonstrating that there is transference of skills acquired on a simulator to proficiency in performing the procedure on a patient. Formal validation studies are different from studies that have the goal of proving certain benefits occur from the use of medical simulation for training. Outcomes studied for simulation-based training may focus on the issues of improving patient safety, increasing the effectiveness of treatment delivery, lowering the costs of health care, or improving team performance in specific settings.

Validation of a simulator to assess or test skills may require multiple tiers of proof that this type of testing is reliable, consistent, and provides a true measurement of a person's ability. Content validity, concurrent validity, and predictive validity are several forms of validation commonly needed to have confidence that a testing tool is reliable and accurate.

Validation studies can only be conducted after agreement has been reached on what needs to be taught and what needs to be measured for correct performance. For simulated medical procedure training, the typical first step is to deconstruct the procedure into a series of steps or tasks that reach a predefined goal. This straightforward description is often uncontroversial, but the techniques used to complete each task may be very operator-dependent. It then must be decided if the simulator must allow all reasonable techniques to be feasible.

A review of several studies provides tangible proof of the validity of medical simulation. For example, transfer of laparoscopic cholecystectomy skills learned on a simulator was demonstrated in a prospective randomized, double-blinded study (Seymour et al. 2002). Those trained on the simulator made six times fewer errors and performed the procedure 29% faster. A training program for advanced cardiac life support skills (ACLS) included a medical simulator (Wayne et al. 2006). Deliberate practice coupled with performance feedback was a feature of this program. The performance of six simulated ACLS scenarios did not decay after 14 months. Furthermore, in a study involving 29 subjects with a spectrum of experience performing carotid stenting, researchers found good correlation of endovascular skill based on clinical experience and skill assessment on a simulator (Hsu et al. 2004).

The American Board of Internal Medicine (ABIM) establishes requirements for certification and maintenance of certification, including the added qualifications for certification in interventional cardiology. The ABIM has investigated the potential role of medical simulation as a tool to measure procedural and technical skills. A pilot study will soon be published that provides an example of a high-quality study to validate medical simulation using rigorous scientific criteria, a multicenter study design, and study conduct by an independent group with expertise in psychometrics. The study found that simulation technology was a valid and reliable evaluation tool. In 10 medical centers, 120 study physicians with a spectrum of clinical skills in interventional cardiology performed procedures on the simulator. Multiple clinical scenarios were designed by clinical experts. Cases had a range of difficulty, with performance metrics established by the medical experts working with the psychometricians from ABIM. The scoring algorithm was based on the logic of the cases and considered both appropriate and inappropriate actions. Each case scenario was analyzed as to its ability to discriminate skill level, and the study also tested the reliability, reproducibility, and validity of the simulator. Preliminary results indicated that simulation can discriminate differences in expertise. The complete results were to be available in 2007, and the ABIM is now looking to include simulation as part of its recertification program.

Medical Simulation in Cardiovascular Medicine

With the FDA's decision in 2004 to approve the Cordis stent, carotid stenting emerged on the medical device market and changed the community's awareness of medical simulation. The approved training program required simulation as a component of the physician education program. In addition, the FDA approval of substituting simulated cases for proctored cases was a major development in the implementation of medical simulation in cardiovascular medicine.

The Agency for Healthcare Research and Quality (AHRQ) in the Department for Health and Human Services has become a major funding organization to investigate the value of simulation-based training to improve the quality, safety, efficiency, and effectiveness of health care. AHRQ recently awarded more than $5 million in new grants for 19 projects under its "Improving Patient Safety Through Simulation Research" request for applications.

Industry sponsorship of simulation-based training has grown substantially in the last several years. The Emory Neuro Anatomy Carotid Training (ENACT), a virtual-reality program funded by Cordis, piloted simulation training in a group of 125 physicians. The validity and feasibility of the technology was studied, as well as a learning curve.

Boston Scientific Corporation utilized medical simulation for the rollout of a new product, Filterwire, to be used to improve the safety of coronary interventions. Over 500 physicians were trained, and the vast majority rated the quality of the simulation and its usefulness as good to excellent. Another novelty was the placement of the simulator on a bus so that it could be driven to hospitals throughout the country, making the training convenient for the physicians and cardiac catheterization laboratory staff.

AGA Corporation, the manufacturer of medical devices to close congenital heart defects, now allows case-based training on a simulator to be substituted for proctored cases. Every basic step can be practiced, from delivery system insertion to device deployment and visual verification of device positioning. Cognitive as well as technical skills are needed for successful completion of the simulated cases. This is a clear example of medical simulation replacing real patients as part of the early acquisition of skills.

Edwards Lifesciences has used medical simulation to train leading interventional cardiologists on the new procedure of percutaneously implanted aortic stent valves. These high-stakes clinical trials in Canada, Europe, and the United States utilize a comprehensive training program built on simulation, including Internet-based simulation of a rapid pacing protocol and supplemental case reviews. The valve implantation technique is novel, involving new skill sets in device placement, and procedural mistakes can cause catastrophic complications, including death. The simulation was built with extensive input from the clinicians and clinical trial coordinators at St. Paul's Hospital in Vancouver, British Columbia, who were the first in the world to have clinical experience with the device. Edwards Lifesciences now trains all investigators on the basic procedure, as well as in troubleshooting using a simulator. Tactile aspects of catheter manipulation, medical imaging nuances, and device delivery sequences are realistically simulated. Proper techniques as well as errors can be repetitively practiced, allowing new clinicians to gain basic proficiency before initiating their clinical investigative site with patients.

Unique Medical Applications

The application of medical simulation to procedure training and assessment of technical skills is important, but it is by no means the limit of useful simulation applications. For example, cognitive skill training with simulation separate from technical skills has been employed to help graduate medical trainees develop cognitive forcing strategies with the goal of reducing diagnostic and subsequent therapeutic decision errors in the emergency room (Bond et al. 2004).

Another innovative use of simulation is to teach the principles and practical application of health economics. The practice of medicine is strongly influenced by the reimbursement mechanisms and economic system within which health care operates. The Clinical Health Economics System Simulation (CHESS) is a computerized team-based quasi-competitive simulator that enables users to compute health care costs for different diagnostic and therapeutic strategies (Voss, Nadkarni, and Schectman 2005).

True rehearsals of patient procedures have been heralded as an already realized application of medical simulation. On careful examination, however, such rehearsals are often limited to an isolated finding in a patient being incorporated in a simulation that is overwhelming generic. The potential impact on planning and execution of procedures in patients, though, is huge. It raises significant liability issues that may dampen specific clinical applications until the field of medical simulation becomes more mature, the regulatory and legal issues become better defined, and the clinical value is validated.

The games industry may have applications relevant to the health care system. Serious Games Initiative 2007 is the term applied to a games industry group looking into health care applications.

Risk management represents another part of the health care system that may accelerate the incorporation of medical simulation. Case scenarios can be designed based on malpractice claims. Error reduction may be facilitated by purposely making mistakes on simulators, learning skills in recognizing and managing complications, and providing documentation to training to improve the quality of care and improve patient safety. As a result of medical simulation–based training, insurance premiums may be lowered (CRICO/RMF 2007).

Challenges for Simulation

The challenges for medical simulation to achieve its potential are numerous. The main inhibitor of implementation is no longer technology development, but culture and policy change. Acceptance of simulation by the medical community will rely on the further publication of scientific studies, the development of economic models and funding, and the continued integration of simulator technology into existing curricula and training programs.

The complexity of health care, the numerous stakeholders, and lack of central command and control in medical education are all barriers to an efficient incorporation of medical simulation. It is likely that the major forces for implementing simulation will come from the medical device industry, which will need acceleration in training on new products, and from institutions with a mandate to implement simulation for patient care and certification goals. Certification boards are expected to increase their utilization of simulation technology to objectively assess proficiency of skills relevant to the specialty. Now that medical simulation has made the transition from an experimental technology to the clinical world, the next five to 10 years may be viewed as the golden age of medical simulation.

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