Beyond the Simulation Laboratory: A Realist Synthesis Review of Clinical Outcomes of Simulation-Based Mastery Learning

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Abstract

Purpose
Translational educational outcomes have been defined as starting in simulation laboratories (T1) and moving downstream to improved patient care practices (T2), patient outcomes (T3), and cost or other value outcomes (T4). The authors conducted a realist synthesis review of the literature to evaluate the translational effect of simulation-based mastery learning (SBML) principles beyond the laboratory. They also sought to address future directions in SBML to improve patient care processes and outcomes and, thus, the quality of health care delivery.

Method
The authors searched multiple databases for simulation-based medical education (SBME) studies published through April 2013. They screened articles using the PICO method—population (P), intervention (I), control (C), outcome (O)—to answer the research question: For (P) any health care providers, does the (I) implementation of SBML training, compared with (C) other training methodologies or no extra training, result in (O) a change in patient care practices or T2–T4 outcomes? Studies implementing SBME interventions with training methodologies that met the seven SBML principles and reporting T2–T4 outcomes were identified.

Results
The 14 included studies used pre/post or cohort study designs; the majority were limited to individual performance and procedural competency. They reported improvement after SBML training in procedure performance, task success, patient discomfort, procedure time, complication rates, or T4 impacts (e.g., cost reduction).

Conclusions
Findings suggest that health professions education conducted using SBML methodology can improve patient care processes and outcomes. Further research is needed to understand the translational impact of SBML for nontechnical skills, including teamwork, and skill retention.

Nearly two decades ago, the Accreditation Council for Graduate Medical Education (ACGME) began the ACGME Outcome Project initiative[1] to replace the traditional curriculum-based, apprenticeship model of graduate medical education with an outcome-based model. This paradigm shift from a process-based, structured curriculum to evaluation of outcomes via a competency-based curriculum is amongst the most profound changes in medical education.[2] This monumental shift has refueled the conversation concerning competence. Although the definition and operationalization of competence in medicine are high-stakes activities, the meaning of competency and the formation of educational programs for its attainment have challenged medical educators for decades.[3] Defining, measuring, and ensuring the competency of health care providers remains a key but elusive goal for health care educators.[4]

In 2008, Dougherty and Conway[5] proposed a "3Ts" translational science classification model with the intent to accelerate the rate at which innovations in health care deliverables are implemented in the U.S. health care system. McGaghie[6] modified the 3Ts road map to apply the model in educational terms as the desired consequences of educational interventions measured at graduated levels beginning in a classroom or simulation laboratory (T1), moving downstream to improved and safer patient care practices and processes (T2), and ultimately to improved patient outcomes (T3). McGaghie et al[7,8] later added a fourth impact level to describe outcomes such as cost savings, skill retention, systemic educational value, and health care system improvements (T4).

Simulation-Based Medical Education as Translational Science

The early simulation-based medical education (SBME) literature documented health care training outcomes that were predominantly measured within simulation laboratories (T1). Several comprehensive reviews[8–16] and meta-analyses[17–23] have documented the more recent SBME literature, providing examples of medical education translational outcomes not only in the T1 environment but also beyond it to the patient care environment (T2–T4).[24] These reviews have demonstrated that SBME uses many different technology and education modalities[25] that can improve patient care. As the translational science of SBME continues to mature, the conversation has evolved from considering whether SBME is an effective way to train health care providers to exploring which SBME techniques are most effective, for whom, and under what circumstances.

Simulation-Based Mastery Learning

Simulation-based mastery learning (SBML) in medical education has a history in the educational literature dating to the 1970s.[26–29] The mastery learning model holds that given the necessary time, under appropriate learning conditions, most students

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can "master" or reach a high level of achievement.[27] The goal of SBML as applied to health care education is to ensure that all learners accomplish all educational objectives or reach competency standards beyond proficiency levels with little or no variation in outcome. The SBML model implies that most learners, with deliberate practice,[9,30–33] formative assessment, and appropriate feedback can and will meet acceptable achievement standards. An important paradigm shift in SBML as compared with other learning methodologies is that the amount of time needed to reach mastery standards for educational objectives varies among learners. A recent report suggests that SBML interventions are more effective than non-SBML interventions.[21]

In this report, we describe the patient care processes, outcomes, and other variables reported after successful implementation of SBML curricula. Our research had two purposes: (1) to conduct a realist synthesis review of the literature to evaluate the translational impact of SBML principles beyond the simulation laboratory and (2) to address future directions in SBML curriculum planning and implementation to understand how SBML may be useful in improving patient care processes and outcomes and, thus, the quality of health care delivery.

Method

We conducted our review according to the reporting standards set by the RAMESES (Realist and Meta-narrative Evidence Syntheses: Evolving Standards) collaboration.[34,35] Realist synthesis is a theory-driven method that is firmly rooted in a realist philosophy of science and places particular emphasis on understanding causation and how causal mechanisms are shaped and constrained by social context. The realist synthesis method examines the question, What works, for whom, under what circumstances, how, and why?[36,37]

This makes the RAMESES style particularly suitable for reviews of simulation-based research.[35] Reports of SBME interventions commonly fail to clearly describe every aspect of their research methods. There is also significant heterogeneity among study designs, participants, and outcomes in the SBME literature. In a quantitative meta-analysis, these differences could introduce biases. Thus, traditional systematic review and meta-analysis techniques may be less applicable in reviews of the SBME literature.[36] Colliver et al[37] suggest that "the medical education field might be better served in most instances by systematic narrative reviews that describe and critically evaluate individual studies and their results, rather than obscure biases and confounds by averaging."

Search strategy and inclusion criteria

Original research reports that evaluated an SBME intervention with a patient care process or outcome measure in a clinical environment were reviewed for inclusion. To identify SBME studies with T2–T4 outcomes, two of the authors (S.G.T. and S.P.) conducted an initial search of the peer-reviewed, English-language literature published through April 2013 using three databases: MEDLINE (via OVID), CINAHL, and Web of Science. The search included terms for the intervention (e.g., *simulat**, *manikin**, *virtual**, *simman**, *Harvey*), topic (e.g., *education*, *health sciences*, *teaching*, *experiential learning*), and outcome (e.g., *patient safety*, *quality of health care*, *risk management*, *evaluation*, *adverse event*).

Studies were screened for inclusion using the PICO[38] method: population (P), intervention (I), control (C), and outcome (O). Our research question was: For (P) any health care providers, does the (I) implementation of SBML training, compared with (C) other training methodologies or no extra training, result in (O) a change in patient care practices or T2–T4outcomes? References from systematic reviews, review bibliographies, and articles in key journals were also reviewed to identify additional studies.

Exclusion criteria

Studies were excluded from consideration if the methods of training described did not adhere to all seven SBML principles (see List 1), outcome data were self-reported, the article did not represent original research, or the evaluation did not have an observed T2, T3, or T4 patient care process or measurable outcome.

Study selection and data extraction

Two of the authors (S.P. and S.G.T.) reviewed the titles and abstracts of the articles identified in the initial search. Both authors reviewed the full text of original research articles with an SBME intervention with a T2, T3, or T4 patient care process or outcome measured in the clinical environment. Two authors (S.P. and T.R.) then independently reviewed the remaining articles to identify articles that met all SBML principles (see List 1).

Three authors (S.P., S.G.T., and T.R.) independently reviewed each article selected for inclusion to conduct the realist review. They extracted and assimilated the information provided, including characteristics of learners, study design, reported outcomes, and study funding. The results were shared among all the researchers. For any disagreement, the entire research team reviewed the article and discussed it until consensus was reached.

Results

A total of 11,905 articles were screened for inclusion. Ninety-three of these articles reported an SBME intervention with a T2, T3, or T4 patient care process, patient care outcome, or health care system outcome (e.g., cost). After critical review for use of all seven SBML principles, 14 articles remained (Figure 1).

List 1

Mastery Learning Criteria: The Seven Key Principles of Simulation-Based Mastery Learning[a]

1. Baseline or diagnostic testing
2. Clear learning objectives, sequenced as units usually in increasing difficulty
3. Engagement in educational activities focused on reaching the objectives
4. A set minimum passing standard for each educational unit
5. Formative testing to gauge unit completion at a preset minimum passing standard for mastery
6. Advancement to the next educational unit given measured achievement at or above the mastery standard
7. Continued practice or study on an educational unit until mastery standard is reached

[a]Adapted from McGaghie et al.[33]

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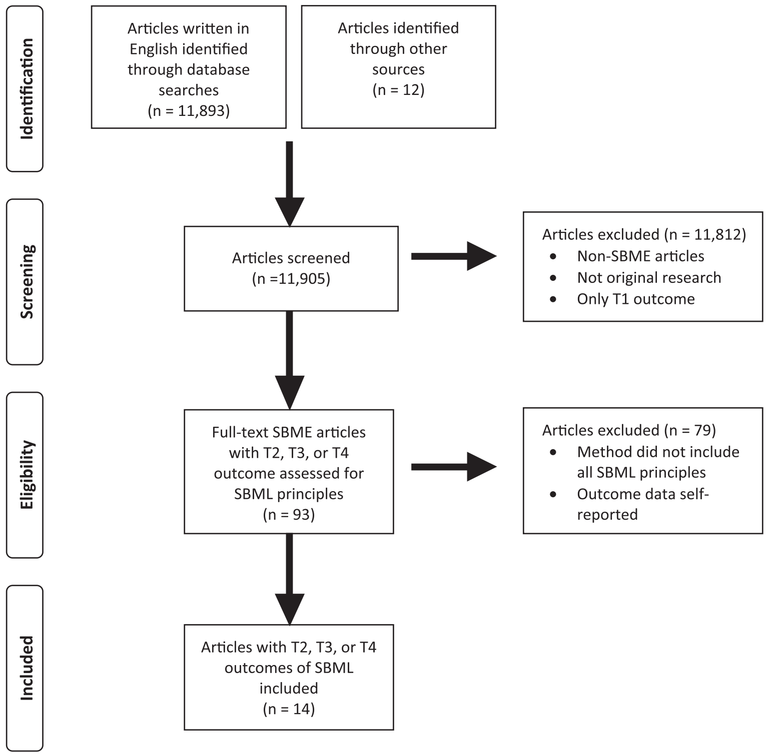

Figure 1 Flowchart of the processes used to search the literature and select simulation-based medical education (SBME) studies with T2, T3, or T4 translational outcomes of simulation-based mastery learning (SBML), published through April 2013. Abbreviations: T1 indicates impact limited to the simulation laboratory; T2, improved patient care processes or practices; T3, improved patient outcomes; T4, collateral effects such as cost or other value.

The 14 included articles with T2, T3, or T4 translational outcomes of SBML are summarized in Table 1.[39–52] These articles are described below in categorized groups based on the specific patient or health care system impact reported: (a) procedure performance, task success, and decreased patient discomfort, (b) procedure time, (c) complication rates, and (d) T4 impact such as skill retention or health care cost reduction. The majority of SBML interventions identified by this review were limited to individuals' performance; most involved postgraduate trainees and evaluated procedural competency. All included studies used a pre/post or cohort study design to compare the outcomes of SBML interventions and interventions that employed traditional teaching approaches. For this review, we defined "traditional" education as training with or without a study plan that all participants are privy to.

Procedural performance, task success, and decreased patient discomfort

SBML resulted in improvement of bedside procedural performance and procedure success rates in several studies. Downstream translational practice and process (T2) outcomes of SBML included improved performance of skills (including hemodialysis catheter insertion,[39] cardiac auscultation,[40] and adherence to advanced cardiac life support [ACLS] guidelines[41]) and improved performance of procedures (including transurethral resection of the prostate [TURP],[42] laparoscopic fascial closure,[43] colonoscopy,[44] and laparoscopic surgery[45,46]). SBML also demonstrated improved patient care outcomes/procedure success rates (T3) as seen in the studies evaluating the use of SBML for colonoscopy[44,47] and TURP procedures.[42] Studies on skill acquisition in colonoscopy[44,47] also reported decreased patient discomfort during the procedure after SBML training.

Procedure time

Several studies demonstrated decreased procedural or operative time after SBML curricula were implemented. Ahlberg et al[47] reported a significant difference in procedure time to reach the cecum during colonoscopy, with the SBML group requiring a median of 30 minutes as compared with 40 minutes for the control group. Yi et al[44] also reported a similar reduction in time to successful colonoscopy completion, with the SBML group requiring 31 minutes versus the 41.5 minutes for the control group.

Larsen et al[45] reported a 50% reduction in the operating room (OR) time required in the intervention group in a laparoscopic virtual reality training trial. Zendejas et al[46] reported a reduction in procedure time during total extraperitoneal (TEP) inguinal hernia repair: SBML-trained residents were able to complete the surgery with a mean time of 34 ± 8 minutes compared with 48 ± 14 minutes for the traditional training group. However, in contrast, Hogle et al[48] reported a statistically significant increase in total operative time in the simulation-trained group compared with the control group.

Complication rates

Reduction of complication rates is an important translational outcome in health care costs and patient well-being. Barsuk et al[49] demonstrated an 85% decline in central-line-associated blood stream infections (CLABSIs) among medical intensive care unit (MICU) patients whose central venous catheter (CVC) placements were performed by residents who completed the SBML intervention compared with patients whose CVCs were placed by traditionally trained residents. This decline in CLABSI rates was replicated in a second study at another institution, with Barsuk et al[50] reporting a 74% reduction after SBML training. Duncan et al[51] demonstrated a reduction of pneumothorax rates following SBML training in thoracentesis; however, this study also incorporated the use of ultrasound, which is known to independently improve the safety of CVC insertion. Zendejas et al[46] demonstrated decreased intraoperative and postoperative complication rates during laparoscopic TEP hernia repair among surgical trainees who completed an SBML curriculum as compared with trainees who completed a traditional curriculum.

T4 impact

In a cost analysis of Barsuk and colleagues'[49] 2009 SBML CVC study, Cohen et al[52] estimated a $700,000 direct cost savings, yielding a 7-to-1 return on investment, associated with this simulation-based intervention. The

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Table 1

Summary of Studies That Implemented All Simulation-Based Mastery Learning (SBML) Principles[a] With Clinical Translational Outcomes at the T2, T3, or T4 Level, Published Through April 2013

Study first author, year	Learner category	Study design evaluating T2, T3, or T4 outcome	Comparison group	Skill	Simulation modality	Clinical outcome: Performance	Success rate	Time	Patient discomfort	Error reduction rate	Cost	Funded study
Ahya, 2012[39]	12 PG	Cohort	Post SBML T1 vs T2 performance	Hemodialysis catheter insertion	TT	+						NR
Ahlberg, 2005[47]	12 PG	RCT	SBML vs traditional	Colonoscopy	VRS		+	+	+			NR
Barsuk, 2014[50]	51 PG	Cohort	SBML vs traditional	CVC insertion	TT					+	+	+
Barsuk, 2009[49]	92 PG	Cohort	SBML vs traditional	CVC insertion	TT					+		+
Butter, 2010[40]	108 MS	Cohort	SBML vs traditional	Cardiac auscultation	CBT	+						+
Cohen, 2010[52]	69 PG	Cost analysis of prior study	SBML vs traditional	CVC insertion	TT						+	NR[b]
Duncan, 2009[51]	44 SP	Retrospective/ prospective	SBML vs traditional	Thoracentesis	TT					+		+
Hogle, 2009[48]	34 PG	Retrospective review	Pre/post SBML	Laparoscopic cholecystectomy	VRS			–				NR
Källström, 2010[42]	24 PG	RCT	Pre/post SBML; SBML vs traditional	TURP	VRS	+	+					+
Larsen, 2009[45]	24 PG	RCT	SBML vs traditional	Laparoscopic salpingectomy	VRS	+		+			+	+
Palter, 2011[43]	18 PG	RCT	SBML vs traditional	Abdominal fascial closure	TT	+						+
Wayne, 2008[41]	38 PG	Retrospective case control	SBML vs traditional	ACLS protocol adherence	HPS	+						+
Yi, 2008[44]	11 PG	Untreated control group	SBML vs traditional	Colonoscopy	TT	+	+	+	+			+
Zendejas, 2011[46]	50 PG	RCT	SBML vs traditional	Laparoscopic TEP inguinal hernia repair	TT	+		+		+	+	+

Abbreviations: T1 indicates impact limited to the simulation laboratory; T2, improved patient care processes or practices; T3, improved patient outcomes; T4, collateral effects such as cost or other value; *Learner category:* PG, postgraduate trainees; MS, medical students; SP, staff physicians; *Study design:* RCT, randomized control trial; *Comparison group:* SBML, simulation-based mastery learning; traditional, traditional health care educational curriculum; *Skill:* CVC, central venous catheter; TURP, transurethral resection of the prostate; ACLS, advanced cardiac life support; TEP, total extraperitoneal; *Simulation modality:* TT, task trainer; VRS, virtual reality simulator; CBT, computer-based tutorial; HPS, human patient simulator; *Translational outcome:* +, positive study outcome; –, negative study outcome; *Funded study:* NR, none reported; +, funding reported.

[a]See List 1 for the seven SBML principles.

[b]Secondary analysis of other studies.

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incremental costs attributed to each central line infection were approximately $82,000 (in 2008 dollars) and 14 additional hospital days (including 12 in the MICU). Zendejas et al[46] also demonstrated collateral effects from SBML, reporting a significant decrease in overnight hospital days after implementing SBML training for laparoscopic inguinal hernia repair. These results not only represent advantages for the health and safety of individual patients but also have notable financial implications for hospitals and health care systems.

Discussion

This review presents a realist synthesis of translational outcomes beyond the simulation laboratory after the implementation of SBML curricula to train health care providers. Our review identified 14 studies describing the implementation of SBML curricula that improved patient care practices or outcomes or demonstrated added health care value.

Several studies[44–47] reported decreased procedural and operative time. In contrast, Hogle et al[48] demonstrated increased operative time. However, they noted that several confounding variables not documented in the medical record (e.g., variations in hands-on operating time by the resident versus attending physician, the procedure's level of difficulty, intraoperative and perioperative complications) were not accounted for in the evaluation of operative time, and time as a variable was not isolated independently.

Although we do not present a formal cost analysis in this review to further evaluate the impact of decreased OR or procedure time, we suggest that reduction in surgical or procedural time may translate into improved OR efficiency and, therefore, financial savings in the health care system. Decreasing time under anesthesia may be beneficial for patients. Time savings in the OR for residents is likely a valuable outcome of SBML. Given that U.S. duty hours restrictions limit trainee time in the OR, improved efficiency after SBML training may increase the overall number of cases performed by residents. The issue of operative time and improved surgical efficiency as a result of SBML warrants further study.

An interesting finding in this review is that the articles we identified predominantly reported on individual providers performing a procedural skill. Almost all of these studies involved postgraduate trainees; the exceptions were one study with practicing staff physicians[51] and one study of medical students.[40] Two studies tested nonprocedural skills (cardiac auscultation[40] and adherence to ACLS protocols[41]). Only one study[43] attempted to address cognitive retention rates associated with acquisition of knowledge and multitasking. Evidence to support translational outcomes of SBML for nontechnical skills—including communication, teamwork, and complex cognitive skills—and skill retention remains scarce. This is due to challenges such as measuring complex clinical outcomes, defining competence and competencies in teamwork and communication skills, and following health care providers over meaningful periods of time.

SBML and the definition of competence

Health care educators have begun to use SBML to define, measure, and confirm health care providers' abilities to ensure a more effective health care workforce. In fact, SBML has been identified as a "best practice" of SBME.[10] The studies discussed in this review have identified SBML strategies that may be better understood in terms of the Dreyfus/Benner model of skill acquisition.[53–56] In that model, the path from novice to expert typically includes development of foundational knowledge, integration of pieces of information, application of information into problem solving, and transfer of information to different contexts.[53–56] The SBML model proceeds through baseline assessment, defined learning objectives, engagement in the educational activity, accomplishment of a minimum passing standard, and advancement to the next educational unit.

The following definition of a "competent" health care provider, based on our review and assimilation of the literature, highlights the implications of SBML principles: a provider who has attained the educational outcomes or competencies at the mastery learning level and has achieved an acceptable level of performance to begin to safely care for patients autonomously (see Figure 2). At the cusp of the advanced beginner to competent and proficient levels of the Dreyfus/Benner models, health care practitioners have a better working knowledge of practice areas, become more autonomous, may require less supervision, and are able to complete more complex tasks using their own judgment.

Health care providers educated to mastery standards also recognize when they are exceeding their own comfort levels and when they can safely proceed independently. Practice and preparation in the simulation laboratory have demonstrated superiority to traditional, apprenticeship methods of clinical education,[9] characterized by the "see one, do one, teach one" adage. SBML prepares health care trainees to enter the clinical environment at a level of competence beyond that of the Dreyfus/Benner novice or beginner. Adaptive expertise,[57–59] or the ability to understand and navigate complexities of various patient and environmental intricacies, is essential to progress to more advanced levels of performance.

SBML and variability of time

It is important to understand that the variability of time is a component of SBML that differs in many ways from the traditional apprenticeship model. In 1971, Bloom[27] reported that if teachers could provide the necessary time and appropriate learning conditions, nearly all students could reach a high level of achievement. The SBML model has been applied in educational environments to differentiate and individualize instruction and feedback to ensure that all learners accomplish all educational goals or achieve competencies with little or no variation in outcome. The SBML model suggests that learners commit to continuous practice with appropriate feedback until set standards are reached. We believe that SBML combined with intentional deliberate practice[31] will play a significant role in the future of health care education. Once learning outcomes and assessment modalities are identified, most health professions students should be allowed to learn at their own pace without penalty while provided continuous formative assessment of their performance.

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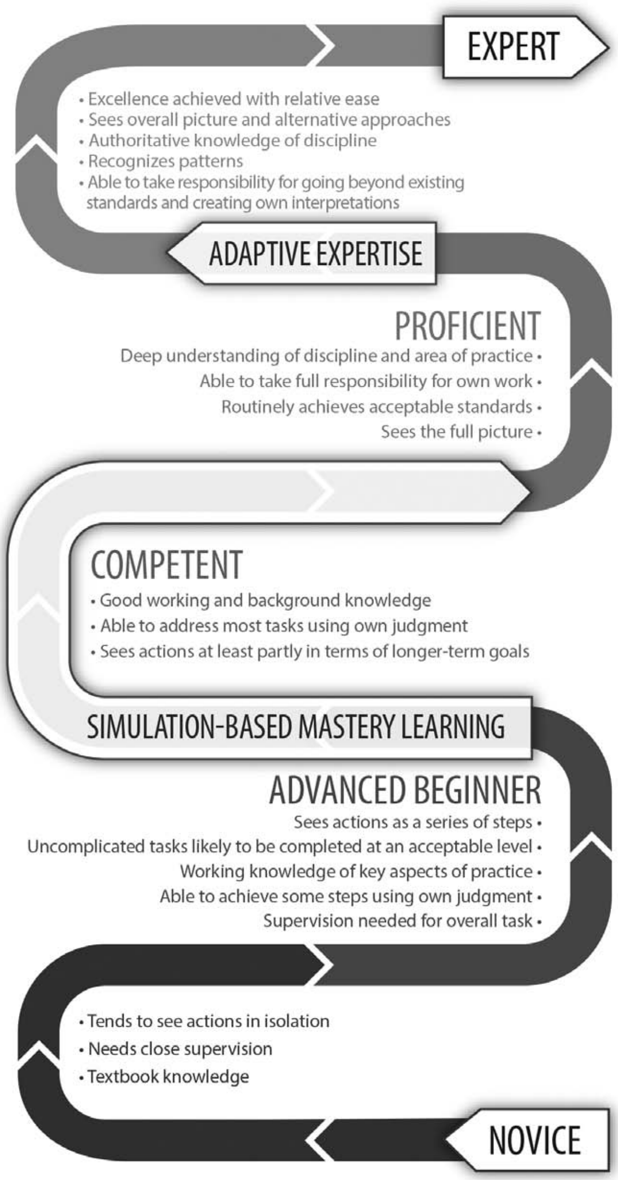

Figure 2 The authors' assimilation and interpretation of levels of knowledge, contextual understanding, and standards of work and autonomy in simulation-based mastery learning (SBML), as previously described by the Dreyfus/Benner model of skill acquisition.[53–56] SBML in the simulation environment prepares health care trainees to enter the actual clinical environment at a competent skill level without risk to patients. Adaptive expertise, or the ability to understand and navigate complexities of various patient and environmental intricacies, is essential to move to more proficient or expert levels of performance.

Cook et al[21] summarized quantitative outcomes of SBML and found that SBML occasionally required more time but was "associated with large benefit in skills." Within reason, the time may be justified if we are training providers to a higher level of performance without risk to patients. In the same systematic review, Cook et al noted that limited evidence suggests that the effect of SBML is optimized when a flipped classroom or pretraining is involved. The flipped classroom[60] approach allows learners to absorb and master acquired knowledge ahead of simulation laboratory time on their own schedule, and reserves face-to-face training time in the laboratory for experiential skill acquisition.

Limitations

Reproducing the results of an SBME intervention is an ongoing challenge as numerous heterogeneous factors contribute to successful SBME interventions. Owing to the large variation in interventions, learner populations, controls (i.e., no intervention or traditional education), and various patient care outcomes reported, we considered a realist synthesis[34,35] to be the most appropriate method to review and report the effects of SBML.

It is important to note that 79 of the SBME articles we identified were excluded from this review. Many of the excluded studies included at least some of the SBML principles, and the majority demonstrated a positive association between SBME and T2, T3, or T4 outcomes. This highlights the importance of understanding when SBML may or may not be a superior training modality as compared with traditional educational interventions or other SBME modalities. Although the studies included in this review met all seven SBML principles, we observed variations in how the simulation intervention in the studies followed these SBML principles. Only two of the studies clearly stated that mastery learning was used as the simulation intervention.[40,50] This was partly because SBML has attracted attention in the simulation field only in recent years.

Finally, publication bias may have influenced the results. Negative trials are less common than positive trials in the general scientific literature.[61] However, given that educators spend significant energy implementing educational programs as performance and quality improvement efforts, rather than studying them with the intent to publish their outcomes, it is also possible that successful SBML interventions at all four translational levels may not be submitted for publication and therefore will remain unknown.

Conclusions

Although the number of articles included in our review is small, the findings of these studies suggest that health care education conducted using SBML methodology can improve patient care processes and outcomes. SBML has been shown to affect performance level, procedural success rate, patient discomfort, procedure time, error rate, and health care costs.

Ensuring that the health care workforce is well trained and competent is likely to have additional far-ranging benefits,

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including better patient care practices and improved patient outcomes.[7] This requires further study.[62] The application of SBML principles to health care educational curricula may help educators define translational outcomes and further understand the meaning of competency. However, translational health professions education outcomes cannot be achieved from single, isolated studies. Rather, in health professions education, translational science results derive from educational and health services research programs that are thematic, sustained, and cumulative.[7] Such translational education research programs must be carefully designed and executed to capture and measure downstream results to aid in the creation of a patient-focused health care system that reliably delivers high-quality care.

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