Simulation research to enhance patient safety and outcomes: recommendations of the Simnovate Patient Safety Domain Group

Philip H Pucher,[1] Robyn Tamblyn,[2] Daniel Boorman,[3] Mary Dixon-Woods,[4] Liam Donaldson,[5] Tim Draycott,[6] Alan Forster,[7] Vinay Nadkarni,[8] Chris Power,[9] Nick Sevdalis,[10] Rajesh Aggarwal[11,12]

[1]Department of Surgery, St Mary's Hospital, Imperial College London, London, UK
[2]McGill University, Montreal, Quebec, Canada
[3]The Boeing Company, Chicago, Illinois, USA
[4]University of Cambridge, Cambridge, UK
[5]London School of Hygiene and Tropical Medicine, London, UK
[6]School of Social and Community Medicine, University of Bristol, Bristol, UK
[7]Ottawa Hospital, Ottawa, Ontario, Canada
[8]Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA
[9]Canadian Patient Safety Institute, Edmonton, Alberta, Canada
[10]King's College London, London, UK
[11]Steinberg Centre for Simulation and Interactive Learning, McGill University, Montreal, Quebec, Canada
[12]Department of Surgery, Faculty of Medicine, McGill University, Montreal, Quebec, Canada

Correspondence to
Dr Rajesh Aggarwal, Steinberg Centre for Simulation and Interactive Learning, Faculty of Medicine, McGill University, Suite 5640, 3575 Parc Avenue, Montreal, Quebec, Canada H2X 3P9; rajesh.aggarwal@mcgill.ca

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ABSTRACT

The use of simulation-based training has established itself in healthcare but its implementation has been varied and mostly limited to technical and non-technical skills training. This article discusses the possibilities of the use of simulation as part of an overarching approach to improving patient safety, and represents the views of the Simnovate Patient Safety Domain Group, an international multidisciplinary expert group dedicated to the improvement of patient safety. The application and integration of simulation into the various facets of a learning healthcare system is discussed, with reference to relevant literature and the different modalities of simulation which may be employed. The selection and standardisation of outcomes is highlighted as a key goal if the evidence base for simulation-based patient safety interventions is to be strengthened. This may be achieved through the establishment of standardised reporting criteria. If such safety interventions can be proven to be effective, financial incentives are likely to be necessary to promote their uptake, with the intention that up-front cost to payers or insurers be recouped in the longer term but reductions in complications and lengths of stay.

INTRODUCTION

Use of simulation-based training has become increasingly well established in healthcare, particularly in (but not limited to) surgical and procedural training. Offering the opportunity to learn in a risk-free environment, simulation can help to displace the outdated but still practiced Halstedian model of apprenticeship, in which trainees improve their skills solely through practice on the patient.[1]

Some evidence suggests that simulation may have a role in abbreviating learning curves,[2 3] improving clinician performance[4] and patient outcomes, as well as reducing complications.[4 5] Studies have reported the effectiveness of simulation in specific skills ranging from surgical procedures,[6] team skills[7] and ward-based care.[8] Evidence of cost-effectiveness is also emerging, whereby the resource cost for simulation programs—sometimes deemed prohibitive—may be offset in the longer term by clinical cost savings, for example, through the reduction of complications.[9 10]

Despite training and education having been repeatedly recommended internationally as a response to addressing systems and human error implicated in patient harm,[11 12] however, the study and application of simulation has remained mostly limited to specific domains—most frequently procedural training, focusing largely on surgical technical skills.[13] The use and evaluation of simulation as part of an overarching approach to patient safety has been insufficiently explored.

In this article, we offer a perspective on the possibilities of simulation and its role in the study and improvement of patient safety. The authors represent an international expert group convened as part of the Simnovate International Summit, which brings together multiple medical and non-medical fields to shape the future of simulation, education and innovation across four domains: patient safety, pervasive learning, medical technologies and global health.

The Simnovate Patient Safety Domain Group

Between September and December 2015, three teleconferences were convened by the members of the Simnovate Patient Safety Domain Group. The group comprises experts in nursing, surgery, medicine, aviation safety, psychology, sociology and international health policy; group members have also published extensively on simulation and patient safety. Teleconferences were recorded and detailed minutes agreed by all members. The group convened in person at the Simnovate International Summit, McGill University, Montreal, Canada, in May 2016 where further discussion and refinement of ideas took place. The findings of these discussions were distilled into this white paper.

Simulation as part of a learning healthcare system

We propose that one important role for simulation is as part of a learning healthcare system, defined by the Institute of Medicine as 'one in which science, information, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded… and new knowledge captured as an integral by-product of the care experience.'[14] This concept is one applicable to all health systems which have improved patient safety and outcomes among their core interests, and not limited to research or teaching institutions. A continuously learning and adapting system thus involves research being efficiently incorporated into clinical governance, translated into practice, overseen with continuous measurement of clinical outcomes and interventions and routine quality control that identifies targets for improvement in near-real time (figure 1).

Much as it has played a key role in the aviation industry's pursuit of safety over the past 40 years, simulation could have an important role in achieving these goals in healthcare (see table 1). Numerous mechanisms have been already adapted from the aviation world for medicine, among them preoperative checklists[15] and crew resource management training.[16] Potentially, further examples still may exist. Simulation can, for example, be used to diagnose system weaknesses before they lead to error. In situ simulation, in particular, has been used in to identify latent threats to patient safety;[17 18] simulated crisis response combined with post hoc video analysis may effectively identify potential team, process or equipment-related pitfalls which might otherwise place patients at risk during an actual event. When sentinel events do occur, simulation also offers a potentially more effective means of analysis compared with current standard practice. In one of the few such studies conducted thus far in healthcare, adverse events extracted from on-going medical malpractice claims were analysed and scripted, and repeatedly reproduced in a simulated clinical environment.[19] Compared with the conventional root cause analysis used in the malpractice claims, repeated simulation was better able to identify system-based errors as opposed to discrete process errors committed by individuals.

Simulation may therefore have benefits across multiple domains of a learning healthcare system, from improved education with abbreviated learning curves and reduced complication rates, to preimplementation trials of interventions, to pre hoc and post hoc systems analysis to identify weaknesses in healthcare systems. Ultimately, these may culminate in improved patient safety and outcomes, with the cost of such programs at least partially offset but reduced expense from avoidable adverse events. To deliver on these benefits, however, the research evidence base needs to improve, and the healthcare infrastructure needs to evolve to support the conduct of this research and implementation of findings.

What needs to happen next is clear from other areas—such as the implementation of enhanced recovery protocols in surgery over the past 20 years. Enhanced recovery was initially a collation of almost 20 disparate elements of care (such as the avoidance of bowel preparation or nasogastric drainage or early mobilisation),[20] many of which possessed moderate evidence on their positive impact on perioperative care for colonic resection. However, as a combined care protocol they had the effect to reduce postoperative lengths of stay by up to 3 or more days.[21] Despite the greater expenditure required for implementation and monitoring, the reduced complications and length of stay has meant that enhanced recovery is now accepted to be cost-effective as well.[21] For simulation, it is clear that advancing the field will require improved conceptualisation of areas such as methods of simulation, definitions and choice of outcomes understanding of the appropriate incentives, with subsequent validation of each approach.

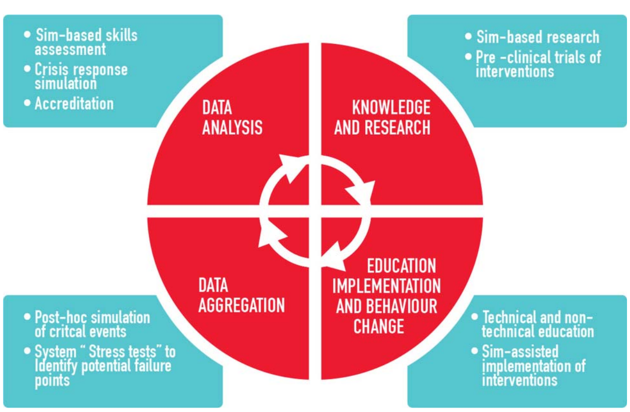

Figure 1 Examples of simulation within the components of a learning healthcare system.

Methods of simulation

An important task in maturing the field is to clarify methods of simulation, characterise the mechanisms through which they work, determine their outcomes and identify the contexts for which they are appropriate. Procedural simulators or task trainers—such as a latex arm on which to practice cannulation, for example—are the most familiar to the healthcare professional and effective for technical skills, but are generally limited to use for a single procedure and often a single learner. Immersive or in situ simulators, conversely, place multiple learners in realistic environments either through the use of key visual and audio cues within a simulated space (immersive),[8 22] or by carrying out simulations within actual clinical space (in situ), for example, by using simulated patients or mannequins on a ward or within an operating theatre. With immersive or in situ simulation, entire multidisciplinary teams may participate in clinical scenarios, with the aim of reinforcing

Table 1 Lessons still to be learnt? Examples of safety mechanisms in aviation and medicine across selected domains

Example domain	Aviation	Medicine
Crisis management	Crisis checklists, simulator training	Checklists increasingly in use but in limited contexts presently
Technical skills	High-fidelity flight simulator, obligatory training	Varied implementation of procedural simulators
Technical error prevention	Standardisation of equipment—every instrument panel is the same for a given model of plane, pilots trained and certified for specific planes	n/a
Non-technical/team skills	Crew resource management (CRM)	Team skills courses, aviation-style CRM
Systems stress testing	Routine obligatory training with simulated poor flying conditions and crisis management	n/a
Disaster investigation	Replication of crisis conditions in simulator to analyse error and risk of repetition	Post hoc analysis of medical records, root cause analysis
Disaster response	National/international response. Real-world crises identified and introduced into obligatory simulation training to prevent repeat process error. Grounding of planes in case of equipment error	Varied. Local centres responsible for managing own response systems

individuals' knowledge and practice, and the functioning of the clinical team as a whole.

Whereas procedural simulation is likely to remain a mainstay of basic technical skills adoption, in situ simulation may be preferable for standard patient simulations, as it allows teams to practice in the same clinical environment as they are employed. Where this is not possible due to space constraints, or the simulation requires modification to the environment (eg, to simulate an equipment fault), immersive simulation may be used to good effect.[8]

The feasibility of online virtual worlds to simulate trauma[23] and surgical[24] scenarios has shown great promise. Such models seek to present key decision-making scenarios through computer-based simulation, often accessible via the internet and as such with the advantages of remote and distributed access, as well as low end-user entry cost. Though many of these platforms remain at an early stage, continued improvements in processing and software mean such technology is likely to play an increasing role in future and will require evaluation.

Selecting outcomes

To date, the number of studies demonstrating significant links between simulation-based interventions and recognised clinical outcomes such as morbidity rates remains relatively small.[25] Current research instead tends to rely on outcomes such as improved technical skills assessments, or surrogate markers such as reduced operative time.[26 27] These, however, are largely circumstantial endpoints, and highlight the fact that the choosing of relevant and measureable outcomes is not straightforward. The feasibility of detecting discernible differences in morbidity and mortality when used as primary outcomes, for example, is challenged by the secular trend towards zero mortality (and low morbidity) for many interventions. Other metrics, such as adverse or sentinel events, suffer from the same problem of being of high impact, but low frequency. Specific errors, complications or care-related processes may be more suitable as clinical endpoints,[28] but require improved definitions and, ideally, a standardised taxonomy integrated across the breadth of simulation research.

Unfortunately, as the field of simulation-based research has matured, the reporting of outcomes have become no less heterogenous.[29] Making meaningful summative judgements of the existing literature, as a result, is often difficult, if not impossible. One means of achieving harmonisation of outcomes may be through the adaptation of existing patient safety taxonomies. The Agency for Healthcare Research and Quality (AHRQ) Common Format[30] and the WHO International Classification for Patient Safety[31] represent two frameworks for patient safety domains, which may be used to classify and select the most appropriate outcomes for various practice domains (see table 2).

Moreover, standardised reporting guidelines have proven effective in addressing the issue of inconsistencies in outcomes reporting in other fields, such as the SQUIRE guidelines for studies of quality improvement in healthcare.[32] We suggest a similar approach should be pursued for simulation and education-based research publications. By focusing on the standardisation of endpoints and their reporting, the aim should be to transition simulation from its origins as a technology-based research concept to an outcomes-based initiative.

Recently published guidelines[33] have sought to adapt existing reporting frameworks for randomised trials (CONSORT[34]) and epidemiological observational studies (STOBE[35]) for use with simulation-based studies. These adapted guidelines, for example, require that the context in which simulation is being used—whether as the subject of research, or as an investigational method—be specified, as well as detailed description of the theoretical concept involved, or intervention used, be included. In this manner, these recommendations may improve transparency and aid the standardisation of reporting, allow easier replication and increase impact of future publications. They have already been endorsed by editors of a number of simulation and education-related journals.[36]

Table 2 Patient safety domain classifications derived from WHO and AHRQ taxonomies, with examples of each

Blood products	Transfusion and blood product related error
Medical devices/equipment	Device failure or misuse resulting in harm
Patient accidents and falls	Avoidable patient accidents
Healthcare-associated infection	Includes central line and catheter-associated sepsis
Medications	Prescribing and administration error
Perinatal	Perinatal and neonatal care
Pressure ulcers	Prevention, detection and treatment
Surgery or anaesthesia	Intraoperative and immediately perioperative (OR) care
Venous thromboembolism	Prevention, detection, treatment
Clinical administration	Management and administrative error resulting in direct harm
Clinical process	Ward-based or outpatient care
Documentation	Medical documentation
Nutrition	Enteral and parenteral feeding, nutrition
Oxygen/medical gas	Prescribing, delivery
Staff behaviour	Teamwork, leadership and communication
Infrastructure/building/fixtures	Infrastructure impacting directly on patient care
Resources/management	Local resources and organisational management

AHRQ, Agency for Healthcare Research and Quality.

The evidence base for the cost-effectiveness of simulation is steadily building,[2 9 10 37] but more work is needed. As the posited relationship between simulation and patient outcomes becomes clearer, estimating the financial impact should become easier. Going forward, greater transparency will be needed also in the reporting of the cost of simulation-based initiatives, taking into account the equipment costs and staffing, teaching space and other ancillary costs involved.

Incentivising simulation

Producing evidence of effectiveness is unlikely to be enough, on its own, to secure the uptake of simulation: as in other areas, incentives are likely to be needed. A welcome move towards incentivising the use of simulation is its increasing incorporation in formalised curricula such as the American College of Surgeons Resident Skills Curriculum.[38] For broader impact, however, more wide-ranging encouragement will be needed. One such approach is illustrated by the Practical Obstetric Multi-professional Training (PROMPT) program, a simulation-based multiprofessional training program that had been shown in to improve perinatal outcomes, reducing by half the number of infants born with low Apgar scores or who suffer hypoxic-ischaemic encephalopathy.[39] In the UK, where it was first developed, implementation of PROMPT relies on dissemination via the course designers and is not mandatory. In contrast, in other regions its uptake has been backed by financial incentives. In Australia, for example, PROMPT has been formally endorsed by major malpractice insurers, who offer reduced premiums in return for evidenced completion of the course. The resulting high uptake of the course has been cited as a key factor in the significant improvement in patient safety attitudes (as measured by Safety Attitude Questionnaire), perinatal outcomes (reduction in number of babies born with an Apgar score of 1) and reduction of length of stay over the implementation period.[40] Such financial incentivisation models serve to 'front-load' the anticipated comparatively drawn out long-term financial benefits of improved care through simulation and should be considered.

CONCLUSIONS

The potential impact of simulation goes beyond its current main use as a tool for technical skills training. This paper has discussed the need for greater incorporation of simulation into the concept of learning healthcare systems to maximise the clinical impact of simulation-based interventions. Evidence for the feasibility of using simulation across the full spectrum of education,[41] assessment,[42] crisis response[19] and quality improvement[43] is now emerging. Integrating each of these into a single responsive framework will enable simulation to act as a powerful adjunct to current systems of adverse event reporting, analysis and avoidance.

Despite this, broad implementation of simulation is lacking, and the full potential of simulation-based interventions for patient safety has yet to be exhausted. This white paper presents an overview of current issues and recommends future directions to enable the transition of simulation in patient safety from a technology-based research domain to an outcomes-based improvement initiative. To enable this, standardisation of taxonomies and further strengthening of the existing evidence base should be sought, and the development of an integrated model of learning healthcare systems pursued.

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