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Procedural Simulation

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The aviation industry realized the potential of simulation for training many decades ago and has harnessed its potential. In the past few decades, medicine has started to look at the potential use of simulators in medical education. Procedural medicine lends itself well to the use of simulators. This effort was put into high gear after 1999 when the Institute of Medicine Publication "To Err is Human: Building a Safer Healthcare System" [1] quantified medical errors and their consequences. It stated that up to 98,000 patients die each year because of medical errors in the United States alone. This led to heightened interest from governmental agencies, lay public, and doctors themselves. Efforts are under way to establish national agendas to change the way medical education is approached and thereby improve patient safety. Universities, credentialing organizations [2], and hospitals are investing large sums of money to build and use simulation centers for undergraduate and graduate medical education [2–4].

The aspiring trainee must somehow acquire the essential knowledge, core cognitive and motor skills, and professionalism that are required for safe practice in patients. The basic procedural skills are acquired through deliberate practice until they become automated; they can then be reconfigured and merged with new cognitive and motor elements to build up tasks that are more complex. This stepwise training is conducted within a curriculum

Procedural simulation should not be viewed independent of the other important topics in this issue. Understanding different types of simulators, their uses, links between simulation, and patient safety puts this important topic in perspective. This article may touch on these topics, but for detailed information please refer to other articles in this issue.

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where the master-apprentice model (MAM) has traditionally been a cornerstone. The mentor provides instruction, example, supervision, assessment, and safety through rescue-intervention. In the current system of medical education, it is rarely possible to master a skill through repeated practice of basic skills before "practicing" on patients [5]. The inexperienced trainee also needs to rely on these basic skills to perform complex procedures in a team environment. The safety of patients and procedural team members, and perhaps the outcome of the procedure, depends on a coordinated effort among team members and the chain of tasks they perform. Any disruption in the fluidity of these tasks may result in injury to a patient or team member with potentially grave consequences. Many experts believe that the MAM of medical education, where "see one, do one, teach one" is the mantra, is no longer a safe option and that medical education syllabi should incorporate the use of simulators to provide optimal patient safety. Despite its time-proved strengths, MAM has its weaknesses, leading some to conclude that it is time for a paradigm shift. For example, different trainees require different amounts of time to master a given skill. Furthermore, training varies depending on the case mix available at a particular training site [3,6].

Many instructors in medicine are not trained to be evaluators, and this may limit the reproducibility, reliability, and objectivity of their assessment of the trainee's proficiency. Further, a mainstay of training is learning from error, and it is indeed unfortunate that patients are at times subjected to the mistakes of trainees learning under supervision [3,4]. These shortcomings lead in turn to legal and ethical concerns, and pressure is mounting for a gradual change in medical education. Procedural medicine (interventional or surgical) education lends itself to change. Intuitively, it is a matter of risk/benefit ratio: the higher the risk of the procedure for the patient, the more benefit the patient obtains if he or she is not the tool for teaching. In addition, procedural medicine carries inherent risk to the operating team members. Seymour and colleagues demonstrated that practice on an appropriate simulator leads to reduced errors in patients [7], and in the future, it may even be shown to improve patient outcomes and safety for team members. Simulators have a key role, not only in basic skills and individual training, but also in performing assessments of proficiency [3].

From this, one has an intuitive understanding of what medical simulation might represent and provide. The definitions differ with different investigators and perspectives; however, there are some common threads. One definition is creation of an environment or a group of environments in which cognitive and physical skills are acquired through the use of audiovisual media, devices, mannequins, or a team (or any combination of these) with or without the presence of a standardized patient. A simulator is a device, method, or audiovisual (or any combination of these) effect that allows all or part of the simulation to occur. With the currently available technology, the replacement of MAM is unlikely. Using a range of simulation methods, however, its augmentation is certainly possible. This augmentation should allow the trainee's early learning curve to be accelerated, allowing them to learn from errors on virtual, rather than real, patients. Incorporation of simulation in procedural medicine curriculum introduces a more moldable and adaptable element into the relatively rigid MAM, allowing it to meet specific performance objectives required for curricular training, objectively measuring indicators of performance to provide reliable and reproducible feedback on proficiency [3,4].

Procedural simulation: its potential and pitfalls

It is unquestioned that, if done in a responsible and careful manner, procedural simulation holds tremendous promise for the future of medical training. It must be recognized, however, that if not used properly, it has pitfalls.

Potential roles of procedural simulation

The potential uses of simulation in medicine, especially procedural medicine, are huge. With the simulators that are currently available, the replacement of MAM is unlikely in the near future. Some of the technologic issues (and fantastic potential) with this are reviewed by Banerjee and colleagues elsewhere in this issue in their description of futuristic virtual reality simulation techniques that are undergoing development. As technology is developed and subjected to validation, there will be gradual incorporation into educational curricula. Procedural simulators may be used for (1) aptitude testing; (2) teaching basic skills before patient interaction; (3) teaching advanced skills before performing complex procedures on patients; (4) procedure rehearsal on real patient anatomy loaded onto the simulator; (5) invention of new procedures (answering "what if I tried this?"); and (6) if done with an evidence basis, credentialing and certification. This is by no means a comprehensive list, but a taste of the possible roles. Almost every branch of procedural medicine, ranging from interventional radiology and vascular surgery, to gastrointestinal medicine, to orthopedic surgery, is exploring simulation for their unique uses [3,4].

Procedural simulations lie on a continuum ranging from part task physical model (low fidelity and passive) simulators to virtual reality or augmented reality simulators (high fidelity and active). In the near-term, because of financial and computational cost considerations, low-fidelity simulators may be useful to teach basic skills, reserving high-fidelity simulators to obtain the more intricate combinations of visual and tactile cues and cognitive and motor skills required to perform complex tasks [5]. The patient's own imaging data may be imported to high-fidelity procedural simulators. This allows "mission rehearsal" of difficult cases in a simulated environment before ever touching the patient. In these ways, simulation may bring great flexibility and safety in training, thereby becoming an indispensable tool in attaining, assessing, and maintaining higher levels of expertise than is currently possible in the traditional MAM [3,4,8].

Given the range of alternatives to practicing on patients that are becoming available, their requirements for relevant content and appropriate fidelity, and the ultimate need for validity to be demonstrable, it can be difficult to ascertain where and how they should be integrated into training. Patient and team safety must be the primary objectives, achieved by eliminating the early learning curve before the first attempt on patients. Although simulation seems to have an obvious role here, when considering a given simulator model for training, it is essential first to determine the development methodology used, and the curriculum on which the simulation is based. Even better, and to avoid unnecessary technology development, the curricular training objectives that actually require simulation should first be identified by subject experts. Once it is determined where simulation should fit with the curriculum, it is possible to determine which of these identified training objectives might be met by existing simulators, and even to effect focused simulator development, specific to the curriculum's requirements. The roles required of simulation should be determined at the design stage of a curriculum, and ideally this information used as a basis for simulator model design. It stands to reason that ultimately, minimum standards will be required in simulator use [3].

Credentialing

Time honored use of written and oral examinations lacks validity for assessing technical skills. High-stakes training requires reliable skills assessment, both for the security and safety of patients and the protection of the trainee. Computer-based simulation can provide a facility to record and evaluate an operator's performance automatically and reproducibly, removing the subjectivity and bias of assessments used in the current MAM. This performance feedback can help the operator develop and theoretically be evidence (summative) for a certification [9]. For simulation effectively to contribute to training and assessment in this way requires that the content of the simulation follows the discipline's curriculum [10], and that the assessment process meets requirements for reproducibility, cost effectiveness, and feasibility [11]. Potentially objective methods, such as checklists, global scoring systems, and standardized patients, have been used to assess proficiency in procedural medicine (surgery); the assessment of many other fields is frequently based on logbook record to show acquisition of experience and, it is hoped, skills [12–18]. This or any other subjective method does not always demonstrate proficiency and does not take into account the differing rates of learning. They are subject to the differing case mix and expertise among training sites. The previously described deficiencies may be addressed with the use of simulation with automated assessment of specific metrics of performance [7,19–21]. Procedural simulation has been used successfully in some surgical procedures (eg, laparoscopy).

Some assessments provided in current simulators use general measures of overall performance, such as time to completion. While such ‘‘high level’’ metrics may infer some indication of skill, measures of detailed actions and errors relevant to specific performance objectives are often lacking. This may be the result of several factors including possible lack of robust input from a group of subject matter experts, or the inability to implement or use additional metrics by the current state of a particular simulator's technology. Detailed and more relevant metrics are yet to be clearly identified for many procedural fields, however, and this requires knowledge of what is happening in the real world task. This can be based on careful collection of video records of procedures performed by recognized subject matter experts. A psychologist is then engaged to detail the skills used, and then, in a further interview of subject experts, to identify the cues, decisions, and psychomotor actions, which comprise the task that was originally performed. This Physical and Cognitive Task Analysis forms the basis of an analysis to identify which procedure steps are most critical and most prone to error: these data can be used as metrics to evaluate the learner's proficiency [3,22–25].

Potential pitfalls

Having proved itself in aviation, space exploration, and industrial applications, simulation is poised to become an important augment to training and assessment in procedural medicine. While adopting it, the educators must keep in mind the potential pitfalls so they can be avoided during development and implementation. Inadvertently overstating or aggressively interpreting the evidence is a pitfall that must be avoided. Whenever possible, the evidence must be collected in a rigorous fashion. The evidence may be obtained by the ‘‘use, validate, improve’’ model. That is, one begins to use these devices along with traditional training, obtain validation evidence while using it, and improve the simulator or curricula if needed. One must also consider some ethical issues. The question is, validate or not to validate. Is anything other than full-fledged implementation, without evidence specific to the simulators in use, unethical? Does transitivity apply in a setting of proved use of simulation in other fields? Will the attempt to obtain the ‘‘holy grail’’ (ie, transfer of training) obtained with a randomized study put patients at an additional risk? These are not easy questions, nor are they free of controversy, but they must be addressed.

Another important question is, if not used carefully, does the use of simulation for training potentially thwart or limit creativity? The different but safe ways of performing procedures, by different operators, must be taken into account when defining metrics and designing curriculum for procedural simulation. Involving subject matter experts from different specialties helps address this issue and creates a more robust set of metrics. Will an improperly designed curriculum teach the trainee bad habits? For example, if ‘‘short cuts’’ are permitted and used during the training on the simulator, the trainee may inadvertently use these same short cuts on patients, placing the patient and team at risk, defeating the goal of the procedural simulation [3,4].

Another potential pitfall is the difficulty providing adequate and meaningful feedback to trainees, which a simulator currently cannot do. This requires a large amount of time and dedication on the part of academic physicians with already busy clinical schedules. Finding the means to insert additional curricula into overtaxed residency requirements is difficult. This is particularly paramount in the face of current "duty hour" restrictions. One option may be to lengthen training programs such that they can include dedicated time for simulation.

One must also consider potential pitfalls that are not always thought of. Since the advent of virtual reality, simulator sickness has been recognized. Although the definition is controversial, symptoms range from nausea and dizziness to sleepiness and apathy [26,27]. It is a well known phenomenon in head-mounted displays [28], but does this exist in procedural simulation?

Simulator design considerations

As a larger point of view, several factors must be considered in design of simulators. It is imperative that the purpose of a procedural simulator is defined in detail, including task requirements; metrics requirement; software environment; hardware and interface (GUI, haptics, and physical interface); and specifications. There may be multiple valid pathways or sequences of steps to perform a procedure, making the definition of a task or procedure difficult. This should also be considered when identifying metrics so that trainees are not penalized for constructive imagination. Task analysis performed with an educational psychologist is crucial in obtaining this information. This information gathering must also be dynamic and evolve with improved procedural techniques and tool change [3,29].

Many validation studies can be performed to determine how relevant the simulation is to performance of the real world procedure or task. For training purposes content validity ("accurate replication of the procedure it claims to model") and face validity ("appearing to test takers to resemble the real world task") [3] is important. To attain face and content validity, the simulation must clearly provide an appropriate level of fidelity. For assessment purposes, however, benchmarks and construct validity are more important. This allows the simulator properly to distinguish the performance of experts from that of novices. It is not enough, however, to demonstrate that performance improves on a simulator. The assessment should be able to predict future performance and competence (predictive validation), confirmed by a separate clinical study. For integration into curricula, face and content validity are particularly important, but the use of simulation for assessment requires at least face, construct, and content validity. Once this has been shown, it seems more likely that skills developed in the simulation will transfer to the conditions of real world procedures in patients, and be maintained over time. This specific benchmark is known as "transfer of training" (or skills transfer).

Although there exist claims of successful validation, few simulators have yet to show improvement in technical skills in patients [29–32]. Virtual reality to operating room evidence exists for laparoscopic simulation [7], for example, but is noticeably lacking in endovascular simulators [29]. It is only a matter of time when further development and validation of simulators will effectively augment the deficiencies in MAM, reducing the use of patients as practice subjects.

Standards

The recent drive to develop and incorporate medical simulation in education has been caused by patient safety concerns. Because of this, the simulation industry has begun to assume a duly deserved center stage in the medical education arena. Because they have limited financial resources, there may be collaborative opportunities for academia and governmental agencies in the development and validation of simulators. The educational institutions must take the lead and set standards for validation, standards for procedural simulation use in their curricula, and even broader device development standards.

Standards for curriculum

There is a fundamental need to now unravel the nature of skills, and the level of fidelity required for their acquisition. It is inescapable that for any practitioner, surgeon, radiologist, or cardiologist to learn relevant skills that transfer to real world tasks in patients, the training environment must have an appropriate level of sensory fidelity, content that mirrors the real world task, and evidence-based metrics that test technical skills. Thus equipped, computer-based simulation should train and assess actual skills required, without the risk of training inappropriate or incorrect skills (negative training) and with greater likelihood of successful, clinical validation.

Based on this, there may be a need to redefine training curricula to identify insertion sites for simulation that meet specific training objectives. A number of the radiological societies have formed individual simulation taskforces and a combined Joint International Task Force to outline a strategy for using simulation methodologies to help train and assess interventional radiologists. Similar efforts are already underway in other specialties. However, such efforts need to occur not only in specialties in isolation, but also collaboratively, across specialties. The difficulties in achieving this include attaining consensus, professional competition, and other political issues. Yet, uniform curriculum standards for specialties performing identical or similar procedures would bring great logistical benefits for creators of simulations of these interventions.

Simulator development standards

A unified standard that facilitates upgrades and allows communication between different simulators is essential for advancement of simulator technology. Cross-platform communication and compatibility may prove to be invaluable for team training using simulation. For example, when performing a procedure under anesthesia, simulated by an appropriate anesthesia simulator, it would be helpful if the procedural simulator were able to communicate with the anesthesia simulator. These may be made by different companies but compliance with appropriate standards would allow the communication. If a complication occurred during the procedural simulation, the anesthesia simulator would detect the change in the patient's physiology and the anesthesiologist would react appropriately. Those involved in simulation, including academicians and educators, industry partners, and end users, have started to assess the future need for a unified, open software, hardware, and interface standards. On the software side, at least two such efforts are underway. First is Simulation Open Framework Architecture, with a goal to create an open software platform for medical simulator development [33]. Second is an effort by the Scientific Computing and Imaging Institute of the University of Utah, the Unified Virtual Environment. It would be ideal to unify such efforts for standardization and advancement of simulator efforts [3].

Similarly, a hardware development framework and standard architecture, defining computational platform and human-computer interface, are needed. An interface analogous to ''plug and play with USB on personal computers'' is also critical. These types of efforts may help prevent duplication of resources. Such standardization may help foster smaller companies that lack the resources of larger companies yet are placed to develop niche simulators to fill needs not yet addressed by their larger counterparts. It may also help drive competition and innovation [3].

Using simulators within a curriculum

It is axiomatic that knowledge of the subject, cognitive and technical skills, and judgment skills are prerequisites in successful procedural medicine practice. Each simulator in theory should be validated, although given rapidly changing technology, limited funding, and time, it may not be possible or practical to validate all simulated tasks to demonstrate transfer of skills. The authors propose that, although it may not be possible to validate all, one can increase the probability of a valid simulator by designing them properly. The ''transfer of training'' is more likely to be demonstrable if the simulator had appropriate fidelity, valid content, and metrics. Although predictive validation remains an important yardstick, uptake of properly developed simulations will lead to circumstances that favor validation, and in turn validation will drive increased use. Therefore, if such simulations are used cautiously as a supplement to, rather than a replacement of, the MAM, validation should become more attainable, with a return on this investment of enhanced patient safety.

Although cautiously using the simulator, curriculum should not be neglected. The curriculum provides a variety of training and assessment tools, providing checks and balances. Use of simulation without curriculum is meaningless. The broad curriculum provides "reliable scope of training and ultimate sanction of certification: simulation would, at least for the foreseeable future, form but a part of this 'big picture'" [3]. Until the technology advances conceivably to provide automated mentorship, it is the human mentor that provides an assessment, with simulation introducing objectivity. Simulation should not be used as a stand-alone training methodology.

The horizon and beyond

The incorporation of procedural simulation in medical education curriculum, in one form or another, is inevitable. The strategies for its incorporation and implementation depend on many factors, and these factors influence the time to maturity. Funding is the most important factor in these endeavors. The spirit of research, willingness of investigators to collaborate, and the willingness of governmental agencies to recognize the limitations of the current medical educational system, however, dictate how long it takes to exploit procedural simulation's full potential. In the future, scenarios will range from using the procedural tools themselves, to gathering metrics, to evaluating performance while working on real patients, to completely immersive simulation (akin to Star Trek's "Holodeck") [3].

The American Board of Surgery has already mandated incorporation of simulation in its curriculum starting in 2008 [34]. The American Society of Anesthesiologists has convened a 21-member Workgroup on Simulation Education, which has produced a comprehensive white paper on simulation in anesthesiology [35,36]. In addition, this committee has recommended the formation of a standing committee of the American Society of Anesthesiologists. Simulation has not penetrated the curriculum requirements by the American Board of Anesthesiology or by the Anesthesiology residency review committee of the Accreditation Council of Graduate Medical Education. Others, such as the Joint International Taskforce of the Society of Interventional Radiology, and the Cardiovascular and Interventional Society of Europe, have already written a strategy for simulation, and are working on implementation [37]. Funding, however, remains an issue in this relative infancy of simulation. Governmental agencies need to step up and fund the effort to develop, validate, and introduce simulation into medical education. It is the moral responsibility of the educators, hospitals, and overseeing governmental agencies to develop and implement simulation strategies for the safety of the patient and the operating team, and perhaps better education for the trainee.

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