

Simulation-Based Assessment and the Regulation of Healthcare Professionals

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Although we still have much to learn about incorporating simulation into regulatory-based assessments, the authors believe that sufficient evidence exists to further advance the use of simulation-based assessments as part of the regulatory systems for healthcare professionals. This position article reviews the current use of simulation-based assessment for credentialing, licensing, and certification programs in medicine, nursing, and dentistry. The findings support the view that simulation-based assessments can make a meaningful and positive difference in credentialing, licensing, and certification programs now.

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Quality and safety in healthcare depend on the complex interactions of competent individuals and competent systems. Yet, despite the release of the seminal Institute of Medicine reports^{1,2} over 10 years ago, quality and safety problems continue to plague the delivery of healthcare.³ The Agency for Healthcare Quality and Research recently reported that the median rate of improvement in outcomes across multiple conditions was only 1.6% per year in the United States since the Institute of Medicine report.⁴ Global migration of healthcare providers is also leading regulators to seek methods to assess international graduates and providers as a condition of licensing or credentialing.⁵

Simulation-based assessment (SBA) provides an opportunity for improving safety and quality as a part of professional regulatory programs. As noted by Gaba,⁶ “simulation ... closes some of the holes left by other [assessment] techniques ...” SBA, as part of a comprehensive, multimodal program, has unique advantages: presentation of rare and challenging “can’t miss” clinical scenarios; safe space to fail without harm to patients; ability to prospectively test skills; compliment work-based assessments; and allow for meaningful standardization in the testing of key skills.^{6–8}

OBJECTIVES

The primary objectives of this article are to outline what is known about the current use and effectiveness of SBA in regulatory-based programs and provide an initial set of recommendations for research and use of SBA in the regulation of health professionals.

METHODS

Because of the heterogeneity and current state of SBA for regulatory purposes, a formal systematic review was beyond the scope of this article. However, the authors performed a comprehensive PubMed search in their respective three disciplines, examined bibliographies of articles, reviewed pertinent websites, conducted informal surveys, and contacted key colleagues to understand the current use of simulation in regulatory programs. For the purposes of this article, we define SBA as the use of any device (eg, a simulator) or set of conditions, such as a standardized patient examination, that attempts to evaluate healthcare providers’ clinical competence authentically.⁸

BRIEF HISTORY OF SIMULATION IN REGULATION

The foundation for SBA as a regulatory requirement began in the 1960s and 1970s when basic and advanced life support courses—partially based on simple mannequins/simulators—were required by many medical and licensure associations.⁷ Courses such as advanced cardiac life support and advanced trauma life support are all examples of competency-driven requirements that became endorsed as a regulated component of maintenance of certification or credentialing in the healthcare profession or as a condition of employment. A second layer in the foundation of SBA is well reflected by the use of simulated/standardized patients (SPs) and the objective structured clinical examination (OSCE) movement that was founded in the 1970s and matured into the 1990s and the 21st century as a well-established high-

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stakes assessment tool which is now being used worldwide in healthcare professional examinations.^{9–17}

Perhaps more importantly, a number of studies are beginning to demonstrate that knowledge, skills, and attitudes acquired and demonstrated in a simulation do transfer into measurable benefits for patients.^{18,19} A logical next step is to consider what role SBA should play in regulatory programs for practicing health care providers. By regulatory, we include those processes required by external entities as a condition to maintain some form of credential, including certification within a discipline, licensure, and privileges within an institution and/or health system.

CURRENT USE: SIMULATION-BASED ASSESSMENT FOR LICENSURE, CERTIFICATION, OR RECERTIFICATION OF HEALTH PROFESSIONALS

Among the three professional disciplines investigated for this report, there are some notable examples of SBA already being used for high-stakes regulatory decisions in medicine and nursing.

At the medical student level, for example, the National Board of Medical Examiners in the United States introduced the standardized patient-based clinical skills examination (USMLE CS Step 2) in 2004 to all graduates of medical school in the United States,¹⁷ reflecting a major shift in the field of medical licensure and regulation by acknowledging the crucial role of clinical and task-based performance assessment as an important component of professional self-regulation. The incorporation of additional simulation modalities to OSCE-based evaluation allows the assessment of clinical and task-based performance and increases the authenticity of the assessment method. The OSCE is also used for high-stakes assessment and certification around the world,^{20,21} including assessment of foreign doctors wishing to practice in another country,¹⁰ for admission to medical school,²² and for medical students and residents seeking to acquire a medical license and certification in several countries.^{11–15}

At the resident level, successful completion of the Fundamentals of Laparoscopic Surgery course is now required by the American Board of Surgery for initial certification in surgery.^{23,24} The Israel Center for Medical Simulation is involved in a national board examination in anesthesiology²³ using high-stakes simulation-based assessment.^{25,26}

One additional example of a regulatory-directed simulation-based assessment is the mandatory requirement by the Food and Drug Administration, as a condition of its medical device approval for carotid stents, of physicians to complete training on a task-based simulator before they can use the stent in eligible patients.²⁷ This condition of approval was actually promulgated by physicians who developed the clinical guidelines for carotid stenting, based on data in other procedures that demonstrated the effectiveness of simulation-based training and assessment.^{27,28}

In nursing, OSCEs are being used in Quebec, Canada, as part of the registered nurse licensure examination²⁹ and for licensure of nurse practitioners in British Columbia and Quebec. An assessment that includes OSCEs is required for all foreign-educated nurses desiring to become registered in any Canadian province.³⁰ In Israel, SBAs with 11 OSCE sta-

tions were introduced in 2008 for 13 nursing specialties. The goal is to test more than 1000 nurses in 15 specialties in 2011 and implement a research agenda that examines psychometric qualities of the examinations along with resulting system changes.³¹

WORKS-IN-PROGRESS: SIMULATION-BASED ASSESSMENTS IN DEVELOPMENT FOR REGULATION BY DISCIPLINE

Medicine

In surgery, the American College of Surgery/Association of Program Directors in Surgery (ACS/APDS) Surgical Skills Curriculum is designed to address the needs of general surgery residents, the ACS/APDS/The Association for Surgical Education (ASE) Entering Surgery Resident Prep Curriculum is designed to prepare fourth-year medical students to enter residency training in surgery, and the ACS/ASE Medical Student Simulation-based Surgical Skills Curriculum aims at addressing the needs of all medical students in years 1 through 3 of medical school.³² All three curricula will include summative assessment tools in the near future.

Several SBAs are being used for as part of the American Board of Medical Specialties maintenance of certification (MOC) program. The American Board of Anesthesiology requires completion of simulator training as part of its MOC program, and the American Board of Internal Medicine provides a cardiac catheterization simulator formative assessment as an option for interventional cardiologists.^{33,34} Finally, the American Board of Family Medicine uses sophisticated computer-based clinical simulations using Bayesian logic as a component of MOC.³⁵

Nursing

In the United States, a few nurse practitioner programs are using standardized patients (SPs) for some part of their course or end of program examinations,³⁶ and Drexel University incorporates an SP-based examination as a requirement for the completion of their undergraduate nursing degree.³⁷ Nursing faculty express many concerns about using SBAs,³⁸ but recent reports from the Carnegie Foundation³⁹ and the Institute of Medicine report, *The Future of Nursing*,⁴⁰ call for efforts to develop and share simulation scenarios and use them for assessment.

Two research projects currently underway by major nursing organizations in the United States have the potential to advance the use of SBA in nursing. The National Council of State Boards of Nursing is following a cohort of students throughout their education and into the first year of practice. Students at 10 RN prelicensure programs (N = 1000) will be divided into three groups, each having a percentage of clinical time replaced with simulation—10%, 25%, and 50%. Goals are to discover the effects of simulation on learning, how it translates after graduation, and to establish a recommended simulation curriculum.⁴¹ The National League for Nursing launched a 3-year study to lay the groundwork for use of SBA in prelicensure RN programs in 2010.⁴²

Dentistry

Task training and the use of simulators have been ubiquitous in all levels of dental education for decades, ranging from simple

dental articulators to simulated patients or manikins incorporating computer-supported audiovisual systems to virtual reality-based simulators.⁴³ Currently being used to assess preclinical competency in predoctoral and specialty programs, their introduction as part of the licensing process is envisioned to replace live patient evaluation. The American Dental Association has funded the development and evaluation of an Airway Rescue Course for Moderate Dental Sedation consisting of on-line monographs, pre- and postassessment, task training, and the use of high-fidelity human simulators to provide yet another possible educational qualifier.⁴⁴

MOVING FORWARD: ISSUES AND CHALLENGES

Although the theoretical and empirical foundation for many simulation-based assessments is strong for current regulatory uses as outlined above,^{7,8,10,17} and as outlined in other articles in this supplement, little evaluative work has yet been done to measure directly the effectiveness and impact of regulatory-based SBA. The ultimate goal should be to demonstrate incorporation of SBA in professional regulation which leads to better healthcare quality and safety for patients and populations. One significant barrier is the lack of courageous leadership to use simulation in high-stakes programs because SBA is not yet “perfect.” The reality is that simulation, similar to all assessment modalities, will always be a work in progress. The formative uses of SBA as exemplified by the American Board of Anesthesiology, American Board of Internal Medicine, and American Board of Family Medicine initiatives already help physicians to improve while concomitantly facilitating the evaluation of the program.^{33–35} For example, a pilot study of the cardiac catheterization SBA found that the activity could discriminate between levels of performance which provided valuable information for future iterations of the assessment.³⁴

The regulatory system of many countries is itself a substantial barrier. In the United States, for example, there are 70 state medical boards and 24 specialty certification boards; achieving consensus is a very difficult, but not impossible, process. There is also a perception that simulation is a replacement for other assessments. Instead, SBA should be complimentary to other assessments in a multimodal system as noted above and by others.^{6,7} There is a deep culture of conservatism around testing which contrasts with the accelerating pace of innovation in education and practice, creating a widening gap between current approaches to assessment and what healthcare providers actually do in practice. Other well-known barriers include the following^{7,8}:

1. Costs and logistics.
2. Standardization across multiple simulation sites.
3. Exposure of simulation modalities to trainees before high-stakes testing.
4. Overreliance on psychometric criteria that can lead to measures (eg, checklists) that may fail to capture the complexities involved in healthcare, such as caring for the patient with multiple comorbidities.
5. Validity, especially in maintenance of licensure and certification where little evidence exists.
6. Transferability to actual clinical practice.

7. Training and recruitment of the raters for high-stakes simulation-based assessment.
8. Evidence base for some SBAs not yet robust enough for high-stakes assessment.

CONCLUSION AND RECOMMENDATIONS

Although we still have much to learn, we believe that sufficient evidence exists to incorporate more SBA into regulatory practices and programs while the community builds the evidence base for SBA in health professions regulation through actual use in regulation. Where the evidence and theory is not yet sufficient for high-stakes, summative-type decisions, SBA can start as a potent and valuable formative component. Given SBA has unique strengths and can help to improve care, we can no longer afford to wait for “perfect” evidence before incorporating meaningful, simulation-based assessments into credentialing, licensing, and certification programs.

More specifically, there are a number of reasons why simulation should be a component of regulatory assessment programs:

1. Rapid pace of change in technological aspects of health care.
 - a. Many health care professions require substantial training within a discipline before entering unsupervised practice, but after leaving training, new knowledge, skills, and procedures emerge. Past experience has shown that the introduction of a new technology without adequate training and assessment can lead to disastrous consequences for patients. Simulation can help healthcare providers to appropriately and safely acquire these new skills.^{18,27,28}
2. Breakdown of traditional disciplines.
 - a. Simulation can serve as both a training tool and assessment method to help ensure that the healthcare provider can demonstrate capability (at a minimum) to do the procedure regardless of their specialty discipline. Simulation may also help to ensure common standards for quality and safety across disciplines.
3. Maintenance of competence.
 - a. There is a limited and imperfect association between volume of a particular task or procedure and quality and safety. Simulation might be a better mechanism for assessing competence for many procedures and tasks over proxies such as volume and experience.^{34,45}

Simulation could potentially help providers attempting to re-enter the workforce. With existing and looming shortages in many disciplines throughout the world, it would be prudent to create mechanisms for re-entry into the healthcare workforce. Simulation might be used for a baseline comprehensive assessment, subsequently tied to work-based assessments, that would allow more capable individuals to return to the workforce sooner.

As SBA is included in professional regulatory programs, we do believe that further investigation and development should be included as part of the implementation and monitoring:

1. Expand investigation of the psychometric qualities, particularly the predictability of simulation-based testing for work-based performance.

2. Examine the impact of high-stakes exams on the transferability of simulation-based assessment to practice, most notably:
 - a. Patient safety and quality care.
 - b. How the results affect the curriculum?
 - c. How it changes the behavior of test candidates?
 - d. How the results affect the behavior of the faculty as teachers and assessors?
3. Advance the assessment measures to higher levels of competencies and skills, such as safety (handoffs, error recovery), team work, multicultural skills, reflective practice skills, and clinical judgment.
4. Develop better process measures for high-stakes simulation:
 - a. Physicians cannot always control the clinical outcomes for patients, process workflow, and associated measures but can still provide valuable evidence of the quality of performance by the healthcare provider.
5. Advance methods of standard setting:
 - a. Where and how should we set the bar?
 - b. Should there be different standards for different groups?
 - c. How should we handle measurement issues around individual performance versus individual within group performance?
6. Investigate methods on how to incorporate simulation into multimodality assessments, such as portfolio and comprehensive assessment programs.
7. Improve methods of assessment for isolated skills versus integrated skills and their assessment in different contexts. For example, an isolated skill would be an ability to tie a knot to do laparoscopic appendectomy. Integration of skills means doing the procedure when there's actual pressure, you need to work in a dysfunctional team and simultaneously Isolated meaning, for example the ability to tie a knot, to do laparoscopic appendectomy ... Integrated means doing it when there's pressure around you, and you need to work in a dysfunctional team and simultaneously manage additional tasks during the procedure.

Finally, because we have so little experience with SBA in maintenance of licensure and certification programs across the globe, we need pilot studies to study the impact of SBA on the behavior of practicing healthcare professionals. In the end, the primary purpose of all of these regulatory processes is to ensure the public that they are being cared for by a competent practitioner. Simulation holds substantial promise to help the involved regulatory bodies meet this responsibility.

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