IMPACT OF UNEXPECTED DEATH IN SIMULATION: Skill Retention, Stress and Emotions

"IMPACT OF MEDICAL CRISIS SIMULATION: Skill Retention, Stress and Emotions" (alternative title for blinding)

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1.1 Investigators responsibilities

The research team combines a strong academic, education and clinical background. **Dr. Sylvain Boet** is a faculty Anesthesiologist at The Ottawa Hospital and a Senior Research Associate at the Academy for Innovation in Medical Education (AIME). He holds a Masters in Education and is currently a PhD candidate. He has published extensively in simulation and medical education. **Dr. Karl Schebesta** is a Fellow in Simulation and Medical Education at the University of Ottawa Skills and Simulation Centre & The Academy for Innovation in Medical Education, is a Senior Research Associate at the Dept. of Anaesthesie at the Medical Universtiy of Vienna and has published in the field of simulation and medical education. **Kristina Khanduja, MBChB, MEd** is a Staff Anesthesiologist at Mount Sinai Hospital and Assistant Professor in the Department of Anesthesia at the University of Toronto. She holds a fellowship in medical simulation and a Masters in Education for health care professionals. **Dr Meghan Andrews** is an Anesthesiology Fellow in Simulation and Medical Education at the University of Ottawa Skills and Simulation Centre & The Academy for Innovation in Medical Education **Dr. Vicki LeBlanc** holds a PhD in psychology, serves as the Associate Director for the Wilson Centre for Research in Education, and is an internationally recognized expert in stress and simulation. **Dr. M. Dylan Bould** is faculty Anesthesiologist at the Children's Hospital of Eastern Ontarioand a Senior Research Associate at AIME. He holds a Masters in Education and has published extensively in medical education and simulation.

All investigators are involved in the development of the original idea, study protocol and scenario scripts. KS, SB and DB will be responsible for REB approval, preparation of a case report form. VL will furthermore provide an expert review of stress and emotion assessment methods. MA, KS, KK, SB and DB will be responsible for recruitment of participants, conducting the trial, data collection and data analysis as well as training of expert reviewers and confederate actors. KS, SB and DB will thereafter prepare the initial manuscript. All investigators will review and optimize the manuscript before it is passed on to a journal. KS and SB will present the results of this trial at international conferences.

2. ABSTRACT

Background

High-fidelity simulation is an increasingly used teaching tool that is proven to be effective for learning. According to the literature, by gradually increasing stress and emotions, more effective learning can be achieved. However, allowing the simulated patient to “die”, as a deliberate stressor, is controversial. There is no previous research on the educational effect of letting a simulated patient die. We aim to evaluate the effects of simulated unexpected death on skill retention, stress levels, and emotions. We hypothesize that the occurrence of unexpected death will impact skill retention, and will be associated with higher stress levels and stronger emotions.

Methods

After Institutional Research Ethics Board approval, 56 residents and fellows of different medical specialties will be randomized to either the intervention (unexpected death) or control (survive) group. Participants from both groups will have to individually manage a simulated cardiac arrest crisis. In the intervention group, the scenario will end by the death of the simulated patient, whilst in the control group the simulated patient will survive. Each participant will be immediately debriefed by a trained instructor. Three months later, skill retention will be assessed in a similar scenario. Crisis management performance of all scenarios will be rated by 2 blinded raters. Biological stress, cognitive appraisal, and emotions will be measured during both scenarios.

Implications

The impact of simulated unexpected death on skill retention of residents and fellows will provide instructors with evidence to optimize scenario design and approach the role of stress and emotions in simulation-based education.

3. BACKGROUND

Trainers are more frequently employing high-fidelity medical simulation to allow learners to acquire complex skills at minimal risk to real patients.[1] The presence of crticial observers during such training invokes a stress response and emotional reactions in participants. Invoking emotional responses, both positive and negative, appears to enhance the participant's memory of the event and can ameliorate learning.[2] Some educational researchers take advantage of such responses to overcome the challenges presented by workload, rising expectations, and resource limitations to create a memorable simulation learning event.

The utility of stress for enhancing learning is controversial and its use may be a net negative.[2,3] Stress is closely associated with anxiety and is generally considered a negative occurrence. Cogntiive appraisal theory considers the perception of whether the resources available to a person facing a stressful incident are adequate; if they are, then the situation is viewed as a challenge whereas inadequate resources cause the situation to be seen as a threat. Situations perceived as a threat invoke anxiety in the subject and activate biological pathways, specifically in the sympathetic nervous system and the hypthalamic-pituitary-adrenal axis. [4,5] Endocrine activity cause the subject to be more attentive and perceptive and to develop stronger memories of the threatening events.[6-9] There appears to be a direct correlation between the cortisol levels in an individual during an event and the degree of retention of the memory of that event, though heightened cortisol may negatively affect the recall of older memories during the event.[6] Despite the promising evidence in favour of heightening cortisol during learning, educators almost must consider the consequences of inflicting negative emotions and stress onto participants. The positive effects of cortisol on memory decay as cortisol concentrations increase, ultimately causing impairment of learning and performance at very high levels.[8] On the other hand, situations appraised as a challenge are not accompanied by cortisol release and may result in less retention.[10]

Evidence consistently suggests that learning and retention are affected by emotional states, both positive and negative.[11] Positive emotions encourage individuals to absorb greater degrees of high-level information, while negative emotions reinforce the learning of specific details. The translation of knowledge to a new situation is facilitated by positive emotions occurring when the knowledge was gained, while negative emotions that occur during learning improve the individual's recall of detail information pertaining to the specific situation in which they were learning. In carefully balancing the effects of emotions and stress on learning, some educators have used intentional stressors as an effective element in educational efforts.[3,12] Many potential stressors are present in medical simulation, including time pressures, unfamiliarity of the environment, ineffective medical treatments and bad patient outcomes. The use of a deliberately bad patient outcome has become a particularly heated discussion within the medical education field and there is a scarcity of evidence to support this discussion.

Critical care situations can invoke a powerful stress response and negative emotions in their demand for expedient actions and quick decisions in rapidly changing situations. The death of a patient can have a potent effect on a provider's emotions even if he or she is highly experienced in clinical care.[13,14] Educators commonly make efforts to prepare medical learners for *expected* death by causing the death of the mannequin in a simulation for which death is the expected outcome.[15] An

unexpected death of the mannequin may occur in a simulation session in which the learner does not correctly manage the situation.[16,17] The use of unexpected death in simulation is unsupported by evidence.[15,16,18] Educators in favour of its use propose that unexpected death may help to cement the event as memorable[2] and thereby enhance learning. [3,12] The other side of the discussion fears that unexpected death in simulation will exacerbate negative emotions and subject learners to undue stress, including the physical manifestations of stress. Such an experience could also cause psychological damage to participants or lead them to withdraw from simulation research. [16,18,19] To date, the literature discussing the impact of simulated death on learning has been limited to retrospective surveys and opinion pieces.[15,16,20] The true effect that unexpected death has on stress levels, performance and retention remains to be seen.

This study aims to elucidate the effect of unexpected death in a simulation scenario on the retention of crisis management skills. We hypothesize that unexpected death will be detrimental to the retention of these skills and will result in increased stress and negative emotions among participants.

4. OBJECTIVES OF THE CLINICAL INVESTIGATION (HYPOTHESIS)

4.1 Primary Objective

Our primary objective is to evaluate the impact of an unexpected simulated death experience on non-technical skill retention at 3 months. We hypothesize that the unexpected death of a simulated patient during a simulated cardiac arrest scenario will impair the retention of this skill.

4.2 Secondary Objectives

Our secondary objectives are:

(i) To assess if unexpected death of a simulated patient is associated with an impaired retention of technical resuscitation skills.

(ii) To examine if unexpected death of a simulated patient is associated with future higher stress levels and stronger emotions during simulated crisis.

(iii) To investigate the relationship between stress levels as well as emotions and future performance in crisis.

We furthermore hypothesize, that simulated death will lead to higher stress levels as well as more negative emotions and will thereby impact the ability to retain critical skills.

5. DESIGN OF THE CLINICAL INVESTIGATION

This study will be designed as multi center, investigator blinded, randomized, controlled, prospective trial with qualitative and quantitative methodology.

5.1 Population

5.1.1 Subject population

Residents and fellows of the departments of anesthesiology, critical care, emergency medicine, medicine, obstetrics and gynecology, surgery and family medicine at the University of Ottawa and the University of Toronto, including all subspecialities, will be invited to participate in this trial. Participants will be recruited by means of personalized contact via email, phone invitations and poster-advertisement at the respective departments.

5.1.2 Inclusion criteria

Participants will be enrolled after approval of the respective site coordinator. Participants are required to refrain from physical strains, smoking, drinking caffeinated or low pH beverages and

eating for at least one hour before enrollment. Furthermore participants will be included between 11 AM and 8 PM, when cortisol levels are most stable.

5.1.3 Exclusion criteria

Residents with physical burden limiting their ability to manage simulated crisis and pregnant women will be excluded. Participants with a known endocrine disease or taking corticosteroids will not be enrolled.

5.1.4 Withdrawal of participants

Criteria for withdrawal

Participants may prematurely discontinue from the investigation at any time.

Participants must be withdrawn under the following circumstances:

- at their own request
- if the investigator feels it would not be in the best interest of the subject to continue
- if the subject violates conditions laid out in the consent form / information sheet or disregards instructions by the clinical investigation personal

In all cases, the reason why participants are withdrawn must be recorded in detail in the case report form (CRF). Should the investigation be discontinued prematurely, all investigation materials (complete, partially completed and empty CRFs) will be retained.

6. METHODOLOGY

Institutional ethics approval will be sought from the Ottawa Hospital Research Ethics Board and the University of Toronto Research Ethics Board for Health Sciences. Informed consent and a confidentiality agreement will be obtained from participants.#Participants will be enrolled after approval from their resident site coordinator. They are asked to refrain form physical strains, smoking, drinking caffeinated or low pH beverages and eating for at least one hour before participating. The trial will be conducted between 11 AM and 8 PM to warranty stable cortisol levels. All participants will be asked to switch of their mobile phones and pagers in order to prevent distraction during the study.

Initial Test

After a standardized accommodation phase of 15 minutes, all participants will be exposed to a prerecorded, 15 minute long video-review of the actual advanced cardiac life support algorithms. We will collect baseline data including demographic data, stress markers and data on anxiety therafter as described below.

Immediately before a short scenario briefing the participants will be randomized to either the intervention (unexpected death) or control (survive) group. Participants from both groups will have to individually manage a simulated in-hospital cardiac arrest scenario as team leader (Appendix C). At the initial test, in the intervention group (unexpected death), the scenario will be designed to ultimately lead to the death of the simulation mannequin, regardless of the participant's performance. In the control group (survive), the mannequin will survive. We will attempt to ensure that participants do not anticipate the series of events in the retention resuscitation scenario based on their experience during the intial rescuscitation scenario (recall bias). Therefore, the scenarios will be different in terms of order of the presenting arrhythmia. For example the participant who manages a patient with ventricular fibrillation (VF), then pulseless electrical activity (PEA), followed by asystole in the initial scenario will go on to manage a patient with pulseless electrical activity (PEA), then ventricular fibrilliation (VF), then return of spontaneous circulation (ROSC) in the retention test. The clinical stems of the scenarios in the intitial test versus the retention test will also

differ slightly in order to eliminate the potential for this recall bias decribed above. In summary, the scenarios are of equal complexity, but differ primarily with respect to the clinical context, initial cardiac arrest rhythm and pre-determined outcome (Appendix C).

Two well-trained confederates will act as registered nurse and as respiratory therapist within the team. These roles were prescripted to ensure standardization for each participant. The conferderates will be instructed to help and to perform tasks when directed but not to offer crisis management advice or differential diagnoses. An individualized, video-assisted, instructor-led, structured debriefing lasting 30 minutes will follow the initial scenario. As suggested by Gaba, highly experienced and well prepared instructors will lead the debriefing phase in order to deal with potential upcoming emotions and issues.[19] All scenarios and debriefings will be video recorded for performance analysis.

Retention Test

Previous data have shown that, even with high-fidelity simulation, resuscitation knowledge and skills deteriorate between as early as 2 weeks and 1 year after the learning intervention, with a faster decay in skill. [21,22] Therefore a retention test is planned 3 months after the initial test. After a short accommodation phase of 15 minutes and assessment of baseline data a standardized scenario briefing will be done. Participants from both groups will be asked to be team-leader in a cardiac arrest scenario to test for skill retention. Again, two confederates, one acting as registered nurse and one acting as respiratory therapist will be team memebers. While the scenarios will be the same as in the initial test, the case presentation of the scenario and the mannequin "outcome" will be switched for the retention test. The mannequin will survive for the "unexpected death" group and it will die in the "survive" group. That way, each participant will be exposed to simulation death in the study once. To maximize learning opportunities for participants in this study, an individualized debriefing with a specially trained facilitator will follow the retention test as well.
All scenarios and debriefings will be video recorded for futher performance analysis.

Following the retention scenario and completion of risk assessment, participants will be interviewed to determine their subjective views of their decision-making and performance within an orally administered survey approximately 30 minutes in length.

Both Phases

The setting and equipment will be the same in the initial and the retention phase, reflecting an appropriately equipped normal ward room at our hospital. SimMan (Laerdal, Stavanger, Norway) will be used as the standardized simulation mannequin in all scenarios. The mannequin will be placed in a patient bed. The mannequin will be operated by an experienced simulation specialist from a separated control room. All scenarios will be peer reviewed and validated by experts in the field of medical simulation and resuscitation. The scenarios will be prescripted for a duration of maximum 15 minutes. The confederates acting as team members during the scenarios will receive extensive precourse training with prescripted responses and interactions. Predefined, peer reviewed cues will be given by the supporting staff in case the participants fail to recognize the cardiac arrest situation. These cues will include the repetition of the case presentation and vital parameters.

Each phase is accompanied by assessment of baseline data, stress parameters and emotions. All scenarios and debriefings will be video recorded to allow performance assessment by two independent experts raters blinded to group allocation.

In order to collect meaningful qualitative data from a maximum of subjects, all subjects will be exposed to unexpected death either during their initial or retention scenario. Subjects of group "unexpected death" will have their simulated patient survive during the retention test while subjects from the group "survive" will have their patient die during the retention scenario. The course of both

subsets of scenarios is the same up until the final two minutes, and the final outcome of the scenarios will not be seen by the expert raters. Therefore, we do not consider this trial as a crossover design.

6.1 Data collection

6.1.1 Demographics and knowledge

Demographic data including age, gender, post-graduate-year level, specialty, previous advanced cardiac arrest experience and training as well as simulation experience will be collected in the initial and retention phase after a short standardized accommodation phase.

6.1.2 Performance Assessment

Non-Technical Skill

Non-technical skills for crisis resource management including leadership, communication skills, problem solving, resource utilization, situation awareness and overall performance will be evaluated by using the established and validated Ottawa Global Rating Scale.[23,24] Two blinded, independent expert raters will review all video recorded scenarios. Both raters will be intensively trained in using the checklist prior to the start of the study in order to improve inter-rater reliability. The same two raters will assess all scenarios.

Technical Skill

Technical skill performance will be measured by using a task specific checklist. For this purpose we will use an internaly validated and adapted version of the American Heart Association's Megacode Checklist. The main items will be the team leader performance, management of the initial tachycardia, management of the pulseless electrical activity and the actions taken during the following ventricular fibrillation. Post resuscitation care will not be assessed to guarantee the blinding of the investigators. Therefore a total score of 18 points instead of 21 will be reachable. Furthermore the overall performance will be rated using "pass" and "fail". The same two investigators who assessed for non-technical skills will assess all scenarios for technical skills as well.

6.1.3 Stress Assessment

Acute stress will be assessed by means of salivary cortisol, the State-Trait Anxiety Inventory (STAI) and questionnaire aligned with the cognitive appraisal theory.[4,5,10,25]

Salivary Cortisol

The activation of the hypothalamic-pituitary-adrenal axis as surrogate for psychological stress will be measured using salivary cortisol levels that show a close to linear relationship to plasma cortisol levels.[4,5,26] Cortisol levels will be measured in both simulation tests (initial test and retention test). Salivary cortisol peaks at 20 to 40 minutes after the onset of a stressor.[4] In order to apporach cortisol kinetic, 5 cortisol samples will be obtained per participant per scenario: when participants arrive at the simulation center (sample 0), just before each scenario (sample 1), immediately at the end of the each scenario (sample 2), 30 minutes after the start of the scenario (sample 3), and at the end of the debriefing phase (sample 4). The cortisol sampling schedule for the initial and the retention test will be identically, resulting in a total of 10 cortisol samples per participants (see Appendix D). A roll shaped synthetic saliva collector (Salivette for Cortisol testing, Starstedt, Montreal, Quebec, Canada) will be used and will be frozen at -20°C until analysis using an ELISA technique at the Technische Universitat Dresden, Germany.

State-Trait Anxiety Inventory (STAI)

To evaluate acute and subjective stress the standardized test battery of the STAI will be used. With STAI state anxiety at the very given moment can be measured using 20 statements to which the participants agree or disagree on a four point Likert-like scale (1 – not at all, 4 very much so). The sub scores are summed up and provide a sensitive basis for acute changes in anxiety related to stressful simulation.[10,25] STAI will be assessed after the resting phase before each scenario and immediately after the debriefing of the initial and the retention scenario.

Cognitive Appraisal

Cognitive appraisal will be measured at the end of each scenario briefing and immediately after the scenario using the method described by Tamoka et al. and evaluated for the use in simulation by Harvey et al.[10,27,28] Primary appraisal (demand) will be measured by asking the question "How demanding do you expect the upcoming task to be?" before the scenario and "How demanding was the task you just completed?" after the scenario. Secondary appraisal (resources) will be assessed at both times by asking "How able are/were you to cope with this task?" 10 point Likert-like scale will be used for this assessment. A cognitive appraisal index will be calculated thereafter by dividing results of primary appraisal by results of secondary appraisal. An index <1 will indicate that resources do not meet demands and the task is appraised as "threat" while an index >1, where resources are greater than demands will indicate a "challenge".

6.1.4 Emotion Assessment

Emotions are inevitably linked to the occurrence of expected and unexpected death while treating a patient or patient simulator.[16] As these feelings may foster or impair the learning effect, emotions that occurred throughout the simulation scenarios will be asessed. Participants will be asked to classify their emotions they experienced throughout the study by using the established Positive and Negative Affect Schedule (PANAS) at the end of each scenario. This assessment will be done immediately after debriefing of the respective scenarios.

6.1.5 Survey

Following each scenario and completion of risk assessment, participants will be interviewed to determine their subjective views of their decision-making and performance. In order to contextualize the effects of simulated death, an open ended orally administered survey will follow the retention test phase (see Appendix E) for all subjects. The orally administered surveys will be approximately 30 minutes in length and will be recorded for transcription. Transcripts will be anonymized. This open-ended survey is intended to provide basic contextual information, thus data will be analyzed using inductive thematic analysis [29-31] to create general themes. Analysis will be guided by a Research Associate with specialized qualitative research training. Findings from the qualitative component will help to inform directions for future research.

6.1.6 Debriefing Asssement

In order to assess the debriefing quality and avoid potential bias by inconsistent quality, all debriefings will be video recorded and rated by two independent expert raters using the validated 8-item 5-point OSAD scale.[32] Again, the raters will be intensively trained in using the scale prior to the start of the study.

6.2 Randomization

In order to create groups of participants that are similar in regards of their baseline characteristics and in order to increase the power of our study we will use the approach of stratified randomization to allocate the participants to the intervention and control group. In order to keep the number of strata and the resulting covariates small we will stratify the participants regarding their level of training (PGY1 – PGY3 residents, vs. PGY4 – PGY 5 residents and fellows),their likelihood of providing acute care (acute care specialities will include anesthesia, emergency medicine and critical care trained personnel). Thereafter computer block randomization will be performed using the algorithm provided at www.randomization.com for all subgroups. Participants will be assigned to the

intervention (initial test ending with asystole) and control (initial test ending with sinus rhythm) groups in a 1:1 ratio. To ensure even allocation to the intervention and controll group blocks of 4 participants will be predefined. Sealed, numbered, opaque envelopes, containing the random allocation, will be opened after the resting period immediately before scenario briefing begins.

6.3 Blinding

Investigators performing data analysis and video raters will be blinded to group allocation by editing audio/video material in such a way that the final end of the scenario, with the occurrence of death or return of spontaneous circulation is not visible. Participants will be blinded to the nature of the study, their group assignment and scenario at the time of enrollement and scenario briefing during the initial and retention test.

6.4 Benefit and risk assessment

6.4.1 Benefits

By participating in this trial all participants will benefit from a short review of the actual resuscitation guidelines and will have the opportunity to improve their technical and non-technical skills in resuscitation and teamwork within two high-fidelity simulation sessions with video debriefing free of charge. Furthermore, as the save environment of simulation and stress exposure training do effectively reduce state anxiety as well as performance anxiety during a real emergency situation and enhance performance during stress, participants will benefit from these positive effects during real clinical emergencies.

6.4.2 Risks

By creating a close to real setting and urging the participants to immerse into the scenario high-fidelity simulation is known to increase physiological and psychological stress throughout the simulation significantly above baseline levels. Especially with the occurrence of death, which is a potent stressor in the real clinical settings, emotions and stress might be aggravated. However, normal stress levels are reached at the end of the adjuncted structurized debriefings at common high stakes simulation sessions.

In order to detect any serious negative reactions to the scenarios, all scenarios will be debriefed by an experienced simulation instructor. The debriefers will specifically ask the subjects about their feelings and thoughts about the death of the “patient”, and will provide debriefing and coping strategies for dealing with death in the real life setting. Participants with overwhelming emotional responses, and who are emotionally troubled by the simulation experience, will be offered a voluntary professional referral to the counseling service of the University of Ottawa or the University of Toronto. In previous studies by one of the co-investigators (V LeBlanc) looking at highly stressful situations with over 400 front line workers and trainees, the subjects’ stress levels consistently returned to baseline levels at the end of the scenarios. Any residual negative emotions following such scenarios were consistently due to reflections on their own level of performance rather than on the emotional components of the scenarios themselves.

Fruthermore there is a minimal risk of physical strain within this study. In order to minimize this risk, all participants will be familiarized with the mannequin prior to strating the first scenario.

7. ANALYSIS

7.1 Quantitative analysis

7.1.1 Primary outcome parameter

The difference in retention of non-technical skills for crisis management between the intervention and the control group (measured by the Ottawa Global Rating), specified as the difference in performance between the initial and the retention test, will be our primary outcome.

7.1.2 Secondary outcome parameters

Secondary outcomes will be (i) technical resuscitation skills (performance and retention) measured by the American Heart Association's Megacode Checklist (ii) stress including salivary cortisol, cognitive appraisal and STAI and (iii) valence of emotions.

7.2 Sample size considerations

A priori sample size calculation was performed on the basis of an estimated Cohen's d effect size of 0.8, which is considered large and acceptable for a teaching intervention.[33] We aim at a two-tailed level of significance of $p<0.05$ and a power of 0.8. Using the recommended sample size estimation approach for ANCOVA[34] with an estimated r^2 of 0.12, derived by a previous, not now published trial (Boet. S et al, Learning crisis resource management: Practice versus observing, CAS 2013 Abstract 1653689, accessible at http://www.cas.ca/English/AM-Abstracts-2013**)**, a number of 46 participants would be needed. In order to account for an estimated attrition rate of 20% we need to recruit 56 participants. G*Power for MAC (version 3.12, Düsseldorf, Germany) was used for sample size calculations.

7.3 Statistical analysis

As it has been suggested as best practice for stratified randomized controlled trials, ANCOVA will be used to analyze the outcome parameters using the level of training (PGY1-3 vs PGY 4-5 and fellows) and specialities (acute care specialities vs. non-acute care specialities) as covariates.[35] Group assignment (unexpected death, alive) will be used as the independent variable. Demographic data will be analyzed using an unpaired Student's t-test or chi-square test, where appropriate.

Curved/linear regression analysis will be performed to assess the correlations between each outcome and stress as well as emotions. As it is common practice, results of Likert-like scales will be treated as interval-measures and thereby analyzed by using parametric tests.[36,37]

7.4 Qualitative analysis

Qualitative data will be analyzed according to grounded theory by sorting, coding and redefining into emergent topics. Thereafter interview transcripts will be compared against each other.[38,39] By using an iterative approach, ongoing preliminary analysis of the results gathered by the semi-structured interviews will lead to adaptation of the interviews. Thereby thematic categories will be established and continuously refined. This process will be performed until coding results in an explanation of the observations, and saturation is reached.

8. IMPLICATIONS AND LIMITATIONS

8.1 Implications

Over the past decades, high-fidelity simulation has gone from being a relatively limited teaching tool to one of the most, cutting edge ways to teach medical trainees. Several studies have demonstrated the effectiveness of simulation in teaching both technical and non-technical skills, such as Crisis Resource Management.[40-42] However, by creating an environment that requires the learners to immerse into a "make-believe world", participants are exposed to a high level of stress and

emotions.[18] As of yet, no work has been done to establish precisely the impact of an unexpected simulation death on skills retention of residents.

Even though medical professionals are exposed to patient death on a regular basis, these events have been shown to be linked to a considerable emotional and stress load, even in the most experienced personnel. However, transferring such an event into the secure environment of medical simulation is a matter of current discussion.[16,18,19] Especially, the impact of the unexpected death of a mannequin remains unclear. While some educators fear exaggerated negative feelings, distraction from the learning objective and refusal of further simulation sessions, the occurrence of death as a "to-be-remembered event"[2] might improve the learning outcome.[43] Presently, simulated death is mostly avoided partly because of lack of reliable data on its impact on learners. This study aims to compare skills retention at 3 months after experiencing or not simulated unexpected death. In doing so, we hope to provide the foundation for an evidence-based approach to effective scenario development in simulation education. The results of this trial will have immediate and practical impact on the simulation scenario design, and may serve as evidence-based guidance for the development of universal simulation guidelines.

Little is known on the emotional effects of medical education including simulation. This study is a collaborative effort between simulation experts, specialists in crisis management, stress and medical education and the findings will be applicable and generalizable across several disciplines. It is the intention of the study to evaluate a skill that is as generalizable as possible. The investigation of stress levels, cognitive load and emotions will deepen our understanding of the effects of simulation-based education on learners and will potentially help to improve teaching effectiveness. The effect of negative emotion on learning and retention has implications for education outside this particular stressor (simulated death) to other causes of learner distress and may be generalizable outside of simulation. Our insights into the effects of emotions and stress on learning and skills may be applicable to other teaching techniques, potentially having a large impact on medical education.

8.2 Limitations

The study design is limited by the sample size. A small difference between the two groups might therefore not result in a significant way and the study might be underpowered to draw definitive conclusions. However, all aspects of the study will be hypothesis generating, no matter of the resulting power and thereby will help to direct further investigations.

9. PUBLICATION

The findings of this study will be published by the investigators in a scientific journal and presented at scientific meetings. Also, we plan to disseminate the knowledge gained from our study via open access methods, in order to increase readership and impact. Open source publication allows readers to read publications for free and is proven to increase citations of publications.

Karl Schebesta will be assigned as first and corresponding author, while Sylvain Boet will be the last and senior author. The ranking of the other authors will be done in accordance to their contribution to the study.

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