

# Patient safety and simulation-based medical education

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SUMMARY Continuous quality improvement is an accepted mandate in healthcare services. The delivery of the best, evidencebased quality of care ultimately depends on the competences of practitioners as well as the system that supports their work. Medical education has been increasingly called upon to insure providers possess the skills and understanding necessary to fulfill the quality mission. Patient safety has in the past five years rapidly risen to the top of the healthcare policy agenda, and been incorporated into quality initiatives. Demand for curricula in patient safety and transfer of safety lessons learned in other risky industries have created new responsibilities for medical educators. Simulationbased medical education will help fill these needs. Simulation offers ethical benefits, increased precision and relevance of training and competency assessment, and new methods of teaching error management and safety culture. Established and successful simulation methods such as standardized patients and task trainers are being joined by newer approaches enabled by improved technology.

# Introduction

The primary goal of health professionals should be the provision of the best possible quality care to patients. Medical education provides a critical means for achieving this goal by helping practitioners develop an appropriate range of skills, knowledge, and attitudes. Although patient safety has been increasingly recognized as a key dimension of quality care, systematic safety education for healthcare professionals is lacking. Recent high-level policy directives have called for the creation of patient safety curricula to fill this gap. Medical simulation tools and techniques have much to offer in this regard, especially in the areas of error management, training for risky procedures, and assessing competences. The objective of this paper is to discuss how innovations in simulation can aid educators in improving training on patient safety issues.

# Patient safety

Many forces have converged to spotlight the issue of patient safety today. These include mounting epidemiological research on patient injuries, cost pressures, rapid advances in progress in safety in other high-risk industries and digital information support, changing cultural norms about acceptable risk and location of control, and the evolution of the quality movement.

Safety, from the patient perspective and in the context of medical errors, refers to 'freedom from accidental injury'. Unfortunately, recent reports on patient safety indicate that healthcare is not as safe as it should be. Even when using the lower estimates quoted by the recent landmark National Institute of Medicine report *To Err is Human*, deaths due to medical errors exceed the deaths from motor vehicle accidents (the eighth leading cause of death in the USA), as well as deaths due to breast cancer or AIDS (Kohn *et al.*, 1999).

The NIOM report was rapidly supported by major government, accreditation, and industry policy statements calling for raising safety, accountability and reliability to the levels achieved in other complex, risky industries (Quality Interagency Coordination Task Force, 2000; United States General Accounting Office, 2000). Primary emphasis is being placed on redesigning error-inducing systems characterized by unnecessary complexity, variation, and opacity in processes.

Many opportunities also exist for risk reduction through training. The reality of medical training is still that health professionals, whether novices or experts, are expected continuously to acquire new knowledge and skills while treating live patients. The mode of training for gaining proficiency at risky procedures, as well as achieving and maintaining competence in handling rare, complex, and critical problems, has been the classic on-the-job apprenticeship model based on *ad hoc* exposure to patients. Patient-free environments such as medical simulation will contribute to improving the training of health professionals in traditional skills while minimizing harm to patients.

The patient safety imperative has raised expectations regarding the responsibility of medical educators and decision makers to insure providers' competences in new areas. These include error management, inculcating safety culture, teamwork, and improving performance in complex systems. Simulation offers options for teaching these skills as well as supporting improved methods for demonstrating and documenting competences.

# Simulation in other high-risk industries

Simulation is defined as "the representation of the operation or features of one process or system through the use of

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another" (American Heritage Dictionary, 1992) or, "the artificial replication of sufficient components of a realworld situation to achieve certain goals" (Gaba, 1997). While simulations have been used for millennia to plan, reduce risk, and increase control (hunting rituals, wedding rehearsals, and mock battles), the term has taken on new connotations in the past 50 years. The costs of training and failures, changing attitudes about tolerable risks and injury reduction, and enabling technology have fueled simulation in risky work including power generation (Wachtel, 1985) and the military (Ressler et al., 1999). Transportation, highstakes legal proceedings (jury selection and mock trials), professional sports training, business executives training (Keys & Wolfe, 1990), homicide investigation training, and costly construction projects are other areas increasingly turning to simulation.

Aviation offers the most familiar example (Garrison, 1985; Rolfe & Staples, 1986). Basic 'Link' simulators filled a critical need in the Second World War for the inexpensive and efficient training of large numbers of prospective young pilots in basic skills. Multiple generations of improvements in technology and training followed, and led to standard competency assessment. A now classic aviation simulation study (Ruffell-Smith, 1979) provided evidence confirming the key role that human and team performance failures played in actual crashes and near misses in aviation (Cooper et al., 1980). Simulators anchored a new human factors curriculum, designed to teach leadership, team coordination, and use of all available resources to manage non-routine situations (Weiner et al., 1993). The concept of learning using a variety of simulation modalities became institutionalized as an integral part of a mature safety culture in aviation (Sagan, 1993).

Currently, commercial aviators are tested in 'stick and rudder' skills every 6 months for certification, and once a year for more complex, full environment performance in a high-fidelity team simulator. Behavior-based simulator team training for Army rotary wing aircraft crews has been linked to significant savings in human lives and dollars (Leedom & Simon, 1995). Simulation-based Aircrew Coordination Training (ACT) in the Navy is believed to have played a significant role in dramatically decreasing accident rates (Prince, personal communication). Interestingly, senior aviation training researchers have recently argued that the costs and use of technology have outstripped current training methods, and much more work needs to be done to improve the pedagogical aspects of training (Salas *et al.*, 1998)

# Simulation in healthcare

Interest in simulation-based medical training has increased for reasons similar to those that led to the advance of simulation in other fields. These include the drive for risk and cost reduction, improved possibilities for demonstration and assessment of a wider range of skills, and the availability of new technologies that enable more sophisticated simulation. In addition, evolution in healthcare delivery has challenged medical education to deal with increasingly limited availability of patients and instruction time, training in highly technical procedures, and the ethical issues raised by the patient safety movement (Buck, 1991; Issenberg *et al.*, 1999).

Medical simulation comprises a wide spectrum of tools and methods, such as simple manikins, organ models, animals and cadavers, some of which have been in use from the early days of medicine. Modern medical simulation encompasses the well-established method of simulated/ standardized patients, as well as the new generation of computer-driven, screen-based, realistic and virtual reality simulators. All types of medical simulation share the feature of separating training and education from the provision of actual patient care.

Effective simulation-based medical education is founded on an understanding of the attributes of the various tools and methods available. Below is a description of the main methods with emphasis on more advanced techniques.

#### Simple models or manikins

These low-tech, relatively low-cost simulators have been used to teach basic cognitive knowledge or hands-on psychomotor skills. Anatomic models have been used to support learning about cardiac function, performance of spinal anesthesia, and prostate and breast examination for example. Devices have been developed to allow practice of First Aid for various injuries/wounds, and insertion of intravenous catheters. Simple manikins are used to train and assess basic life support maneuvers such as mask ventilation, intubation or chest compression.

#### Animal models

These have been used traditionally for physiology and pharmacology education. In addition, they have served for training in interventional procedures, such as ATLS and laparoscopic cholecystectomy. The use of animals in medical education is on the decline, however, owing to growing ethical concerns in the face of the availability of better options such as improved simulation techniques. Direct and indirect costs, convenience, and access to exact human models as opposed to animal approximations are all factors supporting this trend.

### Human cadavers

Typically used in medical school anatomy classes for hands-on dissection, cadaver tissues have also been employed in surgical courses aimed at teaching practitioners new procedures, or as supplements to training in complex injection techniques for pain therapy or nerve blocks. Expense, inconvenience, limited availability and use of formalin-fixed tissues are considerations.

# Simulated/standardized patients (SPs)

SPs serve mostly for the training and assessment of history taking, physical examination and communication skills. Since the introduction of the SP methodology (Barrows, 1968; Harden *et al.*, 1975), SPs have become the single most studied simulation-based educational tool in medicine (Barrows, 1993). Growing recognition of the unique features and advantages of SPs has resulted in their being integrated into medical school curricula, followed by incorporation into major high-stakes licensure exams (Reznick *et al.*, 1996; Sutnick *et al.*, 1993).

#### Screen-based simulators

Computer-based clinical case simulations were first developed in the 1960s but not until the advent of the personal computer in the 1980s did this approach to clinical education begin to proliferate. Since then, these tools have become increasingly prevalent in medical education to train and assess clinical knowledge and decision making as a result of their dropping acquisition cost and low maintenance. In the 1997-98 academic year, 33.6% of medical schools reported using software for clinical case problem-solving, diagnostic, or therapeutic decisionmaking exercises in basic science courses, while 28% utilized this teaching method in a core clerkship (Moberg & Whitcomb, 1999). Areas such as cardiology and pulmonary medicine, where auditory and/or visual skills are important in making a diagnosis, have been particularly attractive in terms of multimedia curricular development (Petrusa et al., 1999; Kompis & Russi, 1997). However, screen-based simulation is available today in almost any clinical or basic science domain in medicine. As self-tutorials with built-in feedback features, screen-based simulators offer a comprehensive learning experience that is less dependent on the involvement of external educators.

# Realistic high-tech procedural simulators (task trainers)

A new generation of highly sophisticated computer-driven realistic simulator devices has extended the envelope and complexity of tasks and procedures that can be modeled for education, training and research. These tools invest static models with rich audiovisual and touch/feel interactive cues, and build on powerful software for teaching, learning, and assessment.

The well-known Harvey Cardiology Patient Simulator presents ausculatory and pulse findings of 27 cardiovascular conditions and supports a comprehensive curriculum. Learning goals, teaching manuals, self-assessment, and an optional multimedia program are available. The Harvey simulators are mostly used for teaching medical students bedside clinical skills (Jones *et al.*, 1997; Gordon *et al.*, 1980). Transferability to actual patients of skills learned on Harvey has been demonstrated. Research also suggests improved efficacy of simulation-based training compared with traditional methods alone (Issenberg *et al.*, 1999).

Another recently available tool is an ultrasound simulator that appears and operates like an actual ultrasound system, with a fully functional control panel, mock transducers and a realistic patient-manikin (Meller, 1997; medsim.com). The system displays real-time ultrasound images obtained from consenting patients while trainees scan a life-like manikin that conceals an emitting device. The system includes performance assessment features and a built-in 'instructor', and is accompanied by an extensive library of clinical cases. These cases are packaged as a comprehensive curriculum covering a wide range of organ systems and pathologies (e.g. abdominal, obstetrics/gynecology including the endovaginal approach, breast, vascular, and others). The ultrasound simulator is becoming a standard curricular device in ultrasound technician schools in the USA and Canada. In addition, it is increasingly used by radiology and obstetrics-gynecology training programs, as well as by surgeons and emergency medicine physicians for training in acute care setting ultrasound (Knudson & Sisley, 2000; Nisenbaum et al., 2000).

Minimally invasive surgical procedures are ubiquitous, and have introduced demands on surgeons to develop new skills. Operating through laparoscopes, while viewing surgical fields on video screens, requires special hand—eye coordination and the ability to operate with reduced feel/touch feedback. These procedures lend themselves to simulation.

Several laparoscopic high-tech surgery task trainers are becoming available (Nick et al., 1998; Gallagher et al., 1999; cine-med.com, 2000; Jambon et al., 2000; limbsandthings-.com, 2000). Features of these tools range in degree of sophistication and include the incorporation of actual laparoscopic instruments, force feedback devices, and high-end computer screen graphics. Manipulation of the surgical tools in the most advanced models under development moves hidden sensors that register force and direction. These actions are transduced, digitally encoded, and the data entered into three-dimensional computer graphics models of organs, such as the gall bladder, which are displayed on a screen. Less advanced models use actual laparoscopic tools that can be inserted in manikin torsos holding organ mockups.

In the endoscopic arena, similar technology has been applied to create tools of increasing fidelity for gastroenterology (simbionix.com, 2000), bronchoscopy (Bro-Nielsen et al., 1999; ht.com), arthroscopy (Logan et al., 1996; Mabrey et al., 2000), and endoscopic sinus surgical procedures (Rudman et al., 1998). Many other high-fidelity task trainer simulators are already available (e.g. in dentistry—Rose et al., 1999; denx.com) or in development (e.g. in intervententional cardiology—Cotin et al., 2000).

Much basic and applied research remains to be done in the area of sensing and touch feedback. In addition, the second-by-second integration of changing high-fidelity feel and the corresponding action of human forces on computergenerated graphics models creates a computational burden too large to be feasibly managed by affordable devices.

# Virtual reality

VR can be defined as "a system that enables one or more users to move and react in a computer-simulated environment" (Encarta® Online Encyclopedia, 2000). Technically, true VR refers to totally synthetic environments, where cues for all senses are computer generated. The trend in VR is for maturing technologies to be first combined in hybrid approaches with simulation methods (role play with live people, use of actual tools), moving to completely digitally represented worlds which real people can enter. A review of the rapidly growing, mostly experimental VR field is beyond the scope of this discussion.

The Visible Human Project (VHP) has been an important resource for many educational programs and device development (www.nlm.nih.gov/pubs/factsheets/visible\_human.html). The VHP digital database available in the public domain consists of a fully imaged man and woman using multiple formats (CT, MRI, photographs). The Next Generation Visible Human supports higher resolutions in three dimensions, and is already incorporated in simulation initiatives in head and neck and orthopedic surgery.

The Virtual Human Initiative, a fledgling collaborative project led by the Oak Ridge National Laboratories, is expected to create the human simulation environment of the 21st century—an integrated system of biological and biophysical models, data and computational algorithms, supported by advanced computational platforms (www.ornl.gov/virtualhuman). This simulation is expected

to have both clinical and educational applications that will radically change the face of medical training and procedural medicine during this century.

#### Realistic high-tech interactive patient simulators

Computerized, realistic patient simulators (RPSs) were first used in 1966 for anesthesia training (Denson & Abrahamson, 1969). The physical characteristics of 'Sim-One' were surprisingly lifelike. Computers were used to record drug levels, generate and display blood pressures and heart sounds, and control motion actuators. 'Sim-One' was an isolated phenomenon, ahead of its time; nearly two decades elapsed before advances in computer technology, bioengineering, learning and behavioral sciences led to the development of RPSs as we know them today (Gaba & DeAnda, 1988; Gravenstein, 1988).

RPSs have been commercialized (Medsim.com, 2000; Meti.com, 2000; Sophusmedical.dk, 2000) from initiatives based at several academic anesthesiology departments (Good & Gravenstein, 1989; Schwid & O'Donnell, 1990; Chopra et al., 1994). RPSs are advanced in the number and detail of the features they possess and the large range of programs and trainee types they support. The common features include a full-length manikin, a computer workstation, and interface devices that actuate manikin signs and drive actual monitors. These devices represent a paradigm shift from what most medical educators and providers are acquainted with in terms of traditionally available instrumented mannequins (Advanced Cardiac Life Support megacode, for example). It is, therefore, useful to consider RPS features in detail in the context of discussing teaching, learning and assessing of advanced competences relevant to patient safety.

RPSs have eyes responsive to light, pain and selected cranial nerve palsies, an anatomically correct and dynamic airway, patient voice, arm movement, heart and breath sounds, and excretion of carbon dioxide. Chest-tube insertion, monitoring of neuromuscular transmission using standard nerve stimulator devices and provision of dynamic physical cues mimicking extremity compartment syndrome are supported features. Physiologic computer models of ventilation, gas exchange, and cardiopulmonary function interact with pharmacological models which can simulate actions of dozens of agents administered by various routes, from anesthetic gases to a variety of vasopressors, narcotics, paralytics, hypnotics and fluids. The physiological and pharmacological models can be automated using scripts or controlled manually through a screen-based interface.

RPSs may be controlled at a short distance via direct or wireless means, as well as 'at the bedside' by a hand-held device connected to the main workstation. Bar coding of drug syringes and the use of an in-line intravenous flow measurement device allow automatic computer recognition of injected drugs and appropriate adjustment of vital and physical signs. Ventilators, defibrillators, rapid transfusion devices, anesthesia machines and other devices easily interface with the RPS.

Patients can be 'designed' on the computer interface using many variables such as weight, blood volume, and indices of heart function. RPSs have been installed in a variety of flexibly staged, low- to high-fidelity immersive clinical environments (ER, ICU, office-based setting, OR) limited only by one's imagination, resources and training objectives.

Performance assessment has only begun to be addressed (Devitt *et al.*, 1998; Gaba *et al.*, 1998; Kapur & Steadman, 1998). However, RPSs have been used for intense, high-fidelity team training (Helmreich & Davies, 1996; Small & Isaacson, 1998; Raemer *et al.*, 1999; Small *et al.*, 1999a) and novel approaches to simulating systems problems and linking simulation to data from adverse event reporting systems (Small *et al.*, 1999b).

To enable team and microsystem simulations, RPSs have been incorporated with standardized patients, simple simulator tools, and complex task trainers like the Ultrasim to create microsystems where beepers go off, phones must be answered, and teachers role playing other standardized practitioners come and go, the objective being to train for coping with ambiguity, time pressure, changing workload, interpersonal issues, and adaptability in problem solving (Small *et al.*, 1999a).

RPS multidisciplinary simulation centers serve medical schools, hospitals, industry, and emergency services. Use varies widely with objectives and resources. Over 150 RPSs exist worldwide following their inception in 1994. Given that this is the first phase of acceptance and dissemination of RPSs, it should not be surprising that devices are underutilized. The advent of an aviation-based, RPS-supported curriculum for training in human factors and patient safety in anesthesiology and its growing influence in other disciplines is one example of how important validated teaching methods are to enable productive use of new technology (Howard *et al.*, 1992).

#### Benefits of simulation

Having considered different simulation tools and methods, it is useful to explore generic characteristics and benefits of simulation applied to healthcare.

# Moral imperative

Patients are entitled to the best quality care. This means being served by experienced professionals trained to the extent possible by modern means. The use of simulation wherever educationally feasible conveys a critical message to the clinician: patients are to be protected whenever possible and are not training commodities. It is therefore an ethical obligation to make all efforts to expose health professionals to clinical challenges that can be reasonably well simulated prior to allowing them to encounter and be responsible for similar real-life challenges.

From the patient's perspective, simulation reduces the exposure of patients to health professionals that are less experienced, and thus contributes to better protection of patient rights to receive quality care that focuses on the patient's needs rather than care compromised by training needs. This is a key component of building the trust of patients and stakeholders in health professionals and the system they operate, a precious value that drives the patient safety movement (Hayes, 1994; Lynoe et al., 1998; Kaldjian et al, 1999). Although not directly linked to patient safety, reduction in animal suffering is also a moral imperative if adequate or better educational methods exist.

# Learner-centered education and training

Simulation is a learner-centered rather than patient-centered educational experience. In the immediate simulation context, the learner's needs receive highest priority. Conflicts with patients' needs to avoid errors in care are eliminated, as well as the accompanying stress on trainees. With live patients, learning time is limited, access is sporadic, and the 'fit' of the learning experience to the trainee's level and needs is often suboptimal. In simulation-based medical education, trainees may receive controlled exposure to a complete range of designated, pre-designed clinical encounters in a systematic curriculum fairly applied to all. This method is also consonant with important principals of adult learning whereby trainees learn at different paces and in different styles.

#### Teacher-enabled environment

Simulation-based education requires educators to take a proactive approach to clinical exposure by designing an optimal learning environment and curriculum to serve the educational objectives. Whereas the apprentice method and learning from actual clinical encounters are constrained by chance, availability, and conflict with clinical operations, simulation-based education provides the opportunity to have full control over the clinical curriculum in terms of content, degree of difficulty, sequence, clinical setting and the variety of clinical scenarios. Opportunities exist also for using similar methods to train teachers, offer high-level feedback, and assess competences.

# Improving performance assessment

Progressive simulation-based assessment enables a shift from traditional cognitive-oriented assessment to a more integrative accounting of knowledge and clinical skills—simultaneously, and in action. These skills include interviewing, communication, teamwork, and performance of risky and complex procedures, management of technology, information systems and other aspects of health-care delivery. Higher level abilities such as coping and decision making under naturalistic conditions can be convincingly evoked. As the fidelity of high-tech simulators improves, it is expected that they too will be incorporated into performance assessment examinations, mainly for routine certification and recertification procedures (Murray, 1998; Issenberg *et al.*, 1999).

# Approach to error management

Simulation-based education enables application of a very effective educational principle: learning from mistakes. Simulation allows physicians in training to take risks, to go further in procedures than would be allowed with live patients, and to make errors without penalty. In the clinical setting, errors must be prevented or terminated immediately to protect the patient. In a simulated environment, errors can be allowed to progress in order to teach the trainee the implications of the error, or to enable him/her to react to the errors and attempt to rectify them.

Because mistakes made during simulated exercises do not cause harm to living patients, they can be reviewed openly without concern of liability, blame or guilt. 'Errors', or more appropriately failures of expertise, can be induced by high workload, distractions, or ambiguous information, in order to train for recovery. This approach is critical to demonstrate convincingly and disseminate widely the philosophy that, in real, complex environments, preventable adverse events are ubiquitous and emphasis should be placed on their recognition, trapping and mitigation.

# Improving incident reporting and safety culture

Debriefing is an inherent part of simulation-based education and is important in creating a culture/atmosphere of openness and trust. Exposure to debriefing in simulated scenarios educates health professionals to recognize the important role it should play in their daily practice and ongoing efforts to improve quality of care. Thus, simulation with proper debriefing can help break the culture of silence or denial in medicine over mistakes and their implications for competence.

Through simulation-based reflective learning, health professionals can be trained to discuss near misses, mistakes, and adverse events in a non-judgmental, productive manner. Stimulation of submission of in-depth event reports as a substrate for simulation training is another aspect of this interplay. Widely inculcating these behaviors is a critical step on the way to establishing safety reporting systems used by high-reliability industries that the NIOM report on patient safety views as a cornerstone of a safer health system.

#### Economic consequences

Comprehensive economic models describing the impact of systematic adoption of medical simulation do not yet exist. On the one hand, acquisition and maintenance costs, including diversion of learners from on-the-job training, can be significant. On the other hand, huge malpractice costs, inefficiencies of training in costly environments, and the impact of the greater number of adverse events that do not advance to lawsuits but still waste large amounts of resources must be calculated. Ultimately, the best safe, ethical practice is good for business.

#### New research horizons

Simulators are like a new microscope that allows educators and learners to see finer details and nuances of performance and competences. In addition, single competences can be built up and larger constructs that only appear in complex, real-world situations can be studied. It will be critical to conduct outcome studies to determine the effect of simulation-based training on performance of health professionals as well as its impact on the function of health systems.

# Barriers to adoption of medical simulation

Rapid, major change creates resistance. Complex new technology takes time to assimilate. Visible costs are relatively high, while significant cost benefits may be indirect, soft, and long term. Other barriers include the lack of trainers experienced in using simulation tools and methods, and the need for more validated, reliable curricula that can be easily

disseminated and operationalized. This is even more true in the case of performance assessment given the complexities of rating higher order performance.

#### Conclusions

The drive for injury reduction and the advance of technology is leading to the institutionalization of simulation as a part of medical education and performance assessment. This evolution is similar to that of simulation in other high-hazard industries in which the public is heavily invested. More research is needed regarding transfer of medical simulation training lessons to actual patient care, learning sustainment, and cost/benefit analyses. Simulation-based medical education should, therefore, validate its practices on a continuous basis in the spirit of evidence-based medicine.

Medical education has an important role to play in improving patient safety by incorporating safety-building methods into curricula, assessment, and lifelong learning of healthcare professionals. Advanced simulation technologies, as the SP experience teaches, offer the potential of teaching skills that were rather neglected in the past. Medical education should also be accountable for its share in enhancing traditional provider competences as well as newer competences in error management, teamwork, and participation in safety culture.

# Short list of 'take-home' points

- Medical educators must respond to the ethical messages, policy directives, and practical challenges raised by the emerging patient safety movement.
- New curricula are needed to train providers more safely, inculcate safety culture, and better assess actual applied knowledge and skills.
- Simulation technology and pedagogy have advanced dramatically in recent years, and have the potential to improve health professionals' competency and safe practice.

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