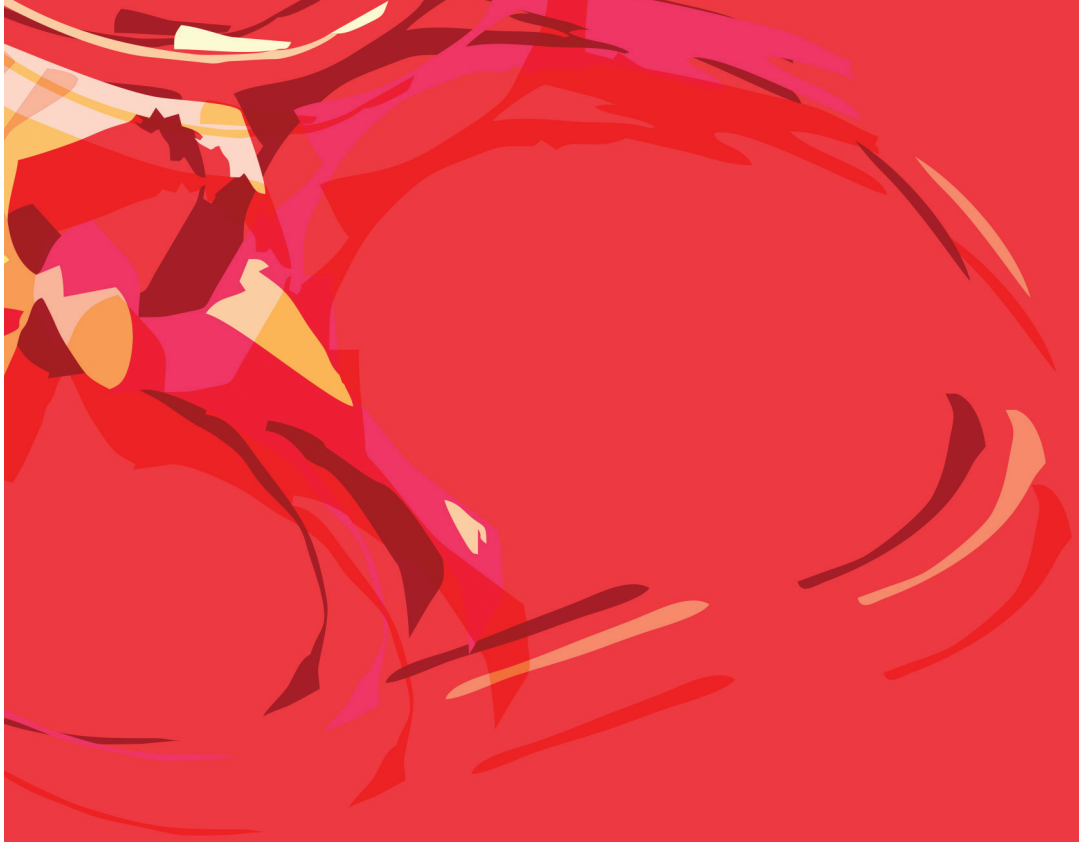
Simulation design matters



Simulation Design Matters

Improving Obstetrics Training Outcomes

Brena Carvalho Pinto de Melo

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Simulation Design Matters

Improving Obstetrics Training Outcomes

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Table of Contents

Chapter 1 9
Introduction

Chapter 2 21
The limited use of instructional design guidelines in healthcare simulation scenarios: an expert appraisal

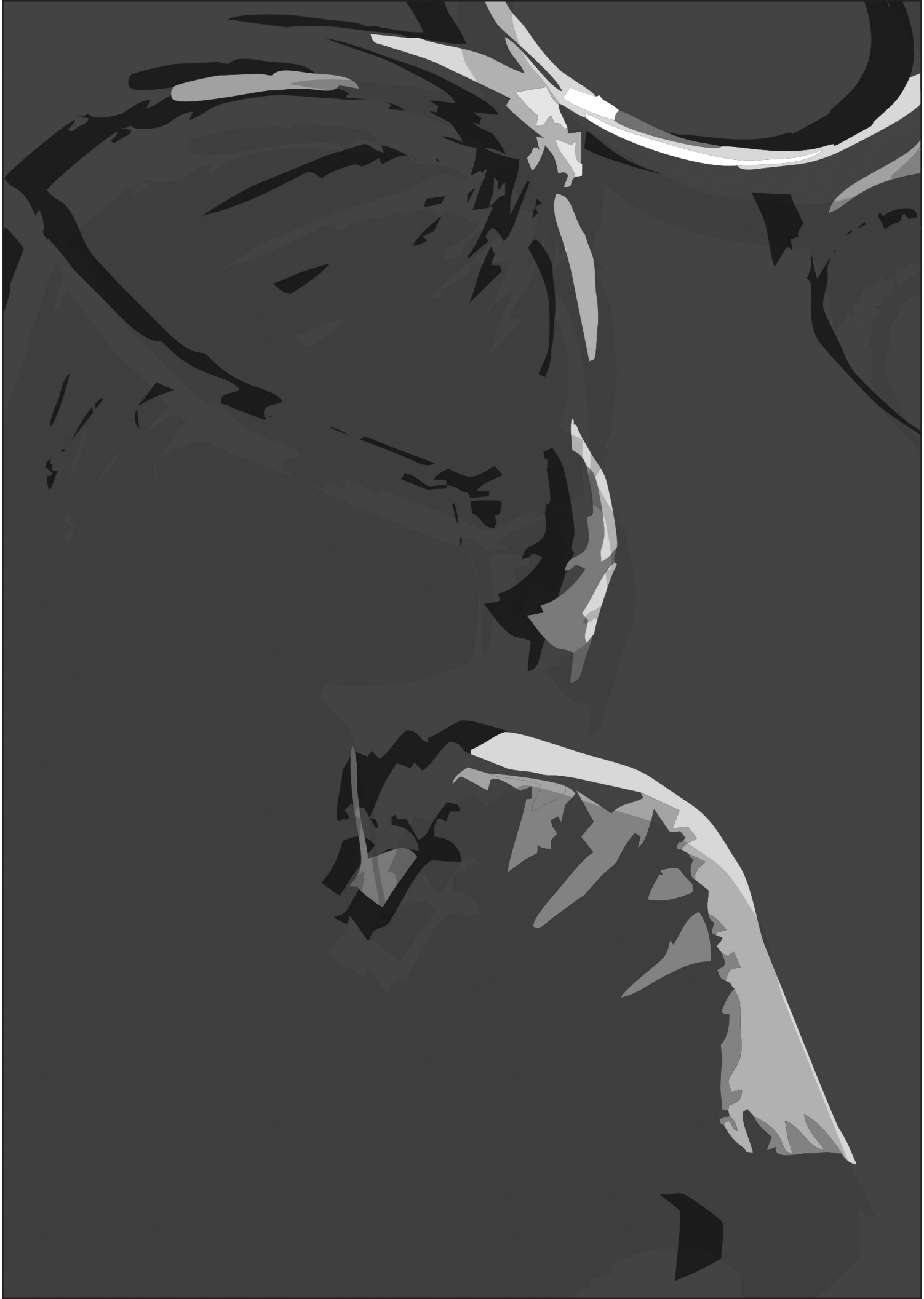
Chapter 3 43
The use of instructional design guidelines to increase effectiveness of postpartum hemorrhage simulation training

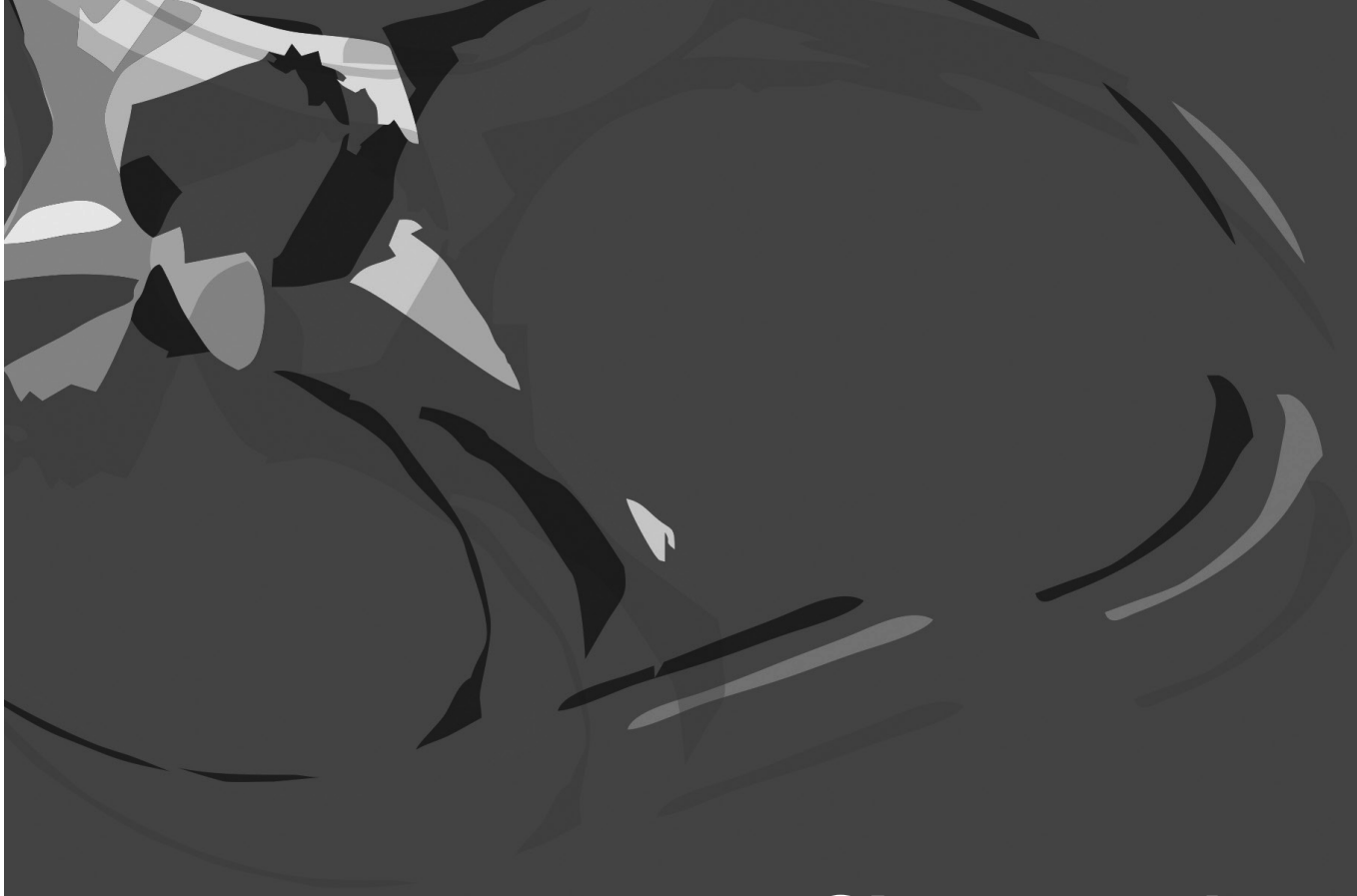
Chapter 4 59
Self-perceived long-term transfer of learning after postpartum hemorrhage simulation training

Chapter 5 79
Effects of an in situ instructional design based postpartum hemorrhage simulation training on patient outcomes: an uncontrolled before-and-after study

Chapter 6 99
General Discussion

Summary 114
Samenvatting 120
Valorization 126
Acknowledgment 132
Curriculum Vitae 138
SHE Dissertations Series 140





Chapter 1

Introduction

Introduction

Healthcare simulation training has widely spread throughout international medical schools in recent decades.[1] The concurrent financial investment it demands is supported by the legitimate argument of improving patient outcome. Evidence, however, on the effectiveness of this type of training format is still being sought.[2]

Why simulate?

The concept of simulation training was originally imported into the healthcare field from the war and airway industries, mainly to present itself as an alternative to an "error safe environment".[3] Its dissemination was propelled by both the goals of increasing patient safety and providing an alternative to supervised practice opportunity to residents after the adoption of duty hour's restriction by residency programs.

Patient safety issues received great attention from the public and scientific communities after the American National Institute of Medicine (NIH) report, "To err is human", in 1999. According to this report, each year, 98,000 people died in US hospitals as a result of preventable medical errors with recent updates on this analysis presenting even more worrisome results with estimations at least twice as large.[4,5]

Residents' duty restriction hours' policy was another reason for great public and scientific commotion and was a consequence of the Libby Zion case. In 1984, Libby Zion, an 18-year-old girl, was admitted in to the emergency room in Boston, USA, with fever and earache. She was pronounced dead after 6 hours. She had been examined and taken care of by two overworked young doctors. Further, a senior clinician was available only over the phone for supervision. Her father, a New York Times journalist, requested an investigation into her death and a grand jury investigation lead to no criminal charges, but unveiled the strenuous workload of residents in training. As a result, this investigation led to a series of recommendations on limiting residents' working hours, which were adopted by the regulating boards. Critiques to this

policy, however, argued that a relevant contributing problem to the case and to other potentially preventable adverse outcomes was lack of supervision.[6] Another downside argument to residents' duty restriction hours was the consequent diminished opportunity to practice, in particular for rare events.[7,8] Simulation training arose as the promising solution to all these problems: patient safety, practice restriction and a lack of supervision.

After the initial boom of this type of training format, a concern regarding its effectiveness began to emerge, particularly due to the evolving technological and budget demands.[9] Systematic reviews analysing both the impact of technology and instructional features on simulation trainings described large study inconsistencies and poor description of instructional features use. As a conclusion, the reviewers recommend adopting instructional design guidelines when devising simulation trainings.[2,10]

Instructional design (ID) guidelines were developed based on sound cognitive psychological theories on how people learn.[11] They have a unique role in helping learners reach complex learning. Complex learning is the integrated acquisition of knowledge, skills and attitudes along with the ability to properly coordinate the qualitatively different constituent skills.[12] Moreover, ID guidelines aim at optimizing long-term knowledge transferability by presenting authentic, relevant, every day real-world problems, while simultaneously emphasizing practice at different levels of complexity and providing feedback and diminished instructional support through training.[13] Two examples of models providing instructional design guidelines are Merrill's First Principles of Instruction[14] and the 4C/ID model.[15] According to Merrill, learning is better promoted when the following five principles are present: (1) learners are engaged in solving real life problems, (2) their previous knowledge is activated as a foundation to new knowledge, (3) the new knowledge is demonstrated to them, (4) they have the opportunity to apply the new knowledge, and (5) they have the opportunity to integrate it into their world. On its turn, the 4C/ID model claims that four interrelated components are essential for complex learning: (1) learning tasks, (2) supportive information, (3) procedural information, and (4) part-task practice.[12,16] Healthcare personnel are expected to achieve complex learning, particularly when managing high-

risk situations with their demanding simultaneous, multidisciplinary, and multitasking tasks.[16,17]

An example of a healthcare high-risk situation is postpartum hemorrhage (PPH). PPH is commonly defined as a blood loss of 500ml or more within 24 hours after birth. It is the leading cause of maternal mortality worldwide with most related deaths occurring within these 24 hours.[18-20] Concerns were raised due to a recent documented rise in its frequency in several high-income countries, along with an increase in US maternal mortality rates.[21] Furthermore, it is frequently occurring, unpredictable and can happen to either high-risk women or women with no prior disease.[22] Additionally, to reinforce the reason for such concern, PPH related deaths are described as preventable in some studies in up to 100% of cases, and attributable to management flaws.[22-26] Simulation training has, therefore, been advocated as the healthcare personnel training strategy to strike this scenery.[18,20,24,26]

The path in reaching optimal simulation training

Demonstrating simulation training effectiveness became of paramount relevance with such high stakes involved: improving patient safety, providing training opportunities for both novices and experienced personnel– either for daily recurrent tasks or rare high-risk events – and enabling for a supervised "error safe" environment. In spite of the expanding number of publications in the field, many of these concerned replication studies, the so-called "me too" studies, and comparison studies between simulation and no intervention.[27] Therefore, sound evidence on the effectiveness of this type of training format is still needed.[28]

When considering training effectiveness, particularly for a complex environment such as healthcare, different domains must be taken into account: the learners' context, work environment related elements and/or patient outcome. According to the Kirkpatrick training evaluation model, there are four different levels: learners' satisfaction, learning outcomes, behavior, and patient outcomes, which may be considered stepping-stones for training evaluation.[29] Critiques of this model underscore it as an oversimplified model, which does not acknowledge moderating variables, such as trainee's motivation and work environment and that failure to reach transfer would be solely attributable to training design.[30-32]

These shortcomings, however, may be compensated by adopting complementary models, such as the training transfer Baldwin and Ford model, when assessing training evaluation, particularly for the behavior/training transfer stage.[33] Moreover, additional studies regarding simulation training effectiveness should also aim to further explore related patient outcomes with detailed description. For instance, they should provide data beyond procedural outcomes, but also report on survival, duration of hospitalization, complications and preferably describe be designed to have patient outcomes as the study primary outcome. A systematic review on patient outcomes in simulation-based medical education, however, highlights these topics as poorly described, reporting large studies' inconsistencies, high prevalence of statistical errors, procedural-solely described and lack of prior definition of primary outcomes.[34] When addressing the need to further promote simulation training translational outcome, the literature again advises exploring the use of instructional design guidelines.[35]

The use of instructional design guidelines for simulation training may be explored from a multitude of perspectives, as exemplified in the following four: use of ID features per se, cognitive impact, influence on work environment and behavior, and the ultimate patient outcome impact.[2,34,36] First, on the use of instructional features per se, it may be worth exploring how they are currently used for specific contents either individually, on the amount of exposure, as well as its intensity. For instance, the debate on a proper definition of authenticity for the simulation training field includes a discussion about simulator fidelity and simulation training environments (simulation center or in situ).[37-39] Second, exploring the cognitive impact of the use of each of the instructional features or their combination in training complex tasks to promote complex learning seems as the long-demanded advance in the frontier of knowledge on simulation training educational research.[40] Third, preliminary data begins to emerge concerning training transfer for simulation training, but still mostly on short term transfer.[41,42] Finally, the complex field of simulation training patient outcome starts to present its first results but still with the methodological limitations previously cited.[43]

The recent epidemiological commotion about PPH alarming mortality rates and its specific clinical management characteristics sets it up as an ideal

content for researching simulation training from an educational perspective. Its optimal clinical management requires complex learning to be reassured by the execution of simultaneous tasks from a multitude of different domains such as: communication, teamwork, situational awareness, systematic approach to problem solving, while providing opportunity to supervised practice of either recurrent and non-recurrent skills.

Bridging the simulation training educational research beyond

In summary, improving patient safety by providing supervised practice opportunity in a safe environment is complex and concerns multiple variables. In addition, one of its basic premises is ensuring effective healthcare personnel training with long-term transferability. The use of instructional design guidelines in simulation training may contribute in reaching this goal. Postpartum hemorrhage due to its omnipresence, unpredictability, and the multidisciplinary care it requires allows multiple learning dimensions to be studied.[44]

We therefore aim to explore the use of instructional design guidelines for postpartum hemorrhage simulation training.

We intend to reach this aim by answering the following questions:

1) How are instructional design guidelines described and used in the current postpartum hemorrhage healthcare simulation literature?

2) What are the different learning outcomes when two instructionally different postpartum hemorrhage simulation training programmes are compared, one based on instructional design guidelines and the other on current best practices?

3) Is there long-term transfer after these two different training formats? Is there a difference in learning outcomes according to the attended training format? What instructional design features may have facilitated and/or hindered long-term transfer?

4) What is the impact on patient outcome at a teaching hospital after Obstetrics and Gynecology residents attending an instructional design based postpartum hemorrhage simulation training programme format?

Structure of the thesis

Our first study, presented in Chapter 2, provides an overview of the currently adopted Instructional Design Guidelines in published articles at which PPH simulation trainings were described. Invited raters (N=40) analyzed 32 articles with regards to: Were they applied to the trainings designs? If so, how? Were the used ID features described in details at the analyzed articles' methods section to allow for reproducibility? A rating scale was elaborated for the detailed analysis. It was based on Merrill's First Principles of Instructions and assessed training description elements such as: authenticity, activation of prior knowledge, demonstration, application and integration.

The study presented on Chapter 3 compared the learning outcomes of two instructionally different PPH simulation training: one based on instructional design guidelines and the other on a prior instructional "best practice". In order to select this to-be-compared "best PPH training" seven experts (five educationalists and two from a healthcare training background) rated previously identified articles from the literature with regards to their instructional perspective. For the quasi-randomized comparison, 20 teams were distributed accordingly: 13 teams attended the ID based training and seven, the BP based. Learning outcomes were compared with regards to the following expected-to-be-executed tasks subscales: communication, teamwork, vital signs, laboratory evaluation, drug management, mechanical management and surgical management.

On Chapter 4, we present the residents perception on the long-term transfer after attending either of the training formats. We analyzed semi-structured interviews, using thematic analyzed. We explored: (1) Whether the residents perceived training transfer on the long term, (2) if there was a difference in long-term training transfer perception according to the attended format and (3) whether they reported any influence of specific instructional design features on their long-term training transfer perception.

The PPH simulation training patient outcome study is described at chapter 5. Data on clinical outcome of women delivering at a high risk teaching maternity was collected at Recife, Brazil, for a six months period in total. To avoid potential seasonality bias, data was collected for the same

three months period one year before the PPH simulation training and for the same three months immediately after the training. During training, active management of the third stage of labor (PPH prophylaxis) was part of the content. Primary outcomes were therapeutic uterotonics use rates within 24h of birth (TUW24h) and blood transfusion rates (BTR). Secondary outcome measures included uterotonic use rates and dosages for each drug, postpartum hemoglobin <6g/dL, B-Lynch suture, uterine artery embolization, hysterectomy, renal insufficiency, obstetric intensive care unit (ICU) admission, mechanical ventilation, length of hospital stay, near-miss maternal mortality and maternal death.

Chapter 6 presents a general discussion on the findings of the previously described studies. The strengths and limitations are discussed along with the implications for practice and for research in simulation training with regards to the use of ID guidelines. The discussion chapter is followed by a summary in English and Dutch.

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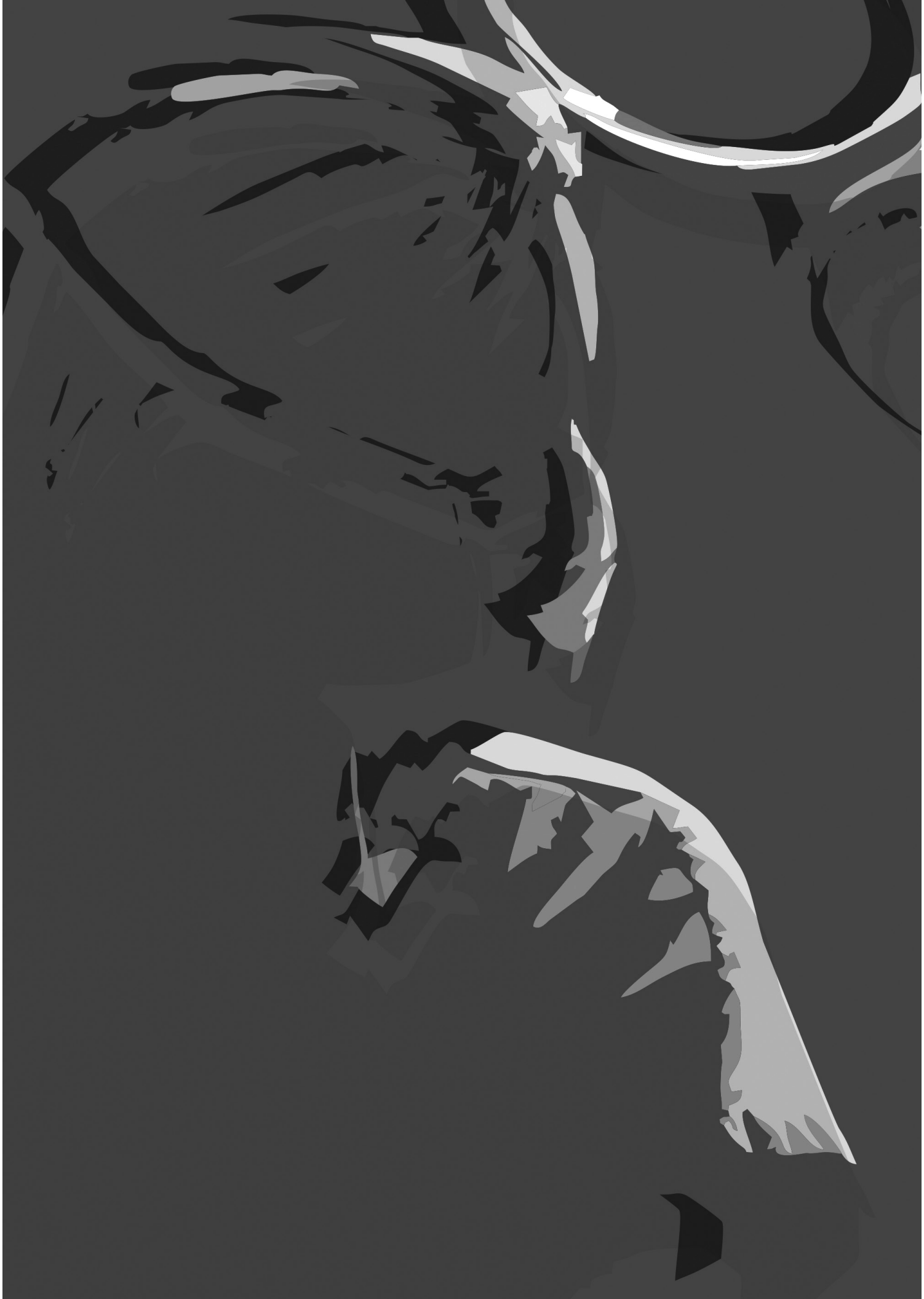

Chapter 2

The limited use of instructional design guidelines in healthcare simulation scenarios: an expert appraisal[1]

[1] This chapter is based on a manuscript submitted for publication: De Melo BCP, Falbo AR, Souza E, Muijtjens AMM, van Merriënboer JJG, & van der Vleuten CPM. (submitted). The limited use of instructional design guidelines in healthcare simulation scenarios: an expert appraisal.

Abstract

Introduction

Healthcare simulation is based on the premise of effective training. Systematic reviews have pointed to the need to adhere to evidence-based instructional design (ID) guidelines.

Objective

The purpose of this study was to explore such adherence in simulation training programs for dealing with high-risk situations. ID guidelines derive from sound cognitive theories and aim to optimize complex learning and learning transfer.

Methods

Raters (N = 40) analyzed simulation training programs as described in 32 articles and assessed adherence to ID guidelines. The 5-point Likert scoring rating scale was based on Merrill ´s First Principles of Instruction and contained items related to key ID features categorized into five subscales: authenticity, activation of prior knowledge, demonstration, application, and integration/ transfer. The authors searched for articles published in English between January 2007 and March 2017 on Pubmed, Eric, and Google Scholar and calculated the Likert-scale mean score, per subscale, and interrater reliability (IRR).

Results

The Likert scale mean scores per subscale were all < 3.00. Among the raters used to assess the papers included in the present study (varying between 7 and 10), the IRR was found to be excellent for the authenticity subscale, good-to-excellent for the integration/transfer subscale, fair-to-good for the activation of prior knowledge and application subscales, and poor for the demonstration subscale.

Conclusion

Our results show poor adherence to evidence-based ID-guidelines in current simulation training programs for high-risk situations.

Introduction

Healthcare simulation training has become a ubiquitously recommended training strategy driven by the goal of improving patient outcomes.[1,2] Achieving such improvement, however, is conditional on a multitude of inter-related elements, including ensuring simulation training is effective.[3,4] The current literature provides extensive evidence of healthcare simulation training leading to positive learning outcomes.[5,6] Uncertainty remains, however, with regard to transfer of learning – learners' ability to apply the acquired knowledge and skills in the workplace after training.[7,8] Systematic reviews exploring the effectiveness of simulation training point to one important condition for achieving transfer: adherence to evidence-based instructional design guidelines.[9,10]

Instructional design (ID) guidelines are derived from sound learning theories and models and are underpinned by a number of cognitive principles that aim to optimize complex learning and learning transfer.[11,12] Complex learning concerns the proper integration of knowledge, skills and attitudes which is essential for the management of high-risk situations.[13] Systematic reviews exploring the impact of simulation training on patient outcomes have already acknowledged the relevance of design features such as variability (clinical variation), repetitive practice of routine aspects, increasing complexity, mastery of learning (uniformly high achievement standards), and providing feedback.[4,10,14-16]

Merrill's First Principles of Instruction,[17] one of a number of sets of ID guidelines currently available, proposes five key instructional principles. These are based on careful analysis of a wide range of cognitive learning models: (1) identification of an *authentic problem* (since learning is promoted when learners are engaged with real-world problems); (2) a*ctivation of prior knowledge* as the foundation for new knowledge; (3) *demonstration* of the task to be learned; (4) *application* of newly acquired knowledge by learners, and (5) *integration or transfer* of new knowledge into the learner's world.

Applying evidence-based ID guidelines to healthcare simulation training formats should be a priority when aiming to transfer learning and improve patient outcomes.[7,9] This is of particular relevance for prevalent high-risk situations, in which achieving adequate complex learning may be essential for maximization of patient safety.[18,19] In this study we aimed to explore the extent to which current simulation training programs for dealing with high-risk situations adhere to evidence-based ID guidelines, as described in the literature.

Methods

In the present study, we invited a panel of healthcare experts to appraise the use of evidence-based ID guidelines in postpartum hemorrhage (PPH) simulation training programs described in the literature by scoring the use, or lack of use, of given guidelines. We chose a common high-risk situation, PPH, as the training content to be investigated owing to its epidemiological importance.[20] This high-risk situation is the main cause of maternal mortality worldwide[21] and most deaths related to it are attributable to management failures.[22] Such characteristics have led to widespread use of PPH simulation training programs in the past decade.

Participants

The participating raters were healthcare experts with a background in the education of health professionals. They were identified in two rounds and invited by email to collaborate. In the first round, from June 2015 to August 2015, we contacted authors and co-authors of previously published articles describing PPH simulation training programs. In the second round, from November 2016 to December 2016, we identified authors of abstracts listed in the Abstracts of the International Association for Medical Education (AMEE) Conference 2016, who covered topics related to either simulation and/or instructional design. Their corresponding contact information was located using Google Scholar profiles and similar webpages and undergraduate

students were excluded. The raters contacted were asked to recommend other healthcare experts with a similar background that could also be invited. After both rounds, 98 raters were invited by email, sixty of whom agreed to participate and 40 of whom eventually returned the completed rating scales.

Materials

The rating scale used for the analysis was based on Merrill's First Principles of Instruction.17 Table 2.1 presents the complete list of the 24 rating scale items which were divided into the following five subscales: (1) authenticity, (2) activation of prior knowledge, (3) demonstration, (4) application, and (5) integration/transfer. Each subscale contained items to be rated on a 5-point Likert scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree. If the corresponding item had not been described in the article reporting the PPH simulation training, raters were allowed to select an option of not described/not applicable

Table 2.1 List of rating scale items used for the analysis of each paper based on Merrill's First Principles of Instruction using 5-point-Likert scale

Subscales	Subitems
Authenticity	*Scenarios are based on real-life tasks*
	Trainees receive relevant theoretical information before they start to work on the scenario(s)
	Trainees receive guidance while they are working on the scenario(s)
	Scenarios differ from each other to the same extent as real-life tasks
	Scenarios are sequenced from simple to complex
	Trainees are encouraged to compare and contrast scenarios
Activation of Prior Knowledge	*Trainees are required to activate their relevant prior knowledge and experience*
	Trainees are encouraged to connect their past experience to new ideas, skills, and attitudes they are expected to learn
	Trainees receive a protocol that helps them to organize the new things they learn
	Trainees have the opportunity to demonstrate knowledge, skills, and attitudes they already mastered before the training
Demonstration	*Trainees are given demonstrations of the skills and/or models of the behaviors they are expected to learn*
	Trainees are given examples of errors, mistakes and things that can easily go wrong
	Trainees' attention is directed to skills, information, and attitudes that are most relevant and/or important
	Trainees receive multiple demonstrations that represent alternative ways of performing the skills that need to be learned
	Trainees receive demonstrations not as simple descriptions but in a lifelike fashion (e.g., real-life modelling, video, animation)
	Trainees learn the steps that contain non-observable decision making and reasoning processes
Application	*Trainees have opportunities to practice or try out what was learned*
	Trainees are tested on new scenarios to see if they can apply what has been learned
	Trainees´ errors when solving problems, doing learning tasks or completing assignments are detected and they receive feedback on this
	Trainees are required to predict challenges and/or explain causes of undesirable outcomes
	Trainees collaborate with peers to enhance their learning
Integration/ Transfer	*Trainees have the opportunity to reflect on, discuss with others, and defend what they learned*
	Trainees have the opportunity to explore how they can personally use what they learned
	Trainees are able to publicly demonstrate to others what they learned

The rating scale was previously tested in a pilot study by seven instruction experts who approved its clarity.

We analyzed PPH simulation training programs as described in articles identified through a search of Pubmed, Eric, and Google Scholar for studies published in English between January 2007 and March 2017 using the keywords: "post-partum hemorrhage, simulation, simulation training, medical simulation, and obstetric simulation". We included the studies retrieved by our keywords search and described PPH simulation training scenario(s). Our search yielded 33 articles and, after exclusion of one article containing a secondary analysis of a scenario already described in one of the other articles, we analyzed 32 articles describing PPH training in total. The articles identified were subdivided into the following five subsets to facilitate distribution for scoring by the raters: articles 1-7, 8-14, 15-21, 22-28 and 29-32. Further information on the selected articles is provided in Table 2.2.

Table 2.2 Information on the articles analyzed (author, year of publication, title and brief methodological description)

Article #	Author, Year	Title	Brief Methodological Description	
			Participants	Objective/Methods
1	*Andrighetti TP et al., 2012*	*Shoulder dystocia and postpartum hemorrhage simulations: student confidence in managing these complications*	*Registered nurses enrolled in a graduate midwifery education program*	*Quasiexperimental design evaluating student confidence*
2	*Birch L, et al.,*	*Obstetric skills drills: evaluation of teaching methods*	*Junior and senior medical and midwifery staff*	*Three teaching methods were employed. Each team of staff were randomly allocated to undertake a full day of training*
3	*Chichester et al., 2014*	*A cost-effective approach to simulation-based team training in obstetrics.*	*Obstetric providers*	*Multidisciplinary learning experience*
4	*Clark et al., 2010*	*Team Training/ Simulation*	*Obstetricians, anesthesiologists, midwives, nurses, pediatricians, and ancillary staff*	*An overview of team and simulation training*
5	*Cooper et al., 2012*	*Managing women with acute physiological deterioration: Student midwives performance in a simulated setting*	*Student midwives*	*An exploratory quantitative analysis of student performance based upon performance ratings*
6	*Scholes et al., 2012*	*Clinical decision-making: midwifery students' recognition of, and response to, postpartum haemorrhage in the simulation environment.*	*Student midwives*	*Students were exposed to instruction on managing maternal deterioration and response to obstetric emergency as part of their curriculum programme*
7	*Deering et al., 2009*	*Use of a postpartum hemorrhage simulator for instruction and evaluation of residents*	*Residents*	*Residents from 3 programs underwent training with a postpartum hemorrhage simulation*
8	*Egenberg et al., 2015*	*Can inter-professional simulation training influence the frequency of blood transfusions after birth?*	*All maternity staff*	*Two cohorts were compared retrospectively using a pre–post design*
9	*Fialkow et al., 2014*	*An in situ standardized patient-based simulation to train postpartum hemorrhage and team skills on a labor and delivery unit*	*Nurses, obstetrical residents, obstetrical attending physicians, anesthesiology residents, and anesthesiology attending physicians*	*Description of the development, content validation, and in situ implementation of a standardized patient-based, interdisciplinary PPH scenario*
10	*Magee et al., 2013*	*Low cost, high yield: Simulation of obstetric emergencies for family medicine training.*	*Family medicine residents*	*Residents were randomly assigned to intervention or control group*
11	*Markova et al., 2012*	*Evaluation of multiprofessional obstetric skills training for postpartum hemorrhage*	*Midwives, nurses, auxiliary nurses and doctors on call*	*A database audit*

Article #	Author, Year	Title	Brief Methodological Description	
			Participants	Objective/Methods
12	*Marshal et al., 2014*	*Impact of simulation and team training on postpartum hemorrhage management in non-academic centers*	*Experienced clinical teams in non-academic hospitals in urban and rural communities*	*Multi-center longitudinal study to evaluate in situ simulation and team training for PPH*
13	*Maslovitz et al., 2007*	*Recurrent obstetric management mistakes identified by simulation*	*Residents in obstetrics and gynecology and midwives*	*To develop a simulation-based curricular unit for labor and delivery teams involved in obstetric emergencies to detect and address common mistakes*
14	*Maslovitz et al., 2008*	*Improved accuracy of postpartum blood loss estimation as assessed by simulation*	*Obstetrical teams consisted of physicians and obstetrical nurses*	*Prospective study conducted as part of the simulation-based training course to assess the accuracy of estimated blood loss by obstetrical teams during a simulated postpartum hemorrhage (PPH) scenario*
15	*Nelissen et al., 2014*	*Helping mothers survive bleeding after birth: an evaluation of simulation-based training in a low-resource setting*	*Clinicians, nurse-midwives, medical attendants, and ambulance drivers involved in maternity care*	*Educational intervention study*
16	*Phillippi et al., 2015*	*Interprofessional simulation of a retained placenta and postpartum hemorrhage*	*Students (nurse-midwifery, nursing students, and nurse-anesthesia students)*	*Interdisciplinary simulation designed jointly by the nurse-anesthesia and nurse-midwifery faculty to provide students with a realistic, complex experience to resolve an ongoing patient crisis*
17	*Robertson et al., 2009*	*Simulation-based crisis team training for multidisciplinary obstetric providers*	*Perinatal health care professionals (attending physicians, nurses, resident, and nurse midwives)*	*Pretest-post-test study design*
18	*Crofts et al., 2007*	*Change in knowledge of midwives and obstetricians following obstetric emergency training: a randomised controlled trial of local hospital, simulation centre and teamwork training*	*Midwives (including those working in hospital or the community) and all doctors, working within the Obstetric Department (including general practice trainees, obstetric and gynecology trainees and consultants)*	*Prospective randomized controlled trial, as part of the wider Simulation and Fire-drill Evaluation (SaFE) study*

Article #	Author, Year	Title	Brief Methodological Description	
			Participants	Objective/Methods
19	*Siassakos et al., 2009*	*Content analysis of team communication in an obstetric emergency scenario*	*Doctors and midwives*	*To assess the utility, content validity and application of techniques used in aviation, for the qualitative analysis of team communication in a 'low fidelity' simulated obstetric emergency scenario before and after clinical training*
20	*Straub et al., 2013*	*Targeted obstetric haemorrhage programme improves incoming resident confidence and knowledge*	*Incoming obstetrics and gynecology (OB) and family medicine residents*	*An educational programme consisting of a lecture and high-fidelity simulation exercise*
21	*Vadnais et al., 2012*	*Assessment of long-term knowledge retention following single-day simulation training for uncommon but critical obstetrical events.*	*Resident and attending physicians*	*Pretest-post-test study design 4 and 12 months later*
22	*Kato et al., 2017*	*Simulation training program for midwives to manage postpartum hemorrhage: a randomized controlled trial*	*Midwives*	*RCT comparing simulation training group versus no training group using a pretest-intervention-post-test design*
23	*Melo et al., 2017*	*The use of instructional design guidelines to increase effectiveness of postpartum hemorrhage simulation training*	*Obstetrics and gynecology residents*	*Pretest–post-test non-equivalent groups study*
24	*Egenberg, et al., 2016*	*Changes in self-efficacy, collective efficacy, and patient outcome following interprofessional simulation training on postpartum haemorrhage*	*Midwives, obstetricians, and auxiliary nurses*	*The study had a multimethod, quasi-experimental pre-post design that combined patient outcome with survey measures.*
25	*Nathan et al., 2016*	*Retention of skills 2 years after completion of a postpartum hemorrhage simulation training program in rural Rwanda*	*Rural physicians*	*A quasi-experimental, pre–post intervention study*
26	*Higgins et al., 2015*	*Teaching an experienced multidisciplinary team about postpartum hemorrhage: comparison of two different methods*	*Experienced clinicians*	*This study compared the impressions of experienced clinicians regarding the effect of two methods of educational interventions in a More^{OB} training program designed to improve recognition and management of PPH*
27	*Hilton et al., 2015*	*Checklists and multidisciplinary team performance during simulated obstetric hemorrhage*	*Multidisciplinary teams*	*Prospective observational study*

Article #	Author, Year	Title	Brief Methodological Description	
			Participants	Objective/Methods
28	*Miller et al., 2015*	*Emergency birth hybrid simulation with standardized patients in midwifery education: implementation and evaluation*	*Graduate midwives*	*This article describes the development and initial evaluation of hybrid simulation used for labor and birth emergency situations.*
29	*Wong et al., 2015*	*The state of Illinois obstetric hemorrhage project: pre-project and post-training examination scores*	*Physicians, registered nurses, advanced practice nurses*	*To describe the implementation of the OBHEP project and to report on change and retention in knowledge among providers, as assessed pre- and post-test.*
30	*Evans et al., 2014*	*Competency-based training "Helping Mothers Survive: Bleeding after Birth" for providers from central and remote facilities in three countries*	*Skilled and semiskilled birth attendants*	*A pre- and post-assessment of participants in BAB (bleeding after birth) training*
31	*Monod et al., 2014*	*Optimization of competency in obstetrical emergencies: a role for simulation training*	*Midwives and obstetricians*	*Observational study*
32	*Highfield et al., 2016*	*Effect of nurse-Led simulation on OB/Perinatal nurses' knowledge & confidence in managing complications & emergencies*	*Registered nurses*	*Pre-/post-test study*

We prepared information tables with text extracts from each article to facilitate raters' analysis. These tables contained: article title, publication date, journal and publishing data, abstract, study design as described in the article, number of participants, and PPH scenario descriptions regarding the following training aspects: presentation, practice, feedback, and assessment.

Procedures

After agreeing to participate as a rater in the study, each rater received, by email, one of the subsets of articles for analysis along with the rating scale, distributed in a crossover fashion to avoid self-rating (among those who were both raters and authors of included articles). We also provided instructions on how to fill in the rating scale (each item to be rated for each paper) and the corresponding subset information tables for each article, which were sufficient for the analysis. The full texts of the articles were also made available for consultation.

We distributed the subsets of articles upon raters' agreement on participating in the study with the intention to reach an even number of final ratings. The raters were consulted regarding the feasibility of a six-weeks deadline for returning the filled-out scales and exceptions were made where necessary. Of the 60 raters who agreed to participate, five declined to participate after receiving the materials for analysis, and 15 did not reply following email contacts. The remaining 40 raters returned their completed rating scales - a response rate of 66.7%. The number of raters scoring the articles was as follows for each subset: subset 1-7 (eight raters), subset 8-14 (eight raters), subset 15-21 (seven raters), subset 22-28 (seven raters) and subset 29-32 (ten raters). Consequently, the data will consist of five blocks each composed of the ratings of Na articles by Nr raters, where Na, and Nr vary as outlined above.

Data Analysis

We used SPSS version 23 (IBM, Armonk, NY, USA) and Excel version 16.13.1 (Microsoft, Redmond, WA, USA) for data analysis. The level of coverage of the five subscales for the 32 articles in the sample was examined by commencing

the analysis by aggregating (per rating scale item) the original rater-within-article data per article by averaging the scores over raters. The resulting article-level item scores were used as indicators of the article's level of observed coverage of the items. In the aggregation, the not described/not applicable and missing answers were therefore recoded as "strongly disagree". A resulting score of < 3.00 thus indicated 'little or no coverage observed'. Subsequently, article-level subscale scores were obtained by calculating the average score of the corresponding items per subscale, thereby providing indicators of each article's level of coverage of Merrill's First Principles (authenticity, activation of prior knowledge, demonstration, application, integration/transfer). We explored the coverage of the subscales for the current sample of article using boxplots, M+-SD, and percentiles were calculated.

Generalizability theory23 was applied to the original rater-within-article data in order to estimate the interrater reliability (IRR) for each of the five subscales. In our study, different raters judged different papers, which implies that the absolute between-rater agreement determines the IRR. Therefore, we have calculated the Dependability Coefficient (Phi) to ascertain reliability. In terms of generalizability theory, each of the five blocks has a so-called a x r design (ratings of Na articles by Nr raters), and data variance components (V) for article, rater, and article-rater interaction (Va, Vr, and Var, respectively) were obtained for each block accordingly. The mean of each component over the five blocks was used to calculate Phi according to the equation: Phi=Va/(Va+(Vr+Var)/Nr), where Nr is the number of raters. Consequently, the IRR is higher for a block with more raters, and thus with these data (with unequal Nr over blocks) we will find a range for the IRR over the five blocks. The IRR was calculated as indicated above for each of the five subscales. The resulting IRR were qualified by applying the classifications proposed in Hallgren (2012) for intra class correlation coefficients (ICCs), measuring IRR (Phi being an example of this): values less than 0.40 (poor), 0.40 - 0.59 (fair), 0.60 - 0.74 (good), and 0.75 - 1.0 (excellent).

Results

Boxplots and descriptors for the subscale scores (5-point Likert) for the sample of articles (N=32) are shown in Figure 2.1 and Table 2.3, the latter also providing absolute IRR (Phi Dependability Coefficient) subscales. For all subscales the mean scores were found to be lower than 2.68, over 75% of the item scores were found to be below 3.04, and more than 50% below 2.71. These findings indicate that the raters noted non-adherence to evidence-based ID-guidelines in a large majority of the PPH simulation training programs covered. The IRR for the authenticity subscale was excellent (Phi = 0.79 – 0.88) but, for all other, subscales IRR varied from fair to good, except for the demonstration subscale (Phi = 0.37 – 0.45), which was considered poor.

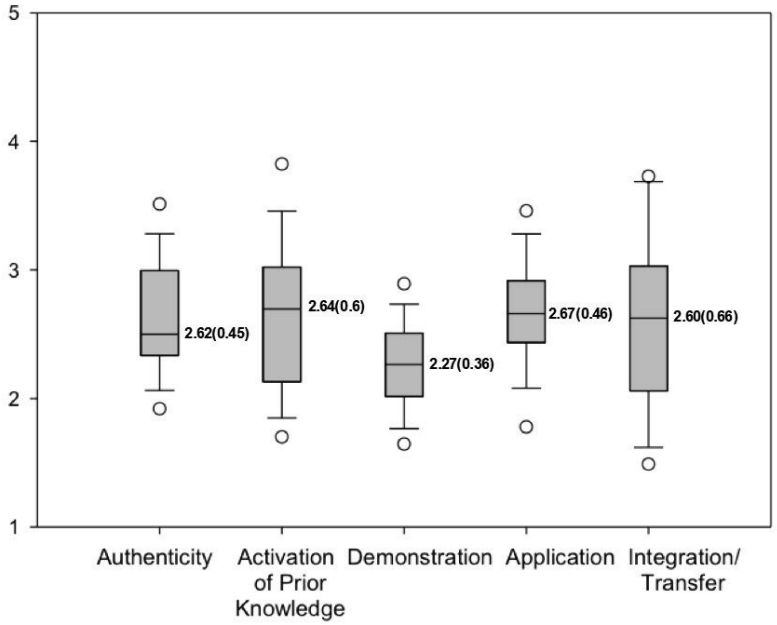

Figure 2.1 Boxplots of mean scores (SD) (5-point Likert scale) of the five subscales for the data at article level (N=32).

Table 2.3 Descriptive statistics of the subscale scores (5-point Likert) of the sample of articles (N=32) and absolute interrater reliability (IRR) for subscales (Dependability Coefficient Phi)

			Percentiles			Absolute IRR	
						Phi Dependability	
Subscale	Mean	Standard deviation	25-th	50-th (Median)	75-th	Coefficient	Classification*
Authenticity	*2.62*	*.45*	*2.34*	*2.50*	*2.99*	*0.79 – 0.88*	*Excellent*
Activation of Prior Knowledge	*2.64*	*.60*	*2.13*	*2.70*	*3.02*	*0.54 – 0.62*	*Fair-to-good*
Demonstration	*2.27*	*.36*	*2.02*	*2.26*	*2.51*	*0.37 – 0.45*	*Poor*
Application	*2.67*	*.46*	*2.43*	*2.66*	*2.91*	*0.59 – 0.68*	*Fair-to-good*
Integration/Transfer	*2.60*	*.66*	*2.06*	*2.63*	*3.03*	*0.71 – 0.78*	*Excellent-to-good*

** IRR Classification according to Hallgren, 2012*

Discussion

Our Likert-scale mean scores were below the neutral score of 3 for all subscales, indicating a pervasive lack of coverage of evidence-based ID-guidelines in simulation training for high-risk situations such as PPH. Our findings are especially striking for four of the subscales – authenticity, integration/transfer, activation of prior knowledge, and application – which had IRR values between fair-to-good and excellent. For the demonstration subscale, the poor IRR level may be the result of incomplete or missing descriptions of the ID features relating to this subscale.

The raters' overall agreement regarding the lack of coverage of evidence-based ID-guidelines for almost all subscales reveals that relevant ID features are significantly underused in simulation training for high-risk situations. This apparent underuse of ID guidelines may jeopardize transfer of learning and probably reflects lack of awareness on the part of the faculty in charge of designing simulation training regarding the importance of adopting evidence-based ID-guidelines.[24] The need to further promote faculty awareness with regard to adoption of evidence-based instructional features has been noted in the case of various methods of instruction, including simulation training.[25,26]

We can do no more than speculate as to the reasons underlying this lack of awareness of the importance of adhering to evidence-based ID-guidelines by faculties that promote simulation training. Absence of available evidence should be ruled out, since, for over a decade, systematic reviews have addressed the potentially deleterious effects on learning and transfer of learning when ID-guidelines are not properly followed.[14,16] Moreover, cumulative evidence has tended to show that positive learning and transfer outcomes are achieved when instructional approaches adhere to evidence-based ID-guidelines, both in simulations of high-risk situations and broader contexts, such as evidence-based medicine and decision making.[6,8,9,19,27] Furthermore, implementation of strategies to enhance faculty awareness with regard to incorporating innovative designs has been acknowledged to contribute to better simulation outcomes and should be further pursued.[24]

We highlight our concern regarding the finding of the overall low adherence to evidence-based ID-guidelines by underlining the relevance of specific items of the rating scale. For instance, we underscore items from the authenticity subscale that make reference to exposure to variability, such as "scenarios differ from each other to the same extent as real-life tasks" and "scenarios are sequenced from simple to complex". A lack of exposure to multiple scenarios may seriously undermine simulation training for high-risk situations, since this compromises a core complex learning principle required for achieving transfer – exposure to wide clinical variation.[12,28] When managing a complex high-risk situation, such as PPH, healthcare professionals should be able to make use of a systematic approach to problem solving and to properly manage the clinical conditions presented. Such an ability depends heavily on exposure to clinical variation.[13,29,30]

The influence of the various ID elements covered by the rating scale items from each of the subscales (authenticity, activation of prior knowledge, demonstration, application and integration/transfer) on learning and transfer of learning has long been demonstrated.[11,12,17,29,31] Thus, even for the subscale with a poor IRR--demonstration-- possible neglect for these instructional features may compromise simulation training effectiveness. For instance, failing to demonstrate the skills to be learned, as stressed by the items "trainees are given demonstrations of the skills and/or models of the behaviors they are expected to learn" or even "trainees receive multiple demonstrations that represent alternative ways of performing the skills that need to be learned" may also significantly impede the complex learning and transfer of learning essential for proper management of high-risk situations, such as postpartum hemorrhage.[12,17,31]

Our overall findings provide further confirmation of the concerns previously raised by systematic reviews on simulation training effectiveness and the lack of use of evidence-based ID-guidelines.[14,16] Moreover, we consider the large number of articles identified and included in the analysis an important strength of our study. We also call attention to the greater number of more recently published studies included in this analysis, demonstrating increasing concern regarding training healthcare providers for high risk situations such

as PPH.[32] Our findings, however, show that, even in recent simulation studies, evidence-based ID-guidelines are neglected in a way that may significantly compromise learning and transfer of learning. They also point to a worrying lack of awareness of these ID guidelines by those who design such simulation training programs.[1,33]

It should be acknowledged that some of the simulation training programs described in the articles analyzed did adhere to evidence-based ID guidelines. However, the strategy adopted in the present study of using mean score per subscale may have contributed to overlooking the instructional power of these specific simulation training programs and this should be considered a limitation of the study. The analysis of only a single simulation training content (PPH) may also be seen as a study limitation, notwithstanding the high degree of similarity between PPH and other high-risk situations. Future studies should, therefore, include a greater range of content for analysis and aim to identify instructional strengths for specific types of simulation training described in the literature. The use of alternative rating strategies may also contribute to greater interrater reliability scores.

In conclusion, our study found a generally low level of adherence to evidence-based ID-guidelines in simulation training programs for high risk situations, such as PPH. Further promoting the awareness of faculties regarding the need to adopt such guidelines when designing simulation training programs for high risk situations may help to improve the effectiveness of simulation training, especially, transfer of learning.

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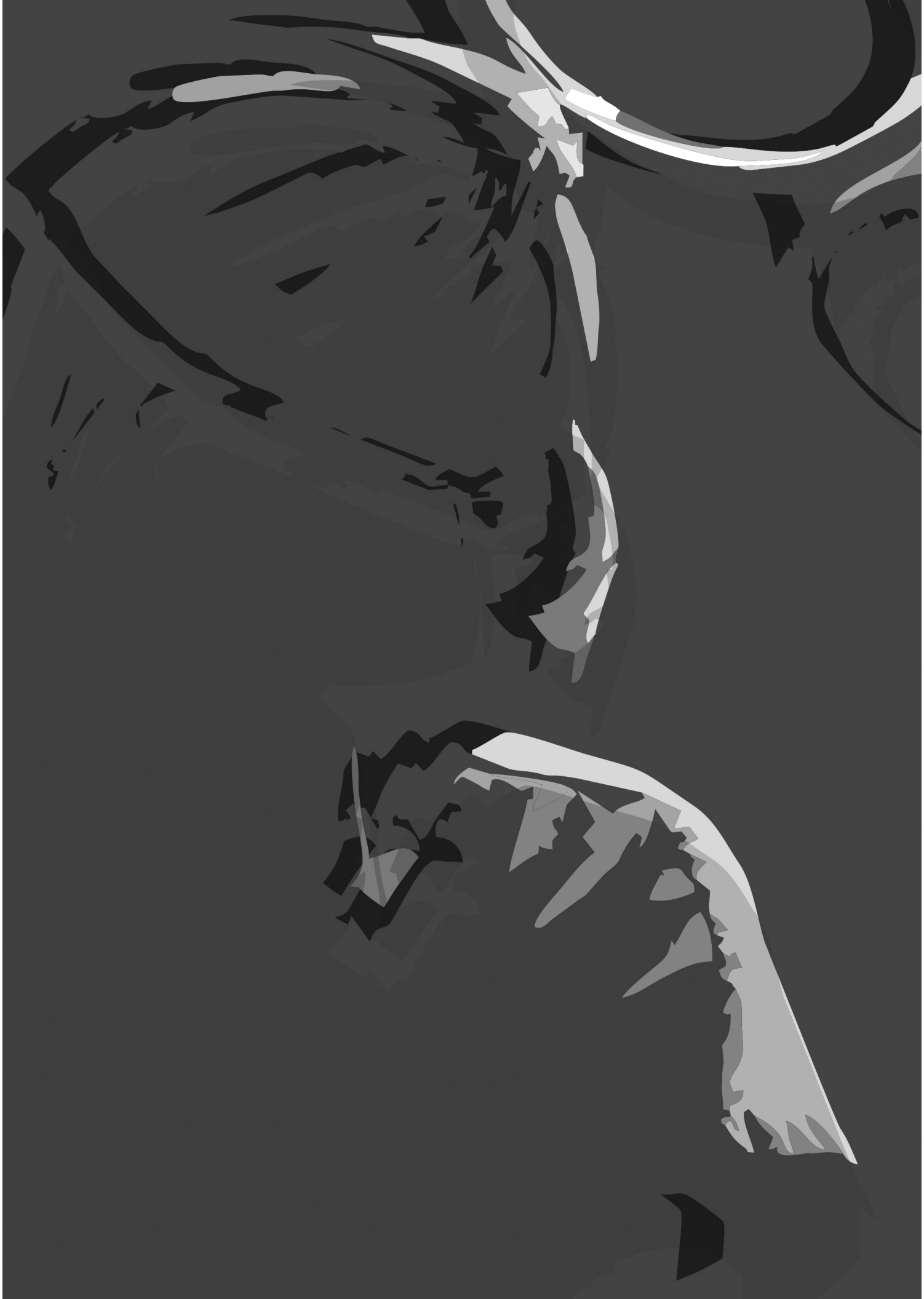

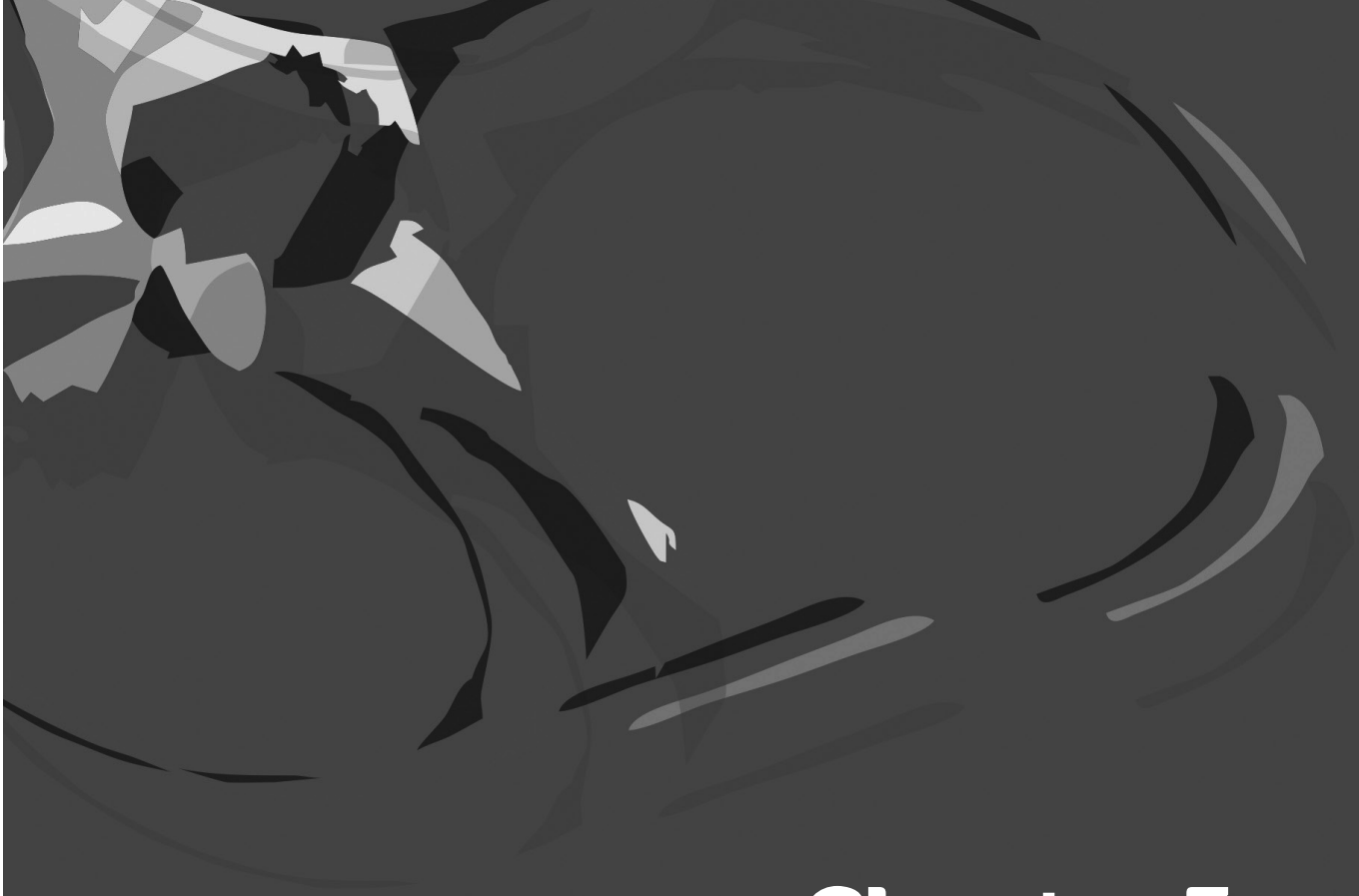

Chapter 3

The use of instructional design guidelines to increase effectiveness of postpartum hemorrhage simulation training[2]

[2] This chapter is based on the published article: De Melo BCP, Falbo AR, Muijtjens AMM, van der Vleuten CPM, & van Merriënboer, JJG. (2017). The use of instructional design guidelines to increase effectiveness of postpartum hemorrhage simulation training. International Journal of Gynaecology and Obstetrics: The Official Organ of the International Federation of Gynaecology and Obstetrics, 137(1), 99-105. DOI: 10.1002/ijgo.12084

Abstract

Introduction

Simulation training has become widespread for the past decade. The search for optimal training effectiveness has raised awareness with regards to simulation design. The use of instructional design guidelines has been recommended.

Objective

To compare learning outcomes of postpartum hemorrhage simulation training based on either instructional design guidelines or best practice.

Methods

A pretest–post-test non-equivalent groups study was conducted among obstetrics and gynecology residents in Recife, Brazil, from June 8 to August 30, 2013. The instructional design group included 13 teams, whereas the best practice group included seven teams. A standardized task checklist was used for scenario analysis and the proportion of correctly executed tasks compared (post-test minus pretest).

Results

The instructional design group scored higher than the best practice group for total number of tasks completed (median difference 0.46 vs 0.17; $P<0.001$; effect size [r]=0.72). Similar results were observed for communication (median difference 0.56 vs 0.22; P=0.004; r=0.58), laboratory evaluation (median difference 0.83 vs 0.00; $P<0.001$; r=0.76), and mechanical management (median difference 0.25 vs –0.15; P=0.048; r=0.39). Speed of learning was also increased. The median differences were 0.20 for the instructional design group compared with 0.05 for the best practice group at 60 seconds (P=0.015; r=0.49), and 0.49 versus 0.26 (P=0.001; r=0.65) at 360 seconds.

Conclusion

The use of simulation training for postpartum hemorrhage that was based on instructional design guidelines yielded better learning outcomes than did training based on best practice.

Introduction

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality worldwide, particularly among deaths that are considered avoidable.[1] Frequently reported assistance failures associated with preventable PPH include delay in diagnosis, poor communication, insufficient teamwork, and lack of adequate education and training.[2,3] Simulation training has emerged as a widespread strategy to overcome such failures. Systematic reviews of simulation-based healthcare education debate the best way to deliver instructional features to ensure optimal effectiveness of training.[4,5] Nonetheless, a growing body of evidence recommends that training formats should be based on reliable educational principles, particularly instructional design guidelines.[6]

The Four-Component Instructional Design model[7] and Merrill's First Principles of Instruction[8] summarize the main guidelines. According to the guidelines, effective instruction should contain authentic, relevant, and daily real-world problems, emphasize practice at different levels of complexity, and provide feedback and diminishing instructional support through training.[7]

When devising a PPH simulation training format based on instructional design guidelines, the learning objectives should be clearly identified and summarized in strategies that aim to overcome recurrent assistance failures. Such learning objectives include situational awareness enhancement,[9] improvement of both communication and team- work skills and attitudes,10 and reinforcement of specific knowledge and skills regarding the correct management of patients with PPH.[1-3]

The aim of the present study was to test the hypothesis that a PPH simulation training program based on instructional design guidelines would lead to better learning outcomes than the use of a simulation training program based on best practice.

Methods

A pretest–post-test non-equivalent groups study was conducted at two of the local teaching hospitals in Recife, Brazil—Instituto de Medicina Integral Prof. Fernando Figueira and Hospital das Clínicas, Universidade Federal de Pernambuco—from June 8 to August 30, 2013. Obstetrics and gynecology residents working at any of the five local teaching hospitals in Recife were considered eligible and invited to participate. These hospitals provide high-risk maternity services and report an equivalent number of deliveries per resident. The present study was approved by the Ethics Committee of the Instituto de Medicina Integral Prof. Fernando Figueira. All participants provided signed informed consent at the training session.

Of all eligible residents, half worked at the Instituto de Medicina Integral Prof. Fernando Figueira. Therefore, residents from this center formed the entire instructional design group (n=36). They were divided into 13 teams: four teams of two individuals and nine teams of three individuals. One participant had to leave the instructional design group for personal reasons before undergoing the post-test. Participants assigned to the best practice group (n=18) came from the other four maternity hospitals and underwent training at Hospital das Clínicas, Universidade Federal de Pernambuco. These participants were divided into seven teams: three teams of two individuals and four teams of three individuals. A similar distribution among teams by age, sex, and year of residency was noted for both training formats. Training occurred in half-day sessions, with one or two teams at each.

According to Merrill,[8] efficient instruction should engage learners in solving real-world problems, activate existing knowledge as a foundation for new knowledge, demonstrate the new knowledge to the learner, provide opportunities for applying the new knowledge, and integrate the new knowledge into the trainee's world. Additionally, the Four-Component Instructional Design model[7] claims that four interrelated components are essential for a training program: learning tasks, supportive information, just-in-time information (i.e. information provided to the learner at the moment that it is needed), and part-task practice. To clearly establish the learning objectives

of the present study, a PPH guideline was created through discussion with a focus group (formed of invited obstetricians and anesthesiologists who were supervisors of residents) and was based on the most up-to-date clinical evidence.[1-3]

Table 3.1 List of examples of expected tasks.

Subscales	Examples of tasks
Communication	The participant introduced himself or herself to the patient, explained the actions to the patient, and asked the patient about comorbidities, medications, and allergies
Teamwork	Team-support behavior and adequate sharing of information
Vital Signs	Checked heart rate, blood pressure, rechecked vital signs
Venous Access	Large caliber intravenous line, order blood samples
Exams	Complete blood count, renal and liver function tests, blood type and cross-match
Drug Management	Loading and maintenance doses of oxytocin
Mechanical Management	Massaged uterus, emptied bladder, and checked for lacerations
Surgical Management	Suture or placental tissue removal if the scenario required action

Figure 3.1 outlines the two training formats and the clinical case scenarios. The instructional design group format comprised eight steps, including three training scenarios with increasing levels of complexity. An obstetrician was present in the delivery room to provide "over the shoulder" just-in-time guidance and corrective feedback to participants, whenever necessary. The best practice group received the PPH guideline before undergoing a three-step training format, one of which was a training scenario. This format replicated the best PPH simulation training[11] and was creating using articles identified in the literature. Seven experts (five from an educational background and two who had healthcare training) used a rating scale based on Merrill's First Principles of Instruction[8] to analyze the articles from an instructional design perspective.

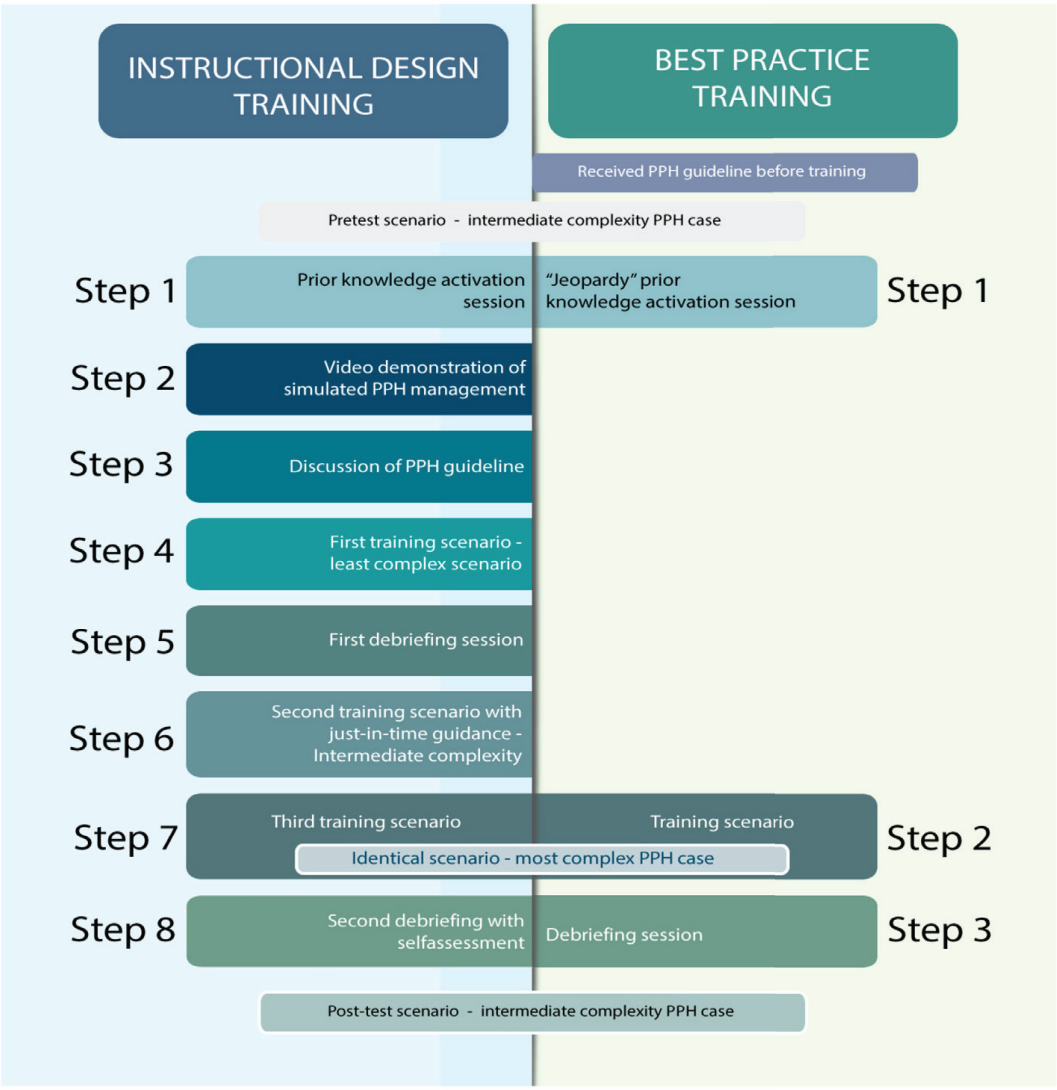

Figure 3.1 Description of the steps for the instructional design group and the best practices group training formats. The pretest and post-test scenarios were identical for both training formats.

The pretest and post-test scenarios were the same for both groups. They were offered immediately before and after the training scenarios and presented an intermediate level of complexity. The third instructional design format training scenario (most complex scenario) was identical to the sole training scenario used in the best practice format and corresponded with a previous description.[11]

All scenarios were scripted as PPH after vaginal delivery and included a standardized patient, a standardized nurse, and a part-task pelvis simulator (EVA Simulador Pós-Parto; ProDelphus, Olinda, Brazil). Consequently, the nature of potentially expected tasks comprised communication, teamwork, and clinical management. The low-cost part-task simulator allowed variation in the site (vaginal laceration, uterus, or both) and intensity of the bleed, and was managed by the standardized patient. The standardized nurses provided the participants with clinical data (vital signs, results of laboratory evaluation, and uterine responses). Both the standardized patients and nurses (who were all volunteer healthcare personnel) received the script for each scenario in advance of training to allow for rehearsal.

At each training session, participants were welcomed, introduced to the training equipment, and asked to suspend their disbelief (i.e. act as though the simulation was a real-life clinical case) and not to share any information about the program until the end of all training sessions. Participants were then asked to form the teams outlined above and provided with the pretest scenario. All scenarios were either run for a maximum of 900 seconds or else interrupted at the point that the team diagnosed and corrected the main cause of the bleeding.

All scenarios were video recorded for either debriefing purposes (the training scenarios) or to enable future analysis for scoring and comparisons (the pretest and post-test scenarios). Two obstetricians were present at each session: BdM attended all the training sessions and 10 additional obstetricians alternated as the second content expert. Each pair of obstetricians was responsible for rating the pretest and post-test scenarios video recordings for each of the teams that they supervised. The experts received the checklists of expected tasks at the beginning of each scenario, whereas the participants received them immediately after attending the first and third training scenario for debriefing purposes.

A standardized checklist of expected tasks (derived from the PPH guideline outlined previously) for each scripted scenario was used in the analysis. A task was considered to be executed if it had been performed by at least one participant (e.g. ordering laboratory evaluation) or, depending on the nature of the task, by all members of the team (i.e. teamwork tasks). Consequently, the unit of analysis was the team rather than individual participants.

At pretest, 38 tasks were expected to be executed; at post-test, 39 were expected. These tasks were distributed among eight learning subscales: communication (9 pretest/9 post-test), teamwork (6/6), vital signs (3/3), venous access (3/3), laboratory evaluation (6/6), mechanical management (4/5), drug management (6/6), and surgical management (1/1). Most pretest and post-test tasks were coincident, particularly for the first five subscales. The expected tasks varied according to the scripted case for the remaining three subscales. The number of tasks correctly executed by each team was registered in total, per subscale, and per time elapsed (in seconds). The entrance of the first team member into the delivery room defined the start of the process (0 seconds). The proportion of correct tasks was calculated for each of these landmarks. The medians of these proportions were used for comparison (instructional design group vs best practice group).

A generalizability analysis was used to estimate inter-rater reliability; a value of 0.93 for one rater (BdM) was considered to represent sufficiently high reliability.[12]

The timepoints used to compare groups of teams were 60, 360, and 900 seconds. The 60-second checkpoint reflected the "golden minute" concept in neonatal resuscitation guidelines; early initiation of basic resuscitation interventions are thought to be essential to prevent progression to circulatory collapse.[13] The 360-second landmark corresponded to an additional 300 seconds, during which correct identification of the cause of bleeding and corresponding preliminary actions were expected.[14,15] The 900-second checkpoint was the cut-off for the amount of time required to assess how the team managed the PPH case.

The data were analyzed using SPSS version 22 (IBM, Armonk, NY, USA). The post-test minus pretest difference in the median of the proportions of executed tasks was compared between the two groups for the various landmarks. The Mann–Whitney U test was used for comparison, with a P value

of less than 0.05 considered statistically significant. The effect size (r) was also calculated,[16] and its magnitude was classified as small (0.10), medium (0.30), and large (≥0.50).[17]

Results

Overall, 54 (55.1%) of the 98 eligible residents attended training during their off-duty hours. Data regarding the proportion of all tasks correctly executed by the two groups is presented in Table 3.2. Both groups presented similar median proportions at pretest. However, when comparing the proportion of all tasks executed from pretest to post-test, a greater increase was found for the instructional design group (median difference 0.46, interquartile range [IQR] 0.147) than for the best practice group (median difference 0.17, IQR 0.262). The U value for the comparison was 5.0 (P<0.001) and the effect size was 0.72.

Table 3.2 Proportion of tasks completed per team for Instructional Design and Best Practice and statistical comparisons

Type of Task	N tasks pre/post	Best Practices based (n = 7 teams)						Instructional Design based (n = 13 teams)						Statistical comparisons between training formats' groups			
		Pre-test		Post-test		Difference		Pre-test		Post-test		Difference					
		Md	IQR	Md	IQR	Md	IQR	Md	IQR	Md	IQR	Md	IQR	Difference of the medians Post-Pre scores	U[c]	p[d]	Effect size r[e]
Communication	9/9	0.33		0.44		0.22		0.22		0.78		0.56		0.33	13.0	0.004	0.58
Teamwork	6/6	0.67		0.83		0.17		0.67		0.83		0.17		0.00	38.0	0.294	0.15
Vital Signs	3/3	0.67		1.00		0.33		0.67		1.00		0.33		0.00	44.0	0.469	0.03
Venous access	3/3	0.67		0.67		0.00		0.67		1.00		0.33		0.33	25.5	0.057	0.38
Exams	6/6	0.00		0.33		0.00		0.00		0.83		0.83		0.83	3.0	0.000	0.76
Mechanical M	4/5[a]	0.75		0.60		-0.15		0.75		0.80		0.25		0.40	24.0	0.048	0.39
Drug Management	6/6[a]	0.33		0.67		0.33		0.17		0.83		0.50		0.17	25.5	0.057	0.36
All total time	37/38[a]	0.41	0.162	0.58	0.237	0.17	0.262	0.35	0.122	0.79	0.105	0.46	0.147	0.30	5.0	0.000	0.72
All within 60 seconds	33/34[b]	0.15	0.061	0.21	0.029	0.05	0.092	0.18	0.076	0.35	0.176	0.20	0.131	0.15	18.0	0.015	0.49
All within 360 seconds	33/34[b]	0.30	0.061	0.53	0.235	0.26	0.237	0.30	0.076	0.76	0.059	0.49	0.135	0.23	9.0	0.001	0.65

Note. Md= Median; IQR = Interquartile range M= management

This table provides an overview of proportions of tasks correctly completed – Medians [13] and Interquartile ranges (IQRs) – in the ID group and BP group, and statistical comparisons for both pretest and posttest on the seven different subscales as well as on all subscales, all subscales in the first minute, and all subscales in the first six minutes.

[a] Tasks for pre-and post-test were not all the same.

[b] Four Tasks had no time indication and therefore were not included in the time related analyses

[c] Mann-Whitney U-statistic

[d] p-value of between-group difference for the Mann-Whitney test (one-sided)

[e] effect size r=z/√N; z is the z-score corresponding to the Mann-Whitney U-statistic; N is the total number of units in the two groups

The instructional design group exhibited a statistically significant greater increase from pretest to post-test than did the best practice group for three of the eight subscales: communication, laboratory evaluation, and mechanical management (Table 3.2). No comparison was made for the surgical management subscale because it comprised only one task, both at pretest and post-test. Additionally, at post-test, the expected task involved manual removal of the retained placental tissue from the part-task simulator. Some of the teams—five from the instructional design group and three from the best practice group—did not complete this task because they did not want to damage the simulated pelvis. Owing to the heterogeneity of the supervisors' approach to overcoming this problem during training, it was decided to exclude the surgical management subscale from the analysis.

Figure 3.2 presents the post-test minus pretest difference in the proportion of tasks completed by both the instructional design and best practice groups of teams after 60 and 360 seconds. A greater increase from pretest to post-test was observed for the instructional design group versus the best practice group at both time points. As shown in Table 3.2, the instructional design group showed a greater increase of correctly performed tasks after 60 seconds (median difference 0.20, IQR 0.131) than did the best practice group (median difference 0.05, IQR 0.092). The U value for the comparison was 18.0 (P=0.015) and the effect size was 0.49, indicating that the instructional design group was not only performing more tasks correctly but also earlier in the process than the best practice group. A similar result was observed after 360 seconds. The median differences for the instructional design and best practice groups were 0.49 (IQR 0.135) and 0.26 (IQR 0.237). The U value for the comparison was 9.0 (P=0.001) and the effect size was 0.65.

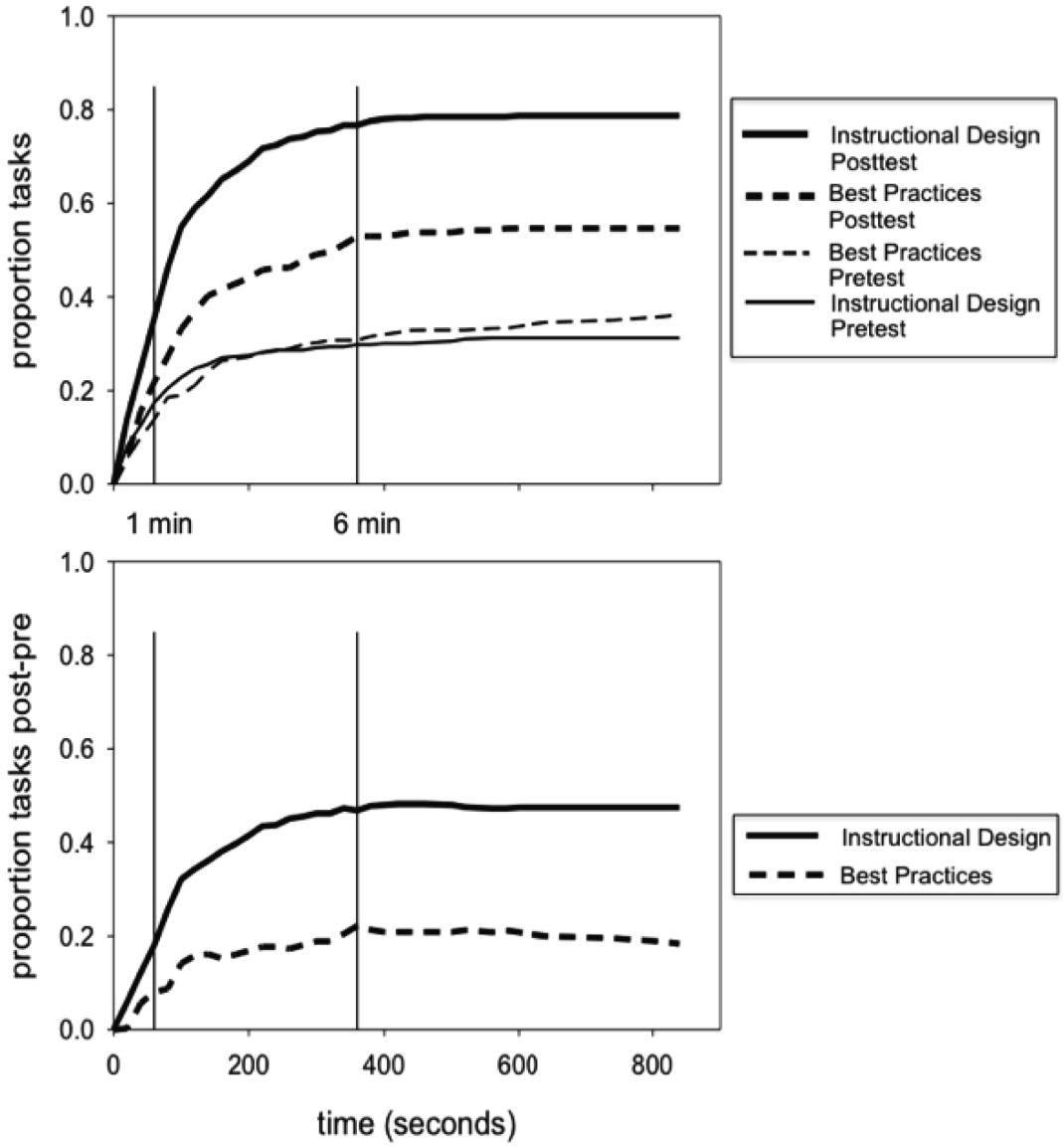

Figure 3.2 Proportion of tasks completed by the teams in the best practices group (dashed line, N=7 teams) and the instructional design group (solid line, N= 13 teams). The upper panel shows pretest (thin lines) and post-test (bold) proportions, and the lower panel presents the post-pre difference for the two groups.

Discussion

The present study demonstrated the effectiveness of the instructional design format for PPH simulation training. Participants who received such training exhibited a substantially greater increase in the number of executed tasks, and within a shorter time frame, than did participants assigned to the best practice training format. Thus, the findings of the present study confirmed the stated hypothesis.

The instructional design format offered several features not included in the best practice format. These features included broad content discussion at the prior knowledge step, multiple learning strategies, video demonstration of the expected tasks; clinical variation, increasing level of complexity, just-in-time information, corrective feedback, decreasing support, and two debriefings, with self-assessment in the second debriefing session. All these aspects are regarded to be effective for learning through simulation[7,18,19] with particular recommendation by the Four-Component Instructional Design model.[20] Furthermore, potential confounding variables were controlled by delivering both training formats in an equivalent hospital environment.[21]

Although the ideal design for the present study would have been to randomly allocate participants to the two training formats, the locally elevated rates of PPH-related maternal morbidity and mortality required prioritization of a large number of participants through flexibility of the training schedule. Of note, however, both groups displayed similar median proportions at pretest.

The present findings could contribute to minimizing the recognized gap in comparative effectiveness research on simulation training formats. As previously noted,[22,23] an extensive body of evidence provides plain description of training outcomes,[24] or comparison of different instructional sequences,[25] but not of different instructional design features.

The level of detail in the present findings allowed some interpretation. For example, the marked increase for the laboratory evaluation subscale could be extrapolated as ability acquired by the trainees to anticipate, recognize, and intercept ongoing management flaws and potential patient compromise.

This acquired ability might lead to increased situational awareness,[9] a factor that is frequently jeopardized in the substandard care of patients with PPH.[2,3]

The use of a portable part-task simulator, ordinary labor assistance material, portable filming, and a video exhibition device (electronic notebook) are all elements that favor future training replication and portability. With regard to PPH, these things could be of particular relevance, given that the most challenging aspects of this condition are its unpredictability and omnipresence.1 Therefore, an effective portable PPH training package might increase the proportion of trained personnel in an undemanding manner. Moreover, the essential structure to the instructional design training format could be easily adapted to other obstetric emergencies, clinical content, and types of trainees.

Despite the nonsignificant differences observed for some of the subscales assessed in the present study, there was an increase in the overall proportion of tasks executed from pretest to post-test. For the teamwork subscale, measurement difficulty is a well-recognized issue owing to its multiple dimensions.[5,26] The low number of expected tasks for the both the vital signs and venous access subscales could have limited the comparison; however, all the expected tasks were correctly executed in the instructional design group. The unanticipated finding of a negative value for the mechanical management subscale among the best practice group might be attributed to the unfamiliarity of these trainees with the simulator, given that they had attended fewer scenarios then the instructional design group. The time-on-task difference between training formats could be highlighted as a potential limitation because it reflects a core difference between current best practice and instructional design training formats.

In conclusion, the findings of the present study indicated the importance of applying established learning principles, such as instructional design guidelines, when designing simulation training formats. Optimum training time and the impact of particular features on knowledge transfer and clinical outcomes remain to be explored.

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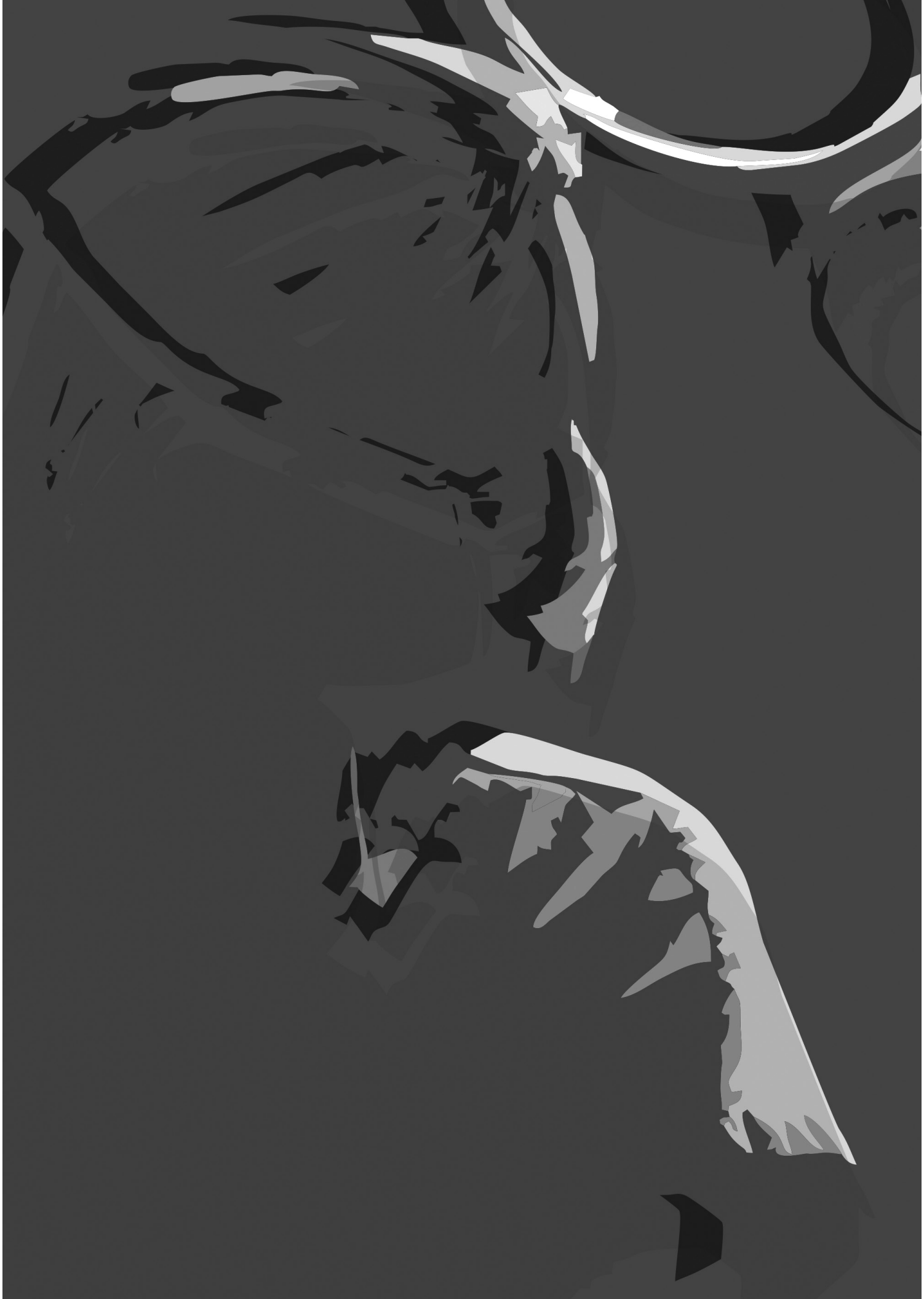

Chapter 4

Self-perceived long-term transfer of learning after postpartum hemorrhage simulation training[3]

[3] This chapter is based on the published article: De Melo BCP, Falbo AR, Sorensen JL, van Merriënboer JJG, & van der Vleuten CPM. (2018). Self-perceived long-term transfer of learning after postpartum hemorrhage simulation training. International Journal of Gynaecology and Obstetrics: The Official Organ of the International Federation of Gynaecology and Obstetrics, 141, 261-267. DOI: 10.1002/ijgo.12442

Abstract

Introduction

Effective simulation training should promote long-term transfer (application of acquired knowledge and skills on the job).

Objective

To explore long-term transfer after postpartum hemorrhage simulation training based on either instructional design principles or conventional best practice.

Methods

In this qualitative study, semi-structured interviews with obstetrics and gynecology healthcare practitioners were conducted between August 7 and September 26, 2015, in Recife, Brazil. The participants were randomly selected from each of two postpartum hemorrhage simulations attended two years earlier (one ID and one conventional best practice). Thematic analysis was used to explore (1) residents' perceptions of long-term transfer of learning, (2) ID elements influencing the perceived long-term transfer, and (3) differences in the participants' perceptions according to the type of simulation attended.

Results

There were 12 interview participants. After either simulation format, residents perceived long-term transfer effects. Training design factors influencing transfer were, in their opinion, related to trainees' characteristics, simulation design, and workplace environment. Trainees who participated in the ID-based simulation perceived better communication skills and better overall situational awareness: "I didn't do that before."

Conclusion

All residents perceived long-term transfer after simulation training for postpartum hemorrhage. Those who attended the ID format additionally perceived improvements in communication skills and situational awareness, which are fundamental factors in the management of postpartum hemorrhage.

Introduction

Postpartum hemorrhage (PPH) is the leading cause of maternal mortality worldwide, with most deaths considered preventable and attributable to human factors such as poor communication and lack of situational awareness. To improve the management of PPH, simulation training is strongly recommended.[1-3] Effective training, however, relies on workplace application of the knowledge and skills acquired during training—in other words, on transfer of learning.[4]

Systematic reviews on the effectiveness of healthcare simulation training have recommend the implementation of instructional design principles, particularly when aiming to achieve transfer;[5,6] yet, these principles are sparsely adopted. Data on transfer from healthcare simulation training are scarce because of the complexity of measuring on-the-job performance, and studies have mainly explored the perceptions of trainees on short-term transfer (hours or weeks after training).[7] Effective training, however, should also promote long-term transfer.[8]

The present study was conducted to explore self-perceived long-term transfer 2 years after having attended PPH simulation training based on either ID principles or current best practice (BP). The ID format applied principles derived from cognitive psychology that are explicitly aimed at optimizing long-term transfer;[9,10] the ID format used in the present study included multiple elements (Table 4.1).

Table 4.1 List of instructional design guideline elements used in the ID simulation format

What	Concept	Application in this study
Authenticity[9]	*Real life, whole-tasks*	*Scenarios script details very similar to reality. SKA tasks expected.*
Psychological fidelity[11]	*Degree to which real-task skill(s) are replicated in the simulated task*	*In situ environment, simulated patient and simulated nurse contributed to trainees' suspension of disbelief (i.e. acting as if the scenario was real)*
Engineering fidelity[11]	*Degree to which the training device or environment replicates the physical characteristics of the real task*	*Scenarios occurring in situ, with simulated patient and interactive part-task simulator*
Paivio's dual coding[12]	*Images visualization associated with instruction help people learn*	*A circle with continuous arrows summarized training content (Figure 4.1)*
Feedback[13]	*Trainees receive information on their performance*	*Trainees received feedback (debriefing steps) on more than one occasion*
Variability[14]	*Opportunity to practice different tasks in more than one scenario*	*Trainees attended three different scenarios*
Increasing complexity[14]	*Learning tasks are presented in an increasing sequence of complexity*	*Scenarios presented in a sequence of increasing complexity*

SKA – Skills, knowledge and attitude

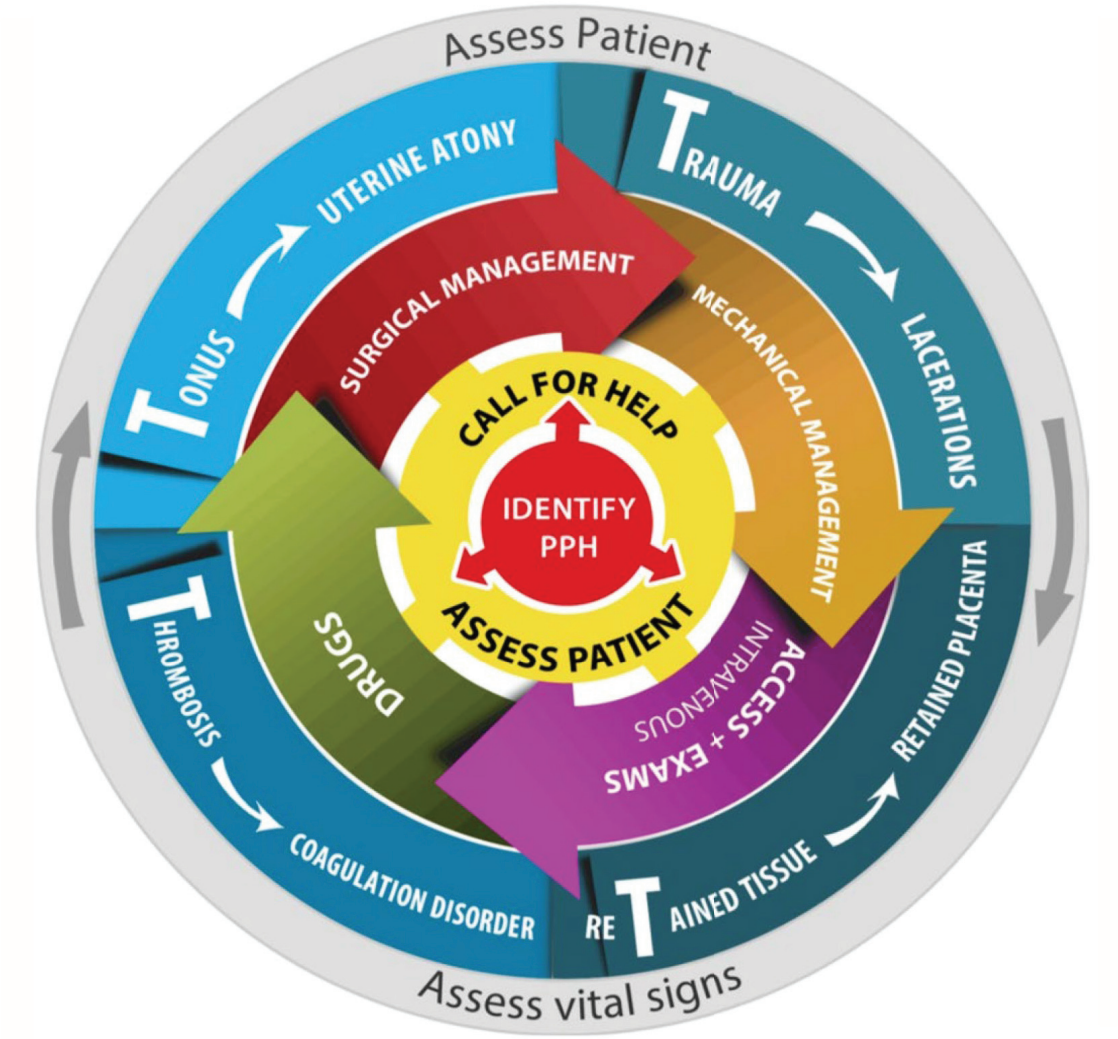

Figure 4.1 Postpartum hemorrhage management protocol.

The current study was designed to address the following research questions. (1) Do the residents perceive transfer 2 years after having attended PPH simulation training (ID or BP format)? (2) Which factors of the simulation training do they perceive as having positively affected long-term transfer? (3) Does the perceived long-term transfer differ according to the format (BP or ID) of the simulation training?

Methods

In the present qualitative study, semi-structured interviews were conducted between August 7 and September 26, 2015, with health-care practitioners who had attended one of two different PPH simulations (based on ID or BP) 2 years previously.[15] At the time of the simulations, all attendees were residents at one of the five teaching hospitals in Recife, Brazil, in one of the 3 years of the obstetrics and gynecology program. Using a simple randomization method (masking of names), six attendees from each simulation format were selected for invitation to interview from a total of 54 attendees. The study was approved by the ethics committee of Instituto de Medicina Integral Professor Fernando Figueira, Recife, Brazil. All participants gave written informed consent.

The two PPH simulations differed with regard to the ID elements (Table 4.1) and the number of steps. The ID-based simulation contained eight steps: (1) prior knowledge activation, (2) video demonstration, (3) dual-coding PPH protocol discussion, (4) training scenario #1, (5) debriefing, (6) training scenario #2 with immediate feedback, (7) training scenario #3, and (8) debriefing with self-assessment. The training scenarios had an increasing level of complexity. The BP simulation contained three steps: (1) prior knowledge activation, (2) training scenario (identical to ID simulation training scenario #3), and (3) debriefing. In both scenarios, the debriefings included participants watching video of themselves from the simulations. This format replicated the "best PPH simulation" previously[16] selected by seven training experts.

The PPH management protocol was developed by a focus group of obstetricians and anesthesiologists based on best available evidence.[1,17] The protocol was presented as shown in Figure 4.1, in agreement with Paivio's dual-coding theory,[12] which states that content presented via a combination of text and pictures is easier to remember than content presented with either method alone.

In both simulation formats, the scenarios included a standardized patient, a standardized nurse, and a part-task pelvis simulator (Postpartum bleeding station; ProDelphus, Olinda, Brazil). The trained domains comprised

skills, knowledge, and attitudes tasks such as communication, teamwork, and clinical management.

The interview guide used open-ended questions to explore residents' perceived long-term transfer (Table 4.2) and was based on Baldwin and Ford's transfer model.[18] According to this model, three factors influence transfer: (1) trainee characteristics (the motivation to attend training, the perceived relevance of the training content, and self-confidence); (2) the training design (application of ID principles); and (3) the workplace environment (organizational feedback, teamwork, and opportunity to use what has been learned).[18,19]

Table 4.2 Interview guide list of questions for the semi-structured questionnaire (the themes are inspired by Baldwin and Ford, 1988)

		Questions
	Introductory Question 1	*Do you consider the simulation training to have changed how you manage a PPH case? If so, in what way?*
	Introductory Question 2	*What were the "take home messages" from the simulations?*
Baldwin and Ford's Training Transfer Framework	**Trainee characteristics**	*What motivated you most to attend the simulations?*
		How relevant do you consider the content of the simulations to be?
	Training design	*How authentic (from a clinical perspective) did you consider the scenarios to be?*
		How much do you recall applying in a real PPH clinical case from what you learned in simulations?
		How much of what was learned do you recall applying in any real PPH case with an etiology different from those of the simulations? How different from the simulations scenario cases was it?
		How much do you think visualizing the PPH protocol facilitated your learning?
		How much do you recall from the debriefing step? How much do you think this feedback contributed to your learning?
		Do you think the increasingly complex sequence of scenarios contributed to your learning?
		How would you describe your confidence in attending a real PPH case after the simulations?
		How did you perceive your confidence during your unsupervised practice (at the rural maternity units)?
	Work environment	*After the simulations, did you have any form of feedback (comments, support, patient clinical outcome information) from the maternity unit supervisors after managing a real PPH case? Was it in your residency hospital or a hospital you work at as a staff member?*
		After the simulations, how would you describe the teamwork on the PPH cases you attended?
	Comments & Suggestions	*Do you have any comments and/or suggestions regarding the simulations? What would they be?*

A fifth-year medical student was trained to conduct all one-to-one interviews in a private room in the hospital. The participants received two visual aids to facilitate recollection: the picture summarizing the PPH protocol (Fig. 1) and a picture summarizing the PPH simulation steps from each training format.[15] The interviews were audio-recorded and typically lasted 20 minutes. They were transcribed verbatim and the participants' identities were coded according to the format of the attended simulation (Resident_ID# or Resident_BP#).

Thematic analysis20 was used to analyze the interviews. Two researchers (BCPM and ARF), who were blinded to the participants' identity but not to the format of the attended simulation, independently read the transcripts of each interview and highlighted, labeled, and grouped relevant quotations in a coding table.

In a first discussion round, the readers compared the highlighted quotations and coding tables and agreed on two preconceived main categories: (1) perceived transfer and (2) simulation factors perceived as potentially affecting transfer. The simulation factors category was composed of three subcategories that were based on the model by Baldwin and Ford:[18] (2a) trainee characteristics, (2b) simulation design, and (2c) work environment. One particular group of similar quotations did not fit into the preconceived main categories and was categorized as "systematic approach to PPH management".[10]

Subsequently, each reader independently created a table for each simulation format (BP or ID) and displayed the findings according to the main categories and subcategories. They then discussed differences in perceived long-term transfer per format. A final table containing the summary columns for each simulation format was translated into English for interpretation and discussion by the other authors. Saturation of the findings was achieved once the collected data allowed sufficient understanding of the dimensions and properties of our key concepts.[21] No further sampling of residents was deemed necessary.

The English-language table contained quotations of the residents, organized by category, and notes from the readers. The notes described

reflections regarding the residents' perception of overall transfer; the potential effects of different simulation factors (in particular ID elements) on transfer; and observed differences in perceived transfer depending on the simulation format.

Results

All 12 potential interviewees accepted the invitations. The mean age of the interviewees was 29 years (range 28–31 years), the mean time since graduation from medical school was 4 years (range 2.5–5 years), and 11 interviewees were female.

The first research question was addressed by ascertaining whether residents from both simulation formats perceived long-term transfer effects. Residents consistently reported a perceived change in PPH management and the use of a more systematic approach to problem-solving after the simulations (Table 4.3).

Table 4.3 Extracted segments of Participants' interview responses

Research Questions	Quotations
First research question: *How do participants perceive long-term transfer while performing on the job 2 years after attending the simulations (ID or BP)?*	
Perceived transfer	***Resident_ID6****: "What changed the most was the sequence of actions. What to start with: massage the uterus first, then go to medication, right? ... Acknowledging teamwork more, being aware of the need to call people to help, stabilize the patient, get a venous access, give her oxygen, monitor her vital signs... These were the things that really stuck in our minds after the training ... Now I have a more clearly defined sequence of actions ..."* ***Resident_BP4:*** *"I think it was mostly, like... more speed in my reasoning! Bleeding: then I do this, then this, then that. Didn't work! Then this, afterwards that ..."*
Second research question: *Which factors of simulation do they perceive as positively affecting this long-term transfer awareness?*	
Trainee characteristics	
Motivation and relevance of content	***Resident_ID3****: "If you work at a maternity, you have to practice. ... You need to have the young personnel trained to be aware of it"* ***Resident_BP6:*** *"Very frequent. Managing it properly will save lives."*
Self-confidence	***Resident_ID5:*** *"A lot, 100%. You realize you are more confident, so you end up assuming more the leadership because of the training."*
Simulation design	
Authenticity	***Resident_BP1:*** *"For sure we deal with very similar cases in our day-to-day work"* ***Resident_ID1:*** *"I recall I got very tense at that point, everybody got nervous. In this sense, it was very real."*
Dual coding	***Resident_ID1:*** *"It is still in my mind today. I think it is great. I remember it every time. I recall the circle."* ***Resident_BP1:*** *"It helps a lot. ... Because we can see it and recall the sequence very clearly."*
Feedback	***Resident_BP1:*** *"I recall we were in a room watching what we had done. It was very useful. ... You can analyze what you did wrong,*

	then you see what would have been right and you remember it." ***Resident_BP1:*** *"I remember well that the last case was much more complex, and we managed it much faster than the initial (simpler) cases."*
Increasing complexity (ID simulation only)	***Resident_ID1:*** *"It helped a lot. We were doing more and more increasingly more complex tasks."* Resident_ID3: *"I think it [the increasing complexity of the scenarios] allowed us to gradually build up more knowledge"*
Work environment	
Feedback	***Resident_BP1:*** *"From a supervisor, once, at my residency. He congratulated me saying I knew how to take action, [how to] handle the case."*
Teamwork and workplace learning skills	***Resident_ID5:*** *"There was this one case, I was with a colleague who had also attended the training. So, things went very smoothly, we were thinking alike and getting feedback from each other. It was very interesting."* ***Resident_ID4:*** *"The anesthesiologists are the ones who complicate our lives the most. I was very upset one day when they kind of neglected a case ... only when the patient began to become unstable did they realize it was for real."*
Third research question: *Are there differences in perceived long-term transfer according to the type of simulation attended (BP or ID)?*	
Differences in perceptions according to PPH simulation format	***Resident_ID4:*** *"First is that thing of introducing yourself, explaining to the patient what is going on and your actions ... I didn't do that before. And collect exams, to remember to collect the exams ..."* ***Resident_ID2:*** *"... already arriving at the scene talking to the patient, already managing the case, ... remembering to collect exams ..."*

The findings relating to the second research question (influence of simulation factors on transfer) were presented as follows: (a) trainee characteristics (relevance, motivation, and self-confidence), (b) training design (authenticity, dual coding, feedback by debriefing, and variability and increasing complexity), and (c) work environment (organizational feedback, teamwork, and opportunity to use what was learned).

The reported motivation for attending the simulations was a desire to learn and improve professional skills. The residents acknowledged that the content of the simulations (management of PPH) was relevant to them. Moreover, they perceived heightened self-confidence in the management of patients with PPH in their real work environment after the simulations, in particular when working in an unsupervised situation (outside their residency programs). The simulations gave them the confidence to assume team leadership when necessary (Table 4.3).

With regard to the training design, the scenarios were considered authentic in so far as they genuinely replicated clinical cases encountered in the residents' workplace practice, with similar reasoning challenges. Furthermore, the simulations occurred in situ (in a real environment) in the presence of a simulated nurse and a simulated patient. All these items contributed to the psychological fidelity (mental similarity to reality) of the simulations, reflected by a perceived sense of anxiety during the simulations (Table 4.3). The engineering fidelity (physical similarity) of the part-task simulator was also mentioned as a factor contributing to the authenticity (overall similarity to real cases) of the simulations.

The dual-coding strategy was also acknowledged as facilitating transfer. Residents strongly recollected the visual representation of the PPH protocol and specifically referred to the central circle with continuous arrows, which reflected the need to execute continuous and simultaneous tasks.

The residents reported that watching themselves on video during the debriefing (feedback) in both simulation formats allowed them to identify and reflect on their own errors and make plans for how to improve their skills. They also acknowledged that the safe feedback environment facilitated learning.

Residents who participated in the ID format were exposed to more than one training scenario and debriefing, which enabled them to try out variations

and practice under conditions of increasing complexity. Residents attending this format reported that exposure to this training sequence facilitated learning (Table 4.3).

As for working-environment factors, organizational feedback was described as poor. With one exception, all residents said they had not received any workplace feedback (feedback from supervisors or institutional feedback).

The residents perceived an improvement in teamwork skills because they were both more aware of them after participating in the simulations and more motivated to take on a leadership role when faced with a real patient with PPH. Residents who had managed a woman with PPH along with a colleague who had also attended the simulation stressed the smoothness of the actions and the shared responsibility in re-evaluating the diagnosis and revising the management plan. However, the residents also cited teamwork conflicts related to resistance from colleagues from other healthcare disciplines who had not attended the simulation training (Table 4.3).

With regard to the third research question, residents who had attended the ID-based simulation attributed the perceived transfer to improvements in both communication and teamwork skills, and also to situational awareness in the workplace. Moreover, only residents who had attended the ID simulation format reported communication with the bleeding woman and the collection of blood samples for examination early in the process, which reflects an awareness that the patient is potentially instable (increased situational awareness) (Table 4.3). The findings relating to the second research question (influence of simulation factors on transfer) were presented as follows: (a) trainee characteristics (relevance, motivation, and self-confidence), (b) training design (authenticity, dual coding, feedback by debriefing, and variability and increasing complexity), and (c) work environment (organizational feedback, teamwork, and opportunity to use what was learned).

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Discussion

In the present study, residents perceived positive long-term transfer 2 years after having attended simulation training for PPH, regardless of the simulation format (ID and BP). The reported motivation to attend the simulations was a desire to improve professional skills. The residents acknowledged that PPH was a relevant training topic and described an increase in self-confidence. Attendees of either simulation format reported the following ID elements as contributors to transfer: authenticity,[9] use of Paivio's dual-coding strategy,[12] and feedback during debriefing.[14,22]. Residents who participated in the ID-based simulation additionally mentioned variability and increasing complexity as ID elements contributing to transfer. Residents from both groups reported an increase in teamwork skills. They also reported poor organizational feedback and team struggles with colleagues who had not attended the simulation. Residents who had attended the ID format perceived better transfer of communication and teamwork skills and higher situational awareness than those having attended the BP format.

The present study makes several contributions to the transfer literature. Whereas most studies[4,7] have explored transfer in the short term (immediately after training or a few weeks later), the present study demonstrated positive transfer 2 years after the PPH simulation training (long-term transfer). Moreover, the perceived improvements in communication skills and situational awareness reinforce the recommendation of applying ID principles when devising simulations, in particular simulations for high-stake situations such as PPH.[1,5,6,10] In addition, because the study explored the perceptions of participants who, in their majority, had already concluded their residency, the study provides a wide range of perceptions deriving from actual workplace performance. This is likely to have had a positive influence on the perception of long-term training transfer.[14]

With regard to the influence of trainee characteristics, the motivation to improve one's professional skills has long been recognized as an important predictor for the effectiveness of transfer.[4,19,23] The present study confirms this notion. The acknowledgement of PPH as a relevant topic for simulation training can be explained by the facts that PPH is a preventable cause of maternal death and that there has been a worrisome increase in the rate of PPH, which has led to recommendations for healthcare personnel to participate in simulation training.[1,2,17] The long-time gap between training and the present evaluation of transfer reinforces the strength of the finding that self-confidence was increased.23 Whereas most previous studies have assessed self-confidence in the short term,[4,7,19] residents in the present study were consulted after several on-the-job exposures to PPH, which will have promoted better on-the-job learning.[14]

As for the training design, the following ID elements were reported as contributors to training transfer. First, authenticity,[9,10] because the scenarios were close to reality and possessed psychological and engineering fidelity, which also contributed to the "suspension of disbelief" among the trainees.[11] Although there is an ongoing debate as to the exact definition of authenticity,[9-11,24] there is a general consensus that it is important for trainees to perceive scenarios as "challenging" and to feel motivated to exert effort;[19] this was indeed the case with the present scenarios. Second, the finding that

visualization of the PPH protocol helped the residents to recall what had been learned reinforces Paivio's dual-coding theory.[12] This might be of particular relevance to simulations of high-stake situations such as PPH, where several tasks have to be performed simultaneously and in collaboration.[25] Third, feedback during debriefing is broadly recognized as being important for learning;[10,22] such feedback was provided more than once in the ID group. The residents stressed the importance of having the opportunity to learn from their own mistakes, a finding that is supported by evidence that error management improves transfer.[4,25] Finally, the fact that attendees of the ID format acknowledged the variability and increasing complexity of the scenarios as contributors to transfer is in agreement with the literature on complex learning.[4,14]

When discussing the impact of the work environment (opportunity to use skills in practice, organizational feedback, teamwork skills) on transfer, the high prevalence of PPH1,[17] is an important factor to consider. Given this high prevalence, the trainees had multiple on-the- job opportunities to apply the acquired skills, but it also emerged that poor organizational feedback was ubiquitous[4], highlighting the need to implement new policies for organizational feedback. With regard to teamwork, the perceived empowerment to take on a leadership role corroborates the need to train teamwork skills, preferably in a multidisciplinary fashion as illustrated by the reported conflicts with colleagues from other disciplines.[25]

The perception of enhanced communication skills and situational awareness by ID format residents reinforces the recommendation to apply ID principles when designing simulation training, particularly for high-stake situations such as PPH. The achievement of long-term transfer is particularly relevant to simulations for clinical conditions in which the optimal coordination of simultaneous tasks from multiple domains has an important impact on patient outcomes.[1,2,14,25]

The fact that the present analysis was based on self-perceived outcomes may be seen as a limitation. Indeed, strict analysis of transfer requires the overcoming of a few methodological challenges. For instance, to analyze PPH management in real life, uninterrupted video recording of all deliveries would

be necessary (with all the accompanying costs and operational implications) because the occurrence of PPH is unpredictable. Another potential limitation is related to the fact that the ID and BP simulation formats contained a different number of scenarios. This reflects a core difference between the two formats: with the larger number of scenarios, the ID format provided multiple practice opportunities, variability, and increasing complexity, which promotes cognitive elaboration because learners are encouraged to compare and contrast scenarios with each other. In fact, these aspects reinforce the trustworthiness of the present findings, which were obtained 2 years after the actual simulations and after potential contamination from unrelated work experiences.[10,14]

In conclusion, the application of ID principles to PPH simulation training led to improvements in the perceived transfer of communication, teamwork, and situational awareness skills. Future studies should explore the contribution of specific ID elements to long-term transfer and their potential impact on clinical outcomes.

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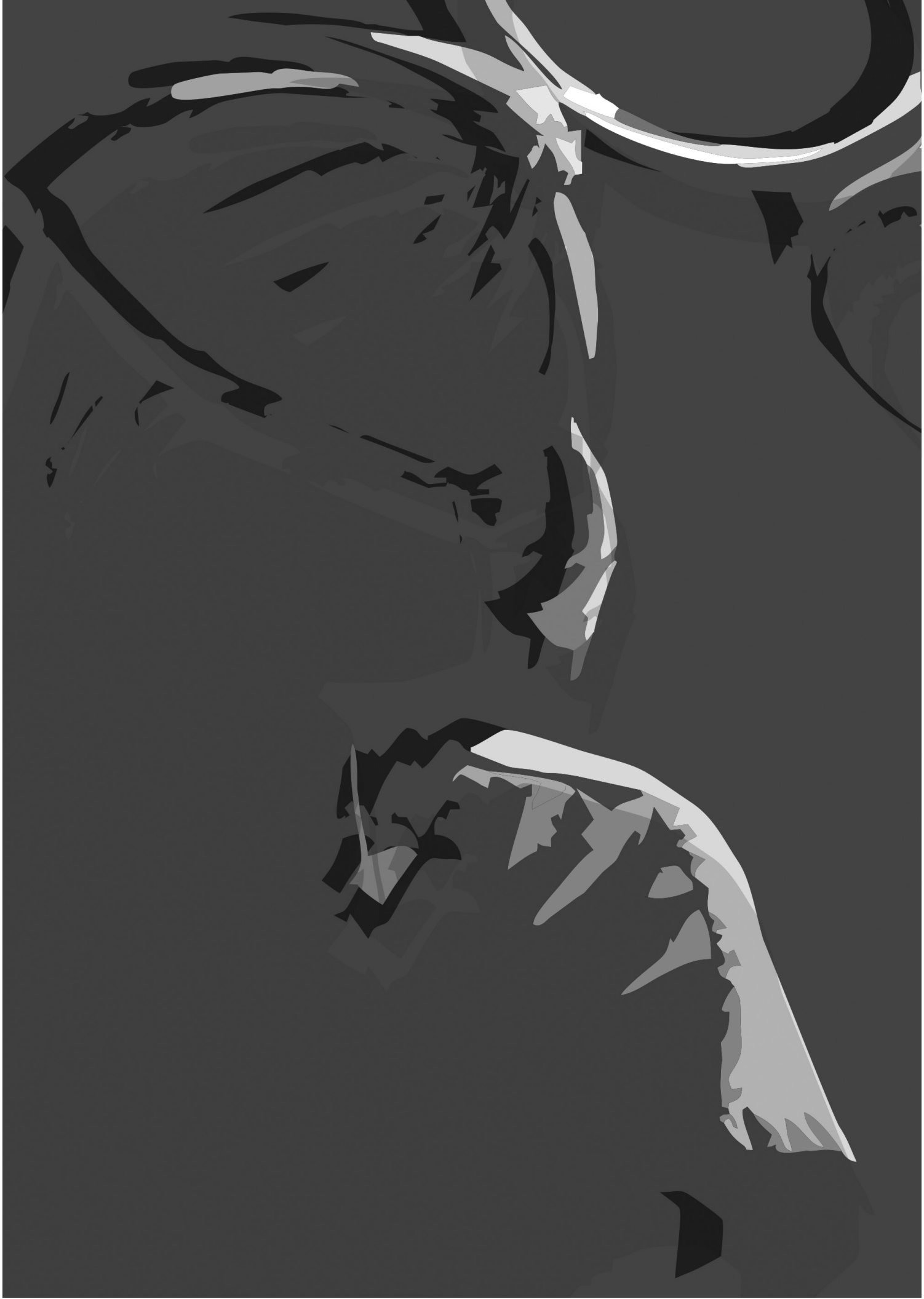

Chapter 5

Effects of an in situ instructional design based postpartum hemorrhage simulation training on patient outcomes: an uncontrolled before-and-after study[4]

[4]This chapter is based on a manuscript submitted for publication: De Melo BCP, van der Vleuten CPM, Muijtjens AMM, Falbo AR, Katz L, & van Merriënboer JJG. (submitted). Effects of an in situ instructional design based postpartum hemorrhage simulation training on patient outcomes: an uncontrolled before-and-after study

Abstract

Introduction

Simulation training ultimate goal is to improve patient outcome. The prevailing heterogeneity of simulation design, however, contributes to the inconsistency of findings on such outcome. The use of instructional design (ID) guidelines has been recommended for optimal simulation training effectiveness.

Objective

Comparing postpartum hemorrhage (PPH) patient outcomes before and after an in situ instructional design (ID) based PPH simulation attended by obstetrics and gynaecology residents.

Methods

This uncontrolled before-and-after study was conducted at a teaching hospital maternity unit in Recife, Brazil and included all women delivering at this maternity. Data from a sample before the simulation (June to August 2012) were compared with those of a sample after (June to August 2013). Primary outcomes were therapeutic uterotonics use rates within 24h of birth (TUW24h) and blood transfusion rates (BTR). Secondary outcome measures included uterotonic use rates and dosages for each drug, postpartum Hb <6g/dL, B-Lynch suture, uterine artery embolization, hysterectomy, renal insufficiency, obstetric intensive care unit (ICU) admission, mechanical ventilation, length of hospital stay, near-miss maternal mortality and maternal death.

Results

2745 women were analyzed, 1388 in 2012 and 1357 in 2013. PPH rates were100 (7.2% of 2012 deliveries) and 80 cases (5.9% of 2013 deliveries) respectively. Comparison of primary post- and pre-simulation outcomes revealed no significant differences: TUW24h (67/100 (67%) versus 47/80

(58.8%); p=0.254) and BTR (29/100 (29%) versus 24/79 (30%) p=0.768). There was found have been an increase in therapeutic oxytocin mean dosage IU within 24h of birth (15.98 +7.4 vs 25.1+12.3; p<0.001). For all other outcome measures, there were no statistical differences.

Conclusion

In situ ID based PPH simulation leads to an increase in the mean dosage of oxytocin after training, in selected cases. This may indicate better situational awareness when managing women with PPH.

Introduction

In recent years, simulation training has been widely promoted for obstetrics emergencies, such as postpartum haemorrhage (PPH).[1-3] PPH is the leading cause of maternal mortality worldwide and most reported deaths are attributed to delays in recognition and management.[4] PPH simulation trainings should therefore aim to optimally manage postpartum bleeding in women by improving birth attendants' situational awareness (ability to perceive, comprehend and project a situation)[5] and complex learning skills (integration of knowledge, skills and attitude).[6] Strong evidence of the impact of simulation on patient outcomes is, however, still lacking.[7,8]

Assessing the impact of simulation on patient outcomes involves assessing the effectiveness of training. According to the Kirkpatrick training evaluation model, there are four levels of measured effects: learner's reaction, learning, transfer of learning (applying what was learned in the workplace), and results (or patient outcomes).[9] The search for evidence regarding the effectiveness of simulation has broadened to include the impact on transfer of learning and patient outcomes (Levels 3&4), after initially focusing on the learner's reaction and learning (Levels 1&2).[7,10-13] The current inconsistency of findings on simulation patient outcome studies may be attributed, however, to the wide variation in reporting of training length, content, design and outcomes.[14-17]

Simulation training design ultimately aims to improve patient outcomes and should prioritize instructional effectiveness, with the use of instructional design (ID) guidelines.[18] ID guidelines derive from sound learning theories and propose the use of instructional features such as authenticity, variability, increasing complexity and feedback for optimal complex learning and training effectiveness.[6,19-21] Systematic reviews of the use of such features in simulation designs have corroborated their effectiveness and demonstrated that these are still not widely used.[22,23]

Proper PPH management requires early recognition and prompt bleeding control (i.e. adequate situational awareness) and minimizes complications

such as blood transfusions, hysterectomy, near-miss maternal mortality[24] or maternal death. It requires the coordination of constitutively different skills (e.g. communication, drug management) as other obstetric emergencies. These characteristics, along with its high epidemiological burden, makes PPH a valuable subject for simulation. Of the wide variety of reported PPH outcomes, those presented most common are uterotonics administration and/or blood transfusion rates.[14,25-27]

In this current study, we aim to compare the outcomes of women presenting with PPH at a tertiary teaching hospital maternity before and after an in situ ID based postpartum haemorrhage simulation training that was offered to obstetrics and gynecology (OBGYN) residents.

Methods

This uncontrolled before-and-after study compared PPH patient outcome data for one sample before in situ ID based PPH simulation training (June to August 2012) and another after (June to August 2013). Data were collected from all women whose births were assisted at the Instituto de Medicina Integral Prof. Fernando Figueira (IMIP) maternity unit. IMIP is a tertiary teaching hospital in Recife, a large city in the Northeast of Brazil. Its maternity section has a delivery rate of 6000/year and a neonatal and obstetrical intensive care unit.

Participants

All women whose labors were assisted at IMIP during data collection were considered eligible for inclusion. Women were excluded from the study when, after assistance, their pregnancies were re-classified as <20 weeks (late abortion). A flow chart of data collection from participants is presented in Figure 5.1.

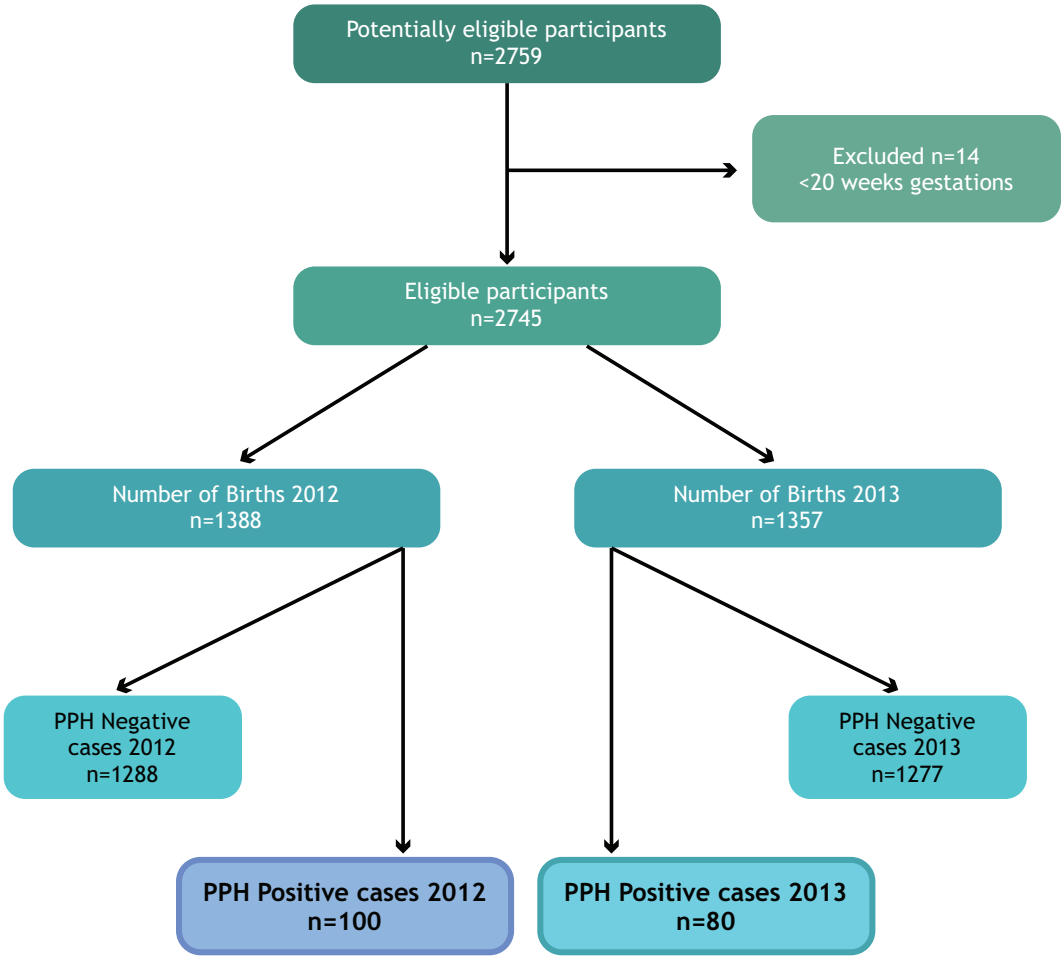

Figure 5.1 Data collection flow chart

Materials

The ID based PPH simulation training was offered to all 45 of the maternity hospital''s OBGYN residents, during their off-duty hours, in situ (at actual hospital facilities). Thirty-six residents, from all three years of the residency program, attended the training, an 80% attendance rate. The nine absences were justified for the following reasons: four residents were on vacation, one was on sick leave, one arrived late on the training day and three decided not to attend for unknown reasons. During each of the two half-day-long in situ simulation sessions scheduled for the first two weekends of June 2013, two groups of two or three OBGYN residents' teams were trained.

The in situ ID-based simulation was designed for a postgraduate audience to address the adequate management of postpartum bleeding and its complex learning demands. It contained multiple steps and the three authentic training scenarios were presented in a simple-to-complex sequence: first, a retained placenta, then laceration and hypotonic uterus, and, finally, an unresponsive hypotonic uterus with hemodynamic instability. The two debriefings sessions provided the team with video recordings and a self-assessment stage. The scenarios included a standardized patient, a standardized nurse – played by trained healthcare personnel volunteers –, and a part-task pelvis simulator (EVA Simulador Pós-Parto®; ProDelphus, Olinda, Brazil; www.prodelphus.com.br). The overall learning objective of the simulation was to achieve complex learning regarding promptly and adequately managing postpartum bleeding according to the PPH guideline presented, covering tasks involving skills, knowledge and attitudes (SKA). The tasks varied in type and were classified into subscales: communication, teamwork, women's vital signs, venous access, laboratory evaluation and blood bank alertness, and drug, mechanical and surgical management (the latter solely by verbal indication). This in situ ID based simulation demonstrated positive learning and transfer of learning outcomes and further design details may be consulted elsewhere.[28,29]

The main outcome measures selected were therapeutic uterotonic use within-24h-of-birth and blood transfusion. Secondary outcome measures included therapeutic uterotonic dosages and rates per drug (oxytocin, misoprostol and ergotamine), within and beyond 24h-of-birth, and other

severity-related PPH outcomes such as: hemoglobin levels <6g/dL, B-Lynch suture, uterine artery embolization, hysterectomy, renal insufficiency (as registered on patient records), obstetric ICU admission, mechanical ventilation, hospital length of stay after birth, near-miss maternal mortality24 and maternal death. These outcomes were selected by a Delphi panel including OBGYN experts,30 which rated the most relevant PPH management outcomes as described in systematic reviews regarding its management.[31,32]

Procedure

Data regarding women's age, parity, gestational age, mode of delivery, newborn birth weight and prophylactic oxytocin administration were collected from all women whose deliveries were assisted at the maternity hospital during the study period. The additional PPH outcomes measures were collected for those women identified as PPH cases, using a specific chart. All the skilled birth attendants (obstetric nurses, OBGYN residents and consultants) were trained for data collection and made aware when data collection was under way by daily rounds.

During data collection, women's patient records were provided with an additional flow chart, which was inserted immediately before the maternity hospital's regular labour and delivery flow chart. All women admitted either in labour or for expectant management were monitored for delivery. The team of professional birth attendants during each of the maternity hospital's two 12-hour daily shifts is composed by four OBGYN medical residents, three OBGYN medical consultants and one obstetric nurse. All deliveries are assisted by at least one of these skilled birth attendants, with the participation of at least one medical OBGYN resident. These are the first responders for to the low risk births, term births with no co-morbidities, assisted by nurses. A PPH case triggers a call. High-risk births, preterm labors and/or cases with co-morbidities are initially assisted by the medical OBGYN residents. Medical consultants are available to supervise residents' deliveries assistance and/or caesarean sections.

Upon delivery, the professional birth attendant used the additional flow chart whether the women presented PPH during birth, while also producing

the routine paper work, typically one hour after delivery. The criteria adopted by the maternity hospital for identifying PPH is based on the traditional definition – cumulative blood loss of greater than or equal to 1,000 mL or blood loss accompanied by signs or symptoms of hypovolemia – as assessed by the professional birth attendant. Women were monitored throughout their stay hospital stay for continuous blood loss. In the event of PPH occurring later than one hour after birth, i.e. after registration of birth records, maternity personnel were urged, during daily rounds, to register the incident on the PPH data collection flow chart.

Women were also monitored if admitted to the obstetric intensive care unit. This unit is a referral centre for severe obstetrics patients from throughout the region and also admits women referred from the maternity hospital's delivery room. Case severity vary widely, from single need for vigilance cases to more complex cases, with need for advanced life support. The prevalence of preeclampsia in the locality is high and women needing magnesium sulphate are admitted for vigilance. In the event of women presenting with PPH, this was registered on the appropriate flow chart. The main author (BCPM) reviewed all completed PPH data collection charts regularly.

Women's delivery assistance during data collection was not modified for any reason, with a naturalistic observation of their management for the full length of their stay in hospital. Data was collected in the same months of 2012 and 2013 to avoid potential seasonality bias and no change was therefore expected regarding PPH rates and the focus was on analysing outcome measures.

This current study was approved by the IMIP's ethics committee on March 17th 2012 under the number CAE:0034.0.099.000-11.

Data Analysis

Data were analyzed using SPSS version 23 (IBM, Armonk, NY, USA). Patient data and outcomes frequency measures were aggregated per year of occurrence, and between-year differences (i.e. post- versus pre-simulation outcomes) were also investigated. The Chi-Square test was used for all categorical variables comparisons and Fisher's exact test used when necessary.

An independent t-test was conducted to compare the means of continuous variables and the Mann-Whitney test was applied for discrete variables.

Results

A total of 2759 women were assisted for delivery at IMIP during data collection. Fourteen were excluded for gestational age <20 weeks (late abortions). Of all 2745 women who delivered during the data collection period, 1388 were in 2012 and 1357 in 2013, with PPH rates of 100 cases (7.2% of deliveries) and 80 cases (5.9%), respectively. Analysis of demographic and clinical data revealed no statistically significant differences between women presenting with PPH before and after simulation for: women's age, parity, cesarean rate, neonatal birth weight or preterm admission (Table 5.1).

Table 5.1 Demographic and clinical characteristics of women presenting with postpartum hemorrhage at a teaching hospital in June, July and August 2012/2013 before and after an in situ instructional design based postpartum hemorrhage simulation training.

	2012		**2013**		**Total**
	1388 deliveries	*Valid Cases*	*1357 deliveries*	*Valid Cases*	*p value*
PPH intrapartum (up to 1h after birth) N (%)	*63(63%)*	*100*	*45(56.3%)*	*79*	*0.412[c]*
PPH postpartum (> 1h after birth) N (%)	*46 (46%)*	*100*	*37(46.3%)*	*80*	*0.973[c]*
Age mean (±SD)	*25.16 ± 6.4*	*100*	*25.92 ±7.6*	*80*	*0.467[a]*
Gesta median (IQR)	*1,5 (1-3)*	*98*	*2 (1-3)*	*79*	*0.72[b]*
Para median (IQR)	*0 (0-1)*	*98*	*1 (0-2)*	*80*	*0.42[b]*
Prophylactic oxytocin N (%)	*82 (82%)*	*100*	*64 (80%)*	*80*	*0.733[c]*
Cesarean N (%)	*37 (37%)*	*99*	*32 (40%)*	*80*	*0.720[c]*
Neonatal birth weight mean (±SD)	*2488.89 ± 1123.55*	*99*	*2642.75 ± 1022.97*	*80*	*0.345[a]*
Admission in labor N (%)	*45 (45%)*	*98*	*35 (43.8%)*	*78*	*0.890[c]*
Induced labor N (%)	*40 (40%)*	*98*	*25 (31.3%)*	*79*	*0.208[c]*
Preterm on admission N (%)	*45 (45%)*	*100*	*32 (41%)*	*78*	*0.595[c]*

Obs1: *a – t-test; b – Mann-Whitney U test; c- Pearson Chi-Square tests; c* - Fisher's Exact Test*
Obs2: *Each variable was calculated based on the number of valid cases (missing cases excluded).*

The differences found between the main pre- and post- in situ ID based PPH simulation outcomes of therapeutic uterotonic rates within-24h-of-birth of 67/100 (67%) and 47/80 (58.8%) (p=0.254) and blood transfusion rates of 29/100 (29%) and 24/79 (30%) p=0.768) respectively were not statistically significant.

As for the secondary outcomes comparison, a statistically significant difference was found for per drug therapeutic uterotonic use within-24h-of-birth, with an increase in the mean dose of therapeutic oxytocin in IUs (15.98+7.4 vs 25.1+12.3; p<0.001) after the simulation (Table 5.2).

Table 5.2 Postpartum hemorrhage women clinical outcomes comparison before and after in situ instructional design based postpartum haemorrhage simulation training at a teaching hospital

	2012	Valid cases	2013	Valid cases	p value
Main Outcomes					
Therapeutic uterotonics use within 24h of birth N (%)	*67 (67%)*	*100*	*47 (58.8%)*	*80*	*0.254[c]*
Blood transfusion N (%)	*29 (29%)*	*98*	*24 (30%)*	*79*	*0.768[c]*
Secondary outcomes					
Per drug therapeutic uterotonics within 24h of birth N (%)					
Oxytocin N (%)	*67 (67%)*	*100*	*46 (57.5%)*	*80*	*0.190[c]*
Mean dose IU mean (±SD)	*15.98 (±7.4)*	*66*	*25.1 (±12.3)*	*46*	*<0.001[a]*
Misoprostol N (%)	*14 (14%)*	*100*	*19 (23.8%)*	*80*	*0.093 [c]*
Mean dose μg mean (±SD)	*592 (±261.54)*	*14*	*736.84 (±164)*	*19*	*0.084[a]*
Ergot N (%)	*5 (5%)*	*100*	*0 (0%)*	*80*	*[*1]*
Mean dose mg mean (±SD)	*0.280 (±0.17)*	*5*	*NA*	*0*	*NA*
Therapeutic uterotonics After 24h of birth N (%)	*2 (2%)*	*100*	*2 (2.5%)*	*80*	*1.000[*10]*
Oxytocin N (%)	*2 (2%)*	*100*	*2 (2.5%)*	*79*	*1.000[*10]*
Dose IU mean (±SD)	*25 (±0)*	*2*	*15(±7.1)*	*2*	*[*1]*
Misoprostol N (%)	*1 (1%)*	*100*	*0 (0%)*	*80*	*1.000[*10]*
Dose μg mean (±SD)	*800 (-)*	*1*	*NA*	*0*	*NA*
Ergot N (%)	*0 (0%)*	*100*	*0 (0%)*	*79*	*NA*
Dose mg (Mean dose)	*NA*	*0*	*NA*		*NA*
Hb < 6g/dL N (%)	*23 (23%)*	*100*	*10 (12.5%)*	*80*	*0.070[c]*
B-Lynch suture N (%)	*0 (0%)*	*100*	*1 (1.3%)*	*80*	*0.444[c*]*
Hysterectomy N (%)	*2 (2%)*	*100*	*2 (2.5%)*	*80*	*1.000[c *10]*
Renal insufficiency N (%)	*4 (4%)*	*100*	*2 (2.5%)*	*80*	*0.694[c *10]*
Obstetric ICU admission N (%)	*25 (25%)*	*100*	*20 (25%)*	*80*	*1.000 [c]*
Mechanical ventilation N (%)	*3 (3%)*	*100*	*5 (6.3%)*	*80*	*0.469[c *10]*
Hospital length of stay after Birth median (IQR)	*3 (2-5)*	*100*	*3 (2-5)*	*80*	*0.284[b]*
Near-miss maternal mortality N (%)	*8 (8%)*	*100*	*3 (3.8%)*	*80*	*0.350[c*10]*

Obs1: *a – t-test; b – Mann-Whitney U test; c- Pearson Chi-Square tests; c* - Fisher's Exact Test; NA- not applicable*
*[*1] -Comparison not conducted due to small sample*
Obs2: *Each variable calculated based on the number of valid cases (missing cases excluded).*

The increase in the misoprostol use rate (14/100 (14%) versus 19/80 (23.8%); p=0.093) and the mean dose in µg within 24h (592+261.54 versus 736+164; p=0.084) and the decrease in the number of near-miss cases (8/100 (8%) versus 3/78 (3.8%); p=0.352) and Hb<6g/dL (23/99 (23%) versus 10/76 (12.5%); p=0.091) after training were not statistically significant. The obstetric ICU admission rate was similar before and after training (24/99(24%) versus 19/79 (23.8%); p=0.976). As for the additional secondary outcomes, the absolute rates were small and similar before and after the simulation. There were no uterine artery embolizations or maternal deaths among the women whose labors were assisted at the maternity hospital during the data collection period (Table 5.2).

Discussion

Main Findings

Our comparative study of uncontrolled before-and-after patient outcomes of an ID based PPH simulation at a Brazilian maternity hospital found similar rates for the main outcomes: rates of use of therapeutic uterotonic within-24-hours-of-birth and blood transfusion. A statistically significant increase was found in the mean dose of oxytocin within-24-hours-of-birth after training.

With regard to other secondary outcomes, there was an increased misoprostol mean dose and usage rate within-24-hours-of-birth after simulation, a smaller number of Hb<6g/dL and fewer near-miss maternal mortality cases. Such differences, however, were not statistically significant, as was also the case for other outcome measurements.

The demographic and clinical data and PPH rates of the women included in the study were similar. No woman included in the study died.

Strengths and Limitations

Our study main strengths are stated in its main goal of exploring the impact on patient outcomes of an in situ PPH simulation designed based

on ID guidelines. Attention should first be drawn to the careful instructional design of the simulation, which aimed to optimize the effectiveness of training and was based on sound evidence regarding instruction.[21,28] The multiple ID features adopted (such as authentic multiple scenarios and easy-to-complex progression) and the in situ simulation using both a part-task simulator and simulated patient promoted the complex learning required for proper PPH management.[19,20,33,34] Second, investigation of patient outcomes (Kirkpatrick's level 4) has long been recognized as essential however complex and subject to system issues.[12,14,25,35]

The data collection time period, during the same three months of two consecutive years was designed to minimize seasonality bias on patient outcomes and may also be regarded as a strength of the study.[36] It should be also noted that producing such detailed analyses of PPH outcomes, in particular in the impoverished Northeast region of Brazil, with no formal research funding, posed a substantial challenge.

The study's limitations included the uncontrolled single-centre study design and the imperfect attendance rate of residents.

Interpretation

Our findings are in keeping with the already anticipated complexity of findings of studies on the influence of simulation on patient outcomes.[7,37,38] In spite of not providing a large set of statistically significant differences, some of the findings indicate a positive influence of the presented simulation design on PPH outcome.

Some of the outcome variables examined may be susceptible to a more straightforward interpretation of the training effect, in view of the immediate cause/effect relation. One example of this is the use of therapeutic uterotonic use, which promptly reflects residents' decisions and actions. Other outcomes measurements are more subject to systems' issues and bias, since they are proxy variables for clinical severity of PPH.

For instance, analysis showed prevalence of 24h-therapeutic uterotonic use to be similar before and after simulation. However, the lower therapeutic usage rate and increased mean 24h oxytocin dosage after simulation clearly point to a more intensive oxytocin administration in selected cases.

Furthermore, increased mean dose of oxytocin (25.1+12.3IU) suggests improved ongoing vigilance of the bleeding woman after simulation, since such dosages are administered on a progressive and continuous basis. These findings indicate increased situational awareness. An increase in uterotonics rates after simulation has been described by another study of a simulation designed to improve basic delivery skills and PPH management among a broader spectrum of healthcare personnel, including unskilled birth attendants. Further comparisons with our findings are limited by the divergent goal of this other study, which was not aimed at complex learning regarding management of PPH among postgraduates.[14]

Our intriguing finding of similar blood transfusion rates before and after simulation may be explained by the number of severe PPH cases being insufficient to demonstrate such differences. A number of findings, nevertheless, support such our interpretations. For instance, the number of women with Hb<6g/dL was small after simulation, and, although not statistically significant, suggests positive influence of the simulation on patient outcomes. Inclusion of a larger number of patients may have revealed a significant difference. Likewise, there were few cases of other severe PPH complications, such as B-Lynch suture, hysterectomy and renal insufficiency. Moreover, no maternal deaths or uterine artery embolizations were registered.

PPH is recurrently included in analysis of the influence of simulation on patient outcomes but comparison of our detailed findings with those of other studies is hampered by the wide diversity of usually single PPH outcomes described. These range from simple PPH cases rates (blood losses between 500 and 1000ml with no signs of hypovolemia) to rates of PPH related near-miss maternal mortality (blood transfusion >4 packed cells).[7,15,26,26,27,38] Divergence in PPH simulation patient outcomes studies can also be found with regards to learning objectives, study population, settings, trainees' profile and training design. The latter is often poorly described and undesired learning outcomes results, such as a 0% pass rate for PPH management skills, have been described.[7,15,26,27,38] These findings further support our interpretations of the positive influence of our simulation design on patient outcomes. For instance, our simulation design has previously produced largely positive learning and transfer of learning outcomes.[28,29]

Due to the need for proper records regarding initial PPH management, our study only included women whose deliveries were assisted at IMIP and such single-centre study design limited the number of patients included.

Similar PPH rates before and after simulation were expected, since the simulation was designed to teach the complex demands of PPH and not labour assistance. The relatively small PPH rates compared to other studies may be explained by the PPH criteria adopted (1000ml or identified hypovolemia), which can cope with lower levels of blood loss with no clinical repercussions. Once again, further detailed comparisons are hampered by the variety of PPH cases described in simulation studies.[7,15,21,27,38] Such divergences could be further minimized by the adoption of simulation reporting guidelines.[16,17]

The attendance rate of our residents was comparable to that of other studies[7,15,26] and may have contributed to some of the noise in our findings. Strategies to maximize participation, such as mandatory participation, should be considered in future studies.[27]

We believe the presented findings may be of value as an exploratory analysis of the impact of an in situ ID based PPH simulation and may support applications for funding for further studies in the near future. These future studies should include multiple centers, in clusters, preferably in a stepped wedged approach.[1,39] Such a study design aims to minimize potential system issues confounders on analysis of patient outcomes and involves random and sequential crossover of clusters from control to intervention until all clusters provide the simulation.[39] The simulation design should also be adapted to include multi-professional training for PPH management. This could be achieved without much effort, since multi-professional roles are already included in the simulation scripts.[1,40]

Conclusion

In situ ID-based PPH simulation training may lead to better situational awareness and better management of postpartum bleeding women. Effective simulation training should be designed using ID guidelines as a way of meeting the complex learning demands of proper PPH management. Future studies

should be designed for multi-professional training and include multiple units, in clusters, preferably as part of a stepped wedge approach.

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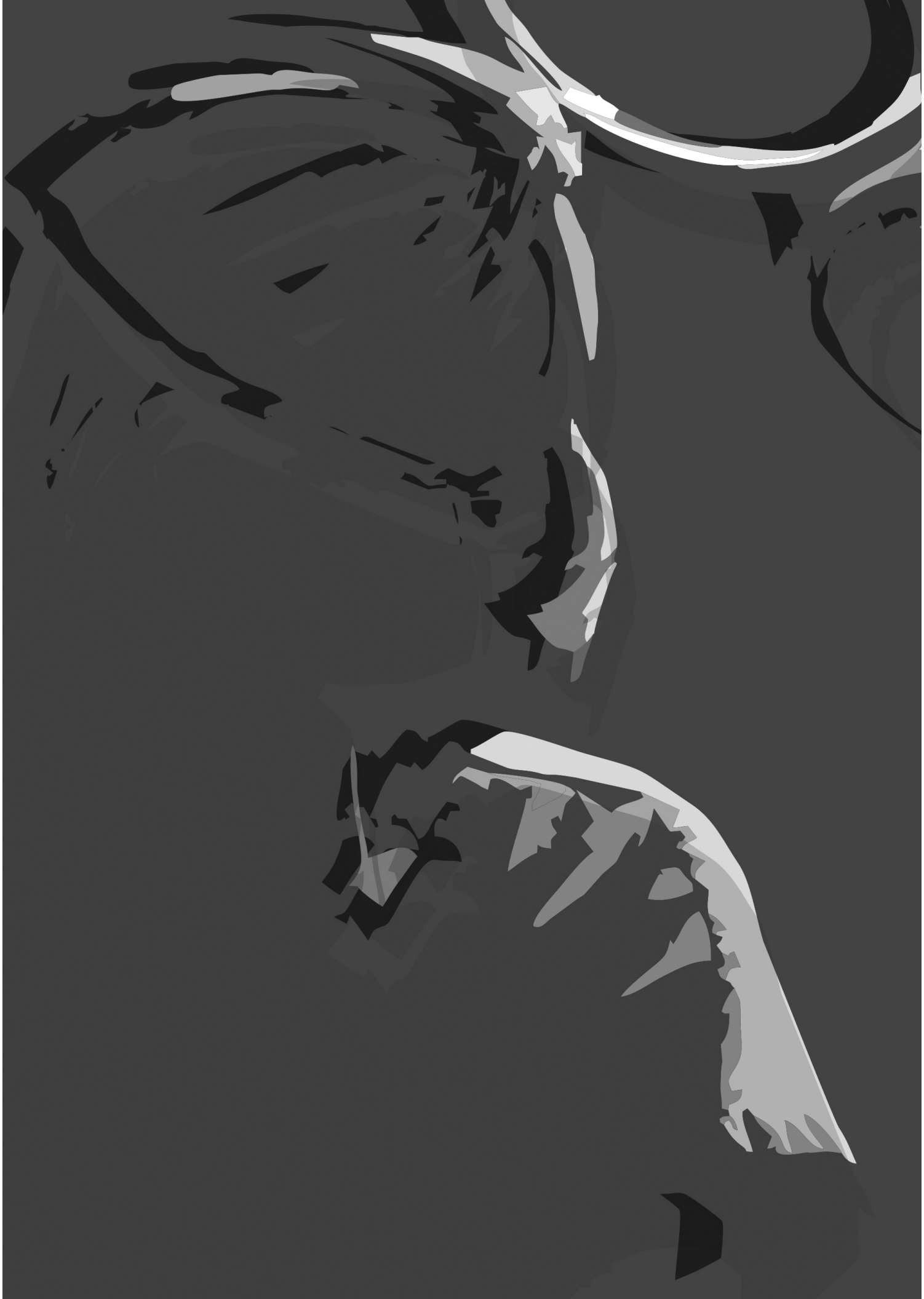

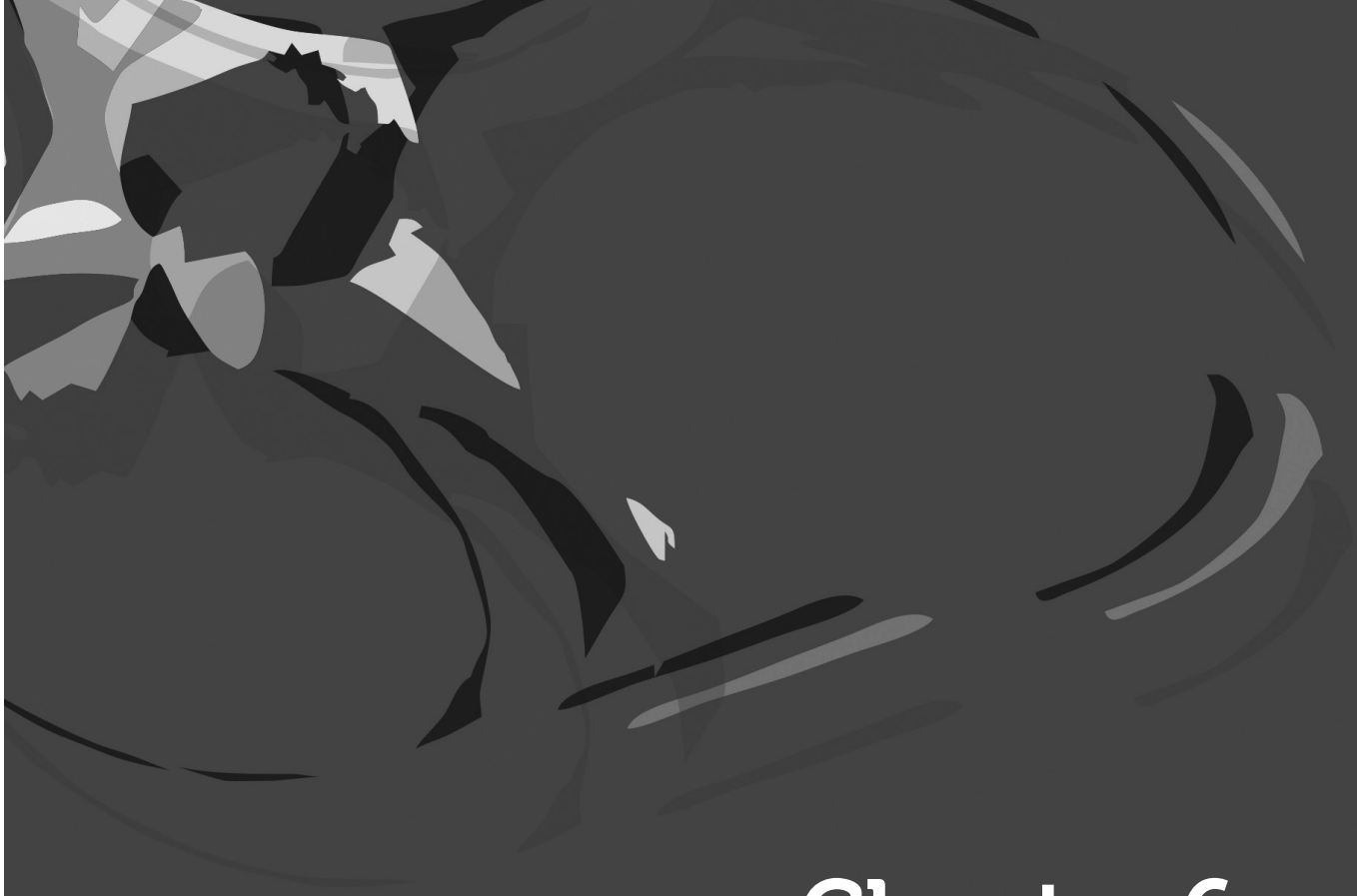

Chapter 6

General Discussion

General Discussion

This thesis aimed to explore the use of evidence-based instructional design (ID) guidelines for simulation training applied to a postpartum hemorrhage (PPH) content. Over the past decade, the worldwide spread of simulation training has been propelled by a genuine will to improve patient outcomes.[1-3] With the aim of optimizing simulation effectiveness, the use of ID guidelines has been recommended for this training strategy, in particular when focusing on the complex learning demands of high-risk situations.[4,5] PPH is an example of a high-risk situation, with wide ecological validity and sound epidemiological relevance as the leading cause of maternal deaths worldwide with most of these considered as preventable.[6-8]

We aimed to explore the use of evidence-based instructional design in four different aspects related to training effectiveness: learning, transfer of learning, patient outcomes, and the use of ID guidelines in PPH simulation trainings as currently described in the literature. Our verified findings provide support to the current recommendation of adopting ID guidelines, as they demonstrate a positive influence on each of the analyzed aspects of training effectiveness. In addition, the verified neglect of ID guidelines use by the majority of simulation trainings described in the literature reinforces the relevance of our findings.

We began this thesis' studies series by analyzing the use of ID guidelines by PPH simulation trainings described in published articles. We found a pervasive neglect of its use by the majority of analyzed simulation trainings, as presented in Chapter 2. Then, as described in Chapter 3, we conducted a pretest-post-test learning outcomes comparison of residents who attended two different PPH simulation trainings: one based on ID guidelines and the other on current best practices. On the post-test, we found the residents who attended the ID based PPH simulation training to execute a greater number of tasks in a shorter period of time than their peers who attended the best practices format. In the study presented in Chapter 4, we explored the self-perceived long-term training transfer after PPH simulation training and found a

greater situational awareness and better communication skills perceptions by the residents who attended the ID based simulation. Ultimately, we analyzed the impact of the ID based PPH simulation training on patient outcomes and, as described in Chapter 5, we found an improvement in PPH management, with fewer patients receiving a greater mean dose of therapeutic oxytocin, which likely reflects an increased situational awareness after the training.

The chapters presented in this thesis may be perceived as having an hierarchical connection, with some parallel to Kirkpatrick's training evaluation model.[9,10] According to this model, training effectiveness should be assessed on four different levels: (1) learner reaction, (2) learning outcomes, (3) behavior (transfer), and (4) results.

In our studies, we did not establish effects on Kirkpatrick's first level (learner reaction) but decided to explore the use of ID guidelines in previously published PPH simulation training studies, as presented in Chapter 2. The reason for this replacement was based on critiques on the Kirkpatrick model, which indicate little correlation between reaction and learning while also underscoring the model's simple taxonomy of training outcomes.[11-14] For the analysis of the remaining perspectives, we avoided simple replication of previously applied study designs and aimed at taking a step further in our analysis strategies. Therefore, we explored multiple aspects of simulation effectiveness through a "wide-angle lens" analysis,[15-17] at each of ours research questions listed below:

1) How are instructional design guidelines described and used in the current postpartum hemorrhage healthcare simulation literature?

2) What are the different learning outcomes when two instructionally different postpartum hemorrhage simulation training programmes are compared, one based on instructional design guidelines and the other on current best practices?

3) Is there long-term transfer after these two different training formats? Is there a difference in learning outcomes according to the attended training format? What instructional design features may have facilitated and/or hindered long-term transfer?

4) What is the impact on patient outcome at a teaching hospital after Obstetrics and Gynecology residents attending an instructional design based postpartum hemorrhage simulation training programme format?

As an example of a widened-angle analysis, our learning outcomes comparison study, presented in Chapter 3, had well specified complex learning tasks for our ID based PPH simulation training. Its whole-tasks learning approach differed from most often described studies in the learning outcomes simulation literature of single procedural tasks by promoting tasks from multiple dimensions (e.g. communication, procedural skills, teamwork, etc.).[18-22]

Another example of a widened training assessment was our approach to exploring learners' perceived long-term transfer at the workplace after the simulation, presented in Chapter 4. Exploring such transfer two years after the training represents an analysis on a much longer period of time than usually reported.[23,24] In addition, we adopted the Baldwin and Ford training transfer model[25] for our analysis to explore not only the influence of the training design on transfer but also the influence of trainees' characteristics (i.e. motivation to learn) and workplace environment (i.e. transfer of training conditions such as workplace feedback). Lastly, for the patient outcomes analysis, presented in Chapter 5, the study was designed to explore patient outcomes analysis in greater level of details than the usually reported impact on single procedural outcomes.[18,23,26] Our patient outcomes study presented results on frequencies of specific PPH-related complications, duration of hospitalization, and specific management measures such as drugs usages and dosages. This is the type of analysis recommended by systematic reviews on simulation training translational outcomes, which critique the frequently reported analysis of single procedural outcomes.[27]

Based on our presented findings, we expect to have successfully demonstrated the overarching benefits of ID guidelines for simulation training design. Our findings demonstrated positive outcomes throughout the complete training effectiveness spectrum – not only did

it lead to significant greater positive learning outcomes, but also to better perceived long-term transfer of learning and improved patient care.

Healthcare simulation training's ultimate goal is patient outcome improvement and, therefore, once embracing the challenge of promoting such training strategy it should be made effective by adopting ID guidelines. Moreover, as a first step, faculty should be made aware of the relevance of adopting such guidelines for designing and implementing simulation training.

Theoretical implications and future research

A few theoretical implications may be derived from our findings of a verified paucity of adherence to evidence-based instructional guidelines in current simulation training design. Moreover, the importance of these guidelines is reinforced by our additional positive outcomes of the use of such guidelines on simulation training effectiveness. These findings urge us to reflect upon the reasons that lead to such recurrent neglect from the healthcare simulation community with regards to training design.

An example of a theoretical implication is the need to further explore the reasons for such neglect from the stakeholders in charge of promoting simulation trainings worldwide. A natural conclusion derived from our presented findings is the sense of widespread "lack of awareness" from these stakeholders with regards to the necessity of adopting ID guidelines. The following step consists, therefore, in exploring possible strategies to promote faculty awareness and overcome potential resistances with regards to such necessity when designing simulation trainings.[28,29]

Effectively promoting faculty awareness with regards to optimal simulation training design is fundamental, particularly when considering simulation's large spectrum of practical purposes. For instance, simulation trainings may span from curriculum-integrated learning to high stakes certificates.[28,29] In addition, they may be applied to promote either learning of complex tasks (using whole-tasks in high fidelity or in-situ simulation) or procedural tasks (using part-tasks for part-task trainers), as well as training

single specialties and/or multidisciplinary tasks.[21,22,30,31] Therefore, in our current era of evidence-based medicine, patient-centered care and the need for a lifelong learning culture among healthcare personnel, a learning strategy such as simulation must be promoted effectively, preferably based on both clinical and instructional best available evidence.[32-34]

Further exploring the effectiveness of specific instructional design features and/or combinations of these design features may also contribute to the current body of knowledge for optimal simulation training design. For instance, our study presented in Chapter 3 (the learning outcomes study) demonstrated the positive learning outcomes of an ID based PPH simulation format consisting of three training scenarios. However, future research may, for example, explore optimal training length with regards to the number of multiple scenarios sufficient to sustain complex learning through repetitive and simple-to-complex practice, or even, how to best demonstrate the to-be-learned tasks.[31,35-37]

Further studies should also explore the impact of ID based training designed for healthcare workers with different levels of expertise, that is, not only for residents, but also for the whole continuum, from undergraduates to senior healthcare personnel. It is known that the effectiveness of training designs is heavily dependent on the prior knowledge or level of expertise of the trainees. Instructional design should, therefore, be adjusted accordingly taking into account the "expertise reversal effect" – avoiding redundant instruction to the experienced learner.[38,39] Furthermore, it is essential to promote training for multiple disciplines, preferably promoting an integration of disciplines in teams.[40,41]

Additional aspects of simulation training effectiveness beyond its design and content also remain to be explored. For instance, not only the faculty should be accounted for when promoting awareness with regards to the need to implement effective simulation training, but also the different stakeholders involved in promoting simulation, from both extremes of the administrative hierarchy: from the executive board to those responsible for ground work. A full-hospital simulation is still a challenge (simulation training exercises that include an entire care pathway and multiple hospital departments, thus truly

mimicking real clinical practice and exploring how to overcome the operational constraints implicated with routine hospital trainings across the entire patient pathway may lead to a significant contribution to simulation transfer.[42] Simulation training transfer is significantly influenced by workplace-feedback and opportunities to use different aspects of the "post-training elements", as described by Baldwin and Ford.[25] Promoting full-hospital simulation may significantly contribute to better understanding relevant training transfer constraints, which are reinforced by the workplace environment.[43,44]

One other aspect of simulation training that is still underexplored is simulation cost-effectiveness.[45] In our series of studies, the combination of a low-technological, low-cost, part-task simulator with a simulated patient, maximized training tasks possibilities within a limited budget. Further exploration of an optimal balance between the financial investment required by simulation designs and settings and their impact on patient outcomes should be investigated further. Currently, the concept of high-value cost-conscious care (HVCC) has been introduced into the healthcare cost literature.[46] HVCC claims tests and treatments should have "high value", meaning high benefit and low harm, in order to be cost-effective and widely promoted. Exploring for such a balance should also be a goal to the simulation training research field, as well on exploring how simulation may contribute to the training of healthcare personnel for HVCC.[47]

Studies Strengths and Limitations

Among the strengths of our thesis, we highlight both the choice for the whole-task complex learning demands of our selected content, PPH, and the multiple practice opportunity provided by the three training scenarios organized in a simple-to-complex sequence. We believe they had a particularly relevant contribution to our verified positive findings on all different training effectiveness levels: learning outcomes, training transfer and patient outcomes. Our presented hybrid-simulation modality, as we combined a low technological, low-cost, part-task simulator with a simulated patient, allowed us to achieve multiple training outcomes – from communication to

procedural tasks and also contributed to training authenticity.[37] In addition, the easy reproducibility of the presented ID based training formats should also be pointed as a strength, in particular when considering the relevance of widely promoting healthcare simulation training for high-risk clinical conditions, such as PPH.[48,49]

Our acknowledged limitations for our reported studies may be associated to those inherent to the constraints of a doctoral dissertation, mostly related to time and funding. For instance, our studies aimed at a single content, PPH. In spite of its wide external validity to other high-risk situations, an ID based simulation training design with positive training effectiveness outcomes should be replicated for other contents, in particular, those with demands for complex learning, both from the field of OBGYN and/or related to other healthcare specialties.[31,50]

A single temporal sample of residents was included for the analysis of patient outcomes in a single center. Future studies should aim at a maximized impact analysis, including more residents in multiple centers, preferably through a stepped wedge cluster approach.[51] Such study type includes an initial period in which no clusters are exposed to the intervention with subsequent clusters' progressively randomized and included to either control or intervention groups. It is used for the evaluation of interventions delivered at the level of the cluster and allows for robust scientific evaluations to be sought from such multiple cluster strategy, allowing, therefore a wider observation of facts.

While our presented study explored self-perceived long-term transfer, a different exploration strategy of the simulation training transfer aspect should also be aimed for. For instance, other methodologies to explore preferably real-time-on-the-job transfer should be considered, such as developing strategies to adequately quantify and analyze such tasks execution would need to be developed.[43] Meanwhile our findings of low institutional feedback reinforce our previous recommendation to further explore how to embrace faculty awareness with regards to simulation training. In addition, measuring and reporting such on-the-job-tasks in the healthcare environment implies a further exploration of how to overcome operational and ethical impediments.[44]

Additional potential limitations were minimized and should in fact be considered as a study strength. For instance, the frequently observed seasonal influence in patient outcomes studies[52] was minimized once we collected our patient outcome data at the same time of the year, one year before and immediately after the training. Such an operational orchestration should be underscored as an additional effort contributing to evidence-based healthcare simulation body of knowledge.[27]

Implications for practice

A few tips on implications for practice may be derived from our findings and are presented in Box 1.

Box 1. Essential Implications for Practice Tips:

Use evidence-based ID guidelines for simulation training	
1	*Multiple scenarios* *Simple-to-complex sequence of scenarios* *Provide feedback and self-assessment opportunities*
2	*Prioritize whole-task learning content*
3	*Design simulation trainings for a multidisciplinary target-group*
4	*Promote faculty awareness with regards to the need of designing effective ID-based simulation*
5	*Promote institutional feedback routines to improve transfer*

Based on our presented findings we recommend designing healthcare simulation trainings carefully adopting evidence based ID guidelines. Multiple practices opportunities should always be provided while promoting clinical variation, simple-to-complex sequencing, and feedback with self-assessment opportunities.

Effective simulation training should always take into account the routine and non-routine aspects of the selected learning content and whole-task practice would provide such learning opportunities. Such precaution may be

especially relevant for complex high-risk situations, in particular those that are epidemiologically relevant such as PPH. As a first step, learning tasks should be well sought, therefore, preferably based on a carefully conducted needs assessment.

Designing simulation trainings for a multidisciplinary audience will contribute to a better transfer of learning. Reaching this goal implies, however, faculty awareness with regards to the benefits of effectively designed training strategies. They must be made aware of the contribution of simulation as an essential stage on the multitude of intertwined elements involved in promoting positive impact on patient outcomes. Not only the faculty, but the whole spectrum of the administrative hierarchy should be made aware of these benefits in order to also embrace and contribute to providing institutional feedback, which is an essential step in promoting better training transfer.

Promoting effective simulation training aimed at maximizing patient safety and improving patient outcomes has become particularly relevant in this current era of residency programs duty's restriction hours. These sets of recommendations should significantly contribute to reaching such patient outcomes improvement.

Take home message

The use of instructional design guidelines for PPH simulation training leads to simulation training effectiveness in terms of learning, transfer, and results. Therefore, in order to reach the ultimate goal of improving patient outcomes, simulation training must be designed to be effective and should thus be based on evidence-based instructional design guidelines.

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Summary

Chapter 1 consists of the thesis introduction, where we present the rationale that motivated our studies series. Simulation ubiquitous spread for the past decade was propelled by the ultimate goal of improving patient outcomes, while at the same time providing training opportunities for both novice and experienced personnel in a supervised "error safe" environment. However, more solid evidence with regards to its optimal training effectiveness is still being sought. Systematic reviews on simulation training effectiveness recommend the adoption of instructional design (ID) guidelines for designing such trainings. ID guidelines were developed with a basis on sound cognitive psychological theories of how people learn. They have a unique role in promoting complex learning, which is the integration and acquisition of knowledge, skills and attitudes along with the ability to properly coordinate the qualitatively different constituent skills. Two models summarize the steps described by the main ID guidelines: Merrill's First Principles of Instruction and the Four-Component Instructional Design model. According to the guidelines expressed in those models, effective instruction should contain authentic, relevant, and daily real-world problems, emphasize practice at different levels of complexity, and provide feedback and diminishing instructional support through training. Postpartum hemorrhage (PPH) was the selected content for our studies series due to both its wide ecological validity for other high-risk situations and its epidemiological relevance. PPH remains the leading cause of maternal mortality in the world, with most resulting deaths considered as preventable for being due to failures in teamwork, communication and management issues. When considering training effectiveness, the widely adopted Kirkpatrick training evaluation model describes four different levels: learners' satisfaction, learning outcomes, transfer from training to the workplace, and results. In our studies series, we aimed to explore the current use of ID guidelines by simulation training programs described in the literature and its impact on learning, transfer and patient outcomes (results).

In **Chapter 2**, we presented our analysis of the use of ID guidelines in simulation trainings for a high-risk situation, as described in the literature. We explored the adherence to such guidelines in PPH simulation training programs as described in articles that were retrieved from Pubmed, Eric, and Google Scholar between January 2007 and March 2017. Invited raters (N = 40) analyzed simulation training programs described in 32 articles, assessing their adherence to ID guidelines, based on Merrill's First Principles of Instruction, by using a 5-point Likert rating scale. This scale contained items related to key ID features categorized into five subscales: authenticity, activation of prior knowledge, demonstration, application, and integration/transfer. The articles were divided into subsets, which were distributed to the raters for analysis with a varying number of 7 to 10 reviewers per article subset. We then calculated the Likert-scale mean score, per subscale, and interrater reliability (IRR). We found a low level of adherence (< 3.00), with the IRR being excellent for the authenticity subscale, good-to-excellent for the integration/transfer subscale, fair-to-good for the activation of prior knowledge and application subscales, and poor for the demonstration subscale. In addition, we discussed the low level of adherence to evidence-based ID-guidelines in simulation training programs for high risk situations, such as PPH. We underscore the need to further promote faculty awareness with regards to the use of ID guidelines for simulation training in particular, when aiming to improve its effectiveness, especially, transfer of learning.

In **Chapter 3** we present a comparison between learning outcomes of two instructionally different PPH simulation training programs, one based on ID guidelines and the other on current best practices (BP). The presented pretest–post-test non-equivalent groups study was conducted among obstetrics and gynecology residents and included 13 teams; seven teams attended the ID based simulation and six the BP. Using a standardized task checklist, we compared the proportion of correctly executed tasks (post-test minus pretest). The presented "whole tasks" simulation trainings were planned to ideally manage a PPH condition and represent the core point of the subsequent studies. Our PPH ID-based simulation training adopted several elements from the four-component instructional design (4C/ID) model, with

overarching principles from other ID guidelines. As its first step, the problem was well designed – optimally managing PPH – and the reflection upon content relevance was promoted through a prior knowledge activation step with the OBGYN residents. As the following steps, the residents who attended the ID based PPH simulation training were exposed to well defined learning tasks, demonstration, variability of cases, increasing complexity, just-in-time information, supportive information, self-assessment, and debriefing sessions that promoted reflection on their own errors. Such a rich exposure to a variety of ID features aimed at promoting complex learning, a goal that was successfully reached. At post-test, the residents who attended the ID based PPH simulation training performed better (and were faster) in essential learning tasks and in specific subscales, results that reflect better development of cognitive schemata. In conclusion, in Chapter 3, we demonstrated that the use of simulation training for PPH based on evidence-based ID guidelines yielded better learning outcomes than did training based on best practice.

A long-term transfer analysis after such PPH simulation is presented in **Chapter 4**, where we show our qualitative study. Twelve OBGYN residents who attended one of the two PPH simulation trainings formats were interviewed using semi-structured interviews. In this Chapter, we also present the Baldwin and Ford (1988) training transfer model to explore such transfer. According to this model, three factors influence transfer: (1) trainee characteristics (the motivation to attend training, the perceived relevance of the training content, and self-confidence); (2) the training design (application of ID principles); and (3) the workplace environment (organizational feedback, team-work, and opportunity to use what has been learned). Our aim was to answer whether trainees perceived a long-term transfer effect two years after attending the simulation trainings. Using thematic analysis steps, we explored which training aspects trainees perceived as positively affecting this long-term transfer, which instructional design features facilitated and/or hindered long-term transfer, and whether there were differences in the participants' perceptions according to the type of simulation attended. We analyzed how the residents attending both training formats perceived positive long-term transfer two years after having attended simulation training for PPH. They acknowledge

PPH as a relevant training topic and reported being motivated to attend the simulations as a desire to improve professional skills and an increase in self-confidence after the training. Attendees of either simulation format reported the following ID elements as key contributors to transfer: authenticity, use of Paivio's dual-coding strategy (a combination of text and pictures that makes information easier to remember), and feedback during debriefing. Residents who participated in the ID-based simulation additionally mentioned variability and increasing complexity as ID elements contributing to transfer. Residents from both groups reported an increase in teamwork skills, but also appointed poor organizational feedback and team struggles with colleagues who had not attended the simulation. Residents who had attended the ID format perceived better transfer of communication and teamwork skills and higher situational awareness than those having attended the BP format. In conclusion, Chapter 4 presents how long-term transfer was perceived by the residents; however, a systematic approach to problem solving was perceived only by those who attended the ID based PPH simulation training. In addition, trainees who participated in the ID-based simulation perceived better communication skills and better overall situational awareness: "I didn't do that before." Such findings may reflect better long-term situational awareness – an ability to anticipate, recognize, and intercept unfolding error chains, a skill that is of extreme relevance in the adequate management of several high-risk clinical conditions, such as PPH.

In Chapter 5 we presented an uncontrolled before-and-after study that analyzed the impact on patient outcomes at a teaching hospital, after the OBGYN residents attended the ID-based PPH simulation training programme. Data from all women delivering at the maternity of this teaching hospital one year before the simulation were compared to those of all women delivering after the simulation was performed. To minimize seasonality biases, the same three months of the year (June to August) were used for the comparison. We described the contribution of well-defined patient outcome measures whose analysis went beyond single procedural outcomes as usually described in the literature. We presented a detailed analysis of specific and relevant PPH outcomes measures. Our main outcome measures were therapeutic

uterotonics usage rates within 24h of birth (TUW24h) and blood transfusion rates (BTR), while our secondary outcome measures included uterotonic use rates and dosages for each drug, postpartum Hb <6g/dL, B-Lynch suture, uterine artery embolization, hysterectomy, renal insufficiency, obstetric intensive care unit (ICU) admission, mechanical ventilation, length of hospital stay, near-miss maternal mortality and maternal death. The results presented in Chapter 5 correspond to 1388 women delivering in the analyzed months before the training and 1357 in the following year. The PPH rates were 100 cases (7.2% of deliveries) and 80 cases (5.9% of deliveries), respectively. No significant differences were found in the comparison between primary post- and pre-simulation outcomes, although an increase was identified in the therapeutic oxytocin mean dosage IU within 24h of birth. For all other outcome measures, there were no statistical differences. Such increased oxytocin mean dosage in fewer PPH patients may in fact reflect improved ongoing vigilance of the bleeding woman after simulation, since such dosages are administered on a progressive and continuous basis. The study presented in Chapter 5 included only OBGYN residents and was conducted in a single center. Future studies should not only include other specialties, aiming at the improvement of teamwork skills, but also be designed in a multicenter stepped-wedged approach (random and sequential crossover of clusters from control to intervention, until all clusters provide the simulation). Therefore, the verified increase in the therapeutic oxytocin mean dosage in fewer and selected PPH cases may indicate better situational awareness when managing women with PPH after an ID-based simulation training.

Chapter 6 is dedicated to the discussion of our thesis, where we present a summary of the findings of our studies series and reflect on their theoretical implications. We discuss our findings on the use of ID guidelines for simulation by previously published articles, which ranges from a concerning low adherence to such guidelines to a wide range of positive uses of ID guidelines for PPH simulation training. We also highlight our thesis strengths, such as the sound analysis of the Kirkpatrick training evaluation model levels, a detailed task analysis for desired learning outcomes, a long-term transfer analysis, and detailed patient outcomes measures. We also reflect upon a potential limitation,

in particular, the single center patient outcomes analysis. We recommend future studies including multiple centers in a stepped wedged approach and including multiple specialties for adequately training teamwork. We conclude our findings by reinforcing the recommendation from systematic reviews that ID guidelines must be used when designing simulation training. This PhD thesis also underscores the importance of improving faculty awareness with regards to this topic as an essential strategy for the improvement of patient outcomes through simulation training.

Samenvatting

Hoofdstuk 1 vormt de inleiding tot dit proefschrift en legt uit waarom de hier gepresenteerde onderzoeken zijn uitgevoerd. De afgelopen tien jaar hebben simulaties een hoge vlucht genomen in het medisch onderwijs. De oorzaak hiervan is het streven naar betere patientuitkomsten en de mogelijkheden die simulaties bieden om zowel beginnende als ervaren beroepsbeoefenaars te trainen in een gesuperviseerde, 'foutenvrije' omgeving. Hoe effectief simulaties zijn voor dergelijke trainingsdoeleinden is echter nog onvoldoende onderzocht. Systematische reviews van de effectiviteit van simulatietraining bevelen aan onderwijskundige ontwerprichtlijnen (Instructional Design of ID richtlijnen) te gebruiken bij het ontwerpen van deze trainingen. Zulke richtlijnen zijn ontwikkeld op basis van solide theorieën uit de cognitieve psychologie over de manier waarop mensen leren. Ze spelen een unieke rol bij het stimuleren van complex leren: de verwerving en integratie van kennis, vaardigheden en attitudes in combinatie met het vermogen de kwalitatief verschillende deelvaardigheden goed op elkaar af te stemmen. De stappen die onderdeel uitmaken van de voornaamste ID richtlijnen zijn samengevat in twee modellen: Merrill's First Principles of Instruction en het Four-Component Instructional Design (4C/ID) model. Volgens de in deze modellen beschreven richtlijnen heeft effectieve instructie de volgende elementen: er wordt gewerkt met authentieke, relevante en alledaagse problemen, er wordt geoefend op diverse complexiteitsniveaus, er wordt feedback gegeven, en de ondersteuning door opleiders wordt tijdens de training gaandeweg afgebouwd. Voor de hier beschreven onderzoeken richtten we ons op haemorrhagia post partum (HPP), aangezien deze aandoening een hoge ecologische validiteit heeft voor andere hoog risico-aandoeningen en vanwege de epidemiologische relevantie ervan. HPP is nog steeds de voornaamste oorzaak van moedersterfte wereldwijd. In de meeste gevallen had de fatale afloop vermeden kunnen worden, aangezien deze vaak veroorzaakt wordt door slechte samenwerking, communicatie en beleid. Voor

wat betreft de effectiviteit van training, geeft het algemeen geaccepteerde trainingsevaluatiemodel van Kirkpatrick vier niveaus aan: tevredenheid van leerders, leeruitkomsten, transfer van de trainingssituatie naar de werkvloer en resultaten. Voor dit proefschrift onderzochten we het gebruik van ID-richtlijnen bij simulatietrainingsprogramma's zoals beschreven in de literatuur en het effect ervan op leren, transfer en patientuitkomsten.

In **hoofdstuk 2** presenteren we onze analyse van het gebruik van ID-richtlijnen in simulatietrainingen voor hoog risico-situaties zoals beschreven in de literatuur. In artikelen gepubliceerd tussen januari 2007 en maart 2017 op Pubmed, Eric en Google Scholar gingen we na hoe zulke richtlijnen in HPP simulatietrainingsprogramma's opgevolgd worden. De door ons ingeschakelde beoordelaars (N = 40) analyseerden de simulatietrainingsprogramma's beschreven in 32 artikelen. Op basis van Merrill's First Principles of Instruction beoordeelden ze de mate waarin de ID-richtlijnen toegepast werden. Het oordeel werd uitgedrukt op een 5-punts Likertschaal. Deze schaal omvat items die betrekking hebben op fundamentele ID-kenmerken verdeeld over vijf subschalen: authenticiteit, activatie van reeds aanwezige kennis, demonstratie, toepassing en integratie/overdracht. De artikelen werden verdeeld in groepen die werden toegewezen aan de beoordelaars (zeven tot tien beoordelaars per groep). Daarna werden de gemiddelde score voor de gehele schaal, de gemiddelde scores per subschaal en de interbeoordelaarsbetrouwbaarheid (IRR) berekend. De mate waarin de programma's de richtlijnen opvolgen bleek laag te zijn (< 3,00), met een zeer goede IRR voor de subschaal authenticiteit, een goede tot zeer goede IRR voor de subschaal integratie/overdracht, een redelijk tot goede IRR voor de subschaal activatie van reeds aanwezige kennis en een slechte IRR voor de subschaal demonstratie. Verder bespreken we de geringe mate waarin de evidence-based ID-richtlijnen worden opgevolgd in simulatietrainingsprogramma's voor hoog risico-situaties zoals HPP. We benadrukken de noodzaak om opleiders meer bewust te maken van het gebruik van ID-richtlijnen, vooral bij simulatietrainingen, en met name om de effectiviteit van de overdracht van het geleerde te verbeteren.

In **hoofdstuk 3** presenteren we een vergelijking tussen leeruitkomsten van twee HPP-simulatietrainingsprogramma's, waarbij de ene gebaseerd was

op ID-richtlijnen en de andere op de huidige best practices (BP). Dit pretest-posttest niet-equivalente groepenonderzoek werd verricht onder arts-assistenten verloskunde en gynaecologie en omvatte 13 teams. Zeven teams volgden de ID-simulatie en zes de BP-simulatie. Met een gestandaardiseerde takenchecklist vergeleken we het percentage correct uitgevoerde taken (posttest min pretest). De gepresenteerde "gehele taken" simulatietrainingen waren gericht op een optimale behandeling van HPP en vertegenwoordigen de belangrijkste taakaspecten zoals geidentificeerd in eerdere onderzoeken. Onze op ID-richtlijnen gebaseerde HPP-training omvatte diverse elementen van het vier-componenten onderwijsontwerpmodel (4C/ID) en de voornaamste principes van andere ID-richtlijnen. Als eerste stap werd het probleem – optimale HPP-behandeling – goed gedefinieerd. In de volgende stap, waarin reeds aanwezige kennis geactiveerd werd, werden de arts-assistenten gestimuleerd te reflecteren op relevante aspecten. In de daaropvolgende stappen werden de arts-assistenten die deelnamen aan de ID-training geconfronteerd met goed gedefinieerde leertaken, hands-on demonstraties, een scala aan casussen van oplopende complexiteit, informatie die net op tijd beschikbaar komt, ondersteunende informatie, zelfbeoordeling en nabesprekingen om hen te stimuleren te reflecteren op hun fouten. Een dergelijke rijke confrontatie met veel ID-kenmerken heeft als doel complex leren te bevorderen. Dit doel werd bereikt. De arts-assistenten die de ID-training hadden gevolgd behaalden hogere scores op de posttest (en waren sneller) op realistische leertaken en op specifieke subschalen, hetgeen erop wijst dat hun cognitieve schemata beter ontwikkeld waren. Ten slotte laat hoofdstuk 3 zien dat het gebruik van een HPP-simulatietraining gebaseerd op evidence-based ID-richtlijnen betere leeruitkomsten oplevert dan een training gebaseerd op best practices.

In **hoofdstuk 4** wordt een kwalitatieve analyse gepresenteerd van langetermijntransfer na een dergelijke HPP-training. Twaalf arts-assistenten verloskunde en gynaecologie die een van de twee HPP-trainingen hadden gevolgd werden ondervraagd met behulp van semi-gestructureerde interviews. In dit hoofdstuk presenteren we ook het Training Transfer Model van Baldwin en Ford (1988) om de transfer van training te onderzoeken. Volgens dit model wordt transfer beïnvloed door drie factoren: (1) deelnemerskenmerken: motivatie om de training bij te wonen, veronderstelde

relevantie van de inhoud van de training en zelfvertrouwen; (2) ontwerp van de training: toepassing van ID-principes; en (3) werkomgeving: feedback vanuit de organisatie, teamwerk en mogelijkheden om het geleerde te gebruiken. Doel was om te zien of de deelnemers vonden dat langetermijntransfer had plaatsgevonden in de twee jaar na afloop van de HPP-training. Met behulp van thematische analysestappen onderzochten we welke aspecten van de training de deelnemers zagen als positieve bijdragen aan deze langetermijntransfer, welke onderwijskundige ontwerpkenmerken de transfer makkelijker of moeilijker maakten, en of de deelnemers aan de verschillende typen simulatie andere ervaringen hadden. We analyseerden wat de arts-assistenten die een van beide trainingen hadden gevolgd vonden van de langetermijntransfer twee jaar nadat ze deze hadden ondergaan. De deelnemers stelden dat HPP een relevant onderwerp is voor een training en dat ze gemotiveerd waren om de simulaties bij te wonen om zo hun professionele vaardigheden te verbeteren, en dat hun zelfvertrouwen was toegenomen na de training. De deelnemers vonden dat de volgende ID-kenmerken het meest bijdroegen aan transfer: authenticiteit, het gebruik van Paivio's dual-coding strategy (een combinatie van tekst en beelden die het makkelijker maakt informatie te onthouden) en feedback tijdens de nabespreking. De arts-assistenten die deelnamen aan de ID-training noemden ook variabiliteit en toenemende complexiteit als ID-elementen die bijdragen aan transfer. Arts-assistenten in beide groepen vonden dat hun samenwerkingsvaardigheden waren verbeterd, maar gaven ook aan dat de feedback vanuit de organisatie soms slecht was en dat er problemen waren met collega's in het team die de training niet hadden gevolgd. De communicatieve en samenwerkingsvaardigheden van degenen die de ID-training hadden gevolgd waren meer verbeterd en hun 'situational awareness' was hoger dan van degenen die de BP-training hadden gevolgd. Ten slotte laat hoofdstuk 4 zien hoe de arts-assistenten aankeken tegen de transfer op de lange termijn. Alleen degenen die de ID-training hadden gevolgd vonden dat ze een systematische aanpak om problemen op te lossen hadden geleerd. Bovendien vonden deze deelnemers dat ze betere communicatieve vaardigheden hadden en de klinische situatie beter konden overzien: "Dit deed ik vroeger niet." Dergelijke resultaten kunnen erop wijzen dat ze een betere en meeromvattende 'situational awareness' hebben: het vermogen om te anticiperen, situaties te herkennen en eerder in te grijpen

wanneer cumulatie van fouten dreigt. Het laatste is een vaardigheid die zeer belangrijk is om hoog-risico aandoeningen, waaronder HPP, te behandelen.

In **hoofdstuk 5** presenteren we een pretest-posttestestudie zonder controlegroep waarin we het effect van training op patientuitkomsten nagingen in een opleidingsziekenhuis waar de arts-assistenten verloskunde en gynaecologie hadden deelgenomen aan de ID-simulatietraining voor HPP. Gegevens van alle vrouwen die een jaar vóór de training op de kraamafdeling van dit ziekenhuis een baby ter wereld brachten werden vergeleken met gegevens van alle vrouwen die een jaar na de training bevielen. Om seizoensinvloeden te minimaliseren werden dezelfde drie maanden gebruikt (juni t/m augustus). We beschrijven het effect van de training op goed-gedefinieerde patientuitkomsten waarvan de analyse verder ging dan afzonderlijke procedureresultaten zoals gewoonlijk beschreven in de literatuur en presenteren een gedetailleerde analyse van specifieke en relevante HPP uitkomstmaten. De belangrijkste uitkomstmaten waren het therapeutisch gebruik van uterotonica in de eerste 24 uur na de geboorte (TUW24h) en de mate waarin bloedtransfusies gegeven werden (BTR). Onze secondaire uitkomstmaten waren onder andere de mate waarin uterotonica werden gegeven en de doses van elk middel, post-partum Hb lager dan 6 g/dL, toepassing van B-Lynch hechtingen, embolisatie van de a. uterina, uterusextirpatie, nierfalen, opname op de verloskundige Intensive Care-afdeling, mechanische ventilatie, opnameduur, bijna fatale afloop voor de moeder en dood van de moeder. De resultaten die in dit hoofdstuk gepresenteerd worden hebben betrekking op 1388 vrouwen die in een periode van drie maanden vóór de training een baby ter wereld brachten en 1357 vrouwen die in dezelfde periode van drie maanden in het jaar daarna een baby ter wereld brachten. Het aantal HPP-gevallen in beide groepen was respectievelijk 100 (7,2% van de bevallingen) en 80 (5,9%). Er werden geen significante verschillen in primaire uitkomstmaten gevonden in beide groepen. Wel werd een toename geconstateerd in de gemiddelde therapeutische oxytocinedosis toegediend binnen 24 uur na de bevalling. Voor alle andere uitkomstmaten werden geen statistische verschillen gevonden. Een dergelijke toegenomen gemiddelde oxytocinedosis bij minder HPP-patiënten kan wijzen op een meer intensieve bewaking van het bloedverlies na de simulatie, aangezien oxytocine progressief en continu wordt toegediend. Het onderzoek

dat in dit hoofdstuk wordt gepresenteerd, omvatte alleen arts-assistenten verloskunde en gynaecologie en werd in één ziekenhuis verricht. Nader onderzoek zou niet alleen andere specialismen moeten omvatten en zich moeten richten op de verbetering van samenwerkingsvaardigheden maar ook meerdere ziekenhuizen moeten omvatten en een 'stepped-wedge' ontwerp moeten hebben (gerandomiseerde en sequentiële uitwisseling van clusters van de controle- naar de interventiegroep, totdat alle clusters de simulatie aanbieden). Aldus kan de waargenomen toename van de gemiddelde dosis oxytocine bij minder en geselecteerde HPP-patiënten wijzen op een betere 'situational awareness' onder behandelaars van vrouwen met HPP na het volgen van een ID-simulatietraining.

In **hoofdstuk 6** worden de hier gepresenteerde studies samengevat en gaan we in op de theoretische implicaties van de resultaten. We bespreken onze bevindingen met het gebruik van ID-richtlijnen voor het ontwerpen van simulatietrainingen zoals beschreven in de literatuur, die uiteenlopen van een zorgwekkende veronachtzaming van dergelijke richtlijnen tot een scala aan manieren om ID-richtlijnen op positieve wijze te gebruiken voor HPP-simulatietrainingen. We geven ook de sterke punten van ons onderzoek weer, zoals de solide analyse van de niveaus van het Kirkpatrick trainingsevaluatiemodel, de gedetailleerde taakanalyse om te komen tot gewenste leeruitkomsten, de analyse van de langetermijntransfer en de gedetailleerde maatregelen ter verbetering van patientuitkomsten. We bespreken ook de mogelijke beperkingen, in het bijzonder het feit dat de patientuitkomsten van slechts een ziekenhuis zijn geanalyseerd. Nader onderzoek zal in meerdere ziekenhuizen moeten plaatsvinden, een 'stepped-wedge' onderzoeksontwerp moeten hebben en meerdere specialismen moeten omvatten om te komen tot een goede training van samen-werkingsvaardigheden. We eindigen met een herhaling van de aanbeveling die naar voren kwam uit de systematische reviews: dat bij het ontwerp van simulatie¬trainingen gebruik moet worden gemaakt van ID-richtlijnen. Dit proefschrift benadrukt ook hoe belangrijk het is om opleiders meer bewust te maken van dit thema, als een essentiële strategie voor het verbeteren van patientuitkomsten door middel van simulatie-trainingen.

Valorization

This Chapter meets the requirements of Article 22 of the Regulation Governing the Attainment of Doctoral Degrees on the inclusion of a valorization paragraph in all PhD dissertations at Maastricht University as of 1 September 2014. Knowledge valorization is the "process of creating value from knowledge by making knowledge suitable for translation into competitive products, services, processes and new commercial activities".

Relevance. The studies presented in this thesis demonstrate positive training outcomes of an instructional design based obstetrics simulation training. The practical implications of these findings may be found on several fronts – from responding to demands on continuous healthcare education to positive impacts on patient outcomes.

The need for evidence-based simulation training which makes good use of instructional design principles emanated from the high budget demands of this training strategy. After initial euphoria, simulation training needed to be optimized and its effectiveness needed to be soundly proved[1]. This thesis may then contribute to this aim by presenting an effective simulation training format that can be potentially applied to multiple different training contents.

The presented studies explored the outcomes of instructional design based simulation training and the selected training content was postpartum hemorrhage (PPH), the leading cause of maternal deaths worldwide[2]. Maternal mortality rates remain unacceptably high, despite the verified global improvement over the past decades, especially because the majority of cases are considered preventable. Management failures frequently associated with high mortality rates are described as miscommunications, teamwork malfunction, and lack of situational awareness[3,4]. Therefore, the positive training outcomes of the explored simulation training may span across several domains beyond PPH clinical management itself.

This thesis aimed to contribute to demands from the international scientific community within a global perspective. However, presenting the

local context at which the studies were conducted may further contribute to reflections upon their relevance. The studies were conducted in the city of Recife, located in the Northeast region of Brazil, a middle-income country. The Northeast region holds 30% of the Brazilian population and accounts for 13% of Brazil's GDP. Its wide socio-economical inequalities lead to healthcare assistance challenges varying from those encountered by high-income countries to those from low-income countries. In spite of improvements on maternal mortality rates, women still die at high rates worldwide, but foremost in low-and-middle-income countries (LMIC).

Brazilian healthcare coverage is free and universal since the creation of Brazil's Sistema Único de Saúde (SUS) by the 1988 Brazilian Constitution. Along with healthcare assistance among SUS attributions lays the planning and provision of healthcare professionals continuous education[5]. Therefore, healthcare policy makers and healthcare community are continuously in search for effective healthcare personnel training and the findings from this thesis may be largely welcomed in benefit of maternal healthcare assistance.

In addition to the challenges encountered by maternal healthcare professionals worldwide, those in LMIC face a daily stressful routine of work overload and personnel shortage. Such reality leads to undesirable neglect to quality assistance and patient safety compromise. However, improving patient safety and quality of care may be achieved through effective personnel training and does not necessarily demand prohibitively expensive investments. By providing effective simulation training, a positive impact may be perceived in several key perspectives: from avoiding patient harm in its individual consequences and societal economical burden to introducing a safe learning environment and a culture in which errors are viewed as an opportunity for learning[6].

Effective strategies contributing to the reduction of maternal mortality benefit society as a whole. In societies economically still under development and with fragile institutions, the absence of a mother brings even further significant compromise to the offspring in various different aspects (vaccination rates completion, neurocognitive development and academic outcomes)[2]. As long as the goal of safe pregnancy and childbirth for all women and all

girls in all countries is still not reached, research and innovation are essential ingredients for success[7]. Therefore, providing effective evidence based postpartum hemorrhage simulation training may significantly contribute to improve our current prospect.

Target groups. Our findings on effective evidence-based simulation training using instructional design principles may benefit healthcare professionals who are in constant need of updating their knowledge, skills and overall competencies. Healthcare professionals are constantly facing changes in an evolving society, from technological advances to interpersonal interactions. Their continuous demands for complex learning and proper integration of a wide range of training contents may find an effective response strategy in simulation training. In addition, such training strategy may also contribute to their need to self-regulate the deep foundations of the psychological sciences of clinical reasoning[8,9].

Overall, healthcare policy makers and stakeholders may also benefit from our presented findings. For those in charge of providing strategies for healthcare professionals to succeed in their continuous search for up-to- date knowledge and skills becoming aware of effective simulation training designs that are easily applicable and reproducible is a helping hand.

Activities/Products/Schedule & Implementation. As previously described, the studies reported in this thesis were conducted in Recife, a city located in the impoverished Northeast region of Brazil. Therefore, it represents a large potential to contribute to the local healthcare system. Our aim is to offer instructional design based simulation trainings in a wide range of contents to healthcare professionals across clinical disciplines.

As a first step, the presented PPH training will be replicated at the Maternity where the studies were conducted, Instituto de Medicina Integral Prof. Fernando Figueira (IMIP), to incoming residents and healthcare teams. Then, the training will be amplified to other epidemiological relevant contents such as eclampsia and sepsis. In sequence, it should be further offered to other healthcare professionals and residents from other disciplines, to further promote teamwork interactions. Later, rare-event contents will be also incorporated and offered as simulation training for the multidisciplinary healthcare teams.

In a longer-term perspective, the plan is to offer effective simulation training to healthcare professionals outside the institution. A simulation training and innovation research center is currently being planned and developed to accommodate training routine to a wider audience through an agreement with healthcare policy makers. The schedule for inauguration is predicted for late 2019.

Innovation. The simulation training format explored in the reported studies provided opportunity for repetitive practice through a variation of multiple clinical scenarios presented in a simple-to-complex sequence. Multiple debriefing opportunities were also provided. Such design led to significant positive learning outcomes, long-term transfer and a positive impact on patient outcomes. These findings and design represent a long-awaited innovation at the current frontier of knowledge in healthcare simulation training research and their benefits were soundly demonstrated[10,11].

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Curriculum Vitae

Brena Melo was born in Santa Barbara, California, USA, in 1977 to a Brazilian couple of PhD students from the University of California. The family returned to Recife, Brazil, before her third birthday. When she was nine years old, the family spent one year in Boston when her parents were admitted to the Massachusetts Institute of Technology (MIT), her father as a Fulbright fellow and mother as special graduate student. The children attended Lawrence School, an award-winning public elementary school in USA. This set of experiences exposed Brena to an environment of excellent educational standards in which knowledge, arts, sports, science and research were enormously prioritized. Still abroad, her little sister broke her arm at school and was admitted to Boston Children's Hospital. Once again, the exposure to an institution of excellence made a life-long impression and awakened her passion for the dynamics of a hospital.

Back to Brazil, after concluding her school years, Brena was admitted to the Universidade Federal de Pernambuco (UFPE) where she graduated from Medical School, in 2001. In the following year she was admitted at the Instituto de Medicina Integral Prof. Fernando Figueira (IMIP) for Obstetrics & Gynecology residency. After concluding this first residency, she decided to widen her clinical scope by attending General Surgery residency at the Serviço de Cirurgia Geral e Transplante Hepático at the Universidade de Pernambuco (UPE) a reference unit in quality of care. After this second residency, she returned to IMIP for her master's degree in Maternal and Child Health in which she studied postpartum outcome in women with preeclampsia according to their uterine artery Doppler. At the same time, she started to work at the Obstetrics Intensive Care Unit and as residency supervisor at the High-Risk Obstetric Ward at the same institution. She also worked at the delivery room of other High-Risk Obstetrics Maternities in the state of Pernambuco: Centro Integrado de Saúde Amaury de Medeiros (CISAM), Hospital Agamenon Magalhães (HAM) and Hospital da Clínicas (HC).

At all these workplaces she was constantly exposed to the daily struggle of the obstetrics assistance typical to low-middle income countries, with constant patient overload and personnel shortage. However, the passion for teaching, sharing and discussing knowledge with peers, residents and students was a constant stimulus to continue her journey as a scholar.

In 2009, Brena spent one month as an observer at St George's Hospital Fetal Medicine Unit exploring partnerships possibilities with IMIP. Her awareness of a standard of excellence in education drove her search and was aligned with IMIP's institutional culture. In her way back home, she was consulted upon her interest in studying medical education at Maastricht University (UM) as result of a partnership between IMIP, its medical school, Faculdade Pernambucana de Saúde (FPS), and the School of Health Professions Education (SHE), at UM, The Netherlands. The opportunity to attend a school of academic excellence was promptly celebrated and the challenge to unveil a new academic field happily accepted. At SHE, she became passionate with instructional design guidelines and its potential practical application in simulation training. She was trained as a scholar and looks forward to locally applying her acquired skills in the training of healthcare professionals.

Brena lives in Recife, Brazil, with her husband, Juliano, and their six years old son, Bernardo.

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