Evaluation of a simulated theatre scenario as a low-cost, high turnover vehicle to promote inter-professional collaboration and increased patient safety

by

Dr Caroline Helen Robertson
Student Number: RBRCAR006

SUBMITTED TO THE UNIVERSITY OF CAPE TOWN

In fulfilment of the requirements for the degree:

Master of Medicine in Anaesthesiology

Faculty of Health Sciences

UNIVERSITY OF CAPE TOWN

Date of Submission: 1 November 2021

Supervisor: Dr Rowan Duys rowanduys@gmail.com

Department of Anaesthesia and Perioperative Medicine

University of Cape Town

DECLARATION

I, *Dr Caroline Robertson*, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research, either the whole or any portion of the contents in any manner whatsoever.

This thesis/dissertation has been submitted to the Turnitin module and I confirm that my supervisor has seen my report and any concerns revealed by such have been resolved with my supervisor.

Signature: Signed by candidate

Date: 6 October 2021

TABLE OF CONTENTS

Acknowledgements, format, and contributions

Thank you to Prof Dyer for contributing his expertise in editing and writing.

All the assistance of the facilitators during the simulation at the Patient safety day is greatly appreciated.

Thanks to Julie Haislip from the University of Virginia for presenting to the University of Cape Town Department of Anaesthesia and Perioperative Medicine, her teaching tool of error simulations in nursing education.

I acknowledge the support and extensive input of my supervisor, Dr Rowan Duys, in planning and co ordinating the project as well as assisting in drafting and editing the article.

This thesis is submitted in a publication-ready format as an innovation article for the journal “Advances in Simulation”. The manuscript has yet not been submitted for publication.

List of Abbreviations

W.H.O	World Health Organisation
S.S.C.L	Safe Surgical Checklists
L.M.I.Cs	Low and middle income countries
H.I.Cs	High income countries
I.C.U.	Intensive Care Unit
B.P.	Blood Pressure
ECG	Electrocardiogram
S.S.I	Surgical site infection

Chapter 1 - Manuscript

Title Page

Evaluation of a simulated theatre scenario as a low-cost, high turnover vehicle to promote inter-professional collaboration and increased patient safety: A prospective cohort study

Caroline Robertson; MBChB, DA (SA), DipPEC (SA), DTM&H (Liverpool), DCH (SA), FCA(SA)
Rowan Duys; MBChB, DA (SA), FCA (SA), Mmed (Anaesth) UCT
Department of Anaesthesia and Perioperative Medicine, University of Cape Town and Groote Schuur Hospital, Cape Town, South Africa

Conflicts of interest:
The authors have no conflicts of interest to declare.

Number of words in Abstract: 363
Number of words in Article: 3986

Abbreviated Title: Simulation for promotion of theatre patient safety

Abstract

Background: Errors related to patient safety are a major contributor to adverse incidents and preventable deaths. Interventions aimed at changing team behaviour and implementing World Health Organisation Safe Surgical Checklists (WHO SSCL) have been associated with improved outcomes. We required a cost- and time-efficient vehicle to address low adoption rates of the WHO SSCL, barriers to interdisciplinary teamwork, and inadequate attention to patient safety.

Method: We aimed to test the feasibility and efficacy of a simulation-based intervention to improve behaviour influencing patient safety in operating theatres. We performed a prospective cohort study using survey tools for attendee feedback immediately after the event and at 6 weeks. We report feasibility and efficacy data plus qualitative feedback from the education team describing the advantages of this instructional design. The intervention was a 2-stage simulation. First, learners watched a 5-minute film, set in the operating theatre, depicting an error-filled WHO SSCL time-out. Second, learners entered a simulated operating theatre environment with multiple errors and risks to patient safety. Learners identified errors and prioritised them in order of importance. Their observations were discussed in a small group debrief session facilitated by novice debriefers before a whole group plenary discussion.

Results: One hundred and three health workers attended the education event and 77 (75%) responded to the Immediate Questionnaire. Surgeons (27), Anaesthetists (18) and Scrub Nurses (12) made up the majority of respondents. Sixty-seven (87%) participants agreed or strongly agreed that they “now have an increased awareness of patient safety”, while 75 (97%) agreed or strongly agreed that they “feel more committed to ensuring a team approach to patient safety”. Thirty (29%) attendees responded to the Delayed Questionnaire distributed via email 6 weeks after the event.

Twenty-eight (93%) agreed or strongly agreed that they felt more committed to ensuring a team approach to patient safety.

Conclusion: The total cost of the event was low. Faculty reported that the instructional design afforded deliberate targeting of the importance of multi-disciplinary teamwork in patient safety. The simulation event was feasible at low monetary, time, and human resource costs. This approach offers a scalable instructional design that targets inter-professional learning.

Keywords: Simulation, patient safety, safe surgery, theatre safety, WHO checklist, low-cost

Introduction

Errors related to patient safety are a major contributor to adverse incidents and preventable deaths.[1] The WHO Safe Surgery Saves Lives (SSSL) campaign and the introduction of the Safe Surgery Checklist (SSCL) acknowledge that human factors, teamwork, and systems for protection against error, are important areas requiring focus to promote a culture of patient safety and improve patient outcomes.[2,3,4]

Data from African low- and middle- income countries (LMICs) show that perioperative mortality is 2-3 times higher than in high- income countries (HICs), despite the fact that the former patients are younger and fitter and generally undergo lower risk surgery.[5,6] Local data describe historical, institutional and cultural barriers to a patient safety culture and how this may contribute to preventable deaths.[7] Interventions aimed at changing team behaviour, including simulation-based training and WHO SSCL implementation, have been associated with improved outcomes in our setting and elsewhere.[2,3,8,9,10]

Cost- and time-effective interventions that address patient safety culture in operating theatres are urgently required.[11] Simulation has been successfully used to address the patient safety culture,[3,10,12] but often requires a high ratio of faculty members to learners, and can be costly and time consuming.[13] Furthermore, when learning events are run in a clinical environment, or “in-situ”, and attempt to immerse learners in the experience, the number of learners that can participate is limited by the space capacity of the venue.

The theatre staff from the 8 hospitals in the large metropolitan area in which our intervention was planned, have limited dedicated time for training and development other than an annual training afternoon of three hours duration during which many operating theatres are closed for elective surgery. We required a vehicle to address low adoption rates of the WHO SSCL, perceptions of hierarchical barriers to interdisciplinary teamwork, and inadequate attention to patient safety, that could reach many learners in less than 3 hours. To meet this need we aimed to test the feasibility and efficacy of a low cost, high turnover simulation-based intervention to improve behaviour influencing patient safety in operating theatres.

To achieve this aim, our objectives were:

1. To design and produce an innovative simulation-based vehicle able to achieve a high turnover of learners, at low cost, and with a focus on the multidisciplinary team.
2. To evaluate the feasibility and the quality of experience of the learners of this vehicle.
3. To evaluate the effect of attending this training intervention on self-assessed knowledge, attitudes, and behaviour with respect to patient safety, with particular emphasis on the WHO SSCL.

We hypothesised that, using a novel simulation-based vehicle, it would be feasible to engage a large group of learners in a short period of time with minimal cost. This intervention would improve knowledge and attitudes towards an interdisciplinary approach to patient safety and the WHO SSCL.

Methods

We performed a prospective cohort study of our intervention with survey-based feedback immediately after the education event and at 6 weeks. Ethics approval was granted by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of Cape Town (HREC 465/2015). Written informed consent was obtained from all participants (Appendix 5). All theatre staff that attended the training day exercise were invited to participate.

A team of approximately 10 healthcare workers with varying skills was consulted to design and run the training event at a tertiary centre theatre complex. This team included patient safety experts, anaesthetists, surgeons, nurses, simulation experts, metropolitan theatre services leadership, a university-based videographer, and an international collaborator with experience in running a similar scenario in an Intensive Care Unit (ICU). The goal of the training event, likely attendees, feasibility, and proposed learning outcomes were discussed, and a draft plan was distributed for input before finalisation.

We used a below-knee amputation for sepsis as the theatre scenario because it is commonly performed in the metropolitan service. Agreement was reached on suitable errors to be highlighted in the performance of the WHO SSCL, taking into consideration the setup of the theatre environment and the communication and teamwork between various role-players likely to be in theatre for such a case. A script was written, and agreement was reached on a description of the “scene” (Appendix 1).

To maximise the turnover of learners, and to facilitate the inclusion of errors and threats to patient safety arising from “dynamic processes” as well as from “static” environmental or system errors, a 2- stage simulation was designed. First, learners watched a 5-minute film, set in the operating theatre, depicting an error-filled WHO SSCL time-out, in which communication and teamwork errors led to an increased risk of patient harm. The video depicted the beginning of an operation, from the moment after a “patient” received a subarachnoid injection of local anaesthetic until the first incision. Having watched the video, learners entered the operating theatre environment depicted, where a replica of the video scenario had been created using a mannikin. Learners were given 5 minutes to explore the theatre environment, noting as many errors or threats to patient safety as they could find (Appendix 2).

An “Error Prioritisation” questionnaire (Appendix 3) was used by participants to document any errors noted as they watched the video and explored the simulated theatre environment. Participants were prompted to highlight their three most important errors. A similar questionnaire had been tested previously,[14] and it was further trialled by the education team.

Following the video phase and their exploration of the theatre environment, learners progressed to a discussion or debriefing phase in their small groups. We had a limited number of trained simulation debriefers and thus designed a debriefing plan to be implemented by novices. Volunteers from departments attending the event were given short, in-person instructions and written guidelines. The structure was kept simple, with debriefers instructed to encourage group discussion around participants’ three most important errors, and a collaborative re-prioritisation of these

errors. Once all groups had progressed through the video-, theatre exploration-, and small group debriefing phases, a plenary session was held for all participants and debriefers. Two experienced simulation debriefers facilitated a whole-group discussion with 3 aims:

To demonstrate the benefit of multi-disciplinary input into behaviour influencing patient safety.

To facilitate input from the experts on patient safety.

To highlight the evidence for the benefits of the WHO SSCL.

Participants were requested to complete the second or “Immediate Feedback” questionnaire immediately after the plenary session. This questionnaire was designed to elicit feedback on the learning event, with particular reference to user experience, new knowledge gained, and whether participants had learned from their interaction with those from other disciplines of healthcare worker. A similar questionnaire had been tested previously[14] and was reviewed by the intervention design team (Appendix 4). This questionnaire included the informed consent form, demographic details of the participants, responses to 8 questions on a 5-point Likert scale, and free text questions.

A link to the third or “Delayed Feedback” questionnaire, hosted by SurveyMonkey (SurveyMonkey Inc. San Mateo, California, USA, www.surveymonkey.com), was emailed to attendees 6 weeks after the learning event. It aimed to elicit self-assessment of behaviour change with reference to patient safety, and included 8 Likert scale questions and free text responses (Appendix 6).

The size of the convenience sample was determined by the number of theatre staff who could be relieved of their clinical duties on the afternoon of the planned simulation from a dynamic variety of primary, district and tertiary hospitals throughout the metro. This was facilitated by postponement of elective surgery across the metro but limited by the number of urgent/emergency surgical procedures requiring completion during this time. Demographic details of respondents and Likert scale responses are reported as numbers (percentage). Free text responses were read by two authors (CR and RD), in order to become familiar with the data. Data were then manually coded and categorised into themes. A consensus was reached as to which themes and quotes should be reported.

Results

In July of 2015, one hundred and three delegates attended the learning event and progressed through the video phase, simulated theatre environment-, small group-, and plenary debriefing session over the course of approximately two and half hours. The response rate to the Immediate Feedback questionnaire was 77/103 (75%) and 30 of these 77 responded to the digital Delayed Feedback questionnaire (29% of the total attendees). Questionnaires that were damaged or incomplete were excluded from the analysis (six).

Respondents represented a variety of disciplines, hospitals and level of experience (Table 1). Surgeons (27), Anaesthetists (18) and Scrub Nurses (12) made up the majority of respondents. Doctors that were not anaesthetists or surgeons were

mainly in management or strategic positions. Fifty eight percent of delegates had more than five years of experience in their positions.

Table 1: Demographic details of respondents to the Immediate Feedback questionnaire

Profession	Experience level of attendee in years					
	<2	2-5	5-10	>10	Missing data	Total n (%)
Nurse Anaesthesia	0	0	1	2	1	4 (5)
Nurse Scrub	3	1	3	4	1	12 (16)
Nurse Floor	0	3	1	0	1	5 (6)
Dr Anaesthesia	0	3	9	5	1	18 (23)
Dr Surgeon	0	12	7	8	0	27 (35)
Dr Other	6	0	1	3	1	11 (14)
Total n (% of all attendees)	9 (12)	19 (25)	22 (29)	22 (29)	5 (6)	77 (100)

Responses to the Immediate Feedback questionnaire are reported in Table 2. The majority of delegates felt that the simulation had been a useful tool for raising awareness of theatre safety. A majority reported a change in awareness of the importance of patient safety. As regards questions that related to learning from delegates from other disciplines, the majority reported that they had learned about errors of which they had not previously been aware, and that they had learned from colleagues from a different discipline. Most participants reported changes in attitude or commitment towards a team approach to patient safety and felt more able to contribute to patient safety in theatre. Most planned to include aspects that they learned during the session in their future practice (see qualitative analysis for

examples). Thirty-nine percent of delegates reported altering their top three priority errors following the group discussion.

Table 2: Responses to Immediate Feedback

	Question	Strongly Disagree n (%)	Disagree	Neutral	Agree	Strongly agree	Total responses
1	I think that the simulation is a useful tool to raise awareness of theatre safety	0 (0)	1 (1)	1 (1)	32 (42)	42 (55)	76 (100)
2	I now have an increased awareness of patient safety	0 (0)	2 (3)	8 (10)	42 (55)	25 (32)	77 (100)
3	I learned about potential errors of which I was not aware before	0 (0)	5 (7)	19 (25)	41 (54)	11 (14)	76 (100)
4	I learned from colleagues from a different discipline	0 (0)	0 (0)	8 (11)	50 (66)	18 (24)	76 (100)
5	I feel more committed to ensuring a team approach to patient safety	0 (0)	0 (0)	1 (1)	45 (59)	30 (39)	76 (100)
6	I feel more able to contribute to patient safety in theatre	0 (0)	0 (0)	12 (16)	43 (57)	21 (28)	76 (100)
				Yes	No	No response	
7	I plan to include aspects I learned today into my practice (Y/N) If yes, what?			7 (9)	46 (61)	23 (30)	76 (100)
8	I changed one or more of my 3 most highly ranked errors after discussing with my colleagues			30 (39)	35 (45)	12 (16)	77 (100)

Themes identified from the free text responses to question 7 included a commitment to improving communication by nurses and doctors:

Scrub nurse #5: “Improve communication”

Surgeon #13: “To improve communication between medical personnel and patients”

Anaesthetist #19: “Good and clear direct closed loop communication”

Nurses and doctors reported commitment to better and correct implementation of the WHO SSCL:

Scrub nurse #3: “importance of WHO checklist being done properly”

Surgeon #8: “real Time Out”

Surgeon #10: “ensure WHO SSCL gets used more effectively”

Anaesthetist #22: “actively encourage proper performance of WHO checklist”

Nurses and doctors described a proposed change in their own individual behaviour, particularly in connection with expressing themselves in the multi-disciplinary team, or about being more assertive, in order to contribute to patient safety:

Scrub nurse #4: “to be more observant and to speak up”

Doctor other #8: “being more assertive in theatre for patient and health staff safety”

The role of the team was acknowledged in promoting patient safety:

Doctor other #7: “involving all team members”

Responses to the Delayed Feedback questionnaire are reported in Table 3 and demonstrate a self-reported change in awareness of patient safety. A majority reported a change in attitude expressed as an increased commitment to a team

approach to patient safety. Many reported a change in their behaviour or practice, which they considered would change patient care. A minority believed that changes in their practice would improve patient outcome.

Table 3: Responses to Delayed Feedback Questionnaire

	Question	Strongly Disagree n (%)	Disagree	Neutral	Agree	Strongly agree	Total responses
1	I am more aware of patient safety after having completed the simulation	0 (0)	2 (7)	1 (3)	21 (70)	6 (20)	30 (100)
2	I have noticed errors that previously I would have overlooked	1 (3)	3 (10)	9 (31)	15 (52)	1 (3)	29 (100)
3	Examples						
4	I feel more committed to ensuring a team approach to patient safety	1 (3)	0 (0)	1 (3)	24 (80)	4 (13)	30 (100)
5	I have changed my practice	1 (3)	2 (7)	11 (37)	15 (50)	1 (3)	30 (100)
6	How?						
7	I believe that this improved patient care	0 (0)	3 (10)	10 (33)	15 (50)	2 (7)	30 (100)
8	I believe that this improved patient outcome	0 (0)	3 (10)	12 (40)	14 (47)	1 (3)	30 (100)

With respect to qualitative analysis of responses to the Delayed Feedback questionnaire, free text responses described errors that delegates would previously have been overlooked. These included environmental or structural risks, risks related to patient consent, and behavioural or procedural issues:

Respondent #9: “Absence of stripe on pack that was not sterilised”

Respondent #6: “I now ensure that all consent forms are filled out completely”

Respondent #5: “Food left in the open or near the anaesthesia machine”

As regards changes in practice, themes included a renewed focus on teamwork, an improved emphasis on specific behaviour influencing patient safety, and more appropriate use of the WHO SSCL:*

Respondent #11: “Encouraged leadership of WHO checklist by nursing staff rather than Anaesthetic”

Respondent #19: “Doing regular theatre walkabouts to pick up areas of concern”

Respondent #20: “Have become diligent about carrying out each step whereas previously only completed part of the list and only for about 50% of patients”

*The discipline of the respondent was not included in the Delayed Feedback questionnaire.

With respect to costs of the education event, the team responsible for the organisation and performance of the simulation were not allocated a budget. The local Department of Health covered the costs of refreshments, and free access was allowed to all other facilities. This included the lecture theatre for the plenary session, the operating theatre, and space for viewing the video. Medical consumables used in the filming of the video and in the setup of the static phase were donated by 2 host hospitals, or were taken from expired stock currently donated to the simulation programme. The mannikin used in the static display was on loan from a corporate sponsor. Filming and editing of the video for the scenario was done free by an e-learning specialist from the Health Professions Education Department of the University of Cape Town. Actors were all healthcare workers in the metropolitan service. Estimated total cost of the event to the organisers was ZAR8800 (USD593).

As regards feedback from the design team, it was concluded that the format and design of the learning event afforded both the educators and the learners' opportunities beyond what could be achieved by a didactic or paper-based scenario. Firstly, use of the video phase enabled a focus on the type of errors that arise because of common teamwork and communication errors such as distractions during the WHO SSCL Time Out. The static phase allowed a focus on fine detail and discipline specific errors. Because learners moved through the theatre environment, ergonomic risks and errors were highlighted.

The event was divided into 4 distinct and short segments plus refreshment breaks. Because the video phase, static phase, small group debriefing, and refreshment breaks could run concurrently, the organisers were able to ensure continued engagement of a large number of learners throughout the afternoon. Furthermore, the focused scenario plus simplified and structured debriefing guidelines enabled novice debriefers to conduct the small group debriefing sessions.

By employing a multi-disciplinary team in the design, filming and setup of the learning event, it was possible to tailor learning objectives and include errors that engaged learners from different disciplines appropriately. In addition, the design allowed a focus on the importance of contributions of all members of the multidisciplinary team. Ninety percent of respondents reported learning from colleagues from a different field.

Preparation of the video necessitated a thorough interaction with the theatre environment and allowed the team to test and improve the script. The video also allowed for standardisation of the simulation experience.

Discussion

We designed and ran a simulation-based learning event, consisting of a video phase, simulated theatre environment static phase, a small group debriefing, and a plenary session. While the event was designed by content experts, the small group debriefing was facilitated by novices with minimal instruction. The learning event incurred nominal costs only. Despite limited resources, we were able to include a multidisciplinary group of 103 learners in a standardised experience in a single afternoon. Most participants reported that the simulation-based event was a useful

tool for addressing patient safety issues, and that their knowledge of-, attitudes towards- and behaviour influencing patient safety and the WHO SSCL had improved. The analysis of free text responses allowed the identification of themes in the Immediate and Delayed Feedback questionnaires including a commitment to improved performance of the WHOSSCL and improved awareness of the role of the whole multi-disciplinary team in achieving patient safety goals.

The design of the event afforded large numbers of learners a standardised learning experience that had a low monetary, time, and human resource costs, but was able to achieve its aims of demonstrating an association with changed perceptions and attitudes towards the WHO SSCL and the importance of teamwork in achieving patient safety.

The “theatre of errors” format creates a static display of a clinical area with errors and risks to patient safety evident throughout the display. A similar approach has been used elsewhere, where it has been associated with positive changes in attitude towards team members.[14,15,16] By introducing a video phase into the simulation, the educators were able to highlight risks to patient safety caused by dynamic team interactions. By running the short static and dynamic phases in parallel, 2 learner groups were engaged at the same time, thus doubling our throughput.

Simulation is a relatively new educational entity in the South African healthcare environment, and there are minimal resources dedicated to this teaching modality.[17] Our learning event was deemed appropriate by users and was associated with changes in self-reported attitudes. This supports the use of simulation in instructional

design when the learning objectives are related to teamwork and focused on the translational aspects of converting guidelines and knowledge into practice.[11,18]

An oft-cited drawback of simulation-based learning is the time, monetary and human-resource cost of running these events,[12] and this is of particular concern in an LMIC with limited resources. Our pilot study was an attempt to demonstrate the feasibility of high-volume, low-cost simulation learning experiences, thus creating a model for wider use.

The science and skill of debriefing simulation-based learning events is a growing area of research with multiple proposed models including scripted self-debriefing.[19,20] The need to use minimally trained facilitators to debrief small groups was weighed against the potential risks to psychological safety that can be mitigated by suitably trained debriefers. However, since our simulation did not place participants as role-players within an active scenario but as observers only, we predicted a low level of emotional activation during the experience and lower risk of harm. We shared an instructional document with tight debriefing guidelines with our debriefer group and delivered a short period of face-to-face instruction with them to further reduce the risk of harm. Although not explicitly asked, there was no evidence from free-text response, personal communication or feedback questionnaires to suggest any negative experiences.

Our model for processing large numbers of learners during a short time period would need to be altered, since the COVID-19 pandemic has created the need for extra precautions during simulations.[21] However, with clear instructions not to touch any of

the static display, to maintain suitable distance during the video phase and debriefing phases, and with appropriate use of masks and hand-washing, we believe the model could still apply and be used safely.

The critical role of teamwork and communication in maintaining patient safety is well established.[3] In the South African context there is limited data describing the hierarchy and patient safety culture in operating theatres, but there is some evidence of the particularly challenging patient safety environment created in high volume theatres with team members drawn from many cultures.[7] There is evidence supporting the efficacy of the roll-out of WHO SSCL.[9] We required a learning vehicle that deliberately targeted the lack of multi-disciplinary involvement in behaviour influencing patient safety and perceived barriers to use of the WHO SSCL. Simulation has been used in other settings to transform systems and workplace culture,[11,18] and we were able to use a multi-disciplinary design team to create a learning experience that engaged all participants and highlighted the value that different disciplines and the WHO SSCL could bring to patient care.

Our study has important limitations. The low response rate to the Immediate Feedback questionnaire (75% of attendees) and Delayed Feedback questionnaire (29% of attendees) introduces a risk of reporting bias. The small sample size precludes analysis of the differences in response between participants from different disciplines, or of changes in responses over time, and limits the generalisability of findings. Self-reported impact is a metric fraught with bias, but since we sought to understand the acceptability and learner experience, it was an appropriate choice of instrument for this feasibility study. Direct observations of participant behaviour after

attending the event, or of patient outcomes, may have strengthened the validity of conclusions about the efficacy of the event but would have been difficult with learners attending from many different operating theatres across eight hospitals. Future studies might employ more in-depth qualitative measures to explore the extent to which this instructional design afforded learners and faculty the opportunity to target multi-disciplinary teamwork and attitudes towards the WHO SSCL.

Conclusions:

We have demonstrated a feasible, acceptable, low-cost, high throughput vehicle for addressing teamwork, the WHO SSCL, and behaviour that influences patient safety in the operating theatre. Our use of a video phase and static theatre phase meant that faculty could highlight dynamic behavioural issues and structural or systemic issues that affect patient safety. We were also able to use novice debriefers without reported adverse effects. This feasibility study has demonstrated that simulation is an acceptable learning vehicle in a sample of South African operating theatre staff. It was engaging for learners from multiple disciplines. How this vehicle may be used to impact theatre staff behaviour remains to be explored in our context. We are therefore challenged to continue the refinement of tools such as our simulation-based intervention, and to encourage roll out of its use to a wider audience.

Declaration:

Ethics approval and consent to participate

The study protocol was approved by the Human Research Ethics Committee of the University of Cape Town (HREC 465/2015).

Consent for publication

Not applicable.

Availability of data and materials

The authors are willing to provide research data on request.

Funding

None.

Authors' contributions

CR, RD conceived and planned study. CR collected and analysed data and wrote the first draft. RD edited and assisted with data analysis. CR and RD contributed to the writing of and approval of the final paper.

Acknowledgements

The authors would like to thank the design and implementation team, the facilitators and the participants who took part in the study.

Competing interests

The authors declare that they have no competing interests.

References

1. Kohn LT, Corrigan JM, Donaldson MS. To Err is Human. 2000 Mar 1 [cited 2021 Aug 14]; Available from: https://www.ncbi.nlm.nih.gov/books/NBK225182/
2. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat A-HS, Dellinger EP, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. http://dx.doi.org/101056/NEJMsa0810119 [Internet]. 2009 Dec 10 [cited 2021 Aug 14];360(5):491–9. Available from: https://www.nejm.org/doi/full/10.1056/nejmsa0810119
3. Sevdalis N, Hull L, Birnbach D. Improving patient safety in the operating theatre and perioperative care: obstacles, interventions, and priorities for accelerating progress. Br J Anaesth [Internet]. 2012 [cited 2021 Aug 14];109 Suppl(SUPPL1). Available from: https://pubmed.ncbi.nlm.nih.gov/23242749/
4. Reason J. Understanding adverse events: human factors. Qual Health Care [Internet]. 1995 [cited 2021 Aug 14];4(2):80–9. Available from: https://pubmed.ncbi.nlm.nih.gov/10151618/
5. Biccard BM, Madiba TE, Kluyts HL, Munlemvo DM, Madzimbamuto FD, Basenero A, et al. Perioperative patient outcomes in the African Surgical Outcomes Study: a 7-day prospective observational cohort study. Lancet [Internet]. 2018;391(10130):1589–98. Available from: www.thelancet.com
6. Biccard BM, Madiba TE, On behalf of the South African Surgical Outcomes Study Investigators. The South African Surgical Outcomes Study: A 7-day prospective observational cohort study. South African Med J [Internet]. 2015;105(6):465. Available from: http://www.samj.org.za/index.php/samj/article/view/10027

7. Chandauka, T. B. Patient Safety Culture in South African Obstetric Theatres. (PHD Thesis) University of Oxford, 2021.
8. Ramsay G, Haynes AB, Lipsitz SR, Solsky I, Leitch J, Gawande AA, Kumar M. Reducing surgical mortality in Scotland by use of the WHO Surgical Safety Checklist. Br J Surg. 2019 Jul;106(8):1005-1011. doi: 10.1002/bjs.11151. Epub 2019 Apr 16. PMID: 30993676.
9. Naidoo M, Moodley J, Gathiram P, Sartorius B. The impact of a modified World Health Organization surgical safety checklist on maternal outcomes in a South African setting: A stratified cluster-randomised controlled trial. S Afr Med J. 2017 Feb 27;107(3):248-257. doi: 10.7196/SAMJ.2017.v107i3.11320. PMID: 28281432.
10. Neily J, Mills P, Young-Xu Y, Carney B, West P, Berger D, et al. Association between implementation of a medical team training program and surgical mortality. JAMA [Internet]. 2010 Oct 20 [cited 2021 Aug 14];304(15):1693–700. Available from: https://pubmed.ncbi.nlm.nih.gov/20959579/
11. Nestel D, Brazil V, Hay M. You can't put a value on that… Or can you? Economic evaluation in simulation-based medical education. Med Educ [Internet]. 2018 Feb 1 [cited 2021 Aug 17];52(2):139–41. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/medu.13505
12. Brazil V, Purdy EI, Bajaj K. Connecting simulation and quality improvement: how can healthcare simulation really improve patient care? BMJ Qual Saf [Internet]. 2019 Nov 1 [cited 2021 Aug 17];28(11):862–5. Available from: https://qualitysafety.bmj.com/content/28/11/862
13. Lin Y, Cheng A, Hecker K, Grant V, Currie GR. Implementing economic evaluation in simulation-based medical education: challenges and

opportunities. Med Educ. 2018 Feb;52(2):150-160. doi: 10.1111/medu.13411. Epub 2017 Sep 26. PMID: 28949032.

14. Kueter C. ‘Room of Errors’ Challenges Health Care Providers to Hone Teamwork Skills | UVA Today [Internet]. 2014 [cited 2021 Sep 16]. Available from: https://news.virginia.edu/content/room-errors-challenges-health-care-providers-hone-teamwork-skills

15. Turrentine F, Schroen A, Hallowell P, Quatrara B, Smith P, Williams M, et al. Enhancing Medical Students’ Interprofessional Teamwork Through Simulated Room of Errors Experience. J Surg Res [Internet]. 2020 Jul 1 [cited 2021 Jul 11];251:137–45. Available from: https://pubmed.ncbi.nlm.nih.gov/32143058/

16. Farnan JM, Gaffney S, Poston JT, Slawinski K, Cappaert M, Kamin B, et al. Patient safety room of horrors: a novel method to assess medical students and entering residents’ ability to identify hazards of hospitalisation. BMJ Qual Saf [Internet]. 2016 Mar 1 [cited 2021 Jul 11];25(3):153–8. Available from: https://qualitysafety.bmj.com/content/25/3/153

17. Swart, Robert & Duys, Rowan & Hauser, ND. (2019). SASS: South African Simulation Survey – a review of simulation-based education. Southern African Journal of Anaesthesia and Analgesia. 12-20. doi:10.36303/SAJAA.2019.25.4.2191.

18. Brazil V, Purdy E, Alexander C, Matulich J. Improving the relational aspects of trauma care through translational simulation. Adv Simul [Internet]. 2019; Available from: https://doi.org/10.1186/s41077-019-0100-2

19. Krogh K, Bearman M, Nestel D. “ Thinking on your feet ”— a qualitative study of debriefing practice. Adv Simul [Internet]. 2016;1(1):1–11. Available from: http://advancesinsimulation.biomedcentral.com/articles/10.1186/s41077-016-

0011-4%5Cnhttp://dx.doi.org/10.1186/s41077-016-0011-4

20. Garden AL, Le Fevre DM, Waddington HL, Weller JM. Debriefing after simulation-based non-technical skill training in healthcare: a systematic review of effective practice. Anaesth Intensive Care [Internet]. 2015 May 1 [cited 2021 Aug 17];43(3):300–8. Available from: https://pubmed.ncbi.nlm.nih.gov/25943601/

21. Lateef F, Suppiah M, Chandra S, Yi TX, Darmawan W, Peckler B, et al. Simulation Centers and Simulation-Based Education during the Time of COVID 19: A Multi-Center Best Practice Position Paper by the World Academic Council of Emergency Medicine. J Emerg Trauma Shock [Internet]. 2021 Jan 1 [cited 2021 Aug 17];14(1):3. Available from: /pmc/articles/PMC8054807/

Appendix 1: Scenario script and setup

Cape Metro Safety Day Room of Errors

Amputation for Sepsis

Cecils-Gone Home is a 65-year-old diabetic with sepsis of his right lower leg, exacerbated by a recent fall into some E Coli infested material, and, under protestation, he has consented to a below knee amputation.

The scenario begins just as the spinal anaesthetic has been performed and the anaesthetist then begins propofol sedation. The surgeon is needed elsewhere in the hospital and thus is attempting to work as quickly as possible.

Role Players required

Patient or mannikin
Surgeon
Assistant Surgeon
Scrub Nurse
Anaesthetist

Patient Prep:

Adult male mannikin or simulated patient.
If possible, mannikin should move from Sitting to Supine
To be marked on **Right** thigh: “Correct”
To be marked on **Left** thigh extending down to below knee: “Not this leg” (“this leg” to be visible on shin)

Theatre Environment Prep:

Displays in Theatre:

A3 size WHOSSCL
A3 size Anaesthesia record
A3 size surgical notes page
Thermometer on the wall
Defibrillator, not plugged in

Dynamic portion of scenario:

Anaesthetist: “Spinal’s going in. You may lie down now Cecil. You’ll be drifting off to sleep as I start this pump.”

Surgeon’s assistant shaves leg with razor then leaves to scrub.

Scrub Nurse: “May I clean”

Scrub Nurse begins cleaning.
Surgeon, already scrubbed, enters scene and begins talking to anaesthetist about recent golf game while assisting Scrub Nurse in draping of leg.
Drapes are accidently laid incorrectly, cover right leg and leave left leg with only: “this leg” exposed.
Surgeon and anaesthetist talking to scrub nurse during this stage about the sorry state of affairs in nursing at the hospital.
NIBP cuff not cycling at this stage, anaesthetist realises and pushes cycle.

Non-invasive blood pressure cuff not working, has become disconnected.
Anaesthetist climbs under table to reconnect…

Anaesthetist (*from under table):* Should we do checklist?
Surgeon: “Yes”
Anaesthetist: I’m Julius Karntremember from Anaesthesia. Patient is for an amputation. Do you want antibiotics?
Scrub Nurse *(just after anaesthetist’s question and before surgeon answers)*:” I’m Florence Notinjail and we don’t have any 2-0 Vicryl”
Surgeon (*whilst anaesthetist is talking):* No! *(Shaking his head)*
Anaesthetist *(in response to what he believes is surgeons answer:* OK!

Surgeon *(whilst adjusting lights with no light handles)***:** I'm Aaron Mostunworthy, we're doing a below knee amputation of left leg for sepsis. Should take me 45 minutes. May I start?
Anaesthetist: Go ahead
Scrub Nurse: I'm fine. Everything is fine.

Assistant Surgeon: I'm Helen Stillhere. Boss, are you sure this is the correct……?
Surgeon and Anaesthetist: (*talking louder and together):* Not now Stillhere, we've got work to do.

Surgeon begins to cut wrong leg

End of dynamic part of scenario.

Appendix 2: List of errors

List of Errors:

Dynamic

Social chat while draping

Spinal: no mask worn

Incorrect marking of legs

Incorrect draping of operative and other leg

ECG not attached at time of spinal (or no monitors attached)

NIBP disconnected

No “pause” for WHOSSCL

Miscommunication of need for antibiotics

No mention of blood loss during WHOSSCL

Incomplete WHOSSCL check by scrub nurse

No light handles

No floor nurses

Assistant Surgeon ignored…flat hierarchy

Consider adding nurse ticking SSCL without checking compliance

Static - SSI:

Only small gloves in theatre

Soiled HME

Static thermometer showing very cold theatre, patient left uncovered after spinal

No temperature probe anywhere

Static – Wrong Side:

Anaesthesia notes say Left Side, other notes say Right side

Xray displayed wrong way round

Static Other:

BP cuff not connected

ECG not connected at time of Spinal Insertion

Open propofol on trolley

No oxygen cannister

Ambubag with no tubing -? blocked

Overfull sharps; sharps lying around

Anaesthesia drugs marked incorrectly or not marked

Defibrillator not plugged in and charging

Appendix 3 - Error prioritisation sheet

THE THEATRE OF ERRORS

Please Circle Your Profession:

SCRUB NURSE/ ANAESTHETIC NURSE/ FLOOR NURSE/ SURGEON/ ANAESTHETIST OTHER_____

Years of Experience: Student ≤ 2 yrs 2-5 yrs 5-10 yrs ≥ 10 yrs

Our Patient:

Amputation for Sepsis

Cecils-Gone Home is a 65-year-old diabetic with sepsis of his right lower leg, exacerbated by a recent fall into some E Coli infested material, and, under protestation, he has consented to a below knee amputation.

The scenario begins just as the spinal anaesthetic has been performed and the anaesthetist then begins propofol sedation. The surgeon is needed elsewhere in the hospital and thus is attempting to work as quickly as possible.

Please List the Errors You Identify:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____

8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
16. _____
17. _____
18. _____
19. _____
20. _____
21. _____
22. _____
23. _____
24. _____
25. _____
26. _____
27. _____
28. _____

Appendix 4: Immediate Feedback Questionnaire

Concerning the simulation:	**STRONGLY DISAGREE**	**DISAGREE**	**NEUTRAL**	**AGREE**	**STRONGLY AGREE**
I think that the simulation is a useful tool to raise awareness of theatre safety					
I now have an increased awareness of patient safety					
I learned about potential errors that I was not aware of before					
I learned from colleagues from a different field					
I feel more committed to ensuring a team approach to patient safety					
I feel more able to contribute to patient safety in theatre					
I plan to include things I learned today into my practice					
If so, what?					
I changed one or more of the 3 most important errors after discussing with my colleagues		NO		YES	

Appendix 5: Informed Consent

Consent Form

This study forms part of an MMed dissertation. We are investigating the use of simulation as a tool to improve patient safety in theatres in South Africa.
The information that you provide will be used for this study and any publications and studies which arise. Your identity and information will be protected, never published, nor handed to a third party.

I consent to participate in this study by responding to this questionnaire and to be contacted in 6 weeks for a follow up questionnaire. I understand I will receive no financial nor any other compensation for my participation in this study.

The UCT FHS Human Research Ethics Committee can be contacted on (021) 406 6338 in case participants have any questions regarding their rights and welfare as research subjects on the study.

Signature: …… **Date: ……..**

E mail address: ……

Cell phone number: ……

Appendix 6: Delayed Feedback Questionnaire

This questionnaire is a follow up to the Room of Errors Simulation that took place 6 weeks ago.

	STRONGLY DISAGREE	**DISAGREE**	**NEUTRAL**	**AGREE**	**STRONGLY AGREE**
I am more aware of patient safety after having completed the simulation					
I have noticed errors that previously I would have overlooked					
Examples:					
I believe that this improved patient care					
I believe that this improved the patient outcome					
I feel more committed to ensuring a team approach to patient safety					
I have changed my practice					
If so, how?					

Appendix 7: Original Ethics Letter and Renewal

Original Ethics Letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: jamees.emjedi@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

06 July 2015

HREC REF: 465/2015

Dr R Duys
Anaesthesia
D24
NGSH

Dear Dr Duys

PROJECT TITLE: THE EVALUATION OF A SIMULATED THEATRE SCENARIO AS A TOOL TO PROMOTE INTER-PROFESSIONAL COLLABORATION AND ENGENDER A CULTURE OF INCREASED AWARENESS OF PATIENT SAFETY IN SOUTH AFRICAN HOSPITALS (MMed Candidate – Dr C Robertson)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th July 2016.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the MMed Candidate, Dr C Robertson will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 465/2015

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 465/2015

Appendix 8: Renewal of Ethics letter

UNIVERSITY OF CAPE TOWN | FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

Form FHS006: Protocol Amendment

HREC office use only (FWA00001637; IRB00001938)			
☐ Approved	☑ Type of review: Expedited	☐ Full committee	
This serves as notification that all changes and documentation described below are approved.			
Signature HREC Chairperson / Designee		Date	11/9/24

Note: All **Major** amendments must include a **Cover Letter** and a local **PI Synopsis** justifying the changes for the amendment. Please note that incomplete amendment submissions will not be reviewed.

Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za with subject line: FHS006 + (HREC Reference number).

The latest forms are found on our website.

http://www.health.uct.ac.za/fhs/research/humanethics/forms

Please also clarify your plan for research-related activities during COVID-19 lockdown.

Comments from the HREC to the Principal Investigator:
Note: The approval of this protocol amendment does not grant annual approval. Please complete the FHS016 / FHS017 form for annual approval at least one month before study expiration.

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	30 August 2021
HREC REF Number	465/2015
Protocol Title	The evaluation of a simulated theatre scenario as a tool to promote inter-professional collaboration and engender a culture of increased awareness of patient safety in South African hospitals
Protocol Number (if applicable)	n/a
Principal Investigator	Rowan Duys
Department / Office Internal Mail Address	ra.duys@uct.ac.za

1.1 Is this a major or a minor amendment? (see FHS006hlb) Major (tick box) Minor (tick box)	√ Major	☐ Minor
1.2 Does this protocol receive US Federal funding?	☐ Yes	√ No
1.3 If the amendment is a major amendment and receives US Federal Funding, does the amendment require full committee approval? **Note:** Any protocol amendments for **Full Committee Review** MUST be submitted on the monthly HREC submission dates. (Please email an electronic copy to hrec-enquiries@uct.ac.za)	☐ Yes	√ No
1.4 Did the initial study require UCT No-Fault Insurance	☐ Yes	√ No

2. List of Proposed Amendments with Revised Version Numbers and Dates

Please itemise on the page below, all amendments with revised version numbers and dates, which need approval.
This page will be detached, signed and returned to the PI as notification of approval. Please add extra pages if necessary.

Change of protocol/article title from: ~~"The evaluation of a simulated theatre scenario as a tool to promote inter-professional collaboration and endgender a culture of increased awareness of patient safety"~~ to **"Evaluation of a simulated theatre scenario as a low cost, high-turnover vehicle to promote inter-professional collaboration and increased patient safety"**

3. Protocol status (tick ✓)

☐	Open to enrolment
☐	No participants have been enrolled
	Closed to enrolment (tick ✓)
☐	Research-related activities are ongoing
☐	Research-related activities are complete, long-term follow-up only
√	Research-related activities are complete, data analysis only

4. Proposed changes will affect: (tick ✓ all the categories that apply)

Protocol	
√	Study objectives, design (including investigator's brochure, clinical activities, study length)
☐	Study instruments, questionnaires, interview schedules
☐	Sample size

☐	Recruitment methods
☐	Eligibility criteria (inclusion and exclusion criteria)
☐	Drug/device (composition, amount, schedule, route of administration, combination with other drugs/devices, safety information)
☐	Data collection/ analysis
☐	Principal Investigator. (Please attach revised conflict of interest and PI declaration statements. Refer: sections 7 and 8.4 in the New Protocol Application Form FHS013)
☐	Consent form and information sheet
☐	Recruitment materials (e.g. advertisements)
☐	Administrative (e.g. change in sponsor's name, change in contact information)
☐	Other. Please specify:

**Note: Amendment changes involving study length, sample size, additional sites and eligibility criteria (i.e. inclusion of minors and /or pregnant woman) need to be declared to the Insurance office. Please liaise via fhs.sponsorship@uct.ac.za regarding the required documentation and information to be submitted to obtain an updated UCT No-fault Insurance Certificate- it should be included herewith*

4.1 In your opinion, will there be any **increase** in risk, discomfort or inconvenience to participants?	☐ Yes	√ No
If yes, please provide a detailed justification/explanation:		

4.2 What follow-up action do you propose for participants who are already enrolled in the study?	
☐	Inform current participants as soon as possible
☐	Re-consent current participants with revised consent/assent forms (append)
√	No action required
☐	Other. Please describe:

5. Detailed description of the change(s)

Please attach, for each amendment, a summary of all changes which clearly indicates:

i. Old wording (e.g. ~~strikethrough~~ text, CHANGED FROM and CHANGED TO)

ii. New wording (e.g. *italicized*, **bold**, tracked)

iii. Detailed rationale/ justification/ explanation for each change

6. Ethics Review for Amendment Levy – cost including vat

Amendment Review Costs including VAT

Please tick amount to be billed:

Submission Type	*Description*	*New fee (Vat Incl.)*	*tick* ✓
Research funded solely from UCT departmental/ divisional/group budget	Major/ Minor Amendments	**R0,00**	☐
Non-sponsored student research for degree purposes at UCT/Other Universities & Colleges	Major/ Minor Amendments	**R0,00**	√
Protocol amendment - Major (FHS006 Form)	Clinical Trial & International Grant Funded Research - Any changes to the protocol that requires Full Committee review	**R8 000.00**	☐
Protocol amendment - Major (FHS006 Form)	Clinical Trial & International Grant Funded Research - Any change to the protocol that requires Expedited review that does not require Full Committee Review	**R5 000,00**	☐
Protocol amendment - Minor (FHS006 Form)	Clinical Trial & International Grant Funded Research - Minor amendments, administrative changes that do not affect study design e.g. changes to informed consent form, changes in study staff, etc.	**R2 250,00**	☐
Protocol amendment - Major (FHS006 Form)	National grant funded research - Any change to the protocol that requires Full Committee review	**R7 000,00**	☐
Protocol amendment - Major (FHS006 Form)	National grant funded research - Any change to the protocol that requires Expedited review that does not require Full Committee review	**R2 500,00**	☐
Protocol amendment - Minor (FHS006 Form)	National grant funded research - Minor amendments, administrative changes that do not affect study design e.g. changes to informed consent form, changes in study staff, etc.	**R1 000,00**	☐

NB: Protocols funded by UCT (e.g. departmental funding / student research) and by certain grant funding organizations (e.g. MRC, NRF, CANSA,) are exempt from these charges.

Please provide details for Invoicing, either complete section 1 or 2 :

1. Invoice billing – Directly to Sponsor

Sponsor's name	
Billing Address of Sponsor:	
Vat Number:	
Contact person:	
Telephone number:	

Email Address:	
2. Internal Journal Billing:	
Fund Number:	
Cost Centre Number:	
Account Holder Name:	
Division of Account Holder:	

7. Amendment Submission checklist (tick ✓)

7.1 Please tick that all the documents are attached before submitting to the HREC. NB: Incomplete submissions will not be processed	
√	Latest FHS006 form completed with all sections completed as per our website
√	Cover Letter
☐	PI Justification/ Summary for the reasons for the amendment
☐	Protocol - Track changes & Clean Copy (where necessary)
☐	Informed Consent Forms (ICF), if applicable (Any changes made to ICF tracked & clean copy)
☐	Any other additional documentation in support of amendment
☐	Updated no fault insurance certificate (if applicable)

Please email this form and supporting documents (if applicable) in a combined pdf-file to hrec-enquiries@uct.ac.za with subject line: FHS006 + (HREC Reference number). The latest forms are found on our website.

8. Signature

My signature certifies that I will maintain the anonymity and/ or confidentiality of information collected in this research. If at any time I want to share or re-use the information for purposes other than those disclosed in the original approval, I will seek further approval from the HREC.

Signature of PI	Signed by candidate	Date	2021/09/03

Appendix 9: Instruction to authors – Innovation article in Advances in Simulation

‘

The ‘Author Guidelines’ for the journal can be found online at

https://advancesinsimulation.biomedcentral.com/submission-guidelines/preparing-your-manuscript/innovations

Innovations

Criteria

Innovations articles detail investigations of novel devices, concepts, or processes in the context of simulation. This can be, for example, scenarios, simulators, teaching concepts, or theoretical concepts. In addition to some form of data collection demonstrating value or impact of the innovation, we seek well-founded conceptual and theoretical rationales for the innovation.

A key to a publishable Innovations article lies in describing the innovation to a degree of detail that allows the reader to understand and assess the development steps, the anticipated scope of applications, and – preferably – how to use the innovation in the reader’s context.

The aim and objectives for the innovation, and the target group for the innovation, should be clearly articulated.

The development process should be explained in terms of any informants or stakeholders that were involved, conceptual or practical justifications, the processes used, the design considerations taken, revisions and iterations during the development process and their rationale, as well as possible tests of prototypes and the final innovation.

The scope of the innovation’s potential application should include as many aspects as possible, including any relevant human and other actors, as well as the physical and social context of the application.

Instructions on how to implement and use the innovation in other contexts should include a thoughtful analysis of any potential pitfalls and workarounds, any resources needed, and a possible cost estimation, if appropriate. A brief summary of any ‘lessons learned’ will also help readers consider how to situate the innovation in their own contexts.

The abstract should be a short, single paragraph summary, no more than 350 words, of the major points raised, making evident the key work highlighted in the article. Innovations articles are typically between 1,800 and 4,000 words. However, we will also consider articles outside this range. If the article describes a simulation-based educational intervention, please refer to the reporting guidelines by Cheng et al.

Advances in Simulation strongly encourages that all datasets on which the conclusions of the paper rely should be available to readers. We encourage authors to ensure that their datasets are either deposited in publicly available repositories (where available and appropriate) or presented in the main manuscript or additional supporting files whenever possible. Please see Springer Nature's information on recommended repositories.

Preparing your manuscript

The information below details the section headings that you should include in your manuscript and what information should be within each section.

Please note that your manuscript must include a 'Declarations' section including all of the subheadings (please see below for more information).

Title page

The title page should:

- present a title that includes, if appropriate, the study design e.g.:
    - "A versus B in the treatment of C: a randomized controlled trial", "X is a risk factor for Y: a case control study", "What is the impact of factor X on subject Y: A systematic review"
    - or for non-clinical or non-research studies: a description of what the article reports
- list the full names and institutional addresses for all authors
    - if a collaboration group should be listed as an author, please list the group name as an author. If you would like the names of the individual members of the group to be searchable through their individual PubMed records, please include this information in the "Acknowledgements" section in accordance with the instructions below
- indicate the corresponding author

Abstract

The abstract should briefly summarize the aim, findings or purpose of the article. Please minimize the use of abbreviations and do not cite references in the abstract.

Keywords

Three to ten keywords representing the main content of the article.

Main text

This should contain the body of the article, and may also be broken into subsections with short, informative headings.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and materials
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections.

If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

Ethics approval and consent to participate

Manuscripts reporting studies involving human participants, human data or human tissue must:

- include a statement on ethics approval and consent (even where the need for approval was waived)
- include the name of the ethics committee that approved the study and the committee's reference number if appropriate

Studies involving animals must include a statement on ethics approval and for experimental studies involving client-owned animals, authors must also include a statement on informed consent from the client or owner.

See our editorial policies for more information.

If your manuscript does not report on or involve the use of any animal or human data or tissue, please state "Not applicable" in this section.

Consent for publication

If your manuscript contains any individual person's data in any form (including any individual details, images or videos), consent for publication must be obtained from that person, or in the case of children, their parent or legal guardian. All presentations of case reports must have consent for publication.

You can use your institutional consent form or our consent form if you prefer. You should not send the form to us on submission, but we may request to see a copy at any stage (including after publication).

See our editorial policies for more information on consent for publication.

If your manuscript does not contain data from any individual person, please state "Not applicable" in this section.

Availability of data and materials

All manuscripts must include an 'Availability of data and materials' statement. Data availability statements should include information on where data supporting the results reported in the article can be found including, where applicable, hyperlinks to publicly archived datasets analysed or generated during the study. By data we mean the minimal dataset that would be necessary to interpret, replicate and build upon the findings reported in the article. We recognise it is not always possible to share research data publicly, for instance when individual privacy could be compromised, and in such instances data availability should still be stated in the manuscript along with any conditions for access.

Data availability statements can take one of the following forms (or a combination of more than one if required for multiple datasets):

- The datasets generated and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS]
- The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
- All data generated or analysed during this study are included in this published article [and its supplementary information files].
- The datasets generated and/or analysed during the current study are not publicly available due [REASON WHY DATA ARE NOT PUBLIC] but are available from the corresponding author on reasonable request.
- Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.
- The data that support the findings of this study are available from [third party name] but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of [third party name].
- Not applicable. If your manuscript does not contain any data, please state 'Not applicable' in this section.

More examples of template data availability statements, which include examples of openly available and restricted access datasets, are available here.

BioMed Central also requires that authors cite any publicly available data on which the conclusions of the paper rely in the manuscript. Data citations should include a persistent identifier (such as a DOI) and should ideally be included in the reference list. Citations of datasets, when they appear in the reference list, should include the minimum information recommended by DataCite and follow journal style. Dataset identifiers including DOIs should be expressed as full URLs. For example:

Hao Z, AghaKouchak A, Nakhjiri N, Farahmand A. Global integrated drought monitoring and prediction system (GIDMaPS) data sets. figshare. 2014. http://dx.doi.org/10.6084/m9.figshare.853801

With the corresponding text in the Availability of data and materials statement:

The datasets generated during and/or analysed during the current study are available in the [NAME] repository, [PERSISTENT WEB LINK TO DATASETS].[Reference number]

If you wish to co-submit a data note describing your data to be published in *BMC Research Notes*, you can do so by visiting our submission portal. Data notes support open data and help authors to comply with funder policies on data sharing. Co-published data notes will be linked to the research article the data support (example).

Competing interests

All financial and non-financial competing interests must be declared in this section.

See our editorial policies for a full explanation of competing interests. If you are unsure whether you or any of your co-authors have a competing interest please contact the editorial office.

Please use the authors initials to refer to each authors' competing interests in this section.

If you do not have any competing interests, please state "The authors declare that they have no competing interests" in this section.

Funding

All sources of funding for the research reported should be declared. The role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript should be declared.

Authors' contributions

The individual contributions of authors to the manuscript should be specified in this section. Guidance and criteria for authorship can be found in our editorial policies.

Please use initials to refer to each author's contribution in this section, for example: "FC analyzed and interpreted the patient data regarding the hematological disease and the transplant. RH performed the histological examination of the kidney, and was a major contributor in writing the manuscript. All authors read and approved the final manuscript."

Acknowledgements

Please acknowledge anyone who contributed towards the article who does not meet the criteria for authorship including anyone who provided professional writing services or materials.

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section.

See our editorial policies for a full explanation of acknowledgements and authorship criteria.

If you do not have anyone to acknowledge, please write "Not applicable" in this section.

Group authorship (for manuscripts involving a collaboration group): if you would like the names of the individual members of a collaboration Group to be searchable through their individual PubMed records, please ensure that the title of the collaboration Group is included on the title page and in the submission system and also include collaborating author names as the last paragraph of the “Acknowledgements” section. Please add authors in the format First Name, Middle initial(s) (optional), Last Name. You can add institution or country information for each author if you wish, but this should be consistent across all authors.

Please note that individual names may not be present in the PubMed record at the time a published article is initially included in PubMed as it takes PubMed additional time to code this information.

Authors' information

This section is optional.

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

References

Examples of the Vancouver reference style are shown below.

See our editorial policies for author guidance on good citation practice

Web links and URLs: All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, as well as the date the site was accessed, in the following format: The Mouse Tumor Biology Database. http://tumor.informatics.jax.org/mtbwi/index.do. Accessed 20 May 2013. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

Example reference style:

Article within a journal

Smith JJ. The world of science. Am J Sci. 1999;36:234-5.

Article within a journal (no page numbers)

Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition. BMC Medicine. 2013;11:63.

Article within a journal by DOI

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. Dig J Mol Med. 2000; doi:10.1007/s801090000086.

Article within a journal supplement

Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. Blood 1979;59 Suppl 1:26-32.

Book chapter, or an article within a book

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic; 1980. p. 251-306.

OnlineFirst chapter in a series (without a volume designation but with a DOI)

Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. Top Curr Chem. 2007. doi:10.1007/128_2006_108.

Complete book, authored

Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science; 1998.

Online document

Doe J. Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. 1999. http://www.rsc.org/dose/title of subordinate document. Accessed 15 Jan 1999.

Online database

Healthwise Knowledgebase. US Pharmacopeia, Rockville. 1998. http://www.healthwise.org. Accessed 21 Sept 1998.

Supplementary material/private homepage

Doe J. Title of supplementary material. 2000. http://www.privatehomepage.com. Accessed 22 Feb 2000.

University site

Doe, J: Title of preprint. http://www.uni-heidelberg.de/mydata.html (1999). Accessed 25 Dec 1999.

FTP site

Doe, J: Trivial HTTP, RFC2169. ftp://ftp.isi.edu/in-notes/rfc2169.txt (1999). Accessed 12 Nov 1999.

Organization site

ISSN International Centre: The ISSN register. http://www.issn.org (2006). Accessed 20 Feb 2007.

Dataset with persistent identifier

Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (Sorghum bicolor). GigaScience Database. 2011. http://dx.doi.org/10.5524/100012.

Figures, tables and additional files

See General formatting guidelines for information on how to format figures, tables and additional files.