

Validation of two clinical scenarios for simulation-based learning for the prevention and control of healthcare-associated infections

Validação de dois cenários de simulação clínica para ensino de prevenção e controle de infecções relacionadas à assistência à saúde

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ABSTRACT

Objective: to validate clinical scenarios for simulation-based learning on the prevention and control of healthcare-associated infections. **Methods:** a methodological study of elaboration, content validation of two simulated clinical scenarios, and evaluation of the simulation design. Specialists (n=10) analyzed the scope, clarity, and relevance of the scenarios, and 44 undergraduate nurses evaluated the design using the Simulation Design Scale. Descriptive statistics, Content Validity Index, and Content Validity Ratio were used for analysis. **Results:** the items in the scenario presented a content validity index ≥ 0.8 and a content validity ratio predominantly ≥ 0.8 . The scale presented an average of 4.7 ± 0.2 , indicating the adequacy of the scenarios by the participants of the simulation. **Conclusion:** the validation allowed the achievement of adequate quality of the proposed scenarios, which can be widely used for teaching infection prevention and control.

Descriptors: Infection Control; Simulation Training; Validation Study; Health Education; Nursing.

* Extracted from the Thesis: Clinical simulation as a teaching strategy for healthcare-associated infection prevention and control measures, defended in 2019 at the Federal University of São Carlos, São Carlos, São Paulo, Brazil.

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RESUMO

Objetivo: validar cenários clínicos para o ensino baseado em simulação sobre prevenção e controle de infecções relacionadas à assistência à saúde. **Métodos:** estudo metodológico de elaboração, validação de conteúdo de dois cenários clínicos simulados e avaliação do *design* da simulação. Especialistas (n=10) analisaram abrangência, clareza e pertinência dos cenários, e 44 graduandos de enfermagem avaliaram o *design*, utilizando a Escala do *Design* da Simulação. Para análise utilizou-se procedimentos de estatística descritiva, Índice de Validade de Conteúdo e Razão de Validade de Conteúdo. **Resultados:** os itens do cenário apresentaram índice de validade de conteúdo $\geq 0,8$ e razão de validade de conteúdo predominantemente $\geq 0,8$. A escala apresentou média de $4,7 \pm 0,2$, indicando adequação dos cenários pelos participantes da simulação. **Conclusão:** a validação permitiu alcance de adequada qualidade dos cenários propostos, os quais podem ser amplamente utilizados para o ensino de medidas de prevenção e controle de infecção.

Descritores: Controle de Infecções; Treinamento por Simulação; Estudo de Validação; Educação em Saúde; Enfermagem.

INTRODUCTION

Healthcare-associated infections (HAI) are infections acquired and related to health care in any environment where it is provided⁽¹⁾. Among the HAI prevention measures, standard (PP) and specific (SP) precautions are the basis for the implementation of safe health care⁽²⁾.

The dissemination of HAI prevention and control measures has been recurrent in publications by renowned national and international bodies and associations. Even though these measures are well-defined and widely known, the adherence of health professionals is still sub-optimal⁽²⁻⁴⁾. Thus, it is necessary to rethink nursing education in the prevention and control of infection, in order to develop essential competencies in this area during their academic training⁽⁵⁾.

Among the educational strategies aimed at the development of competencies, the World Health Organization (WHO) recommends the use of simulation at different levels of fidelity in nursing education⁽⁶⁾.

The clinical simulation consists of an active teaching-learning strategy that reproduces real-world situations and helps the learner to consolidate knowledge, develop technical and relational skills, and create habits of reflection in a safe environment for them, for facilitators and/or teachers, and for patients^(6,7).

Several areas present positive results on the use of simulation in the development of nursing competencies, such as patient assessment, home birth care, cardiorespiratory resuscitation, care for disaster victims, palliative care, communication with end-of-life patients, critical patient care, and teamwork⁽⁶⁾.

A literature review⁽⁸⁾ investigated the use of simulation as an educational strategy in the area of HAI prevention and control. In this review, 27 publications were identified, in which the themes of the scenarios used included hand hygiene, infection prevention and control in suspected cases of Ebola and severe acute respiratory syndrome (SARS), prevention of central venous catheter-associated bloodstream infection, prevention of urinary tract infection, prevention of

ventilation-associated pneumonia, and prevention of surgical site infection. None of the publications included in the review presented information on the process of building these scenarios.

In Brazil, two studies detail the construction of simulated scenarios in the area of HAI prevention and control, one on the prevention of infections associated with peripheral catheters⁽⁹⁾ and the other on sepsis⁽¹⁰⁾.

Thus, in order to expand the supply of materials of this nature, the present study was developed seeking to validate clinical scenarios for simulation-based learning on HAI prevention and control.

METHODS

This is a methodological study of construction (Step 1), validation of simulated scenarios (Step 2), and evaluation of the simulation design (Step 3). The study was carried out from December 2017 to June 2018, at a Brazilian public university, in the interior of the state of Minas Gerais, Brazil.

Step 1 consisted of building two scenarios for clinical simulation, using the National League Nursing Jeffries Simulation Theory (NLN/JST)⁽¹¹⁾, the recommendations of the International Nursing Association for Clinical Simulation Learning (INACSL) as a theoretical framework, and Standards of Best Practices: Simulation⁽⁷⁾, by the *Agência Nacional de Vigilância Sanitária* (ANVISA)⁽⁴⁾ and Centers for Disease Control and Prevention⁽²⁾.

For the 'Context', the definition of the location of the simulation (skills and simulation laboratory of the educational institution) and the indication of the purpose of the scenarios (academic training) were considered. For the 'Background', the theoretical perspective of experiential learning, the mixed modality of simulation with the provision of standardized participants, the preparation of participants, and the necessary didactic resources, as well as the time allocated to each stage of the clinical simulation, were considered.

The conceptual component 'Design' contemplated the specific learning objectives, the physical and conceptual elements of fidelity, the simulation sequence (from briefing to debriefing), the progression of activities, the detailing of the facilitator's roles, of the standardized participants (teacher and companion), and learners (both volunteer participants and observers), and feedback in the form of "tips". Although the prebriefing is not part of the NLN/JST proposal, it was included, following INACSL's recommendations⁽⁷⁾.

The conceptual component 'Experience in simulation' included provisions for maintaining psychological fidelity (confidentiality between facilitator and participant), to achieve an experimental, collaborative, and learning-centered environment. The conceptual component 'Facilitator and Educational Strategy' emphasized the importance of the facilitator in responding to the demands of the participants, adjusting, for this, the educational strategies in progress.

The conceptual component 'Participant' exposed the innate attributes (age, gender, anxiety level, self-confidence) and the modifiable attributes (preparation for the simulation) that need to be considered by the facilitator, at all stages of the simulation. Finally, the conceptual component 'Results' presented the expected outcomes in relation to the simulation and the participants, namely satisfaction and self-confidence towards learning, knowledge gain, skills and attitudes development, behavior/performance changes, and the possibility of transferring learning to the real clinical environment⁽¹¹⁾.

Step 2 consisted of content validation of the simulated scenarios, to which 25 nurses were invited, selected for convenience, by consulting the curriculum of researchers registered in the Lattes Platform of the National Council for Scientific and Technological Development (CNPq), using the available filters. The criteria used for the selection of specialists were experience in simulation and/or control of HAI for more than two years and participation in events, research, and publications in the respective thematic areas. Those who did not submit the analysis of the scenarios within the stipulated time (30 days) were excluded. The number of participants considered for carrying out the content validation was based on the recommendation of composing a group of at least five to ten expert judges in the area of the instrument⁽¹²⁾.

An invitation letter was sent to the expert judges, by email, containing information about the research (objectives and relevance of the concepts involved), the criteria for their appointment as judge, and a link, generated by the Google Forms® platform, to access the electronic survey form. If there is an agreement to participate, the judge should access the link sent, read the Informed Consent Term (ICF) and 'accept'. From then on, he accessed the participant's professional characterization questionnaire and specific instructions on

the procedure for judging content validity and the instrument itself.

In order to ensure that all essential elements of the scenarios were covered, the Scenario Validation Checklist⁽¹³⁾ was used. The clinical scenarios were organized and presented to the specialists as follows: I – Overview of the Scenario, II – Preparation of participants and teaching resources, III – Learning Objectives, IV – Expected Results, and V – Scenario Design.

The experts rated the content of the simulated clinical scenarios items for clarity, relevance, and comprehensiveness, on a 4-point Likert scale, ranging from (1) unclear/relevant/comprehensive to (4) clear/relevant/comprehensive. There was a space at the end of each item for the inclusion of suggestions for changes and/or wording adjustments⁽¹²⁾.

After the adjustments suggested by the specialists, according to the recommendations for studies of this nature⁽⁷⁾, the scenarios were submitted to a pilot test with the target audience, consisting of four undergraduate nursing students in the same place where the next stage of the study would be carried out. Standardized participants were previously trained to perform their roles, as recommended⁽¹⁴⁾.

The pilot test and the application of the scenario were carried out in a room of the skills and simulation laboratory of the institution where the study was developed, where the available infrastructure is still below what is necessary for this type of pedagogical activity.

Stage 3 of the study consisted of evaluating the design through the application of clinical scenarios. Through e-mail and posters available in the common spaces of the university, nursing students enrolled from the fifth to the ninth periods of the course, that is, in the intermediate or final stages of graduation, were invited. Interested students were consulted about the date and time available for scheduling their participation, which would take place in two moments. As an inclusion criterion, they should have attended the subjects in which the contents relevant to the simulated clinical scenarios were addressed. Students who did not participate in all proposed activities were excluded.

At first, the participants filled out a characterization instrument (age, gender, graduation period, participation in previous simulations, participation in courses, workshops, and symposia on HAI). Subsequently, they participated in a dialogic expository class to level their knowledge of HAIs and prepare for participation in the scenario, as provided for in the validated material.

The second moment consisted of the execution of the clinical scenario, with groups of up to ten students, divided into volunteer participants (two students acted in the scene) and observer participants (up to eight students observed the execution of the scene). A script was not used as an observation guide so that there was no influence on the debriefing

session, which was conducted with both groups (volunteer participants and observers). The number of observers ranged from two to eight participants. At the end of the activity, all responded to the Simulation Design Scale (SDS)⁽¹⁵⁾.

The SDS aims to identify elements that need to be adjusted and/or improved in the design and implementation of the simulation from the point of view of the participants in the simulated experience. The scale is self-administered and contains 20 items organized into five factors: Objectives and information; Support; Problem-solving; Feedback/reflection and Realism. Each item is scored on a five-point Likert scale, ranging from strongly disagree (1) to strongly agree (5). There is also an option (not applicable) that should be checked when the statement did not refer to the simulated activity performed. The higher the average obtained, the better the students' assessment of the elements of the clinical scenario in which they participated⁽¹⁵⁾. This scale was chosen because it is widely used in national studies in samples with nurses and nursing students. Among nurses, it presented adequate results for reliability and validity, while among nursing students, the analysis of internal consistency in different studies showed Cronbach's alpha from 0.89 to 0.93⁽¹⁵⁻¹⁷⁾.

Content validation data were analyzed by calculating the Content Validity Index (CVI) and the Content Validity Ratio (CVR). The CVI of each item evaluated was obtained from the sum of responses (3) and (4) and subsequent division by the total number of responses, and the item was considered validated if CVI resulted in values ≥ 0.80 ⁽¹²⁾. The CRV compares the CVI ratio to an expected number if the experts were responding at random. The CVR value range between -1 and 1, and with the participation of 10 specialists, in this study, a minimum CVR of 0.62 was prospect⁽¹⁸⁾.

The SDS data were double-entered, processed, and analyzed in the Statistical Package for the Social Sciences (version 20.0, SPSS, Chicago, Illinois, USA). A descriptive analysis was carried out (frequency and measures of central tendency and dispersion), the internal consistency was calculated using Cronbach's Alpha (α) of the scale and its factors, the simple Student's t test to compare the means of the scale score with the participants' characterization data, and Pearson's correlation to verify the relationship between the scale scores and the age of the participants. P values < 0.05 were considered statistically significant.

The study was approved by the Research Ethics Committee of the Universidade Federal de São João del-Rei (No. 2,299,159). The participants, specialists, and students formally registered their consent to participate in the study after reading the informed consent. All recommendations and ethical principles in research involving human beings, provided for in Resolution 466/2012, were respected.

RESULTS

The clinical scenarios constructed were about standard precautionary (PP) and specific precaution (SP) measures in general, associated with HAI prevention measures by topography. Thus, the first scenario comprised SP associated with bloodstream infection (BSI) prevention and urinary tract infection prevention measures (Scenario A). In turn, the second scenario covered PP and SP (contact precaution) associated with ICS prevention measures (Scenario B).

The selected simulation modality was the mixed one, using standardized participants and mannequins, of low fidelity and low/medium complexity since the scenarios envisaged the clinical reasoning of the prevention and control measures of HAI for patients in clinical situations in a safe environment and not the execution of the techniques.

As the scenario was built, taking into account the physical facilities available at the institution, it had already been planned to set up a simple ward, with materials, equipment, and low-cost (and low-fidelity) simulators, envisioning the ease of replicating the scenario, in different realities, without compromising the complexity of the simulation. These precautions were intended to ensure the greatest environmental (or physical) fidelity of the scenario.

As for psychological fidelity, two standardized participants were inserted so that they could replicate the clinical practice environment, with the participation of a professor and a member of the patient's family (simulator) represented in the scenario, thus using the mixed simulation. The role of the family member was foreseen to enable communication about the patient's health status (simulator) with the other participants in the scenario since the low-fidelity simulator cannot communicate. The option for inserting the role of the teacher in the scenarios was so that the student, already accustomed to the systematic monitoring of the teacher and/or preceptor, during the performance of technical nursing procedures, really felt in the occupied position, when in activity.

Regarding the content validation stage, of the 25 experts invited, 19 expressed interest in participating, and only 10 returned to the analysis within the established time. Most specialists were female (n=9; 90%), aged between 30 and 40 years (n=8; 8%), nursing graduates between 2006 and 2010 (n=5; 50%), and who had six to 15 years of professional experience (n=7; 70%). As for the highest degree mentioned, five had a doctorate (50%) and four had a master's degree (40%). Regarding professional performance, five worked in higher education teaching, five in the Skills and Simulation Laboratory; two in the Infection Control Service, and one in care practice. It is noteworthy that in this item the specialist could mark more than one answer option.

The CVI analysis of the items showed results ≥ 0.80 , regarding their clarity and relevance for most items, and, regarding the scope, the CVI was ≥ 0.90 , in both scenarios.

In the CRV analysis, some items and sub-items were slightly below the minimum reference value (0.62), as shown in Table 1.

Table 1. Content validity index and content validity ratio, according to the items and sub-items of the simulated scenarios, regarding clarity, relevance, and scope, Divinópolis, MG, Brazil, 2018 (n=10)

Scenario items	Scenario A						Scenario B					
	Clarity		Relevance		Scope		Clarity		Relevance		Scope	
	CVI	CVR	CVI	CVR	CVI	CVR	CVI	CVR	CVI	CVR	CVI	CVR
I - Scenario overview	0.9	0.8	0.9	0.8	0.9	0.8	0.9	0.8	0.9	0.8	0.9	0.8
II - Preparation of participants and teaching resources	0.8	0.6*	0.9	0.8	0.9	0.8	0.9	0.8	0.9	0.8	0.9	0.8
III - Specific learning objectives	0.8	0.6*	0.9	0.8	0.9	0.8	0.9	0.8	0.9	0.8	0.9	0.8
IV - Expected results	0.9	0.8	0.9	0.8	0.9	0.8	0.8	0.6*	0.9	0.8	0.9	0.8
V - Scenario design					0.9	0.8					0.9	0.8
Evaluation	0.9	0.8	0.9	0.8			0.9	0.8	0.9	0.8		
Prebriefing	1	1	1	1			1	1	1	1		
Participants and team	0.9	0.8	0.8	0.6*			0.9	0.8	0.8	0.6*		
Materials, equipment, and simulators	1	1	1	1			1	1	1	1		
Characterization and itineraries	1	1	1	1			1	1	1	1		
Environment and physical space	1	1	1	1			1	1	1	1		
Briefing	0.9	0.8	0.9	0.8			0.8	0.6*	0.8	0.6*		
Scenario development	1	1	0.8	1			0.9	0.8	0.8	0.6*		
Verification list	0.9	0.8	0.8	0.6			0.9	0.8	0.9	0.8		
Debriefing	1	1	1	1			1	1	1	1		

Note: CVI: Content Validity Index; CRV: Content Validity Ratio; * CRV lower than the minimum expected (0.62)

In items with a CRV lower than the reference value (<0.62), the main changes made, based on the judges' suggestions, were terminological adjustments, spelling corrections, use of synonyms, and text detailing. Adaptation of the learning objectives, greater detail in the description of the role of the facilitator, and standardized participants (companion and teacher) were also carried out, as well as the inclusion of some PP measures (hand hygiene, use of gloves) in the checklist.

The items from scenarios A and B, after adjustments, are shown in Figure 1.

Figure 1 does not include the standardized script for participants, the checklist, and the development of scenarios. Figures 2 and 3 present the progression of scenarios A and B, respectively, after the considerations made by the experts.

The final version of the clinical scenario was applied to undergraduate nursing students. For that, some adaptations

were required, such as the delimitation of physical spaces (bedroom, nursing station, purge, and observation room), using adhesive tape; the occupation of the space destined to the scenario, simultaneously, by the team and participants; and performing the debriefing in the same location as the simulation. In addition, it was necessary to use a camcorder with a tripod to record the simulations.

Of the 114 students who met the inclusion criteria, only 44 (38.6%) completed all the proposed activities.

The leveling and preparation activity of these participants was repeated six times, with an average frequency of eight students per session, respecting their availability. The clinical scenario was reproduced seven times, with an average frequency of six students at a time.

Participants were on average 22 years old (± 1.7), most were female (77.3%), attending the fifth to seventh semesters

Figure 1. Scenarios A and B, after the considerations made by the experts, Divinópolis, MG, 2018

(continue)

SUBJECT: Measures to prevent and control infections related to healthcare	
Scenario A	Scenario B
Name: HAI prevention and control measures for adult patients using invasive devices in a hospital inpatient unit.	Name: Infection prevention and control measures for hospitalized patients in contact SP.
Target audience: nursing students from the 5th to the 9th period	
Location for simulation: Infirmary of the Skills and Simulation Laboratory Debriefing Location: Classroom	
Purpose of the simulation: educational	
Time:	
Scenario A	Scenario B
Prebriefing = 5 minutes	Briefing = 5 minutes
Simulation =15 minutes	Debriefing = 30 minutes
Modality: Mixed simulation (scenic simulation and dummy-based simulation)	
Competencies previously required for participation:	
Scenario A - Peripheral catheter installation, preparation, and administration of drugs and intravenous fluids; - Care with the indwelling urinary catheter (indication, insertion technique, and handling); - Measures for the prevention and control of HAIs (chain of transmission of microorganisms and measures to break the links of transmission; measures of PP, aseptic technique and antisepsis, measures to prevent infection associated with invasive devices, aiming at the protection of the professional and the patient)	Scenario B - Measurement of vital signs; - Installation of a peripheral catheter, preparation, and administration of drugs and intravenous fluids; - Measures for the prevention and control of HAIs (chain of transmission of microorganisms and measures to break the links of transmission; measures of PP and SP, aseptic and antisepsis technique, measures to prevent infection associated with invasive devices, aiming at the protection of the professional and of the patient)
Didactic strategy: expository-dialogued class on HAI prevention and control measures in hospital care, studies in small groups with the discussion of clinical cases.	
SPECIFIC LEARNING OBJECTIVES:	
Scenario A Develop clinical reasoning and implement HAI prevention measures for hospitalized adult patients undergoing invasive procedures; Identify and apply standard precautionary measures (HH, use of PPE, waste management, environmental control, sharps); Identify and apply care in the handling and maintenance of peripheral venous catheters, aiming to prevent infection; Identify and apply care in the maintenance and handling of a urinary catheter, aiming to prevent infection.	Scenario B Develop clinical reasoning and implement HAI prevention and control measures for adult patients hospitalized in SP; Identify and perform HH at the relevant times; Identify and implement the use of gloves and an apron for precautionary measures of contact with multidrug-resistant microorganisms; Guide the patient and family on the measures that should be adopted to minimize the cross-transmission of microorganisms; Identify and implement measures to prevent and control bloodstream infection associated with a peripheral catheter in medication administration.
EXPECTED RESULTS - At the end of the activity, learners are expected to be able to:	
Scenario A Evidence knowledge gain on HAI prevention and control measures; Recognize and implement HAI prevention and control actions for patients using peripheral catheters; Recognize and implement HAI prevention and control actions for patients with bladder catheterization; Understand the relevance of HAI prevention and control measures; Recognize the responsibility of the health professional for HAI prevention and control measures; Feel satisfied and self-confident with learning about HAI prevention and control measures.	Scenario B Evidence knowledge gain on HAI prevention and control measures; Recognize and implement precautionary measures by contact with patients with multidrug-resistant microorganisms in clinical practice environments; Recognize and implement HAI prevention and control actions for patients using a peripheral catheter in contact precautions in clinical practice environments; Understand the relevance of HAI prevention and control measures; Recognize the responsibility of the health professional about HAI prevention and control measures for patients in SP; Develop clinical reasoning skills and the ability to organize work, aiming to adopt HAI prevention and control measures; Feel satisfied and self-confident with learning about HAI prevention and control measures.

Figure 1. Scenarios A and B, after the considerations made by the experts, Divinópolis, MG, 2018 (continuation)

DESIGN					
<p>a) Assessment methods Formative assessment through the measurement of knowledge about HAI prevention and control measures and participation in the debriefing; Assessment of the performance of learners who actively participate in the simulation; Assessment of student satisfaction and self-confidence.</p>					
<p>b) Prebriefing (facilitator) Identification of participants' expectations with the simulation; Information on the general objective of this simulation; Information on the sequence of sessions (briefing, scenario execution, and debriefing); Information about the simulation modality – mixed simulation – which will use a simulator and two standardized participants (companion and teacher); Guidance on the roles of facilitator, standardized participants, and learners (...); Establishment of the fiction contract: "Try to insert yourself in the context of the development of professional performance, as if you were in practice. This is a safe environment, in which you can express your opinions and decisions, but, for this, external participation mustn't occur so that they can maximize the opportunity to develop professional skills. However, to be successful in this teaching strategy, they must understand and respect the limits of the structure of the place of this activity."; Recognition of the scenario: "This scenario represents an Infirmary (room, nursing station, and purge) with the patient's chart, medications, supplies, medical and hospital equipment, among other materials necessary for patient care. You must recognize all the details to facilitate the service. As such, you should explore the landscape and available resources."</p>					
<p>c) Participants and simulation team Participants: 02 undergraduate nursing students (participants) 08 undergraduate nursing students (observers) Team: 01 Facilitator (main researcher) 01 Standardized Participant - Teacher who will accompany the Practice 01 Standardized Participant - Patient Companion</p>					
<p>d) Materials, equipment, and simulators</p> <table border="1"> <thead> <tr> <th>Scenario A</th> <th>Scenario B</th> </tr> </thead> <tbody> <tr> <td> <p>Materials and equipment Saline solution, equipment, identification label, serum holder, cotton, alcohol, alcoholic product, liquid soap, paper towel, individual collection container, bladder catheter, closed sterile collector, adhesive tape, stethoscope, tray, gauze, syringe, needle, saline solution 10 or 20 ml, saline solution 500 ml, thermometer, sphygmomanometer, tray, flexible intravenous device, sterile cover, glove, glasses, mask, wall clock. Patient's chart with the forms: admission, medical prescription, nursing prescription, diuresis control, and nursing notes. Simulator: Low-fidelity full-body simulator.</p> </td> <td> <p>Materials and equipment Saline solution, IV set, identification label, serum holder, cotton, alcohol, alcohol gel, liquid soap, paper towel, tray, syringe, needle, dipyrone, saline solution 10 or 20 ml, gauze, macronebulization mask, tape crepe, stethoscope, thermometer, sphygmomanometer, tray, flexible intravenous device, disposable apron, sterile cover, diaper, nightgown, trash cans, bag for common and infectious garbage, container for disposal of sharps, clock at 7:45 am. Patient's chart with the forms: admission, medical prescription, nursing prescription, nursing notes, blood count, catheter tip culture result, SP identification plates. Simulator: Low-fidelity full-body simulator.</p> </td> </tr> </tbody> </table>		Scenario A	Scenario B	<p>Materials and equipment Saline solution, equipment, identification label, serum holder, cotton, alcohol, alcoholic product, liquid soap, paper towel, individual collection container, bladder catheter, closed sterile collector, adhesive tape, stethoscope, tray, gauze, syringe, needle, saline solution 10 or 20 ml, saline solution 500 ml, thermometer, sphygmomanometer, tray, flexible intravenous device, sterile cover, glove, glasses, mask, wall clock. Patient's chart with the forms: admission, medical prescription, nursing prescription, diuresis control, and nursing notes. Simulator: Low-fidelity full-body simulator.</p>	<p>Materials and equipment Saline solution, IV set, identification label, serum holder, cotton, alcohol, alcohol gel, liquid soap, paper towel, tray, syringe, needle, dipyrone, saline solution 10 or 20 ml, gauze, macronebulization mask, tape crepe, stethoscope, thermometer, sphygmomanometer, tray, flexible intravenous device, disposable apron, sterile cover, diaper, nightgown, trash cans, bag for common and infectious garbage, container for disposal of sharps, clock at 7:45 am. Patient's chart with the forms: admission, medical prescription, nursing prescription, nursing notes, blood count, catheter tip culture result, SP identification plates. Simulator: Low-fidelity full-body simulator.</p>
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Scenario A	Scenario B				
<p>Simulator characterization and props: Simulator with saline venous access and indwelling bladder catheter without fixation and with drainage (600ml) and identification bracelet.</p>	<p>Simulator characterization and props: Simulator with a medium female wig, identification shirt, and bracelet, peripheral venous access with continuous saline infusion, macronebulization mask in tracheostomy, hyperemia in the right subclavian region, identification bracelet, diaper. Simulator parameter: Blood pressure 130/90 mmHg, radial peripheral pulse 65 bpm).</p>				
<p>Script for standardized participants (Teacher and companion): (...)</p>					

Figure 1. Scenarios A and B, after the considerations made by the experts, Divinópolis, MG, 2018 (conclusion)

f) Environment/physical space:

<p>Scenario A <u>Nursing Station:</u> bench for medication preparation, patient's chart with all forms previously filled in (medical prescription, nursing prescription, nursing report, and admission sheet), place for storing medication, sink with liquid soap and paper towel, dispenser with alcoholic preparation, bins for disposal of waste (common, infectious, sharp), protective eyewear and surgical mask. <u>Infirmary Room:</u> bed identification, two beds (one open bed and one operated bed), stepladder, serum support, bedside table, feeding table, device for alcohol gel, trash can for common waste, graduated collection bottle. <u>Purging:</u> Bin for common and infectious waste, dispenser for alcoholic preparation, container for health products to be processed.</p>	<p>Scenario B <u>Nursing Station:</u> bench for medication preparation, patient's chart with all previously completed forms (medical prescription, nursing prescription, nursing report, admission sheet, catheter tip culture result, blood count), place for storing medicines, HH sink with liquid soap and paper towels, dispenser with alcohol preparation, waste disposal bins (common, infectious, sharp), disposable apron, gloves, protective glasses, and surgical mask. <u>Infirmary Room:</u> with bed identification, two beds (one open bed and the other closed), stepladder, serum support, bedside table, feeding table, device for alcoholic products, trash can for common, infectious, and sharp waste. <u>Purging:</u> Bin for common and infectious waste, dispenser for alcoholic preparation, container for health products to be processed.</p>
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g) Briefing (Case Description) - carried out by the facilitator

<p>Scenario A You, nursing students, are in a Practice environment, in the medical clinic sector of the São Bertolino hospital. The professor who is following the practice distributed the activities to be developed during the practice and you were responsible for the nursing care of the patient Ivan Cordisburgo Souza Valadares (SECTOR D ROOM 20-B), 65 years old, hospitalized two days ago due to complications from benign prostatic hyperplasia. He is an alcoholic, has periods of mental confusion, maintains saline peripheral venous access, has an indwelling urinary catheter, and is accompanied by his daughter. Upon receiving the patient's shift, the professor was informed that the doctor had made some changes to the medication for the day and that the patient is doing diuresis control (for 24 hours, which ends at 8:00 am). After this information, the professor asks them to divide the nursing activities to be carried out at the beginning of the shift, that is, to check if there are medicines to be administered and to close the diuresis control. You will have up to 3 minutes to plan the activities. Do you have any doubts? Would you like me to repeat any information?</p>	<p>Scenario B You, nursing students, are in a Practice environment, in the medical clinic sector of the São Bertolino hospital. The professor who is following the practice distributed the activities to be developed during the practice and you were responsible for the nursing care of the patient Paulina Etelvina Conceição, who was admitted to ROOM 18-A, Sector E, 15 minutes ago, coming from Intensive Care (ICU). She was hospitalized in the ICU for 18 days, due to a Hemorrhagic Stroke. During her stay in the ICU, she acquired an HAI, has an MRSA (methicillin-resistant Staphylococcus aureus) bacteria resulting from central venous access in the right subclavian, and needs SP measurements. The patient is accompanied by her niece and there is no other patient in the room (there are two beds). Paulina receives oxygen in a 50% venturi mask, saline solution through a peripheral venous catheter, eliminations in a diaper, and presents hemiplegia on the right. Paulina's vital signs have not yet been verified in Sector E. She emphasizes that for patients in SP it is not recommended that several people assist the patient, but that now, at the beginning of the shift, two students will take care of the patient. In this way, the professor asked them to prioritize care, checking the patient's medical record which medication should be administered, and that they also check vital signs. With this information, you will have up to 3 minutes to plan the activities. Do you have any doubts? Would you like me to repeat any information?</p>
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h) Scenario development (See Figures 2 and 3)

i) Verification list (Model used)

Sequence of actions	Apprentice A: _____			Apprentice B: _____		
	Accomplished		Observation / Difficulty	Accomplished		Observation / Difficulty
	Yes	No		Yes	No	
1.						
2.						
3.						
4.						

j) Debriefing

The roadmap for the debriefing is based on Promoting Excellence and Reflective Learning in Simulation (PEARLS).
Clarification about the debriefing session: We will spend up to 30 minutes with the debriefing which will consist of four phases. (...) First, the questions will be open to those who participated in the scenario and then to the observers.
Reactions: What were the feelings you had when participating in the simulation?
Potential follow-up question: Other reactions? How are others feeling?
Description: Could someone summarize the case of this simulation? From your perspective, what were the main situations you had to deal with?
 Potential follow-up question: What happened next? What did you do for the patient?
Analysis (transition from description to analysis will be flagged): Now that it's clear what happened, let's talk about the activities performed. I consider that there were aspects that were well-managed and others that would seem more challenging. I would like to talk about each of them. What aspects do you think you did well and why? What aspects would you like to change and why?
 Performance gaps should be closed using directive feedback: I noticed that you(s) (cite the behavior), next time you are going to do (suggest the behavior) because (justify).
 Are there issues that have not yet been resolved? (If not, go to the last phase: So, let's close the debriefing).
Application/Summary: I would like to close the debriefing by asking each of you to highlight two points that this simulated activity will help in clinical practice.

Figure 2. Development of scenario A, after the considerations made by the experts, Divinópolis, MG, 2018

Scene (duration)	Speech by a standardized participant	Expected action	Possible tips to be used
Nursing Station (0-2 min)		Apprentices A and B Sanitize their hands; Check the patient's medical record (check the need to install saline solution and end the diuresis control at 8 am) Sanitize their hands; They go to the room and present it to the patient.	Teacher: "Vital signs were checked at 6 am and there were no changes. The next time will be at 9 am."
Patient Room (2-5 min)	Companion: "My dad stayed up most of the night and didn't sleep until they gave him medicine. He is very confused and agitated." If asked about the collecting flask but he cannot say whose it is; The patient does not complain of pain in the peripheral catheter.	Apprentices A and B Sanitize their hands; They present themselves to the patient and identify possible complaints. Apprentice A Checks the conditions of venous access for the installation of saline solution. Apprentice B Checks urine collection bottles without identification in the room, on the floor, and next to the other bed; Checks for unfixed bladder catheter.	Teacher: "Did you see if there is the necessary material in the room to do the activities? How is the venous access?"
Nursing Station (5-10 min)		Apprentice A Sanitizes hands; Checks the medical prescription; Fills in the identification label; Performs the disinfection of the tray; Sanitizes hands; Gathers the material; Prepares the saline solution and syringe for flushing; Discards the generated waste; Sanitizes hands. Apprentice B Gathers the material for fixing the bladder catheter and the bottle to measure diuresis.	
Patient Room (10-14min)	Companion: If questioned, reinforce that the father is now sleeping, but that he has disconnected speeches and is constantly fiddling with the bladder catheter.I.	Apprentice A Identifies the patient and checks the medication; Places the medicine tray on the bedside table; Sanitizes hands; Places the saline solution bottle on the support; Performs the disinfection of the connector; Performs the flush; Installs the saline therapy and controls the drip; Sanitizes hands; Takes the tray with the generated waste for disposal. Apprentice B Sanitizes hands; Explains the procedure to the patient; Performs catheter fixation Sanitizes hands; Identifies the individual collector (can be performed at the Nursing Station); Puts on the PPE and empties the collection bag, using an individual collection container, avoiding contact with the drainage tube; Keeps the collection bag below the level of the bladder and the flow of urine unobstructed; Disregards the diuresis and rinses the collection flask; Leaves the urine collector in a dry environment; Discards the generated waste; Sanitizes hands.	Teacher: "Have you done all the activities?"
Nursing Station (14- 15 min)		Apprentice A Discards the generated waste; Sanitizes hands. Apprentices A and B They begin to record the nursing procedures performed.	Teacher: "Let's now write down what has been accomplished."

Figure 3. Development of scenario B, after the considerations made by the experts, Divinópolis, MG, 2018

Scene (duration / time)	Speech by a standardized participant	Expected action	Possible tips to be used
Nursing Station (0-7 min)		<p>Apprentices A and B Sanitize their hands; They verify the precaution established in the medical record.</p> <p>Apprentice A Provides PPE (apron and gloves); Performs cleaning and disinfection of the tray, thermometer, stethoscope, and sphygmomanometer; Gathers the material (thermometer, sphygmomanometer, stethoscope, squirt bottle with alcohol and cotton) to leave in the room; Discards the generated waste; Sanitizes hands.</p> <p>Apprentice B Checks the medication on prescription Sanitizes hands; Performs cleaning and disinfection of the tray; Sanitizes hands; Gathers the material for the preparation of the medication; Prepares medication and syringe for flushing and locking.</p>	<p>Teacher: If participants go to the patient's room before planning activities, say: <i>"As the patient is in specific precaution, let's first plan care before entering the room."</i></p> <p>If the apprentices have difficulty gathering the materials: <i>"You saw that there are materials in Paulina's drawer (18-A)"</i>.</p>
Patient Room (7-14 min)	<p>Companion: - As soon as the participants enter the room: <i>"I'm glad you came. I'm very happy that my aunt came here. She has improved a lot, she is still very sleepy."</i> - <i>"They said she is in isolation, but why is that? It's very dangerous? Can I keep her?"</i> - If the apprentices put on an apron, ask: <i>"Why are you wearing this outfit? Should I use it, too?"</i> - If they don't, ask why the other people who entered the room were wearing gloves and aprons; - If students do not guide the companion's HAI prevention and control measures, you should ask if you can leave the room frequently: <i>"It's really bad to stay here alone, is it okay for me to go out to smoke? I get very anxious"</i> - If participants do not respond, do not question further.</p> <p>Teacher: - If the participants ask them to enter the room together, say: <i>"You can start the activities, I will be there soon."</i> You must wait for the students to put on their aprons and glove.</p>	<p>Apprentices A and B Introduce themselves to the patient and companion; They explain the procedures; Sanitize their hands; Put on the apron and glove before touching the patient; They guide the family member and the patient about precautionary measures by contact.</p> <p>Apprentice A Checks the vital signs; Leaves the materials in the room for the exclusive use of the patient; Removes the gloves, removes the apron inside out, and discards it; Sanitizes hands.</p> <p>Apprentice B Identifies the patient and checks the medication; Places the medicine tray on the bedside table; Identifies absence of phlogistic signs in peripheral venous access; Removes gloves, sanitizes hands, and puts on a new pair of gloves; Performs the disinfection of the connector; Performs flushing and administers the drug; Performs flushing and look; Disposes of waste; Removes gloves and disposable apron inside out and discards them; Sanitizes hands; Puts on gloves to pick up the tray and directs it to the Purge without touching the surfaces.</p>	
Nursing Station and Purge (14 – 15 min)		<p>Apprentice B Leaves the tray for cleaning and disinfection in the Purge; Removes and discards the glove; Sanitizes hands.</p> <p>Apprentices A and B The notes start at the Nursing Station.</p>	<p>Teacher: <i>"Shall we record what was accomplished?"</i></p>

(63.6%), with no experience in the health area (93.2%), nor participation in previous simulations (52.3%), or in events about HAIs (90.9%), and who also did not develop research in simulation or HAIs (84.1%). Of these, 28 participated as volunteers in scenarios A or B and 16 were only observers in both scenarios.

The SDS presented a mean of 4.8 ± 0.3 and an internal consistency of 0.86, the results of the means and internal consistency of each factor are described in Table 2. It is noteworthy that none of the participants disagreed or completely disagreed with the statement of the items.

In the factor 'Objectives and information', for most students (90% or more), the information, objectives, and tips were adequate; 97.7% clearly understood the purpose and objectives of the simulation, and all stated that the information was sufficient and clear. In the factor 'Support', 97.2% felt supported in the learning process and all received support at an opportune time. As for the factor 'Feedback/Resolution', 2.3% of the students were undecided about whether the feedback was given promptly. In the 'Realism',

95.5% of the participants agreed that the scenario resembled a real situation and that the real-life elements, conditions, and variables were properly incorporated.

Table 3 presents the results of the association of SDS with the graduation period and participation in previous simulations. It is verified that the students in the final phase of graduation presented a superior evaluation with a significant difference in the SDS ($p=0.021$) and with the factor 'Problem Solving' ($p<0.001$). Students who had participated in previous simulations had higher averages on the scale ($p=0.001$) and in the factors 'Objectives and Information' ($p=0.002$) and 'Problem Solving' ($p=0.001$).

Analyses were also carried out, according to how the learners participated in the simulation (observation or participation), showing a significant difference, only for the factor 'Feedback/Resolution' ($p=0.009$), with the students who participated in the simulation showing a higher evaluation of this factor. There was no statistically significant difference between sex, age, or participation in courses and workshops on HAI.

Table 2. Descriptive analysis of the Factors of the Simulation Design Scale, according to undergraduate nursing students ($n=44$), Divinópolis, MG, Brazil

Variables	Mean \pm SD	Median (p25-p75)	Minimum	Maximum	Alpha
Simulation Design Scale	4.8 \pm 0.3	4.9 (4.6-5)	4.1	5	0.86
Objectives and information	4.7 \pm 0.4	5 (4.5-5)	3.6	5	0.79
Support	4.7 \pm 0.5	5 (4.3-5)	3.3	5	0.59
Problem-solving	4.8 \pm 0.3	5 (4.6-5)	3.8	5	0.67
Feedback/Resolution	4.9 \pm 0.2	5 (5-5)	4.3	5	0.50
Realism	4.6 \pm 0.5	5 (4-5)	3.5	5	0.56

Table 3. Mean and standard deviation (SD) of the Simulation Design Scale scores, according to nursing students' graduation period ($n=44$) and participation in the previous simulation, Divinópolis, MG, Brazil

Variables	Graduation period (mean \pm SD)		p value*	Participation in previous simulation (mean \pm SD)		p value*
	Intermediate	Final		No	Yes	
Simulation Design Scale	4.6 \pm 0.2	4.8 \pm 0.1	0.021	4.6 \pm 0.3	4.8 \pm 0.1	0.001
Objectives and information	4.6 \pm 0.4	4.8 \pm 0.2	0.057	4.5 \pm 0.4	4.9 \pm 0.1	0.002
Support	4.6 \pm 0.5	4.7 \pm 0.3	0.298	4.5 \pm 0.5	4.8 \pm 0.3	0.076
Problem-solving	4.6 \pm 0.3	4.9 \pm 0.1	<0.001	4.6 \pm 0.3	4.9 \pm 0.1	0.001
Feedback/Resolution	4.9 \pm 0.1	4.9 \pm 0.1	0.872	4.8 \pm 0.2	4.9 \pm 0.1	0.098
Realism	4.5 \pm 0.5	4.6 \pm 0.4	0.447	4.5 \pm 0.5	4.6 \pm 0.4	0.705

Note: *Student's t test for independent samples

DISCUSSION

During the elaboration of the scenario, there was a systematic, flexible and cyclical planning, which considered the norms proposed by the INACSL Standards of Best Practices: Simulation⁽⁷⁾, in addition to the conceptual elements of the NLN/JST⁽¹¹⁾. International researchers point out the need to develop simulated scenarios that are structured and standardized in all facets of design and claim that developing a simulation, using NLN/JST, provides meaningful and engaging experiences for participants⁽¹⁹⁾.

In the content validation of the scenarios, no expert suggested the inclusion of essential elements in the scenarios. It is believed that the elaboration of scenarios, based on the concepts of the NLN/JST⁽¹¹⁾, the best practices in simulation of the INACSL⁽⁷⁾, and the use of the Scenario Validation Checklist⁽¹³⁾, may have contributed to this.

The physical, conceptual, and psychological aspects of fidelity were considered in the elaboration process. Psychological fidelity works in synergy with physical and conceptual fidelity in promoting involvement with the participant⁽⁷⁾. For conceptual fidelity, care was taken to ensure all the elements of the scenario were related realistically, without misunderstandings, and were evaluated by experts.

With the learning objectives of the two scenarios, it was possible to cover most of the central and generic competencies for the prevention and control of HAI⁽⁵⁾, such as communication, decision-making, ethics, maintenance of the aseptic chain, waste management of health services, implementation of infection prevention actions, care for infected patients, and use of PP (use of PPE, HH) and SP.

It was established that only the first specific objective would be disclosed to the participants, in the prebriefing. Publications in the field of clinical simulation^(7,13,20) consider that the objectives of the scenarios must be measurable and achievable at the end of the simulation and must include psychomotor, affective, and cognitive skills such as communication, delegation of activities, performance of procedures, principles of the topic addressed, among others.

It is considered that this research met the recommendations for the development of simulated scenarios since researchers⁽²¹⁾ indicate that there is insufficient production of methodological studies that clearly describe the path used.

Validation by a group of experts enhanced the quality of the content of the scenario, as the weightings performed improved the material produced, thus adjusting aspects that could compromise the performance of the activity^(9,22,23), and ensuring they are ready for pilot testing before being implemented⁽⁷⁾.

One innovation in scenario validation and scenic simulation studies, brought about by the present study, was the proposal for the standardized participant to represent a teacher in the scene, in line with the recommendations of

the literature regarding the expansion of the possibilities of their performance⁽¹⁴⁾. In general, the teacher makes up the simulation team as the facilitator of the activity, mediating and leading it at all stages. In addition, it is believed that the tips and clues that could be offered by the standardized participant-teacher, when necessary, would favor the achievement of the proposed learning objectives.

The internal consistency of the SDS ($\alpha = 0.86$) represents values that guarantee its reliability⁽²⁴⁾, however, it was slightly lower than the values found in the validation of this instrument for Portuguese (SDS = 0.93)⁽¹⁵⁾ and a Korean study (SDS=0.94)⁽²⁵⁾. However, when comparing the mean of the instrument with those of other studies, it appears that it was similar or superior⁽²⁴⁻²⁵⁾. It is noteworthy that no participant disagreed with the items on the scale, unlike the results found in other studies^(19,25).

An international study with third and fourth-year undergraduate nursing students, similar to this study, found that the perception of simulation design, directly and indirectly, affects learning outcomes and effective strategies must be planned and implemented in order to provide students with psychological safety, such as the guidelines provided in the prebriefing⁽²⁵⁾.

The factor 'Objectives and Information' includes items relevant to the learning objectives and the information contained in the scenario (from prebriefing to debriefing) that were carefully reviewed in the validation. The results found allow us to infer that the changes made in these items made it possible for the participants to understand since the average presented is considered high and similar to other studies^(17,25). The information provided before the simulation (prebriefing and briefing) and the information provided during (tips) was considered sufficient by the participants. As for the proposed learning objectives, it is considered that they were clearly understood by the participants, as recommended by the literature⁽⁷⁾.

The items of the factor 'Support' relate to the facilitator's responsibility in conducting the simulation with a view to the proposed objectives. The facilitator must meet the participant's individual needs to progress in the scenario, but it must be replicable whenever the scenario is repeated⁽⁷⁾. In order to ensure replication, including by other facilitators and institutions, scripts were used for both the facilitator and the standardized participant. The facilitator was trained to provide, during all simulation sessions (prebriefing, briefing, scenario development, and debriefing), an environment of respect, confidentiality, compassion, commitment, collaboration, honesty, mutual respect, and involvement in the teaching-learning process, as recommended^(7,11).

As for the factor 'Problem Solving', similar to another Brazilian study⁽¹⁷⁾, it is evident that all participants agreed that the simulation was designed for their level of knowledge and

skill, reaffirming the suitability of the design for the target audience of this study.

In the factor 'Feedback/Resolution', it is considered that the use of a theoretical model^(7,11), a trained facilitator, and a structured debriefing script contributed to the results of this study, which are slightly superior to the results of other research carried out in the East Medium⁽¹⁹⁾. Participants considered that feedback was provided at an opportune time and that the simulation created an opportunity to analyze their behaviors and actions related to HAI prevention and control measures. Researchers⁽²⁵⁾ consider that, from the debriefing, students were able to identify their weaknesses and strengths.

In the factor 'Realism', the lowest SDS score was obtained, which was expected due to the limitations of the location where the clinical simulation took place. Several adaptations were necessary for the space to represent the hospital environment. However, students agreed or fully agreed that the scenario had factors and situations that resembled a real situation. This points to the importance of rigor in the planning of scenarios and the fiction contract, as the physical spaces available for carrying out simulated activities, in most higher education institutions in Brazil, are adapted, not always being able to replicate, with minimally acceptable levels of realism, the different scenarios of professional performance.

Still regarding realism, in addition to contributing to the perception of how real the simulated experience is, it influences the learning process, as it generates the same psychological responses in the learner as the practice, thus promoting the development of critical thinking and decision-making skills in a real clinical setting⁽²¹⁾.

The higher averages of the EDS for students who are completing their graduation allow us to infer that greater experience in the field of practice may have enabled a greater ability to solve the problems posed by these simulations, as well as having favored a better understanding of the factors that make up the design of the scenarios. It is verified that the previous participation in clinical simulation allowed a superior evaluation of the simulation design and enabled the participants to make comparisons and better understand the fiction contract proposed for these simulations.

The indifference in the evaluation of the scale, according to their form of participation in the simulation, indicates that all learners had the same vision of the simulation design. Furthermore, this scenario can be used to teach HAI prevention and control measures to small groups, in which not all learners actively participate in the simulation.

As a limitation of the study, it is considered that the consensus of the researchers was used for the changes and that a new round of content analysis should be carried out for the items that did not receive the indices expected by the experts. During the execution of the scenarios, the improvisation of physical spaces (nursing station, patient room, and purge),

and the presence of the standardized participant-teacher, the facilitator, and the observer participants in the same space as the simulation participants were considered limitations. These limitations are considered to have impacted the realism of the scenario and the psychological safety of the participants.

It is expected that the public availability of the material prepared may favor the use of this scenario in the teaching of HAI prevention and control measures in the university context.

CONCLUSION

The content validation by the experts ensured a higher quality of the proposed scenarios, supported by the simulation participants who emphasized the good quality of the scenario design. The improvisation and adaptations in the physical space may have impacted the evaluation of the realism of the scenario.

It is considered that the elements of the scenarios were clear and adequately structured for the participants' level of knowledge (5th to 9th period of the undergraduate course) and that the form of participation in the simulation did not interfere with their perception.

The validated clinical scenarios can be widely used in learning, based on simulation of HAI prevention and control measures, and can be replicated in different places, including in institutions that do not have laboratories with adequate structure or sophisticated technological resources, with different standardized facilitators and participants, with the potential to achieve the proposed learning objectives and outcomes.

Furthermore, researchers, professors, and institutions should invest in the elaboration and validation of simulated scenarios that meet the Brazilian context since there are still no national simulation programs that develop simulated clinical scenarios, contrary to the reality of developed countries.

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