Setting standards for simulation in anesthesia: the role of safety criteria in accreditation standards

La création de normes pour la simulation en anesthésie: le rôle des critères de sécurité dans les normes d'agrément

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Abstract

Purpose *In this article, we describe a critical event which occurred in a simulation centre, and we also review possible safety issues for participants and staff involved in medical simulation training.*

Principal findings *The authors report an incident with the potential of harming trainees and staff which occurred during a full-scale simulation. The episode raised the question of training safety in simulation centres. In this instance, the computer program controlling the mannequin enabled a continuous and non-regulated outflow of carbon dioxide which led to an intense reaction in the soda lime canister. The absorbent canister became too hot to be touched (a temperature probe, later placed in the centre of the front canister, measured 53°C). All activities involving the mannequin and anesthesia machine were stopped immediately.*

Conclusions *Simulation in healthcare is a valuable educational tool to train for a variety of clinical encounters in a safe environment without harming a patient. Due to technological progress and the use of authentic equipment recreating near real environments, simulation training has become exceedingly realistic. The Society for Simulation in Healthcare (SSH) has published revised accreditation standards for simulation centres which incorporate training safety sub-criteria to address and manage. By highlighting recommendations of other high-risk industries*

on this issue, SSH proposes a possible approach to enhance safety in medical simulation.

Résumé

Objectif *Dans cet article, nous décrivons un événement critique survenu dans un centre de simulation et passons en revue des questions de sécurité potentielles pour les participants et le personnel prenant part à la formation en simulation médicale.*

Constatations principales *Les auteurs rapportent un incident survenu pendant une simulation à grande échelle qui aurait pu potentiellement blesser les personnes en formation et le personnel. Cet épisode a soulevé la question de la sécurité de la formation dans les centres de simulation. Dans le cas présenté ici, le programme informatique contrôlant le mannequin a permis le débit continu et non régulé de dioxyde de carbone, ce qui a entraîné une réaction intense dans le réservoir de chaux sodée. Le réservoir absorbant est devenu trop chaud pour pouvoir être manipulé (par la suite, un thermomètre placé au centre du réservoir frontal a mesuré une température de 53°C). Toutes les activités impliquant le mannequin et la machine d'anesthésie ont été immédiatement interrompues.*

Conclusion *La simulation est un outil éducatif précieux en soins de santé; il permet de former le personnel à plusieurs situations cliniques dans un environnement sécuritaire et sans mettre en péril un patient. En raison des progrès technologiques et de l'utilisation d'équipement authentique recréant des environnements quasi réels, la formation en simulation est devenue très réaliste. La Société pour la simulation en soins de santé (Society for Simulation in Healthcare – SSH) a publié des normes d'agrément révisées destinées aux centres de simulation; ces normes intègrent des sous-critères de sécurité de la formation qui doivent être pris en compte. En mettant en*

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exergue les recommandations d'autres industries à haut risque concernant cette question, la SSH propose une approche possible afin d'améliorer la sécurité en simulation médicale.

Simulation training has become popular in many healthcare disciplines and has been accepted as a valuable tool to improve patient care and patient safety.¹⁻⁴ One of the key features of simulation training in healthcare has been to replicate the clinical environment as accurately as possible. Although controversial, there has been the assumption that the higher the fidelity of the simulation, the more effective the learning.⁵ Although this replication of the operating room (OR) environment may improve training, it also creates safety concerns.

The popularity of simulation training can be attributed to at least two factors. First, the patient safety movement has been a priority for healthcare providers in the last two decades.⁶ Emphasis has led to a focus on healthcare professional training, and simulation in anesthesia has been a pioneer in this respect.^{7,8} Second, new rules have limited working hours for healthcare professionals, thereby allowing for fewer real-life clinical learning opportunities.

In many studies, the link between patient safety and simulation technique has been explored, but the safety of healthcare instructors and trainees themselves has been overlooked. Although there is obviously no risk to patients when healthcare professionals train at simulation centres, might there be some risks to the healthcare professionals themselves?⁹⁻¹¹ Accumulation of various real devices acquired from the workplace and used in full-scale or immersive simulation scenarios leads to safety issues for healthcare professionals. Simulation training in anesthesia often involves a variety of simulators ranging from part-task trainers (e.g., a simulated arm with which to practice peripheral venous cannulation) to full-scale high-fidelity mannequins. Immersive simulation creates realism by replicating actual workplace environments (e.g., ORs, emergency wards, ambulances), therefore letting the trainees engage in a wider range of clinical activities under realistic conditions.¹² However, even though simulation-based healthcare training is safe for patients, there remain risks to staff and participants involved in training in simulation centres that can be anticipated and managed.

After a safety-related incident occurred in our simulation centre, we conducted a workplace safety review. In this article, we briefly describe that incident and contextualize the episode within the relevant literature. Also, by relying on the experience of other high-risk industries that use simulation training and reviewing their

recommendations, we suggest an approach to safety for staff and participants at healthcare simulation centres.

Critical simulation incident

An incident threatening staff and trainee safety occurred during a high-fidelity simulation session in our simulation centre. A simulation scenario was being carried out using a high-fidelity mannequin (SimMan® 3G, Laerdal Medical, Stavanger, Norway) placed in a simulated OR. The mock OR comprised a fully functional anesthesia machine, the AS/5 Anesthesia Delivery Unit (ADU) (Datex-Ohmeda, Helsinki, Finland), an anesthesia cart equipped with drug vials, syringes and needles, infusion sets, and a variety of other devices used commonly in anesthesia care. The mannequin was placed on a stretcher and covered by an authentic surgical drape. An authentic and fully functional electrocautery machine was also present in the simulated OR as well as a surgical instrument table with a collection of authentic surgical instruments.

The mannequin's trachea was intubated and its lungs were ventilated (10 breaths·min⁻¹ at tidal volumes of 600 mL and 5 L·min⁻¹ oxygen fresh gas flow – standard settings necessary for leaks typical of these mannequins) using the anesthesia machine. The mannequin's carbon dioxide exhalation function was enabled, and after ten minutes of ventilation with a gas mixture of oxygen and carbon dioxide, fogging was observed in the endotracheal tube and circuit, and condensation appeared in the soda lime canister. The front half of the two chambers of the canister containing carbon dioxide absorber showed a deep purple color and precipitation of moisture. In addition, the absorbent canister was too hot to be touched (a temperature probe, later placed in the centre of the front canister, measured 53°C). All activities on the mannequin and anesthesia machine were stopped immediately.

The soda lime canister had been in simulated use for over three months on an estimated bi-weekly basis and it likely contained dried out soda lime, as the anesthetic machine was operated with fresh oxygen gas flows of 5 L·min⁻¹ as a default setting. When a gas mixture containing an unknown concentration of carbon dioxide flooded the canister on returning from the mannequin, the chemical reaction within the absorbent was more pronounced than in an average clinical setting where the carbon dioxide fraction is known. We hypothesized from this observation that the carbon dioxide fraction released by the mannequin might have been above the normal physiologic level. We further theorized that the computer program controlling the mannequin enabled a continuous and non-regulated outflow of carbon dioxide that led to an intense reaction in the soda lime canister. Subsequent

modifications to the mannequin's software now allow carbon dioxide flow solely during the expiration phase. This software modification was incorporated in a subsequent general update of the software of SimMan 3G as communicated by the manufacturer.

When simulation becomes too realistic

Generally, a simulator is a device that attempts to recreate attributes of the clinical setting for training. The majority of simulators used for training in anesthesia have been screen-based computer simulations for teaching knowledge or cognitive skills, or they have been hardware-based for teaching psychomotor skills (i.e., CPR mannequins).¹³ Since the introduction of Resusci® Anne and SimOne as the first full-body simulators used in medical training in the late 1960s, sophisticated mannequins have been developed that incorporate the latest technology.^{14,15} Low-fidelity simulators that were used for basic training of chest compressions and mouth-to-mouth ventilation in resuscitation have been transformed over the years into physiologic highly realistic simulators. Today, they have many advanced features, such as radial pulses, the ability to sweat or tear, and automatic chest movements. SimMan 3G and METI Human Patient Simulator (HPS®), which incorporate advanced technology, are good examples of commercially available computer-controlled high-end adult simulators used in healthcare. The main feature difference between SimMan and HPS is the ability to interface the mannequin with clinical patient monitors.¹³ SimMan requires a proprietary monitor, whereas HPS connects to standard patient monitors. In the case of SimMan, inspired gas concentrations and ventilatory mechanics are set and modulated by the person operating the simulator. This not the case with HPS, where inspired and expired gases are sampled and carbon dioxide levels are measured by a standard capnograph to mimic practice in clinical anesthesia.

Reproducing a realistic OR environment for anesthesia crisis resource management (ACRM) training may require fully operational anesthesia and surgical equipment whenever possible.¹⁶ To achieve higher levels of realism, the clinical setting is emulated by importing real devices that improve environmental fidelity. However, these devices also carry certain risks. For example, inexperienced trainees may encounter hazards when they use real anesthesia machines, ventilators, or surgical tools such as scalpels, forceps, and surgical cautery. The use of gas bottles, defibrillators, and other devices increase the impression of being in a real OR to the consequence of all associated hazards. Also, there remains the possibility of injuries from sharp instruments and needles. Real drug vials are often handled, and participants are prompted to use them in the context of the simulation scenario. In

training sessions, trainees often deal with critical situations (e.g., resuscitation of cardiac arrhythmias in an anesthesia context); therefore, they frequently ask for the defibrillator required to manage the scenario. Most representatives of simulation centres agree that the use of live defibrillation plays an important role in simulation-based training.¹⁷ Electrical accidents, in general, have been reported and some accidents due specifically to live defibrillation have been reported.^{18,19} Also, although fires and explosions in real ORs are rare, there remains the risk of their occurrence in a mock OR.^{20,21} Hazardous material and safety considerations in the anesthetic and surgical environment have been identified and published.²¹⁻²⁴ Most publications of hazards in anesthetic practice refer to the influence of anesthetic gases and nitrous oxide.^{25,26} This exposure does not seem to be a training safety issue when real anesthesia machines are operated at simulation centres, as real anesthetic gases are not usually used for training. However, trip-and-fall injuries occur and have been reported as a concern in simulation centres.²⁷

The stress and anxiety expressed by practitioners and trainees about simulation training has been a subject of research.^{28,29} The impact that errors and perceived poor performance has on participants (i.e., emotional and physical distress) during simulation scenarios is relevant to psychological safety.³⁰ Even though simulation provides a safe environment where errors can occur without harm to a patient, there still remains a possible risk of psychosocial stress for each individual involved in a training session. Self-reported stress levels seem to decrease the more experienced the participant becomes.³⁰ However, when being judged by peers, the effects of (self) perceived poor performance on the individual learning process remains unknown.

The reported incident highlights that certain risks are involved with the use of fully operational medical instruments and equipment at simulation centres. It raises concerns about the safety of both the participants and the staff involved. Where are the risks and who should be responsible for the safety of healthcare professionals and trainees in simulation centres? The participants should carry responsibility for their own safety, as would be expected in any clinical setting. Also, instructors should safeguard participants during the scenarios, and the training centre should ensure that manufacturers are responsible for the quality of their products. We suggest that the institution responsible for the simulation centre should ensure that existing safety regulations are followed as recommended.

Perspectives from simulation in industry

The use of high-fidelity simulation is commonly incorporated into training exercises for many high-risk professions,

including the armed forces, aerospace training, commercial aviation, and the nuclear power industry.^{31–34} Many of these industries have experienced concerns with safety issues during high-fidelity simulations of high-risk situations. In commercial aviation, for example, pilots rarely encounter a higher-risk situation than the loss of engine power immediately after takeoff. In 1995, the pilots of a Fairchild Swearingen Metroliner, a 19-seat twin-engine propeller airliner, were killed practising engine failure during a real night takeoff at Tamworth airport in Australia. A recent analysis of firefighter mortality in the United States showed that 10% of all “on-duty” deaths from 1996 to 2005 were related to training exercises involving apparatus and equipment drills, live fire training, or underwater/dive training.³⁵ Firefighter training injuries or incidents, such as near-miss collisions in civil aviation and military training exercises, have raised questions regarding how to ensure safe and effective training.^{35,36} Such reports recommend that so-called “safety cells” be established. The role of safety officers is to supervise and control implementation of safety recommendations and guidelines.

In professional fields where simulation training approximates real-life situations, the need for training safety guidelines has been recognized.^{35–37} Analysis of training accidents has resulted in the creation of safety guidelines (published as official guiding principles of the corresponding professional associations) with the aim to facilitate high-fidelity simulation training within a controlled and secure framework.

Training safety in simulation centres

It is our view that simulation training can be risky for staff and participants in simulation centres. It should be perceived as such, and the concern should be addressed in all simulations. It is important to realize that risks lie not only in immersive simulation settings but also in simulation centres using fully operational devices. Standards play an important role in creating confidence in the effect and outcome of simulation-based education, research, and assessment. This assurance can be achieved by a broad consensus to a framework of standards and compliance by all parties involved in simulation. In their recently published article, Cumin and Merry support the initiation and implementation of standards for simulation centres.³⁸ They illustrate an approach to define standards using simulators as a characteristic example. In 2010, the Society for Simulation in Healthcare (SSH) published revised accreditation standards for simulation programs in healthcare (see Fig. 1).³⁹ The sixth criterion of *Mission and Governance* has been outlined in more detail and now requests “evidence of mechanisms to

protect and address physical and psychological safety of individuals involved in simulation”.

The focus on realism has brought equipment into an environment for which it was not primarily intended. Office premises are converted into professionally equipped emergency facilities or operation rooms in which full-scale high-fidelity simulation scenarios are run, in some instances, with older devices. Therefore, equipment safety standards recommended by the manufacturers should not be taken for granted when a modern anesthesia ventilator is set up and used outside the operation room—a regularly occurring scenario during anesthesia services performed for various in-hospital procedures where a patient needs anesthetic or analgesic monitoring and support (i.e., radiology, cardiology, or obstetrics). The risks of anesthesia performed outside the OR have been reviewed.⁴⁰ Aside from human error, including improper technique, inadequate knowledge, or neglect of available data, system errors, e.g., equipment failure, can also lead to accidents.

It is not within the scope of this paper to present a detailed guideline for simulation centre safety; the diversity of possible training situations and trainees and the accompanying variety of equipment used would create an impractically long list of possible safety measures. However, safety in a simulation centre should be a concern when implementing real-world equipment. The following five-step strategy might be a possible approach for simulation centre safety (Fig. 2). The first step could be to identify possible risks or hazards of used equipment. This phase could include evaluation of explosive material or possible sites of ignition and could involve health issues, such as defining areas where injuries could occur (e.g., using needles, glass vials, sharp ends) and identifying psychological risks. The second step could include recognizing safety requirements and implementing a schedule for periodic maintenance checks by a technician. Also, institutional resources may be considered when assessing safety issues. In professional environments, such as an OR, regular safety checks are recommended to ensure patient and staff safety. For example, anesthesia machines, defibrillators, and surgical instruments go through scheduled technical checks by trained biomedical technicians. Additionally, anesthesia staff perform safety checks daily. Gas tanks for surgical use must meet official safety and quality standards, and electrical devices go through regular inspections. Storage, use, and disposal of syringes, needles, and drug vials are regulated. The third step could relate to personal safety, e.g., use of gloves and antistatic shoes are advised at all times. The entire education community and medical institution should be responsible for the establishment of such a safety plan (see also Fig. 3).

The fourth step could be to create an incident reporting system as another strategy to ensure training safety.

Fig. 1 Overview of Standards for Simulation in Healthcare (SSH) 2010

Hazards could be prevented if data regarding incidents and experiences is gathered to facilitate predicting potential problems and generating solutions. This type of reporting

system, introduced as a “critical incident technique” by Flanagan in 1954, was used to prevent loss of military pilots and aircrafts during training.⁴¹ Critical incident

Fig. 2 Shared responsibility for safety regarding simulation training in healthcare

Fig. 3 Needs analysis for safety in a simulation centre

reporting has been widely accepted and used as a method to study errors that occur during administration of anaesthesia.⁴² Adapting an established tool in patient safety management to within the scope of training safety in simulation centres may reveal security gaps unknown to those involved in simulation. The fifth step could be to analyse the data summarized in the incident reporting system, which could lead to further implementation of training safety guidelines.

Conclusions

Simulation in healthcare is a safe educational technique without the potential of harming patients. However, the staff and participants involved may encounter dangers. The safety concerns include risks ranging from the equipment used in the simulation centre to the emotional stress experienced by each member of the training group. The Society for Simulation in Healthcare has taken these concerns into account by incorporating training safety as a new category in their recently published newly revised accreditation standards. We have provided an overview of possible safety issues involved with simulation training and the methods by which other professional fields have addressed such issues in their training.

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References

1. Palter VN, Grantcharov TP. Simulation in surgical education. *CMAJ* 2010; 182: 1191-6.
2. Abou-Elhamd KE, Al-Sultan AI, Rashad UM. Simulation in ENT medical education. *J Laryngol Otol* 2010; 124: 237-41.
3. Weinberg ER, Auerbach MA, Shah NB. The use of simulation for pediatric training and assessment. *Curr Opin Pediatr* 2009; 21: 282-7.
4. McLaughlin S, Fitch MT, Goyal DG, et al. Simulation in graduate medical education 2008: a review for emergency medicine. *Acad Emerg Med* 2008; 15: 1117-29.
5. Issenberg S, Mcgaghie W, Petrusa E, Gordon D, Scalese R. Features and uses of high-fidelity medical simulations that lead to effective learning: a BEME systematic review. *Medical Teacher* 2005; 27: 10-28.
6. Cooper JB, Long CD, Newbower RS, Philip JH. Critical incidents associated with intraoperative exchanges of anesthesia personnel. *Anesthesiology* 1982; 56: 456-61.
7. Ziv A, Small S, Wolpe P. Patient safety and simulation-based medical education. *Medical Teacher* 2000; 22: 489-95.
8. Gaba DM. Anaesthesiology as a model for patient safety in health care. *BM J* 2000; 320: 785-8.
9. Cooper CL, Clarke S, Rowbottom AM. Occupational stress, job satisfaction and well-being in anaesthetists. *Stress Medicine* 1999; 15: 115-26.
10. Baird WL, Morgan M. Substance misuse amongst anaesthetists. *Anaesthesia* 2000; 55: 943-5.
11. Gilbert M. Stress and the anesthesiologist. *Acta Anaesthesiol Scand* 1993; 37: 141-4.
12. Gaba DM. The future vision of simulation in health care. *Qual Saf Health Care* 2004; 13 Suppl 1: i2-10.
13. Cumin D, Merry AF. Simulators for use in anaesthesia. *Anaesthesia* 2007; 62: 151-62.
14. Grenvik A, Schaefer J. From Resusci-Anne to Sim-Man: the evolution of simulators in medicine. *Crit Care Med* 2004; 32: S56-7.
15. Cooper JB, Taqueti VL. A brief history of the development of mannequin simulators for clinical education and training. *Qual Saf Health Care* 2004; 13 Suppl 1: i11-8.
16. Gaba DM, DeAnda A. A comprehensive anesthesia simulation environment: re-creating the operating room for research and training. *Anesthesiology* 1988; 69: 387-94.
17. Turban JW, Peters DP, Berg BW. Live defibrillation in simulation-based medical education-a survey of simulation center practices and attitudes. *Simul Healthc* 2010; 5: 24-7.
18. Schulte TE, Tinker JH. Narkomed 6400 anesthesia machine failure. *Anesth Analg* 2008; 106: 1018-9.
19. Cummins RO, Chesemore K, White RD. Defibrillator failures. Causes of problems and recommendations for improvement. *JAMA* 1990; 264: 1019-25.
20. Prasad R, Quezada Z, St Andre A, O'Grady NP. Fires in the operating room and intensive care unit: awareness is the key to prevention. *Anesth Analg* 2006; 102: 172-4.
21. Rinder CS. Fire safety in the operating room. *Curr Opin Anaesthesiol* 2008; 21: 790-5.
22. Spiegelman AD, Swan JR. Skin antiseptics and the risk of operating theatre fires. *ANZ J Surg* 2005; 75: 556-8.
23. Tannenbaum TN, Goldberg RJ. Exposure to anesthetic gases and reproductive outcome. A review of the epidemiologic literature. *J Occup Med* 1985; 27: 659-68.
24. Berguer R, Heller PJ. Preventing sharps injuries in the operating room. *J Am Coll Surg* 2004; 199: 462-7.
25. Byhahn C, Wilke HJ, Westphal K. Occupational exposure to volatile anaesthetics: epidemiology and approaches to reducing the problem. *CNS Drugs* 2001; 15: 197-215.
26. Gray WM. Occupational exposure to nitrous oxide in four hospitals. *Anaesthesia* 1989; 44: 511-4.
27. Brogmus G, Leone W, Butler L, Hernandez E. Best practices in OR suite layout and equipment choices to reduce slips, trips, and falls. *AORN J* 2007; 86: 384-98.
28. Pliego J, Rajab H. Residency education: impact of clinical simulation training on anxiety and self-confidence. *Sim Healthcare* 2007; 2: 50 (abstract).
29. Kurrek MM, Fish KJ. Anaesthesia crisis resource management training: an intimidating concept, a rewarding experience. *Can J Anaesth* 1996; 43: 430-4.
30. Girzadas DV Jr, Delis S, Bose S, Hall J, Rzechula K, Kulstad EB. Measures of stress and learning seem to be equally affected among all roles in a simulation scenario. *Simul Healthc* 2009; 4: 149-54.
31. Page E, Smith R. Introduction to military training simulation: a guide for discrete event simulationists. IEEE Computer Society Press; 1998: 53-60.
32. Stanton N. Simulators: a review of research and practice. Human factors in nuclear safety 1996: 117-40.
33. Schwartz J, Peck M, Hall C. Historical review of air-bearing spacecraft simulators. *J Guid Control Dyn.* 2003; 26: 513-22.

34. Moroney W, Moroney B. Flight simulation. In: Garland DJ, Wise JA, Hopkin VD (Eds). Handbook of Aviation Human Factors. CRC; 1999: 355-88.
35. Fahy RF. U.S. Firefighter Deaths Related to Training, 1996-2005. Published 2006, Available from URL: <http://www.nfpa.org/categoryList.asp?categoryID=417&URL=Research/Fire%20reports/Fire%20service%20statistics> (accessed February 2010).
36. Meyers S. Why Are We Killing Ourselves: A Look at Accidental Shootings of Police Officers by Police Officers. OpTac International 2002; Available from URL: <http://www.optacinternational.com/officersafety/> (accessed February 2010).
37. General Accounting Office WD, National Security, International Affairs. Army Ranger Training: Safety Improvements Need to Be Institutionalized. 1997.
38. Cumin D, Weller JM, Henderson K, Merry AF. Standards for simulation in anaesthesia: creating confidence in the tools. Br J Anaesth 2010; 105: 45-51.
39. SSH Society for Simulation in Healthcare. Accreditation. 2010 Revised Standards. Published 2010, Available from URL: <http://www.ssih.org/SSIH/ssih/Forums/SSHCommittees/CATS/Certification1/Default.aspx> (accessed January 2011).
40. Lagasse RS. Anesthesia safety: model or myth? A review of the published literature and analysis of current original data. Anesthesiology 2002; 97: 1609-17.
41. Flanagan J The critical incident technique. 1954.
42. Staender S, Kaufmann M, Scheidegger D. Critical Incident Reporting Systems in Anaesthesia. Safety in Medicine. Oxford: Pergamon, Elsevier Science; 2000: 65-82.