External Validation of an Instructional Design Model for High Fidelity Simulation:
Model Application in a Hospital Setting

by

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ABSTRACT

The purpose of this study was to investigate the use of the design characteristics component of the Jeffries/National League for Nursing Framework for Designing, Implementing, and Evaluating Simulations when developing a simulation-based approach to teaching structured communication to new graduate nurses. The setting for the study was a medium sized tertiary care hospital located in the southwestern United States. Participants in the study were an instructional designer (who also served as the researcher), two graduate nursing education specialists, one unit based educator, and 27 new graduate nurses and registered nurses who had been in practice for less than six months.

Design and development research was employed to examine the processes used to design the simulation, implementation of the simulation by faculty, and course evaluation data from both students and faculty. Data collected from the designer, faculty and student participants were analyzed for evidence on how the design characteristics informed the design and implementation of the course, student achievement of course goals, as well as student and faculty evaluation of the course. These data were used to identify the strengths and weaknesses of the model in this context as well as suggestions for strengthening the model.

Findings revealed that the model generally functioned well in this context. Particular strengths of the model were its emphasis on problem-solving and recommendations for attending to fidelity of clinical scenarios. Weaknesses of the model were inadequate guidance for designing student preparation, student support, and debriefing. Additionally, the model does not address the role of
observers or others who are not assigned the role of primary nurse during simulations.

Recommendations for strengthening the model include addressing these weaknesses by incorporating existing evidence in the instructional design of experiential learning and by scaffolding students during problem-solving. The results of the study also suggested interrelationships among the design characteristics that were not previously described; further exploration of this finding may strengthen the model.

Faculty and instructional designers creating clinical simulations in this context would benefit from using the Jeffries/National League for Nursing Model, adding external resources to supplement in areas where the model does not currently provide adequate guidance.
DEDICATION

I would like to dedicate this dissertation to my family, all truly a gift from God, who gave me the tools and the encouragement to pursue my dream.

The first dedication is to my parents, of blessed memory, who instilled in me a passion for teaching through their example. The pursuit of the “aha moment” has been part of who I am for as long as I can remember.

The second dedication is to my grandparents, of blessed memory, for the values they taught me. Pap who taught me hard work and discipline through loving instruction and high expectations, Gram who was so dedicated to her students and to life-long learning, Pop for his sense of fun and overcoming challenges, and Nan for her great faith in God.

The third dedication is to my sisters, who helped me learn about life. You have been generous in sharing stories of the strong women in our family and you are both strong women in your own right; you have been an inspiration to me in the tough times.

Finally, I dedicate this to the two most special people in my life, Alex and Alicia. I owe a tremendous debt of gratitude to my husband for your love, patience and believing in my ability to do this; and my daughter for your love, encouragement and willingness to sacrifice some of our time together so I could pursue my dream. My fondest hope is that my journey will inspire you to follow your own dreams.
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Introduction

Clear and effective communication among health care professionals (interprofessional communication) is critical to patient safety (Nadzam, 2009). Frank (1961) described a professional group as one that has its own specialized language and frameworks, which can be very efficient for within group communication but may cause difficulties when communicating across groups. Interprofessional communication at its best occurs when all members contribute to a shared view of the problem and collaboratively address the aspects of the problem from their unique professional perspective (Frank, 1961).

Interprofessional Communication

As early as 1999, Baggs, Schmitt, Mushlin, Mitchell, Eldredge, Oakes, and Hutson identified that collaboration between physicians and nurses was positively correlated with improved patient outcomes in the intensive care unit. Conversely, breakdowns in interprofessional communication have been linked to medical errors and poor patient outcomes (Varpio, Hall, Lingard & Schryer, 2008). According to the Joint Commission, the national body that accredits health care organizations, communication breakdowns have been identified as a root cause of nearly every major medical error reported to this organization since it began maintaining records in 1996 (The Joint Commission, n.d.).

Physician and nurse communication has long been affected by differences in professional socialization (Arford, 2005). Registered nurses are encouraged to communicate about patients in a descriptive narrative format whereas as
physicians are encouraged to take a more action oriented approach with rapid diagnosis of the problems requiring a solution (Haig, Sutton & Whittington, 2006; Nadzam, 2009; Thomas, Bertram & Johnson, 2009). Common barriers to effective interprofessional communication are identified as a lack of structure for sharing information (Haig, Sutton & Whittington, 2006; Nadzam, 2009) and different expectations regarding what information should be included (Nadzam, 2009; Nelson & Venhaus, 2005; Weinberg, Miner & Rivlin, 2009). One method suggested for improving interprofessional communication about patient care problems is the use of a structured communication tool (Nadzam, 2009, Nelson & Venhaus, 2005).

**Structured Communication.** The purpose of using a structured communication tool is to create common expectations regarding what patient information will be shared during interprofessional communication (Nadzam, 2009; Nelson & Venhaus, 2005). Reisenberg (2009) performed a systematic review of research on mnemonics for structured communication and found a total of 24 different systems were reported on in the literature, however the mnemonic of Situation, Background, Assessment, and Recommendation (SBAR) was the most frequently reported.

The Institutes for Healthcare Improvement advocate the use of the SBAR structure for communication among all health care professionals. SBAR was originated by Michael Leonard, MD at Kaiser Permanente (Denver) to provide a model for structured communication (Beckett & Kipnis, 2009). Although
systematic validation of the effectiveness of any mnemonic for structured communication in healthcare is lacking (Riesenber, Leitzsch & Little, 2009), the SBAR approach has gained wide acceptance within the healthcare field, is one of the communication methods recommended by the Joint Commission (Nadzam, 2009), and several case reports of SBAR implementation demonstrate gains in both nurse and physician satisfaction with communication (Beckett & Kipnis, 2009; Haig, Sutton & Whittington, 2006; Mulligan, 2010; Kanaskie & Booth, 2009; Woodhall, Vertacknik & McLaughlin, 2008).

However, simply providing the structure for communication does not guarantee that the content is adequate for safe patient care. The ability to effectively use a structured communication tool depends on the professional’s clinical and diagnostic reasoning (Nelson & Venhaus, 2005). Diagnostic reasoning can be defined as the process of recognizing cues and analyzing clinical data that leads to application of a diagnostic label (Wong & Chung, 2002). Diagnostic reasoning requires several skills including data collection through physical examination, eliciting subjective information from the client, integration of the results of diagnostic testing and collaboration with other health professionals (Carpenito, 2000). Once the initial data is collected it must be analyzed, primarily through the processes of differentiating normal and abnormal findings and determining which findings are most important. The nurse generates hypotheses regarding potential client problems, searches the data at hand for patterns and compares the evidence with the hypotheses to select the most likely problem. This step in the process may require collection of focused data to
confirm or disconfirm the hypotheses (O’Brien, 2004). The final step is labeling
the diagnosis as either a nursing diagnosis or collaborative problem which
requires joint treatment between nursing and another healthcare discipline, most
frequently the physician (O’Brien, 2004). When a collaborative problem is
identified, the nurse must communicate clearly and effectively to obtain the best
care for the patient.

**New Graduate Nurses.** New graduate nurses are expected to enter the
profession with strong communication skills. Diede, McNish and Coose (2000),
in a survey of nurse administrators in health care settings identified
communication skills as the most desired skills for new graduate nurses, with an
importance ranking of 3.87 on a 4 point scale. However, graduate nurses have
identified less than ideal interprofessional communication experiences that have
contributed to feelings of insecurity, which they report leads to a practice of
delaying contact with a physician “until the last minute” (Dyess & Sherman,
nurses and found a strong theme of experiencing verbal abuse from physicians
which detracts from the nurses’ ability to participate in interprofessional
communication. A qualitative study of medical residents’ views on
communicating with nurses lends support to the perception that there is a lack of
respect for nurses who are viewed as less experienced and therefore less
competent (Weinberg, Miner, & Rivlin, 2009).

New graduate nurses often lack the critical thinking skills required to
competently participate in interprofessional communication (Nelson & Venhaus,
The skills required include “problem identification, statement of known facts, … interpretation, analysis, evaluation, inference and explanation” (Kanaskie & Booth, 2009, p. 65). Del Bueno (2005) reported that only 35% of new graduate nurses, in a sample drawn from more than 350 health care agencies in 46 states, met entry expectations for clinical judgment when assessed using a standardized tool for nursing competency. A similar study with a sample drawn from a single institution was more positive, with 74.9% of all new graduate nurses meeting entry expectations for critical thinking (Fero, Wilsberger, Wesmiller, Zullo, & Hoffman, 2008). It is important to support the new graduate nurse in acquiring the skills necessary for thinking and interprofessional communication; new graduate nurses reported that SBAR improved both their problem solving and their communication skills (Kanaskie & Booth, 2009).

New graduate nurses also lack experience in interprofessional communication, due in large part to legal restrictions on nursing students in receiving physician orders (Thomas, Bertram & Johnson, 2009). Clinical simulation is one educational strategy that has been used successfully with undergraduate nurses to both improve critical thinking and interprofessional communication skills.

**Teaching Interprofessional Communication Using Clinical Simulation.** To counteract the lack of experience in interprofessional communication, undergraduate nursing programs have used high fidelity clinical simulation to provide practice in structured interprofessional communication (Guhde, 2010; Thomas, Bertram & Johnson, 2009) with success in assisting the
students to construct more organized communication and develop increased confidence in interprofessional communication. Thomas, Bertram & Johnson (2009) state that students continue to require support after the transition from academia to practice.

Mulligan (2010) utilized high fidelity clinical simulation including SBAR with new graduate nurses as one method of supporting critical thinking while the novices gained more experience. The outcomes of this study included an increased frequency of recognizing when additional help was needed and physician reports of improved communication. These studies provide evidence that high fidelity clinical simulation is a viable option for teaching interprofessional communication skills. However, the studies do not include design details such as level of fidelity, complexity of the patient scenarios, or the structure of debriefing including sources of feedback which could guide faculty in designing and developing similar effective clinical simulations.

**Instructional Design of High Fidelity Clinical Simulation**

**Experiential Learning Theory.** Experiential Learning Theory (ELT) as described by Kolb (1981) is the most commonly cited learning theory applied to the design of simulation in nursing (Kaakinen & Arwood, 2009; Rourke, Schmidt & Garga, 2010). ELT provides a model of how humans learn from experience (Kolb, 1981). The ELT model describes a four-stage cycle:

Immediate concrete experience is the basis for observation and reflection.

Observations are assimilated into a ‘theory’ from which new implications
for action can be deduced. These implications or hypotheses then serve as guides in acting to create new experiences. (Kolb, 1981, p. 24).

This cycle may be repeated by the learner, with each new experience acting as a catalyst for additional learning (Kolb, 1981). Although there are critics of ELT (Moon, 2004), this model currently underpins much of simulation design in nursing education.

**Instructional Design Theory.** Cant & Cooper (2009) completed a systematic review of simulation-based learning in nursing education and found that the most common structure for a simulation-based learning experience consisted of an initial briefing followed by the experience and debriefing. This structure follows the recommendations of Lindsey and Berger (2009) in an instructional design theory for experiential instruction. These authors state that there are three universal principles for structuring experiential instruction: framing the experience, activating experience and reflecting on experience (Lindsey & Berger, 2009). These universal principles are evident in the simulation design framework created by Jeffries (2005) as part of a study of best practices in simulation-based education in nursing sponsored by the National League for Nursing.

**Simulation Design Framework.** A framework for the design, implementation and evaluation of simulation in nursing education was developed to guide academic nursing faculty in designing effective high fidelity clinical simulation as part of the “Designing and Implementing Models for the Innovative
Use of Simulation to Teach Nursing Care of Ill Adults and Children: A National, Multi-Site, Multi-Method Study (Jeffries & Rizzolo, 2006). This study was carried out in four phases, with model development and research instrument development included in the initial phase. In the second phase, eight project directors with the assistance of nursing faculty utilized the framework to design, implement and evaluate a simulation experience. The results from this phase of the study are not included in the report, so little is known about the faculty experience in using the framework as it was initially designed. During the third phase of the study, baseline measures of student learning and satisfaction with learning were obtained prior to implementation of simulation. The second part of phase three was conducted with 395 students who received the education provided in phase two and then randomly assigned to one of three conditions: paper/pencil case study, simulation with a moderate fidelity simulator, and simulation with a high fidelity simulator.

There were no significant differences in knowledge based on posttest score comparisons. The researchers did find that learners using the high fidelity simulator scored higher on satisfaction with the learning experience and self-confidence than those in the other groups. Additionally, student perceptions of the incorporation of the education practices of active learning, feedback and diverse learning styles were significantly increased with high fidelity simulation.

**Framework Description.** The framework consists of three major components: contextual elements, design elements and outcomes. Jeffries (2005,
2006; Jeffries & Rogers, 2007) theorized that the contextual elements of teacher and learner characteristics as well as the degree of adherence to a set of educational practices will impact simulation design and both of these elements together impact overall outcomes of the clinical simulation. Each of these general components is further detailed to provide guidance to the simulation designer, who may or may not be the teacher.

**Contextual Elements.** The first component to consider is that of contextual elements, including teachers and students as well as embedded educational practices. The teacher in simulation-based education may take on the role of either facilitator or observer, depending on the intent of the simulation (Jeffries, 2005). Teachers using simulation require a specific set of competencies, among which are “tolerance for ambiguity, observe and interpret behavior, form questions and listen to answers, select appropriate directive and non-directive postures, have a good sense of timing, and make judgment calls” (Lederman, 1984, p.424). Teachers need to create a learning environment that is challenging while maintaining a level of psychological safety that encourages student participation and risk taking (Rudolph, Simon, Dufresne & Raemer, 2006). Taking on the role of facilitator is often unfamiliar to teachers and requires practice (Lederman, 1984). In the same manner, students are also taking on new roles in being more responsible for their learning (Lederman, 1984).

Student factors of interest in this model include age, level of experience and type of program. The degree to which students become engaged in the
simulation and take responsibility for their learning also impacts the outcome (Jeffries, 2005). Student engagement and motivation can be enhanced by framing the experience prior to active participation (Lindsey & Berger, 2009). Informing students of the objectives and assessment criteria as well as providing clear direction on roles and expected behavior can improve the student experience. Orientation to the environment is essential, as unfamiliarity with equipment has been identified as a barrier for nurses engaging in simulation (DeCarlo, Collingridge, Grant & Ventre, 2008). The experience itself, particularly the narrative nature, also provides motivation (Cannon-Bowers, 2008).

The third sub-component of context is the embedding of educational practices that can improve learning outcomes (Chickering & Gamson, 1987). Many of these practices are inherent in simulation-based education, but the degree to which each is enacted can be altered by the teacher. Attending to the inclusion of these educational practices will have a positive impact on overall outcomes (Jeffries, 2005). Chickering and Gamson (1987) identified seven principles of good practice recommended for undergraduate education that Jeffries has incorporated into the Simulation Model.

“Good practice in undergraduate education:

1) Encourages contacts between students and faculty
2) Develops reciprocity and cooperation among students
3) Uses active learning techniques
4) Gives prompt feedback
5) Emphasizes time on task
6) Communicates high expectations
7) Respects diverse talents and ways of learning” (Chickering & Gamson, 1987, p.2)

These principles will be discussed in more detail below as they pertain to specific design considerations as outlined in the second component of the model.

**Design Characteristics.** The second component of the Simulation Model is that of Design Characteristics and Simulation. In the first publication of the model, Jeffries (2005) included the elements of objectives, fidelity, complexity, cues and debriefing. In successive iterations of the model, the element of complexity was expanded to problem-solving (Jeffries, 2006; Jeffries & Rogers, 2007), the element of cues was expanded to learner support (Jeffries, 2006) and then to student support (Jeffries & Rogers, 2007), the element of debriefing was listed as feedback but described as part of guided reflection (Jeffries, 2006) which was changed back to debriefing (Jeffries & Rogers, 2007) in the most current model. This literature review will use the terminology from the most current publication of the model: objectives, fidelity, problem-solving, student support, and debriefing (Jeffries & Rogers, 2007, p. 23).

**Objectives.** Within this framework, objectives must be clearly written to allow the student to participate effectively in the simulation (Jeffries & Rogers, 2007). Other important features include matching the objectives to learner’s
knowledge and experience (Jeffries, 2005), and including intended outcomes and expected behaviors (Jeffries & Rogers, 2007). Jeffries (2006) recommended that the number of objectives be reflective of the complexity of the simulation but ideally no more than three to four objectives for a 20-minute simulation (p. 166).

**Fidelity.** The element of fidelity is defined as the level of realism found within the simulation (Jeffries, 2005), both in the technology used and in the environment within which the simulation occurs. Fidelity may include the level of reactivity of the technology, ranging from a low-fidelity static task trainer that does not respond to learner input, to high-fidelity simulators that can enact a range of responses based on learner actions (Issenberg, McGaghie, Petrusa, Lee-Gordon, & Scalese, 2005). Fidelity is also impacted by other elements within the environment including equipment and other props (Jeffries, 2006), and to the tasks the learner is being asked to perform (Lindsey & Berger, 2009).

The level of fidelity is a simulation design decision that is based on both the learner characteristics and the learning objectives (Hertel & Mills, 2002). Jeffries (2006) states that “simulations should be as realistic as possible (p. 166). According to Lindsey & Berger (2009) this approach increases the likelihood of transferring skills learned to the real world. However, creating simulations that are too realistic and complex may overwhelm the learner and overshadow the original learning objectives (Hertel & Mills, 2002; Lampotang, 2008).

The literature also presents mixed results regarding the importance of high fidelity in simulations. Hoadley (2009) compared the use of a high fidelity and low fidelity mannequin on cognitive and performance skills learning in advanced
cardiac life support and found no significant difference between the groups. However, Crofts, Bartlett, Ellis, Hunt, Fox and Draycott (2006) found that midwives and obstetricians had a higher successful delivery rate after simulation using a high fidelity mannequin as compared to a low fidelity mannequin. These findings suggest that decisions regarding fidelity are context specific.

**Problem-solving.** Another important simulation design feature is the opportunity for problem solving (Jeffries, 2006). Within the framework, problem-solving is viewed as decision points that learners created for themselves (Jeffries, 2006). Problem orientation is a key component of most experiential learning, where decisions are made in the analysis and solution of the problem (Lindsey & Berger, 2009).

Jeffries (2005) discussed complexity in terms of the level of uncertainty found within the scenario; complexity increases with the number of problems presented, the number and stability of the relationships between the problems and the presence of irrelevant data. Complexity of a problem is also judged by the number of cognitive operations and degree of cognitive burden that is placed on the problem solver (Jonassen, 2004). In terms of complexity, the goal of the designer is to create simulations that are challenging while still allowing the learner to be successful (Jeffries, 2007; Lindsey & Berger, 2009).

Problems vary by more than just complexity; there are also factors of structuredness, dynamicity, and domain specificity (Jonassen, 2004) that can be considered during the design process. A key feature of structuredness is the degree to which the problem solution can be predicted or known (Jonassen, 2004),
ranging from well- to ill- structured. An ill-structured problem is characterized as being ill defined and open ended, similar to many problems found in the real world (Ge & Land, 2004). The skills required to solve ill-structured problems differ from those used to solve well-structured problems (Jonassen, 2004). Dynamicity, or the degree to which the problem changes over time, also contributes to complexity (Jeffries, 2005; Jonassen, 2004). Domain specificity refers to how embedded problem-solving skills are within the context of the problem (Jonassen, 2004). An abstract problem would be approached using the same rules each time, whereas a domain specific problem solution may require specific procedures. When designing a simulation, these problem characteristics can be manipulated to match the difficulty of the simulation to the characteristics of the learner (Jeffries, 2005).

*Student support.* Student support includes the cues provided during the simulation (Jeffries & Rogers, 2007) as well as facilitation of reflection on decision-making during debriefing and guided reflection after the scenario has ended (Jeffries, 2006). The provision of cues during the simulation should “offer enough information for the learner to continue with the simulation, but do not interfere with his/her independent problem solving” (Jeffries & Rogers, 2007, p. 29). The decision to provide support during a scenario is based on balancing learner needs so that the learner uncovers their own strengths and weaknesses but does not become so overwhelmed as to have their self-concept threatened (Glavin, 2008). These decisions may be made by the designer prior to implementation and by faculty during the implementation (Glavin, 2008).
Debriefing. Debriefing allows students and faculty to review what happened during the scenario and to reflect on the meaning of scenario events (Jeffries & Rogers, 2007). The word debrief originated in the military and means “to obtain information (from someone) at the end of a mission” (www.dictionary.com, n.d.). This definition refers to obtaining information from the person having the experience, but does not address the teaching-learning aspect of debriefing as it applies to simulation-based learning (Lederman, 1984, Stewart, 1992). Although debriefing is considered an essential element of simulation-based learning, it remains a poorly understood teaching/learning strategy (Dreifuerst, 2009).

The primary goals of debriefing are to provide emotional support to learners (Flanagan, 2008) and help the learner achieve the learning objectives and goals (Glavin, 2008). Dreifuerst (2009) defined five attributes of debriefing that demonstrate the complexity of this teaching/learning activity: reflection, emotion, reception, integration, and assimilation/accommodation.

Reflection allows the learner to review the experience and ideally make sense of the events that occurred (Dreifuerst, 2009; Lederman, 1984; Moon, 2004; Rudolph, et al, 2006). Merrill (2002) in discussing reflection as a component of instruction stated that “learning is promoted when learners can reflect on, discuss, and defend their new knowledge or skill” (p.50). Reflection has the potential to lead to meaningful learning by allowing students to take a deep approach to learning, reconsider things already known in a new way, or generate new ideas (Moon, 2004).
Reflection can be used to uncover one’s own assumptions and learn to self-correct in professional practice (Dreifuerst, 2009; Kuiper, Heinrich, Matthias, Graham, & Bell-Kotwall, 2008; Rudolph, et al, 2006). Rudolph, et al (2006) recommended an approach to debriefing that assists learners to uncover underlying assumptions, termed frames, that led to either correct or incorrect actions during the simulation scenario. This approach has been used by Rudolph and colleagues with reports of anecdotal success (Rudolph et al, 2006), but there is currently little empirical evidence to support this model. Emotions can play a powerful role in enhancing learning by experience, although at times emotion can be a barrier (Moon, 2004). Students often experience strong emotions during the scenario and need an opportunity to release those emotions (Dreifuerst, 2009; Flanagan, 2008). Additionally, students may need to be encouraged to step out of the role assumed during the scenario (de-role) in order to optimize emotional readiness for debriefing (Flanagan, 2008; Stafford, 2005). Venting of emotions and de-roling are frequently the initial activities in the debriefing period (Flanagan, 2008).

According to Dreifuerst (2009), reception is the learner’s willingness to accept feedback. Feedback “has long been recognized as the most important form of learner guidance” (Merrill, 2002, p.50). In order to learn from errors one needs to know how to recognize, recover from, and avoid future commissions of the error (Merrill, 2002). In their systematic review of best practices in simulation based education, Issenberg et al (2005) reported that “feedback (knowledge of results of one’s own performance) is the single most important
feature of simulation based medical education” (p.21) and that the source of feedback was less important than its presence.

The statement that the source of feedback is not as important is called into question by other authors. There is evidence that including both self and peer assessment may improve learning outcomes; as demonstrated in a study conducted by Perera, Mahamadou and Kaur (2009) in which medical students developed significantly better communication skills using self, peer and faculty feedback when compared to faculty feedback only. The incorporation of self assessment and peer feedback, rather than relying on faculty feedback, is considered by some authors to be the ideal in conducting a debriefing session (Dieckmann et al, 2000; Flanagan, 2008).

Feedback strategies used during debriefing should assist the learner to appraise strengths and identify challenges in a way that is non-threatening (Dreifuerst, 2009). Rudolph, Simon, Rivard, Dufresne and Raemer (2007) identified three approaches to providing feedback during debriefing: judgmental, non-judgmental, and good judgment. Judgmental debriefing conveys criticism in a direct and harsh manner, which often leads to learner humiliation and reluctance to ask questions. Non-judgmental debriefing avoids the problems of judgmental debriefing, but often at the expense of providing specific corrective feedback. The good judgment approach uses questions to help learners uncover the assumptions underlying their overt behaviors, thus receiving feedback and learning self-assessment skills (Rudolph, et al, 2007).
Integration is described by Dreifuerst (2009) as facilitating the incorporation of lessons learned during simulation and reflection into a conceptual framework. Two nursing studies looked at clinical reasoning models that could be used for this purpose. Lasater (2007) developed a rubric to evaluate student clinical reasoning skills based on a model developed by Tanner (2006). Lasater (2007) describes this rubric as a tool to assist both self-assessment and faculty assessment of student’s clinical reasoning skills both in simulation based education and in direct clinical care. Kuiper et al (2008) conducted a descriptive study using the Outcome-Present State – Test Model of clinical reasoning as a framework for debriefing which demonstrated that clinical reasoning skills used during clinical simulation were similar to those used in clinical practice, but did not report data regarding student’s learning or performance gains using the model. These two studies provide little evidence for designing integration, and Dreifuerst (2009) states that this aspect of debriefing is often not mentioned.

Assimilation/Accommodation is the final attribute of the debriefing experience and includes both transfer of learning to the clinical area and supports the student’s ability to participate in reflection beyond action, using the learning to anticipate potential patient problems (Dreifuerst, 2009). Exploring how one will apply new knowledge in future experiences is a critical last step in experiential learning (Flanagan, 2008; Lindsey & Berger, 2009). Directly questioning participants in regards to how they will apply their learning is one recommended method of fulfilling this goal (Flanagan, 2008; Jeffries & Rogers, 2007; Lindsey & Berger, 2009).
The evidence base for making design decisions based on the characteristics listed as important in this model is increasing, but there is currently not enough research in any one area to provide strong guidance for manipulating the various design features (Jeffries, 2007).

**Outcome Measures.** Jeffries and Rogers (2007) identified five outcomes of simulation-based education in nursing: learning (knowledge), skill performance, learner satisfaction, critical thinking, and self-confidence. Jeffries (2006) stated that the outcomes in the model were taken from outcomes reported in the simulation literature. Learning or knowledge outcomes are measured based on the cognitive objectives for the simulation and can be measured with any valid and reliable tool (Jeffries & Rogers, 2007). Based on both empirical and anecdotal evidence, simulation-based learning appears to be an effective teaching-learning strategy (Cannon-Diehl, 2009).

Developing one’s procedural skills performance is becoming increasingly important for nursing practice (Jeffries, 2005). Simulation-based learning provides an environment conducive to developing skills without putting patients at risk (Jeffries, 2005). Simulation environments allow for deliberate practice, which is shown to improve both the psychomotor and cognitive skills necessary for developing expertise (Issenberg et al, 2005). Procedural skill outcomes are frequently measured using checklists of critical elements (Jeffries, 2005).

The development of critical thinking through simulation-based education has shown mixed results (Cant & Cooper, 2010). Ravert (2008) measured gains in critical thinking scores for undergraduate nursing students under three
conditions 1) human patient simulation, 2) small group case discussion, and 3) no additional instruction. Ravert measured critical thinking using two standardized instruments, and found that all groups improved in critical thinking over the course of the study but did not find significantly different gains between the groups. Becker (2007) compared case discussion with human patient simulation in developing critical thinking skills in advanced practice nurses. The findings, based on coding of discussion sessions, revealed a greater increase in critical thinking skills in the human patient simulation group. It is difficult to make comparisons across the studies due to the differences in methods of outcome measurement.

Self-confidence is improved when the student is able to transfer skills into the clinical area (Jeffries, 2006). In the literature, self-efficacy is most often reported and is seen as a pre-requisite for self confidence (Leigh, 2008). There are several recent studies exploring the relationship between simulation and self-efficacy or self-confidence. In a qualitative study conducted by Pike and O’Donnell (2010), undergraduate nursing students reported low self-efficacy in communication skills even with the use of clinical simulation. Additionally, one participant related that although she felt confident about using cardiac resuscitation skills in the simulation laboratory, the skills and confidence did not transfer to a similar situation in clinical practice. Wagner, Bear and Sander (2009) describe a simulation designed to prepare undergraduate nursing students to teach postpartum mothers in the clinical area. The students reported high levels of confidence in teaching and enjoyed the clinical experience. The study did not
employ a comparison group, so the contribution of the simulation cannot be separated from the other teaching/learning modalities used to prepare students. Kuznar (2009) found no significant difference in clinical self-efficacy in undergraduate nursing students between an experimental group who experienced clinical simulation and a control group that did not have that experience, although qualitative data indicated that students who experienced clinical simulation often spoke of how specific experiences impacted clinical practice. Lyles (2009) measured self-confidence in a group of undergraduate nursing students who had experienced clinical simulation compared to a control group, and found a higher level of confidence in skills performance in the experimental group. These results are promising, but there is not sufficient research to determine that simulation is better than traditional methods in increasing self-efficacy (Leigh, 2008).

In their systematic review of the nursing simulation literature, Cant and Cooper (2010) reported that of the twelve studies that met criteria, all supported the effectiveness of simulation-based education in increasing knowledge/skills, critical thinking, and/or self-confidence. Few studies detail the design of the simulation that may contribute to these outcomes.

**Summary**

The introduction of structured communication tools, such as SBAR, into high-fidelity simulations has been shown to improve undergraduate nursing student’s skills in organizing communication. The literature confirms that this skill remains underdeveloped in registered nurses who are new to practice (new graduate nurses). Further education is warranted during the new graduate period.
and there is support that high fidelity clinical simulation is an appropriate teaching learning strategy for developing this skill.

As part of a landmark study on simulation-based learning in nursing, Jeffries (2005) developed a framework to guide faculty in the design, development, implementation and evaluation of clinical simulations. The framework consists of three components: contextual elements, design characteristics, and outcomes, all of which have sub-elements that are theorized to affect the quality of clinical simulation design. The framework was validated for the purposes of the research study (Jeffries & Rizzollo, 2006) but data from the framework validation phase was not reported. Further testing of the framework components is warranted to continue improving the utility of the model and the quality of the clinical simulations produced (Jeffries & Rogers, 2007).

**Study Purpose and Questions**

The purpose of the current study is to investigate the use of the design characteristics component of the Framework for Designing Implementing and Evaluating Simulations (Jeffries, 2005; Jeffries, 2006; Jeffries & Rogers, 2007) in developing a simulation-based approach to teaching structured communication to new graduate nurses. The following research questions will be addressed:

1. How do the design characteristics of the Jeffries model, including objectives, problem-solving, student support, fidelity, and feedback/guided reflection, function in designing clinical simulation in this context?

2. How does faculty provide student support during the implementation phase?
3. How much debriefing time is focused on course objectives and application of learning to practice?

4. How does faculty perceive the effectiveness of the clinical simulation-based instructional program?

5. What are the knowledge and skill outcomes for graduate nurses who participate in the simulation?

6. How do students perceive the instructional program in terms of satisfaction and self-confidence in learning?

7. What are the strengths and weaknesses of the design characteristics in designing a clinical simulation in this context?

8. How can the model be strengthened for use in this context?
Method

Design and Participants

This study was designed as a field evaluation for the external validation of a model (Richey, 2005; Richey & Klein, 2007). The model under investigation was the Framework for Designing, Implementing and Evaluating Simulations as published by Jeffries and Rogers (2007). The study focused on the processes used to design the simulation, the implementation of the simulation by faculty, and course evaluation data from both students and faculty.

Participants in the study were two new graduate nursing education specialists, one unit based educator, and new graduate nurses and registered nurses who have been in practice for less than six months. The two nursing education specialists were recruited two weeks prior to the scheduled course; the unit based educator was recruited after the first scheduled course had been delivered. Student participants were recruited at the beginning of a scheduled course on interprofessional communication. There were 27 student participants. The researcher was also the instructional designer for the course.

The setting for the study was a medium sized tertiary care hospital located in the southwestern United States. The hospital hires approximately 60 new graduate nurses per year, primarily in two cohorts. The hospital has a 3,000 square foot simulation center with four simulation environments, and a classroom. Each simulation environment and the classroom have both video recording and video playback capabilities.
Materials

The materials consisted of an instructor’s guide for conducting a clinical simulation-based course focused on interprofessional communication, and pre-programmed clinical scenarios utilizing a high-fidelity human patient simulator within a simulated medical-surgical environment.

The instructor’s guide consisted of course objectives, detailed scenario outlines, and a library of potential debriefing questions. Each patient case featured an event that requires communication with a licensed independent practitioner, a role assumed by a faculty member. As the cases progress, the communication requirements became more complex as defined by the model (Jeffries & Rogers, 2007). The suggested debriefing questions served as an initial guideline for the debriefing process: faculty tailored feedback based on observations during the scenario.

Data Sources

Establishing validity in a field evaluation study for model validation required collecting data from a variety of sources and included information regarding the context of the design project (Richey & Klein, 2007). Triangulation of data from designer, instructor and learner sources improves the ability to make inferences about the data as it relates to the validation of the instructional design model (Richey, 2005).
**Designer Data.** The principal investigator served as the instructional designer. To minimize the potential bias that this type of research design may create, data from the designer, faculty participants and student participants were triangulated during the data analysis phase. Demographic data including age, gender, ethnicity, education, design experience in both general and simulation-based courses were collected using a data collection sheet (Appendix A1). A design log (Appendix A2) was kept by the designer to provide data regarding model use during the design phase, as well as any problems encountered and impressions of the model during the design phase. In addition, design documents were reviewed by an outside faculty member with expertise in both nursing content and instructional design for validation of the design prior to implementation.

**Faculty Data.** Demographic data including age, gender, ethnicity, instructional experience in traditional and simulation-based courses, highest degree, and education in facilitating simulation-based education were collected using a data collection sheet (Appendix A3). A preparation log (Appendix A4) was kept by all faculty detailing the time required to prepare, impressions of the various components of the instructor guide, and any problems or confusion encountered during preparation. All phases of implementation were observed and videotaped to collect data on how student support was implemented and how objectives and application to practice were addressed during debriefing. A researcher-designed observation sheet (Appendix A5) was used to analyze the data. A nurse researcher with a background in qualitative research independently
scored a portion of the videotapes to establish reliability. After each implementation of the course, faculty participated in a semi-structured interview regarding perceptions of course effectiveness, the level of fidelity and complexity in the scenarios, the experience of providing learner support, and perceptions regarding debriefing (Appendix A6).

**Student data.** Demographic data including age, gender, ethnicity, educational background (ADN or BSN), prior experience with simulation-based education, and overall perception of simulation-based education was collected via questionnaire (Appendix A7).

**Knowledge and skill outcome.** Participants completed a pretest and posttest (Appendix A8) on the day of the course using a four-question, short answer form requiring construction of a report in the situation, background, assessment and recommendation (SBAR) format in response to a videotaped patient assessment. A different patient assessment videotape was used for the pretest and posttest. The critical patient assessment data was the same in both videotapes, but surface features, such as age and gender, were different.

The organization and accuracy of the responses were scored using a researcher-designed rubric (Appendix A9). To develop the rubric, two registered nurses with one year of experience each viewed the videotape and completed the four open-ended questions of situation, background, assessment and recommendation. The researcher reviewed each for common content to develop the rubric. Further refinement was accomplished by incorporating feedback from
three master’s prepared nurses, two new graduate nursing education specialists and one clinical resource nurse who specializes in adult acute care.

The responses for the pretest and posttest were scored for inclusion of important elements of (1) patient identity and current problem (situation); (2) diagnosis, pertinent history and current treatment (background); (3) reporting of salient assessment data; and (4) recommendations reflective of the severity of the patient’s condition that do not include harmful recommendations. Participants received a score of 0-3 for each component of the report with a total possible score of 12. The researcher scored all pretests and posttests, 20% of the pretests and 20% of the posttests were scored by an undergraduate nursing faculty experienced in scoring using a rubric to determine inter-rater reliability.

Design characteristics. Student participants completed the Simulation Design Scale (Appendix A10) instrument developed by Jeffries (2005). This 20-item instrument focused on the use of the five design features, measuring both the presence of the features in the simulation and the importance of those features to the learner. Initial content validity was established by ten content experts in simulation development and testing. In the initial study, reliability was tested using Cronbach’s alpha which was found to be 0.92 for the presence of features and 0.96 for the importance of features (Jeffries, 2007).

In addition to the questionnaire, student participants were asked three open ended-questions (Appendix A11) to further explore perceptions of student support and feedback during the course.
1. What actions (if any) were taken by your teachers that supported you in learning about interprofessional communication today?

2. What feedback did you receive that was helpful to your learning?

3. Were there actions taken by either your teachers or your fellow students that were not helpful to your learning or made you uncomfortable? Please explain.

Student perceptions. Participants completed the Student Satisfaction and Self Confidence in Learning questionnaire (Appendix A12), which was a 13-item instrument designed to measure student satisfaction with the simulation activity and self-confidence in learning. In the original study, Cronbach’s alpha was 0.94 for the satisfaction scale and 0.87 for the self-confidence scale (Jeffries, 2007).

Instructional context. Participants completed a four question survey (Appendix A11) on the adequacy of the simulation environment, audiovisuals, seating and course scheduling related to their overall orientation schedule.

Procedures

The participants were employees of a tertiary care facility located in the southwestern United States. The course was incorporated into the New Graduate Nurse Education Series sponsored by the employer. Participation in the course was required; however participation in the study was voluntary following informed consent. The course was provided twice within a one week period, with approximately 15 students on each day.
Participants were given a unique study identification number on the day of the course but a master list was not kept. Participants independently took a pretest by initially viewing a videotape of patient assessment requiring communication with a licensed independent practitioner and completing four open-ended questions regarding the patient situation, background information, assessment data and recommendations for further action.

Following the pretest, faculty oriented participants to the course objectives and the learning environment. As is typical in the setting of simulation-based training, the large group was randomly divided into three groups of four to five people and then each small group was assigned to a patient case. The first small group directly participated in the patient case while the others observed via live video. At the conclusion of the scenario, two faculty members debriefed the scenario. During the debriefing, video of the patient case was available for review. Both direct participants and observers took part in the debriefing session. This pattern was repeated for the subsequent patient cases, allowing all members of the group an opportunity to directly participate in a patient case. All patient cases and debriefing sessions were videotaped.

Following the last patient case and debriefing, participants viewed a videotape of a patient assessment that required communication with a licensed independent practitioner and completed a posttest that had four open-ended questions related to patient situation, background information, assessment data and recommendations (SBAR). Participants also completed three questionnaires.
Regarding satisfaction with simulation design and self-confidence in learning. In addition, participants were asked three open-ended questions regarding learner support and feedback.

**Data Analysis**

External validation of an instructional design model is accomplished through “validation of the impact of the products of model use” (Richey, 2005, p. 174). The data analysis plan in this study focused on documenting evidence regarding effectiveness of a course designed while using the model, taking into account the influence of context on design and development research (Richey & Klein, 2007).

**Designer log.** The designer log was analyzed for statements that document the use of the model during the design phase. Additionally, the log was reviewed for evidence of decisions made during the design phase and designer reflections on how the model supported or did not support the instructional design. The overall time and resources required to design the course were be quantified.

**Faculty log.** The faculty log was analyzed for the process used to prepare to implement the class as well as time required. Problems, confusions and modifications made to the design by the faculty were analyzed for potential areas where effectiveness of the design may have been lacking.

**Demographics.** Demographic data was collected on the designer, faculty and students. The demographic data collected on the designer and faculty are
described as part of the context of the design and implementation. Descriptive statistics were completed for student demographic data.

**Observation Data.** Observation occurred during both the simulation and debriefing sessions. Data collected during the simulation was analyzed for patterns in the provision of student support by faculty. Data collected during the debriefing phase was analyzed for the time spent addressing each course objective and application to practice.

**Faculty interview.** The faculty interviews were coded for themes to be compared with model descriptors of the design characteristics and outcomes included in the model. The areas included product effectiveness, need for revision, and perceptions related to the specific design characteristics of fidelity, complexity, student support and debriefing.

**Test Scores.** Scores from the pretest and posttest were reported descriptively. A paired t-test was used to evaluate for significant differences in performance between the pretest and posttest.

**Questionnaires.** The Simulation Design Scale and Student Satisfaction and Self-Confidence in Learning scores were analyzed using descriptive statistics, including the mean and standard deviation for each item.

**Student Post-Course Survey.** Open-ended questions were coded for themes that further explain the student’s perceptions of feedback and support during the course. The Likert scale questions regarding the learning environment were reported descriptively as a component of the contextual data.
To improve validity in a model validation study, it is critical to collect and analyze data from a variety of sources. The analysis plan incorporated both quantitative and qualitative data from the designer, faculty and students that was then combined to answer the larger question of model validity within this specific context.
Results

Data were collected throughout the design, implementation and evaluation phase of the course. Results are reported below for each of these phases.

Design

Following the tenets of design and development research (Richey & Klein, 2007), the simulation-based course was designed by the researcher in collaboration with two faculty who served as subject-matter experts, provided input on objectives, reviewed and suggested revisions to the clinical scenarios prior to course implementation. The goals and objectives of the course addressed both accuracy of patient assessment and quality of structured communication. The course incorporated a pre-briefing to prepare students for simulation-based learning and three clinical scenarios that included student participation or observation of the case with each clinical scenario followed by structured debriefing.

Design Context. The course was designed within the context of a New Graduate Nurse Support Program (NGNSP) at a medium-sized, tertiary care facility located in the southwest United States. The NGNSP provides both classroom and clinical support to entry level registered nurses during the first year in their professional nursing role. The program is coordinated by two nursing education specialists (1.8 FTE).

Resources available to the designer included access to extensive clinical reference material, a training version of the electronic medical record currently in
use at the facility, as well as clinical equipment that is currently used (e.g., intravenous infusion pumps, blood glucose meter). The simulation center budget allows for purchase of mock medications and disposable medical equipment that is the same as that used in the care facility.

**Designer Demographics.** The course designer was a female registered nurse with 29 years of experience in nursing. In addition to holding a registered nurse license, the designer has a Master of Science degree in nursing and a Master of Education degree in Educational Technology. The designer has 10 years of experience as an educator, responsible for designing, developing, implementing and evaluating both classroom and online courses for physicians, nurses, and other allied health professionals in a hospital setting. Additionally, the designer has eight years of experience in teaching in undergraduate nursing programs. The designer has two years experience in simulation-based education and has designed, developed, and implemented courses as well as consulted with a variety of subject matter experts in designing simulation-based education.

**Course Description.** Prior to the simulation-based course, the new graduate nursing education specialists provided didactic education regarding use of structured communication and principles for communicating with physicians. The goal of this portion of the class was to meet pre-requisite knowledge for the simulation-based course.

The course was designed using the Simulation Design Model developed by Jeffries (2005) as a guide. The course objectives were (1) collect objective and
subjective assessment data that includes the clinical trigger for each situation, (2) perform a focused assessment based on the clinical trigger to provide the necessary clinical information, (3) select data to be reported to the provider, (4) organize data into situation, background, and assessment categories, (5) select recommendations that are either appropriate for further diagnosing the patient problem or treating the patient problem, (6) demonstrate the use of write down, read back method of receiving telephone orders, and (7) provide appropriate nursing interventions as required by patient condition. The course consisted of three clinical scenarios based on complications that arise in medical surgical settings: uncontrolled post-operative pain, gastrointestinal bleeding, and new onset acute confusion. Two of these clinical scenarios were suggested by faculty; the new onset acute confusion case was selected in response to a quality of care initiative currently being promoted at the care facility.

The course began with a scripted pre-briefing including a description of what to expect in simulation-based education, the course objectives and learner expectations, and orientation to the simulation facility and equipment. Each clinical scenario included the following elements: clinical scenario with a patient event to trigger problem solving and prompt a call to the physician, background clinical information including patient history, physical findings, current nursing assessment and orders, medication orders, and pertinent diagnostic testing results.

Pre-scripted student support was provided for faculty to enact the role of the patient or the provider. Patient information sharing was scripted so that information was not provided until the student specifically asked, for example the
patient would provide an answer to pain intensity but would not divulge the quality or location of the pain until specifically asked by the student. Patient cues were built based on textbook descriptions of signs and symptoms of the illnesses being portrayed in the clinical scenarios. Environmental student support was provided through materials in the room that contained specific patient information that might be necessary for identifying the issue.

The provider role was also pre-scripted by the designer so that faculty would give different orders depending on the information provided by the student during structured communication. For example if the students called with a concern about patient pain without additional information a particular order would be given, and as specific information was gathered and communicated by the students the orders would change and be more effective.

Faculty was provided observation sheets to record learner actions during the scenario to assist with preparing for debriefing. In addition, a list of potential questions based on course objectives was developed for faculty use during debriefing.

A tryout of the clinical scenarios was conducted with two faculty two weeks prior to implementation and revisions were made based on faculty input. The course design was also reviewed by an expert nurse educator for content and instructional design quality with the following comments: the overall goals and seven learning objectives are meaningful for the level of the new graduate nurse and the context of working in an acute-care health facility. The time plan seems
reasonable, with twice as long allowed for debriefing/guided reflection after each case as is planned for each simulated scenario. The script for introduction to simulation and orientation to the simulation room are typical of the information that is provided to participants in simulation centers. The patient data, including laboratory diagnostic data, physical assessment findings, clinical presentation, and medications ordered, is consistent with the common conditions represented in each of the three cases.

A question arose from the expert nurse educator regarding a mismatch between the first set of objectives in the design document and the set of objectives shared with the learners. This was an intentional change requested by the faculty to avoid cueing the student into the specific behavior, as they wanted to see if the students would remember without being specifically instructed to include the write down/read back procedure for receiving physician orders.

**Designer Log.** A log was kept by the designer/researcher during the design process as a method of reflecting upon the use of the simulation model during course and clinical scenario design and development. The designer recorded total design time of 40 hours.

The designer log was coded for themes in both decision making and reflection. This process uncovered three primary themes: decisions about design characteristics, challenges encountered in designing the course, and interrelationships between the design characteristics. Themes directly related to
the utility of the model were: adequate guidance, lack of guidance and use of outside simulation design resources.

Decisions made within the design characteristics included fidelity, student support and problem-solving, and to a lesser degree objectives and debriefing. The design characteristics of fidelity, student support and problem-solving are discussed below in greater detail.

**Fidelity.** Fidelity is often thought of as the capability of the technology to faithfully reproduce a patient condition. However, in the design log, fidelity also refers to how the case is written and how the environment is prepared. Reflection on fidelity fell into subthemes: the function of fidelity, how to ensure fidelity, and barriers to fidelity. The designer reflected on the function of fidelity to support students in achieving objectives:

It stands to reason that the key events must reflect the most important aspects of the illness script being used. Distracters must also be plausible, and patient data must be consistent across documents (e.g. what is in the history and physical matches the Nursing Kardex). Ignoring this fidelity could lead students down the wrong path as they try to make sense of an errant pattern.

Several methods were used during design to ensure fidelity in both how the scenarios were written and how the environment was prepared. In writing the scenarios, the designer referred to a variety of sources to create realistic patient cases for the scenario, including textbooks, online resources and expert opinion. When designing the patient case regarding pain management, the designer wrote that she “Maintain(ed) fidelity by looking for best evidence in medication
management to keep the scenario at least plausible”. This included using a nursing textbook, online opioid calculators and contacting a physician who specializes in pain management. Environmental fidelity was promoted by using moulage to create body fluids such as urine and liquid stool. Materials made available to students were reviewed by the course faculty for adequate fidelity during a tryout of the scenarios. The designer recorded revisions made related to fidelity, for example “The report adds to both fidelity (it is what a nurse would receive) and student support (don’t have to look everything up). Use of institution specific order sets should improve fidelity”.

Barriers to fidelity were noted in the log related to the capabilities of the human patient simulator and access to the current medical record. The third patient case scenario was written to reflect acute onset confusion, which can have different clinical presentations. The decision regarding patient presentation was based partly on known human patient simulator capabilities; “to adequately portray delirium, the limitations of the mannequin have to be taken into account; therefore this will be hypoactive delirium. Agitation is not an option with the mannequin – it just isn’t real”. Methods of overcoming barriers to fidelity were also recorded in the log; “Using an EXCEL spreadsheet that has key features of the Cerner® MAR [medication administration record] since there isn’t a way to directly use Cerner® at this time”.

**Student support.** The designer made several references to including student support focusing on adequacy of cues and how to make those cues available. Student support is written into the patient case scenario by providing
sufficient and appropriate cues for the student to use in problem-solving. An example of the use of cues as student support are found in this decision regarding the gastrointestinal bleeding case scenario: “Cues available are: patient script regarding symptoms, a stool that has the appearance of an upper GI bleed, vital signs (lying and sitting) that reflect hypovolemia, history includes two meds associated with GI bleed and recent physiologic stress”. The designer wrote that decisions on how to make cues available to learners are not always obvious:

Probably the most difficult, because you don’t want to just “give it away” – you want learners to work for it, but how concealed is too concealed? I decided to tightly script the patient and provider roles so that information is only given on request to decrease the potential of faculty leading too much and lessening the problem solving aspects of the scenario. The lack of predictability of learner actions in the scenario makes tight scripting difficult”.

Problem-solving. Problem-solving includes both the events that trigger decision-making and considerations of the level of complexity of the scenario in terms of the learner’s level of knowledge and skill. The designer documented decisions and concerns related to both how to trigger problem solving and physician communication within the case scenarios and how to alter complexity to fit the learner. The designer documented an approach to considering the problem-solving that would be required by listing the questions that would need to be answered within the case scenario: “What is needed to do a thorough assessment? What do we think is going on here? What merit does the antibiotic argument have? What information should I share with the physician? What orders should I request or anticipate?” In this same case scenario, the designer recorded reflections on aspects of complexity, giving “careful consideration of
complexity; how available are the cues in the scenario, how many conflicting cues to distract learners away from the real problem?”

Objectives and Debriefing. The designer reflected on the challenge of writing objectives to meet the model criteria of providing enough information to allow the learner to participate in the simulation effectively. This was an area in which the designer noted that faculty input would be important. In designing debriefing, the designer noted that an observation sheet based on expected student actions was developed to assist faculty in note taking during the scenario so that they would not need to “trust their memory”. The designer also recorded the development of reflective questions based on objectives and application to practice for use by faculty during debriefing to meet model recommendations that debriefing be focused on the objectives.

Interrelationships. Interrelationships between design characteristics were also noted in the designer log. Decisions made about one characteristic often impacted others. For example, “building problem solving into the scenario flows naturally from the objectives”. The interplay between problem-solving, student support and fidelity were documented as “fidelity and student support are intimately tied to complexity” and “fidelity is tightly tied – because if the cues aren’t plausible, they won’t support the learner”.

Several log entries discussed challenges in the design of the case scenarios. While several of these challenges fell under the various design characteristics, a variety of other challenges also arose such as selecting the best types of patient cases, designing for an interactive learning session where there is
lack of predictability of what the learner will do within the scenario, limitations of equipment and the level of detail required. An example of a challenge faced is documented as part of the tryout session discussion; “timing of family interaction is a subject of debate among faculty – it is difficult to know what the best timing would be, as the family is there to distract the nurse from the real problem”.

Commentary on the utility of the Simulation Design Model (Jeffries, 2005) was evident in the designer log. In terms of providing adequate guidance, the designer noted during the design of the second case scenario that the “model makes you think about what the problem-solving aspects are going to be relative to the objectives. It is flexible enough to encompass almost any problem designed into the scenario”.

However, areas in which the model did not provide adequate guidance were also noted, particularly in designing learner preparation and debriefing. In learner preparation, the designer noted that “it is difficult to determine how much detail learners need in the objectives to be able to participate in the simulation”. This theme of preparation arose again during the tryout: “The model doesn’t give good information about designing the pre-brief; the scenario tryout experience suggests that objectives alone are not enough to allow learners to fully participate”. Lack of guidance in preparing for debriefing was also evident in this statement written in the design log:

Other than making sure the objectives are re-stated and used for debriefing, little guidance is provided for how this is done. The model is not very robust for the part that most experts agree is the most important aspect of simulation-based learning.
Closely tied to lack of guidance is the theme of use of outside simulation resources. This is particularly noted in designing pre-briefing and debriefing activities, where other models and literature were used for guidance.

In summary, the designer log provides insight into the use of the model design characteristics and the challenges met in the process related to application of the model and addressing areas where the model was viewed as not providing sufficient guidance.

**Faculty Participants.** Two primary and one substitute faculty participated in the course. The role of the two primary faculty members was to provide input into course objectives, participate in a tryout, and teach the course on both days. Each primary faculty member maintained a log while preparing to present the course. The substitute faculty member taught the course on the second day.

**Faculty Demographics.** There were three faculty members who participated in the course, two primary faculty and a substitute who assisted with instruction during the second day of the course when one primary faculty was unavailable to teach. All faculty members are Caucasian females ranging in age from 32 to 47 years and possess a license to practice as a registered nurse.

The most senior faculty holds a Master of Science in Nursing and has 11 years of experience as a nursing education specialist, responsible for the NGNSP, critical care course, and cardiac monitoring education. This faculty member has three years experience in providing simulation-based courses, starting before a
formal simulation environment was constructed at the care facility. She received formal preparation for providing simulation-based education including an institution-provided course and participating in a course in programming the human patient simulator provided by the vendor. This faculty currently teaches approximately 16 simulation classes per year in five different courses, as well as assisting with simulation-based courses conducted by an inpatient nursing unit and cardiac catheterization laboratory. This faculty has been involved in all aspects of designing and delivering simulation-based courses, including development of goals and objectives, writing clinical scenarios, programming the human patient simulator, facilitating the clinical scenario for students, and debriefing.

The second most senior faculty holds a Bachelor in Health Arts and a Master of Science in Nursing. This faculty has six years experience as a Nursing Education Specialist, with one year in the NGNSP role as well as coordinating clinical rotations for undergraduate nursing programs. This faculty has one year of experience with simulation-based education but no formal training, and is involved in approximately three courses per year. She has been involved in writing objectives and designing one simulation course and has served in the faculty facilitation and debriefing roles.

The substitute faculty holds both a Bachelor of Science in Nursing and a Master of Science in Nursing Education. This faculty has 3.5 years experience as an educator with primary responsibility to a single nursing unit, as well as two years experience in simulation-based education. Her formal preparation for
providing simulation-based education includes a vendor-provided course in programming the human patient simulator and a communications in simulation class. This faculty teaches approximately six simulation-based classes per year in four different courses, having been involved in all aspects of designing and delivering simulation-based courses, including development of goals and objectives, writing clinical scenarios, programming the human patient simulator, facilitating the clinical scenario for students, and debriefing.

**Faculty Log.** The two primary NGNSP nursing education specialists described above kept a log of their activities during preparation to teach the course. Analysis of the faculty logs revealed three major themes, faculty roles, fidelity, and preparation.

*Faculty roles.* Both faculty noted that there was initially confusion regarding their role in implementing the simulation, as demonstrated by the entry, “…defining the roles of both (faculty) in this simulated environment, such as; who would be keeping time, how would the groups be divided, who would be giving the participants the report on the patient prior to beginning the simulated scenario”. The faculty noted that discussions provided needed clarity, “Today it was clear as to what our roles were going to be in the simulation”.

*Fidelity.* Both faculty discussed the input given regarding fidelity in the scenario. For example, one faculty documented that it would be important for “orders [to be] given the way new grads would see them ordered on the computer”. Concern for environmental fidelity was evident in the discussion of
“what materials and equipment would be needed to allow the new grads to implement the first intervention to carry through with orders received”.

Preparation. Both faculty documented time used to review materials and discussions on how to organize the day, “we discussed the details of who was going to be the provider/debriefer and the patient”. Faculty documented preparation times of 6.5 to 8 hours total, including tryouts, meetings and personal review of materials.

Course Implementation

Context for implementation. The course was implemented within the care facility’s Simulation Center. The Simulation Center is a 3300 square foot facility with a 20-seat classroom and four simulation environments: an operating room, an intensive care/emergency department room, a medical-surgical hospital room, and an outpatient room. The simulation rooms are built around a core control room used by the simulation staff to run and record simulation activities.

All scenarios were scheduled in the medical-surgical environment which is designed to be similar to a standard hospital room, including a non-functional bathroom. The Simulation Center provided a SimMan 3G® human patient simulator for the clinical scenarios as well as the necessary clinical equipment. Two facility limitations identified by faculty included a non-functioning computerized medication station and the inability to meaningfully use the electronic medical record in the simulation center.
All simulations are recorded using a web-based system for capturing, annotating and archiving videos obtained during scenarios and debriefing. This system also allows students who are not direct participants in the scenario an opportunity to observe the scenario in real time. This capability permits observers to consider their own approaches to the situation and participate in the debriefing.

**Student Participants.** Following approved institutional review board procedures, participants were recruited by the researcher on the day of the course prior to the beginning of instruction. Twenty-seven students gave permission to use their data for the study. Twenty-six completed all aspects of the study; one participant completed all but the evaluation questionnaires. Subsequent to obtaining permission, participants completed a demographic survey and took the pretest. After the course, participants completed the posttest and evaluation questionnaires.

The participants were mostly female (22 of 26, one non-report) and of those reporting, all were white, non-Hispanic. All participants had recently graduated from an entry-level program in nursing, with 12 holding an associate degree in nursing and 15 holding a bachelor’s degree in nursing. Fourteen participants held a certificate or degree outside of nursing with 11 holding a bachelor’s degree and one with a master’s degree. The mean age of the group was 29.92 years (SD 9.46, range 22-57) with 23 participants having clinical experience beyond nursing school, ranging from several months as a volunteer to 17 years as a patient care technician. The majority with experience held positions as patient care assistants or nurse externs for varying lengths of time.
The majority of participants had experienced clinical simulation in their undergraduate nursing programs, with 23 reporting at least some clinical simulation experience. The median was 3.5 simulation experiences per semester, the lowest being one simulation during the entire nursing program to a high of 20 hours of simulation per semester. Of those who had experience with simulation, their overall attitude towards the use of simulation in clinical learning was favorable [mean 4.08, SD 0.78] on a 1-5 scale, with five being very useful.

**Implementation methods.** The course was scheduled to be given twice during a single week, with content being repeated for two different groups of students. The course was implemented as scheduled on the first day, facilitated by the two NGNSP nursing education specialists assisted by the simulation center systems analyst and a volunteer. During the faculty interview after the first day, two revisions for the second day were recommended; a clarification of one medication order and a different presentation of moulage related to the gastrointestinal bleeding scenario. In addition, faculty was reassured that deviating from the script when providing student support was permissible. The course was implemented on the second day with a change in faculty, facilitated by one NGNSP nursing education specialist and a substitute faculty with experience in simulation-based education again assisted by the simulation center systems analyst and a volunteer.

Prior to each scenario, the participants were prepared for the clinical situation by the faculty using a description of the patient’s condition in the form of a handoff report. Each scenario had five roles: two primary registered nurses, a
team leader registered nurse who could be called as an extra resource, a family member who was provided a script and an allied health staff who could be called to perform a range of activities including obtaining laboratory specimens from the human patient simulator. During the scenario, primary registered nurses were expected to assess the patient through interacting with the human patient simulator and other persons or materials in the room, identify the priority patient problem and contact the physician. The family member served as a source of patient information and added to the overall complexity of the situation in two scenarios. Students who were not directly participating in the scenario observed the simulation from the classroom.

During each scenario, one faculty member provided the voice of the patient based on a script of the presenting signs and symptoms. The other faculty member was the primary observer and played the role of the physician. Both of these roles allowed the faculty to provide additional student support to allow learners to progress through the scenario. The simulation center volunteer ensured that the human patient simulator was running and assisted with video capture.

**Student support during the scenario.** According to the model, support is provided to help students progress through the scenario (Jeffries & Rogers, 2007). Faculty may provide additional cues during a scenario to assist students in focusing on the patient’s primary problem or assist them in moving through the situation. Ideally, student support does not interfere with problem-solving within the scenario (Jeffries & Rogers, 2007).
Faculty may provide cues in a variety of ways, including through the voice of the patient, in response to telephone calls, providing direct in-room assistance, changing elements within the environment to re-focus attention or requesting another person to enter the scenario with information meant to re-direct the student. Often these decisions must be made quickly based on student actions within the simulation.

Faculty approaches to student support were observed during the clinical scenarios and are summarized in Table 1. Prior to the researcher coding the observations, two independent raters coded the videotape of the scenario and discussed coding. This process was repeated until 90% agreement was reached.

In general, the majority of student support was provided by faculty through either the voice of the patient and the role of the provider. Direct assistance and changes in the environment were used, but no instances of coaching another student prior to entering the room were noted.

Differences in student support provided were noted between the same scenarios from the first implementation to the second. For example, during the initial clinical scenario each day, faculty provided patient prompts more frequently on the second day (4 vs. 9) and initiated giving prompts earlier (7 minutes 50 seconds into a 23 minute scenario vs. 58 seconds into a 22 minute scenario). The additional patient prompts provided by faculty on the second day were geared to refocus the students on the presence of back pain in addition to surgical pain. There were more provider prompts supplied by faculty on the
second day (3 vs. 5) including asking the students if the patient was on pain medication at home (approximately 18 minutes into the 21 minute scenario), which was the primary issue for this clinical scenario. This question was not asked by the faculty provider on the first day, and students did not discover this issue during the clinical scenario.

There were two instances of environmental support during the three clinical scenarios on the first day, both related to changes in vital signs. This increased to three instances on day two, with a change in vital signs or heart rhythm evident in each scenario. Direct support was given twice on the first day, with faculty answering a process question and assisting with initiating telemetry. One instance of direct support was given on the second day, answering a clinical question in the absence of information. Additionally, the faculty was required to provide verbal answers to neurologic physical assessment questions that could not be produced by the human patient simulator.

Table 1

*Types of Non-Predesigned Student Support Provided by Faculty*

<table>
<thead>
<tr>
<th>Day</th>
<th>Scenario</th>
<th>Patient</th>
<th>Provider</th>
<th>Environment</th>
<th>Direct</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>6</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>9</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
Debriefing. Faculty facilitation of debriefing allows students to receive feedback and reflect on the clinical scenario based on course objectives and make connections to clinical practice (Jeffries, 2005). Faculty debriefing sessions were analyzed for time spent on discussion related to both course objectives and application of learning to practice. Table 2 details the percent of time spent on each aspect, as well as time spent in other activities, such as logistics or tangential topics. Prior to the researcher coding the observations, two independent raters coded the videotape of the debriefing and discussed coding. This process was repeated until 90% agreement was reached.

In general, the greatest percentage of time was spent discussing application to practice (M = 24%), appropriate nursing interventions (M = 23.1%), and focused assessment (M = 21.2%). The percentage of time spent discussing focused communication skills of selecting and organizing information and selecting recommendations received a smaller portion of time, M = 8.4% and 3.8% respectively. The objective related to using write down and read back techniques for taking provider orders was not addressed in any debriefing session.
Table 2

*Percent of Debriefing Time Spent per Objective and Application to Practice*

<table>
<thead>
<tr>
<th>Objective</th>
<th>Day 1 Case 1</th>
<th>Day 2 Case 1</th>
<th>Day 1 Case 2</th>
<th>Day 2 Case 2</th>
<th>Day 1 Case 3</th>
<th>Day 2 Case 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recap of what happened</td>
<td>5.9%</td>
<td>3.7%</td>
<td>8.0%</td>
<td>8.0%</td>
<td>6.8%</td>
<td>4.4%</td>
</tr>
<tr>
<td>Collecting objective and subjective assessment data</td>
<td>15.3%</td>
<td>1.0%</td>
<td>16.9%</td>
<td>6.1%</td>
<td>13.5%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Performing focused assessment</td>
<td>28.2%</td>
<td>32.2%</td>
<td>18.2%</td>
<td>6.0%</td>
<td>31.2%</td>
<td>11.4%</td>
</tr>
<tr>
<td>Selecting and organizing data to be reported to the provider</td>
<td>7.5%</td>
<td>15.1%</td>
<td>17.2%</td>
<td>6.4%</td>
<td>2.4%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Selecting recommendations</td>
<td>1.9%</td>
<td>0.0%</td>
<td>4.9%</td>
<td>4.7%</td>
<td>4.5%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Using write down/read back</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Appropriate nursing interventions</td>
<td>20.8%</td>
<td>26.5%</td>
<td>28.9%</td>
<td>21.4%</td>
<td>9.4%</td>
<td>31.5%</td>
</tr>
<tr>
<td>Application of learning to practice</td>
<td>20.3%</td>
<td>21.5%</td>
<td>5.9%</td>
<td>33.0%</td>
<td>32.2%</td>
<td>30.8%</td>
</tr>
<tr>
<td>Other</td>
<td>0%</td>
<td>10.0%</td>
<td>0%</td>
<td>14.34%</td>
<td>15.4%</td>
<td>9.33%</td>
</tr>
</tbody>
</table>
Course Evaluation

Participant Achievement. Two independent raters scored 20% of the pretests and posttests. The inter-rater reliability was 0.75 for the pretest and 0.81 for the posttest (Pearson’s R).

A paired-samples $t$ test was conducted to evaluate whether assessment scores changed significantly from pretest to posttest (Table 3). The results indicated that the mean posttest score was 4.89 out of a possible 12 points (SD = 1.93) and was significantly better than the mean pretest score ($M = 3.11$, SD = 1.40), $t(26) = 4.44$, $p < .01$. The 95% confidence interval for the mean difference between the two scores was 0.95 to 2.60.

A paired-samples $t$ test was conducted to evaluate whether assessment scores changed significantly from pretest to posttest on each of the four components of the SBAR report. Scores improved significantly for the first component ($t(26) = 2.60$, $p < .05$, with 95% confidence interval of 0.16 – 1.39), small but non-significant increases were noted for the second and third question; none of the participants achieved a score greater than zero on the fourth component in either the pretest or posttest.
Table 3

*Pretest and Posttest Scores*

<table>
<thead>
<tr>
<th>Question</th>
<th>Pretest Mean</th>
<th>Pretest SD</th>
<th>Posttest Mean</th>
<th>Posttest SD</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Situation</td>
<td>1.67</td>
<td>1.36</td>
<td>2.44</td>
<td>1.09</td>
<td>p &lt; .05</td>
</tr>
<tr>
<td>Background</td>
<td>1.52</td>
<td>1.01</td>
<td>1.74</td>
<td>1.20</td>
<td>p = .25</td>
</tr>
<tr>
<td>Assessment</td>
<td>0.63</td>
<td>0.69</td>
<td>0.70</td>
<td>0.82</td>
<td>p = .73</td>
</tr>
<tr>
<td>Recommendation</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Score</td>
<td>3.11</td>
<td>1.40</td>
<td>4.89</td>
<td>1.93</td>
<td>p &lt; .01</td>
</tr>
</tbody>
</table>

**Simulation Design Scale.** Participants completed the simulation design scale after completing the course. The scale measured the participants’ perceptions regarding the presence of the design characteristics in the simulation-based course just completed and asks if that particular design characteristic is important to the participant. Results are summarized in Table 4.

**Presence of Design Characteristics.** A total of 26 participants completed the Simulation Design Scale. The scale is scored from 1 to 5, with anchors at 1 indicating strong disagreement with the statement and 5 indicating strong agreement with the statement. Each question also allows the participant to indicate that the characteristic is not applicable. Overall, the participants either agreed or strongly agreed that each of the design elements were present in the simulation course.

The highest scores were found for the design characteristic - Feedback and Guided Reflection. Specifically, average scores on two questions - (1) “Feedback
was provided in a timely fashion” (M = 4.56, SD = 0.87) and (2) “There was an opportunity after the simulation to obtain guidance/feedback from the teacher in order to build knowledge to another level” (M = 4.6, SD = 0.91) - indicated a high level of agreement that this design characteristic was present.

Two scores were below the mean of 4.0 (indicating some disagreement with the statement) and were explored in further detail to determine if differences exist between the first and second day participants. The overall mean for the question, “The simulation provided enough information in a clear manner for me to problem-solve the situation”, was 3.81 (SD = 0.94). This question is categorized as presence of Objectives and Information. Further exploration of this finding suggests that participant perceptions of the quality of the information given was similar across the two days (Day 1 M = 3.79, SD = 0.80; Day 2 M = 3.83, SD = 1.11). The mean score on the question: “The simulation provided me an opportunity to goal set with my patient” was 3.46 (SD = 1.17), and was part of the Problem Solving characteristic. This finding was not as consistent across days (Day 1 M = 3.29, SD = 0.99; Day 2 M = 3.67, SD=1.37). The sample size is too small to conduct inferential statistics, but the participants on the second day tended to agree with this statement more than the first day participants.

**Importance of Design Characteristics.** This scale measured participants’ opinions of how important each design characteristic is to them when learning in a simulation-based course. Overall, participants agreed or strongly agreed that all of the design characteristics are important.
The most important design characteristics for this group of participants were being “supported in the learning process” (M = 4.81, SD = 0.49) and the “opportunity after the simulation to obtain guidance/feedback from the teacher in order to build knowledge to another level” (M = 4.81, SD = 0.57). The least important characteristic was the “opportunity to goal set with my patient” (M = 4.35, SD = 0.75).
## Table 4

### Presence and Importance of Design Characteristics

<table>
<thead>
<tr>
<th>Objectives and Information</th>
<th>Presence</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>There was enough information provided at the beginning of the simulation to provide direction and encouragement</td>
<td>4.23</td>
<td>4.65</td>
</tr>
<tr>
<td>I clearly understood the purpose and objectives of the simulation.</td>
<td>4.42</td>
<td>4.54</td>
</tr>
<tr>
<td>The simulation provided enough information in a clear manner for me to problem-solve the situation.</td>
<td>3.81</td>
<td>4.54</td>
</tr>
<tr>
<td>There was enough information provided to me during the simulation.</td>
<td>4.08</td>
<td>4.54</td>
</tr>
<tr>
<td>The cues were appropriate and geared to promote my understanding.</td>
<td>4.15</td>
<td>4.38</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Student Support</th>
<th>Presence</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support was offered in a timely manner.</td>
<td>4.40</td>
<td>4.69</td>
</tr>
<tr>
<td>My need for help was recognized.</td>
<td>4.30</td>
<td>4.60</td>
</tr>
<tr>
<td>I felt supported by the teacher’s assistance during the simulation.</td>
<td>4.20</td>
<td>4.65</td>
</tr>
<tr>
<td>I was supported in the learning process.</td>
<td>4.38</td>
<td>4.81</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem Solving</th>
<th>Presence</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent problem-solving was facilitated.</td>
<td>4.28</td>
<td>4.62</td>
</tr>
<tr>
<td>I was encouraged to explore all possibilities of the simulation.</td>
<td>4.19</td>
<td>4.69</td>
</tr>
<tr>
<td>The simulation was designed for my specific level of knowledge and skills.</td>
<td>4.31</td>
<td>4.73</td>
</tr>
<tr>
<td>The simulation allowed me the opportunity to prioritize nursing assessments and care.</td>
<td>4.00</td>
<td>4.77</td>
</tr>
<tr>
<td>The simulation provided me an opportunity to goal set for my patient.</td>
<td>3.46</td>
<td>4.35</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Feedback/Guided Reflection</th>
<th>Presence</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback provided was constructive.</td>
<td>4.42</td>
<td>4.77</td>
</tr>
<tr>
<td>Feedback was provided in a timely manner.</td>
<td>4.56</td>
<td>4.65</td>
</tr>
<tr>
<td>The simulation allowed me to analyze my own behavior and actions.</td>
<td>4.38</td>
<td>4.73</td>
</tr>
<tr>
<td>There was an opportunity after the simulation to obtain guidance/feedback from the teacher in order to build my knowledge to another level.</td>
<td>4.60</td>
<td>4.81</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fidelity (Realism)</th>
<th>Presence</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>The scenario resembled a real-life situation.</td>
<td>4.36</td>
<td>4.65</td>
</tr>
<tr>
<td>Real-life factors, situations, and variables were built into the simulation scenario.</td>
<td>4.36</td>
<td>4.69</td>
</tr>
</tbody>
</table>

Presence scale 1=Strongly disagree to 5=Strongly agree  
Importance scale 1=Not at all important to 5=Very important
Satisfaction and Self-Confidence in Learning. The Satisfaction and Self-Confidence in Learning Instrument is divided into two categories - satisfaction with current learning and self-confidence in learning. Results are detailed in Table 5. In general, participants were satisfied with their current learning. The scale included five questions; three focused on the teacher and teaching methods and two focused on materials. The participants were slightly more satisfied with teaching than with the materials and activities available. For example, the mean score on the question, “The simulation provided me with a variety of learning materials and activities to promote my learning the medical surgical curriculum” was 4.15 (SD = 0.88), with one participant disagreeing with the statement and five undecided.

The self-confidence in learning section of the instrument is broken down into four questions regarding confidence in obtaining knowledge and skills; two questions relate to the ability to obtain necessary resources for learning and two questions relate to student and faculty responsibility for determining what is to be learned from the simulation activity.

The participants generally agreed that the content of the simulation was important (M = 4.15, SD = 0.54), that the simulation helped develop skills important to clinical practice (M = 4.00, SD = 0.69), and were confident in their own ability to use simulation to learn (M = 4.19, SD = 0.69). The participants expressed less confidence in their mastery of the content of this simulations (M = 3.85, SD = 0.67).
The participants were positive regarding the resources used by the instructor during the simulation (M = 4.46, SD = 0.58) and their ability to get help if needed (M = 4.38, SD = 0.64). Participants felt that students (M = 4.54, SD = 0.51) were more responsible for determining what was to be learned from the simulation and approached neutral (M = 3.19, SD = 1.13) regarding the instructor’s responsibility for determining what should be learned.

**Open-Ended Questions.** To further explore student support and feedback, three open-ended questions were included in the post-course survey. Participants also had an opportunity to add other comments they felt were important.

The first question focused on the participant’s identification of activities that most supported their learning during the course. The most common responses were the opportunity to debrief the case (N = 10) and to receive feedback on what went well and what needed improvement (N = 8). The opportunity to practice physician communication was also a common response (N = 8). Additional responses included the didactic portion of the day (N = 6), the SBAR laminated card that was provided (N = 2), group interaction (N = 2), and the opportunity to assess the patient and determine the problem during the scenario (N = 1).
Table 5

*Student Satisfaction and Self-Confidence in Learning*

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The teaching methods used in this simulation were helpful and effective.</td>
<td>4.42</td>
<td>0.64</td>
</tr>
<tr>
<td>The simulation provided me with a variety of learning materials and activities to promote my learning the medical surgical curriculum</td>
<td>4.15</td>
<td>0.88</td>
</tr>
<tr>
<td>I enjoyed how my instructor taught the simulation</td>
<td>4.50</td>
<td>0.58</td>
</tr>
<tr>
<td>The way my instructor(s) taught the simulation was suitable to the way I learn.</td>
<td>4.15</td>
<td>0.67</td>
</tr>
<tr>
<td>I am confident that I am mastering the content of the simulation activity that my instructors presented to me.</td>
<td>4.31</td>
<td>0.79</td>
</tr>
<tr>
<td>I am confident that this simulation covered critical content necessary for the mastery of medical surgical curriculum</td>
<td>3.85</td>
<td>0.67</td>
</tr>
<tr>
<td>I am confident that I am developing the skills and obtaining the required knowledge from this simulation to perform necessary tasks in a clinical setting</td>
<td>4.15</td>
<td>0.54</td>
</tr>
<tr>
<td>My instructors used helpful resources to teach the simulation</td>
<td>4.00</td>
<td>0.69</td>
</tr>
<tr>
<td>It is my responsibility as the student to learn what I need to know from this simulation activity</td>
<td>4.46</td>
<td>0.58</td>
</tr>
<tr>
<td>I know how to get help when I do not understand the concepts covered in the simulation</td>
<td>4.54</td>
<td>0.51</td>
</tr>
<tr>
<td>I know how to use simulation activities to learn critical aspects of these skills</td>
<td>4.38</td>
<td>0.64</td>
</tr>
<tr>
<td>It is the instructor’s responsibility to tell me what I need to learn of the simulation activity content during class time</td>
<td>3.19</td>
<td>1.13</td>
</tr>
</tbody>
</table>
The second question addressed what feedback the learners felt was most helpful to their learning. The majority of respondents provided a general answer such as debriefing, but four specifically mentioned the feedback obtained during peer discussions, four stated that they appreciated exploring other perspectives including the teacher’s perspective, and two stated they received feedback that helped them identify personal strengths and weaknesses.

The third question addressed behaviors or activities that were not helpful to learning. Four participants stated that being watched or videotaped during the scenario was stressful, two participants stated they would have liked an opportunity to be directly involved in the case rather than observe, one participant stated that being in a scenario produced anxiety, and one participant shared that it appeared that students participating in the scenario felt uncomfortable due to lack of preparation.

The fourth question invited participants to share any other comments regarding the day. Three stated it was difficult to hear, two mentioned a desire to be directly involved in the simulation, one requested feedback on the pretest answers, and one stated that the class schedule was not convenient for night shift employees.

**Participant Satisfaction with Facility.** The adequacy of the physical facility was evaluated on a Likert scale (1=strongly disagree to 5=strongly agree). Participants were satisfied with the room arrangement (M = 4.42, SD = 0.50), the quality of the audiovisual equipment (M = 4.19, SD = 0.75), and seating
arrangements (M = 4.27, SD = 0.60). Two participants commented that it was difficult to hear when using the flat screen in the classroom. Participants also agreed that course scheduling was convenient (M = 4.31, SD = 0.74) with one comment that the class schedule was not convenient for staff who routinely work from 7:00 pm to 7:00 am.

**Faculty Evaluation.** A semi-structured interview was conducted after course implementations. The interviews were analyzed for faculty evaluations of fidelity, problem-solving, student support, and leading debriefing during implementation. In addition, general impressions and areas for improvement were analyzed.

*General impressions.* In general, faculty felt the course went well, with the second day running more smoothly than the first day. The students on the first day did not discover the core issue in any of the three scenarios; students on the second day discovered the issue in each scenario. During guided reflection, the students were hard to engage on day one whereas the students on day two were noted to be engaged and bringing up topics of interest. The faculty member who only participated in the second day commented on the overall “positive vibe” felt during the course. Despite the difficulties on the first day, faculty related that “all [students] felt they learned and gained some skills”.

*Fidelity.* Faculty found both positive and negative aspects to fidelity during implementation of the scenarios. Faculty commented that the “scenarios chosen made using the mannequins feasible” and that the mannequins were
“fairly close, pretty realistic”. All acknowledged that there were limitations to the mannequins, such as “not being able to move to demonstrate that the patient was still awake”. One faculty commented, “It was good to have a faculty person as the voice of the patient as the students needed responses in the moment and to have dialogue. Having mannequin-canned phrases would not have worked as well”.

Fidelity in the environment was seen as the biggest challenge. Faculty specifically identified challenges with obtaining blood glucose, not having supplies in the room similar to what is available on the patient care units, not having a functional automated drug dispensing machine which required having medications “laid out in the room”, and not having a functional electronic medical record. Faculty identified that these issues “presented a challenge” to the students during scenario participation.

**Problem-solving.** All faculty felt the problem-solving required within the scenarios matched the needs of the students even though the “first day was challenging with the students not picking up at all”. Faculty shared that students “appreciated that these were medical-surgical scenarios and not crash and burn like in school”. A related finding was that students entered the scenarios with pre-existing ideas from previous simulations and “all expected the worst”. In particular, for the second scenario students were “prepared for respiratory problems and were not looking beyond that”.
Student support. When asked about providing student support, one faculty member shared that it was “instinctual”. All faculty shared that they chose to give additional support when students are “struggling” with the scenario, defined as “not getting to the heart of the matter”. Another stated that they chose to provide support when the “information given was not adequate” for problem solving.

Faculty enacted both the patient and provider roles during the scenarios, and determining how much support to provide in the moment was not a simple decision. One faculty commented on providing support in a particular patient role:

I didn’t want to give too much information, I was slow to respond but not out, it was difficult to balance because I couldn’t do movements to show I was still awake. It was difficult to strike a balance between lethargic but not totally out.

Similarly, enacting the role of provider came with difficult decisions regarding student support:

How far do you go and let them not be successful? You don’t want to hold their hand and lead them down a path, but it would be natural for a provider to ask these questions. You want to try to have a successful outcome.

Faculty agreed that providing student support in the moment requires striking a balance. This was complicated during the course due to faculty perceptions of the requirements of the research, “we thought we had to follow the script closely since this was research, even after you told us, better by the third scenario on the first day, it became more comfortable to deviate”.

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Debriefing. The experience of debriefing was different each day of the course. One faculty shared that the “first group was tough, the primary nurse beat herself up that she didn’t recognize the issue, she did hear the positive feedback, but it was challenging...difficult”. This faculty stated that she managed this by focusing on what went well and at the end of the debriefing “come around to what the scenario was about”. Despite these challenges, the faculty shared that “nobody felt unsafe”. The second day was less challenging; one faculty observed that “students declared topics that we had determined we wanted to talk about; only a few times did we need to ask questions to redirect”.

In terms of addressing objectives during the debriefing, faculty stated that they “did achieve communication” but one acknowledged that “[we] talked about communication less than intended but the clinical was their need and it helps with communication, it met their learning needs”.

Revisions to course. Although the overall impression was favorable, there was one major area of concern regarding student participation; “If they were assigned the role of team leader or allied health, some sat all day. The first day, no team leaders or allied health were used”. The situation was slightly different on the second day, but not every student had an opportunity to actively participate in a scenario. All faculty agreed that changes need to be made to give all a chance to participate at some point in the day.
Discussion

The purpose of this study was to validate the use of the design characteristics of objectives, student support, problem-solving, fidelity, and feedback/guided reflection (more commonly termed debriefing) outlined in the Framework for Designing, Implementing and Evaluating Simulations (Jeffries, 2005; Jeffries, 2006; Jeffries & Rogers, 2007). The study was conducted in the context of providing simulation-based education on structured communication to new graduate nurses in an acute care setting. In this chapter, each model design characteristic will be discussed in terms of function and utility during the design, implementation and evaluation phases of the project from the perspective of the designer, faculty and students.

Function of Design Characteristics

The design characteristics listed in the model include objectives, problem-solving, student support, fidelity, and feedback/guided reflection (debriefing). These design characteristics reside within a larger framework which includes the contextual factors of teacher, student and educational practices and expected outcomes of simulation, which include knowledge, skill, critical thinking, satisfaction and self-confidence. Although not the focus of this study, the influence of these factors was noted during the design, implementation and evaluation of the project.

Objectives and Information. According to the model “objectives of the simulation must reflect the intended outcome of the experience, specify expected
learner behaviors, and include sufficient detail to allow the learner to participate in the simulation effectively” (Jeffries & Rogers, 2007, p.27). Additionally, objectives are shared with learners prior to the simulation and serve as the focus on debriefing along with application of learning to practice (Jeffries & Rogers, 2007).

The designer in the current study developed objectives for the simulation, including statements of expected learner behaviors. The designer noted that writing detailed objectives that would truly guide student participation was difficult and requested faculty input. Following revision, the appropriateness of the objectives was also confirmed through review by a nurse expert. The designer noted the use of the objectives in making design decisions regarding problem-solving and debriefing, indicating that the objectives were useful to the designer. Data collected during the design phase suggest that it is important to develop clear objectives that are agreed upon by faculty.

During the tryout of the scenarios, the designer noted in the log that “providing objectives alone was not sufficient preparation for simulation”, resulting in the development of a pre-briefing script for use by faculty. This script was used by faculty at the beginning of the simulation course each day.

During implementation of the course, there was conflicting evidence regarding how prepared the students felt as they entered the simulation. For example, a student commented that other participants appeared to be uncomfortable as a result of not being prepared. However, student evaluation
data demonstrated overall agreement that the objectives were clear. Faculty
shared in their evaluation that students entered the simulation with pre-existing
ideas of what to expect based on their school experience where most simulations
were based around a patient in crisis. The students felt “thrown off” when those
situations did not arise.

Although the objectives were peer reviewed, used to drive design, and
students agreed that the objectives were clear; there is evidence to suggest that
objectives alone are not adequate in preparing students to participate in the
situation. Within the context of students coming from different undergraduate
nursing programs, addressing prior experience and expectations with students
before the simulation may be useful in uncovering pre-existing ideas of what to
expect within the clinical simulation scenario and assisting students to modify
expectations.

**Problem-solving.** Within the framework, problem-solving is viewed as
decision points that learners create for themselves (Jeffries, 2006). Jeffries (2005)
discussed complexity of problem-solving in terms of the level of uncertainty
found within the scenario; complexity increases with the number of problems
presented, the number and stability of the relationships between the problems, and
the presence of irrelevant data. According to the model, the goal is to match the
complexity of the scenario to the student’s abilities so that the situation is
“challenging to the learner but attainable” (Jeffries & Rogers, 2007, p.28).
The designer noted that creating events that trigger problem-solving “flowed naturally from the objectives”. The designer also noted that matching the complexity of scenarios to the student’s abilities was difficult, in that the students were all recent employees from diverse undergraduate programs with little time to determine current skill and ability levels. This problem may be more pronounced in the workplace where formal education is episodic when compared to an academic program. The designer attempted to address this difficulty by conducting scenario tryouts with faculty who are most familiar with the students. This tryout occurred with faculty having no prior knowledge of the scenarios, to mimic the student experience. Discussions after the tryouts led to modifications that were intended to strengthen the problem-solving aspect of the clinical scenarios.

During implementation, the students who participated on the first day were unable to uncover the core clinical issues embedded in any of the scenarios, which led to concerns that the problem-solving challenge was not correctly calibrated. However, student participants were successful in discovering the core clinical issues when the course was repeated with a different group.

Overall evaluations of the course indicated both student and faculty satisfaction with the level of challenge presented in the scenarios. Faculty stated that they felt the challenge of the scenarios was appropriate to the students, and student participants agreed with the statement that the “simulation was designed for my specific level of knowledge and skill”.

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These findings suggest that calibrating complexity to individual student abilities in the design phase is not exact. In order to meet the goal of the model to make the scenarios challenging but attainable, other mechanisms must be available that can alter the complexity in response to student activity within the scenario; within the context of the Jeffries model, this is one function of student support and fidelity design characteristics.

**Student support.** Student support includes the cues provided during the simulation (Jeffries & Rogers, 2007) as well as facilitation of reflection on decision-making during debriefing and guided reflection after the scenario has ended (Jeffries, 2006). The provision of cues during the simulation should “offer enough information for the learner to continue with the simulation, but do not interfere with his/her independent problem solving” (Jeffries & Rogers, 2007, p. 29). Additionally, Jeffries & Rogers (2007) recommend that the faculty determine the content and the timing of cues prior to handing the scenario to the facilitator. Within the context of the current study, the designer would be considered faculty and the faculty would be considered the facilitators.

The designer noted that determining the content of the cues requires use of resource materials to create scenarios that accurately reflect the patient condition, which is closely related to fidelity. The recommendation to determine the timing of cues in advance was more problematic. Both the designer and the faculty documented concerns with the balance of student support required to meet student needs without interfering with their problem-solving. The decision to require students to independently review patient information and to only receive specific
information during the simulation when it was requested had an impact on the faculty’s approach to implementation and ultimately student performance both during the simulation and debriefing.

With two faculty available to implement the scenario, one provided cues via the voice of the patient and changes to the human patient simulator’s status while the other faculty provided cues as the voice of the physician on the telephone in response to student SBAR report. The majority of student support that was not pre-determined was provided through the voice of the provider and the voice of the patient. Prompts given through the patient voice were primarily to give additional assessment information or to refocus the student on the primary problem. Prompts given through the provider voice were primarily to ask for additional assessment data and to encourage the student to consider recommendations. The environmental cue of changes in vital signs was also used to add to assessment data and refocus on the primary problem.

The faculty stated that providing student support during this course was different than usual because they felt obligated to adhere to the scripts provided for the patient and physician. One faculty member stated that she felt more comfortable in deviating from the script by the third scenario on the first day. This was evident in an observation of student support provided, where additional assessment data was provided much earlier in a scenario on the second day as compared to the first. Another factor in student support was the recruitment of a substitute faculty for the second day. This faculty had less time to prepare and also did not feel the same duty to adhere to the script.
Faculty described the decision-making process for providing student support entailed watching for signs that the student is struggling during the clinical scenario. This finding supports the statement by Jeffries and Rogers (2007) that the primary purpose of student support during a clinical scenario is to allow students to progress in the scenario.

Additionally, the faculty stated that providing unscripted student support during the scenario requires a balance between providing too little support (which leaves the student unable to progress) and too much support (that would disrupt the problem-solving process). This echoes the guidelines put forth in the model regarding student support (Jeffries & Rogers, 2007).

Student participants generally agreed that they felt supported by the assistance provided by faculty during the simulation and throughout the entire learning process. Students also agreed that there was enough information available to during the scenario to support their problem-solving. Participant responses to an open-ended question regarding the feeling of support in learning focused primarily on the debriefing and not the clinical scenario.

There may be a relationship between the faculty approach to student support and how the students performed during the clinical scenario. During the first day, faculty attempted to enact the scripts written by the designer and observed that none of the groups was able to successfully identify the core issue in the scenario. Conversely, on the second day when faculty felt more
comfortable deviating from the script, all groups were able to successfully identify the core issue in the scenario.

Although one faculty stated that the decision to provide student support is “intuitive” it became clear during the discussions with faculty that this is not always the case. Evidence gleaned from observations of student performance during clinical scenarios demonstrates that the approach to providing student support may impact student performance and overall a more flexible approach to student support may be beneficial.

**Fidelity.** The element of fidelity is defined as the level of realism found within the simulation (Jeffries, 2005), both in the technology used and in the environment within which the simulation occurs. When designing a clinical simulation, Jeffries and Rogers (2007) advocate for attaining the highest level of fidelity possible.

Fidelity was a theme in the designer log, with entries regarding ensuring fidelity in the clinical scenarios through use of current resources and in creating the clinical simulation environment. Design decisions took into account existing barriers to fidelity, such as known human patient simulator capabilities.

Fidelity was a primary concern recorded by faculty in preparing for implementation of the simulation. Included in their preparations were lists of supplies and props that would be needed for students to carry out nursing interventions. Faculty reviewed the scenario content and materials, requesting revisions to materials to more closely mimic the experience on the patient care
unit. Concerns regarding barriers to fidelity, particularly the lack of a functioning automated medication dispensing machine and access to a version of the electronic medical record were raised by faculty prior to implementation. Although these limitations were not resolvable prior to implementation of the course, methods to minimize the impact of these concerns were discussed.

In the course evaluation, faculty shared that students were challenged by instances within the clinical scenarios where fidelity was lacking. In particular, these were – how to obtain a blood glucose test, the lack of an electronic medical record, and the appearance of moulage that did not lead to the intended assessment. Overall, students agreed that the scenarios were realistic and they appreciated having medical-surgical scenarios that they could envision managing in actual nursing practice.

These observations lend credence to the importance of fidelity for these students. In this context, access to familiar supplies and methods of accessing patient data was of particular consequence in their ability to progress in the clinical scenario.

**Feedback and guided reflection.** Debriefing consists of both feedback and guided reflection about student actions during the simulation. The focus of debriefing should include both course objectives and the application of learning to clinical practice (Jeffries & Rogers, 2007). The designer noted that little guidance for designing debriefing is provided by the model, but in following the guidelines, questions to prompt reflection on the objectives and application to nursing
practice were developed. The designer noted the need to use outside resources to further develop the debriefing and provide guidance to faculty. One design decision made using an alternate resource was to develop observation sheets based on expected student actions during the scenario.

Faculty did not specifically discuss plans for use of the observation sheets or debriefing questions in their log. Observation of faculty during scenario implementation revealed that the observation sheets were minimally utilized. Faculty did not specifically comment on the observation sheets; however it appears that they were not valuable in this context.

Observation of debriefing demonstrated that the majority of the discussion was focused on three particular objectives: nursing intervention, application to practice and focused assessment. Although the goal of the course was to improve structured communication, relatively little time was spent discussing those related objectives during debriefing. This observation was corroborated by faculty statements that less time was spent on communication than what was originally intended. Faculty felt that the direction of the discussion came from the participants and met their learning needs. These findings highlight the role of faculty in facilitating reflection based on student’s expressed needs which may be different from the original course goals.

Faculty evaluations revealed that debriefing was more challenging on Day 1 when they felt that participants were not successful in uncovering the core issues in the scenarios. Faculty statements about the person in the role of primary
nurse “beating themselves up” and about students being “more difficult to engage” support this assessment of debriefing. Perceptions of faculty were different on Day 2 when they felt that students were successful in discovering the core issue, took initiative in bringing up topics for discussion in debriefing, and exhibited a “positive vibe”. These findings suggest that promoting student success during problem solving may improve the quality of debriefing, as the students seemed to be more open to discussion after success in the scenario.

Participants were positive about the debriefing, mentioning it most frequently as the aspect of the course that supported their learning; they said it provided specific feedback as well as an opportunity to learn from the experience of the faculty present. The participants also expressed appreciation for the positive approach taken by faculty during debriefing, even when the groups were not feeling successful. Participants agreed that the debriefing allowed them to analyze their own behaviors and actions. These findings support the notion that debriefing is an important aspect of learning from the perspective of students.

**Product Evaluation**

The effectiveness and efficiency of the product developed when using a model is a key component of model validation (Richey, 2005; Richey & Klein, 2007). The overall perception of both student and faculty participants in the current study was that the course was effective in promoting learning of clinical knowledge and skills. However, student mastery of the overall course goal (improving structured communication with physicians) was only partially
achieved. Although there was a significant increase in SBAR scores from pretest to posttest, the greatest increase was in communicating the patient situation. There was only slight improvement in selecting and organizing background and assessment data. Overall, pretest and posttest scores were low, with a mean pretest score of 3.11 and mean posttest score of 4.89 out of a possible 12 points.

One possible explanation for this finding is related to debriefing. Relatively little time was spent exploring the objectives for selecting and organizing data or making recommendations. Despite having reflective questions available to discuss this aspect, faculty acknowledged that there was less time spent on it than was originally intended.

Faculty also felt that all participants achieved at least some learning during the course, noting the presence of “aha moments” and discussions of what might be done differently in the clinical area. Faculty perceptions that the clinical scenarios prompted student learning were reinforced by the willingness of students to introduce topics and ask questions during the debriefing, which was more evident in during the second day of the course.

Participants also perceived that learning had occurred. Participants agreed with the statement “I am confident that I am developing the skills and obtaining the required knowledge from this simulation to perform necessary tasks in a clinical setting”, indicating that the participants felt they were able to address their learning needs during the course. In addition, participants stated the benefit of
discussing the actions taken during the scenario as allowing them to consider how situations could be approached differently.

Both faculty and student participants expressed satisfaction with the course. In particular, student evaluations reflected an overall greater satisfaction with the course faculty relative to course materials, but responses were positive for both. The most frequently mentioned dissatisfaction with the course was the knowledge that their actions were being observed by peers in a different room and that videotaping was occurring, even though this is standard practice in simulation-based learning. Although they appreciated the need for observation, one participant stated it was so anxiety provoking as to impede learning. Both student and faculty participants were concerned that not everyone had the opportunity to participate directly in a clinical scenario. This is positive in that students wanted the opportunity to challenge themselves in simulation. A change to the schedule to ensure greater direct participation for each student is a faculty goal.

Conclusions

The goal of this study was to explore how the design characteristics of the Jeffries model functioned for designing, implementing, and evaluating a clinical simulation to teach structured communication to new graduate nurses in an acute care setting. The overall evidence confirms that the model is useful in this context; the clinical simulations designed using this model contributed to student learning and satisfaction with the course. Faculty were also satisfied with the
course overall in terms of enacting the faculty role and student learning. However, there were findings along the way that highlighted strengths and weaknesses within the model as it was used in this study context.

**Model strengths.** The design characteristics included in the model are valued by students as contributing to a positive learning experience in clinical simulation. Particular strengths of the design characteristics are the guidance provided in designing and implementing problem-solving and fidelity.

The model focuses designers on creating problem-solving situations as the basis for clinical simulation; this direction was important in developing the clinical scenario narrative that would trigger the decision points called for in the objectives. The model is also explicit in describing the factors that alter the level of complexity, such as adjusting the amount of information available, how information is made available, and how much conflicting information is included. The designer may use this to guide decisions regarding the types of information to provide to adjust the complexity of the clinical scenario.

Achieving the highest level of fidelity possible within a clinical scenario is also advocated by Jeffries’ model; a recommendation that contributed to student success in the current study. The perception that there was a possibility of encountering similar patient situations in actual nursing practice was motivating to students. Conversely, areas where fidelity was lacking presented a barrier to students when participating in the clinical scenarios.
**Model weaknesses.** The model provided minimal guidance in designing instruction to prepare students for simulation and for structuring guided reflection. Although the model recommends writing objectives that provide sufficient detail for students to be able to participate in the simulation, this was shown to be insufficient preparation in this context. Similarly, other than recommending reflecting on the scenario in terms of the objectives and application to practice, little guidance for structuring debriefing is provided by the model. This is a particularly important concern given that students in this study indicated that guided reflection was the activity that most supported their learning. For both preparation and guided reflection, the designer referred to resources beyond the current model.

Within the design characteristic of student support, the model suggests pre-determining the content and timing of cues to be provided to students during a clinical scenario. Based on the findings of this study, this may not be the best approach in every situation. Overall, the balance of providing student support in the form of cues during the clinical scenario was an area of uncertainty for both the designer and faculty. Additionally, the model states that student support also occurs within guided reflection but does not provide any further information regarding how to design or implement student support in that phase of the simulation.

The model depicts the five design characteristics as separate and equal entities within the realm of design. The researcher’s experience was that the characteristics interact in ways that impact the students’ ability to problem-solve
the scenario. The model as illustrated by Jeffries and Rogers (2007) does not clarify these interactions.

Another weakness of the model is that it focuses only on designing activities for the participant who will assume the role of primary nurse in the clinical scenario. Due the number of students enrolled in nursing courses, it is typical that observers will be present when simulations are implemented. The Jeffries model does not address engagement of observers or participants assuming non-nurse roles in clinical scenarios.

**Strengthening the model.** Based on the findings of the current study, there are four areas where the model could be strengthened: (1) provide greater clarity and flexibility when designing and implementing student support, (2) increase guidance in student preparation and guided reflection, (3) expand the model to consider all students who may be present, and (4) define the interrelationships of the design characteristics.

Guidance in providing student support in designing and implementing the clinical scenario and guided reflection could be informed by the research on scaffolding in education. Scaffolding is defined by Merrill (2002) as “performing parts of the task that the student cannot perform and gradually reducing the amount of guidance and shifting control to the student” (p. 50). Evidence related to both cognitive scaffolds to assist students during the process of problem-solving and metacognitive scaffolds which promote reflection on action (Lajoie, 2005) could provide an expanded conceptualization of student support. For
example, Merrill (2002) states that learning from errors made in the problem-solving process requires instruction on error recognition, error recovery and error avoidance. Using this principle of instruction during guided reflection may enhance learning from the clinical scenario.

Providing enhanced guidance to designers and faculty regarding learner preparation and guided reflection and feedback may be accomplished by referring to other currently available models. The approach to debriefing proposed by Rudolph, Simon, Dufresne, and Raemer (2006) includes both student preparation and debriefing. Dreifuerst (2009) has also proposed a comprehensive framework for debriefing that includes reflection, emotion, reception, integration, and assimilation/accommodation. The designer and faculty could overlay one of these models of debriefing while maintaining a focus on the course objectives.

Expanding the model to consider others present would assist designers develop roles in addition to the primary nurse and would help faculty implement learning activities for students who may be required to observe the simulation. There is little literature on the topic of observer engagement. However a case report by Kalmakis, Cunningham, Lamoureux and Elshaymaa (2010) demonstrated that student observers who were provided with a case-specific observation sheet demonstrated engagement in a clinical scenario enacted by peers in a simulation laboratory. Further exploration of techniques to assure engagement of observers would be beneficial to faculty who manage larger groups in simulation environment.
The Jeffries model would also be strengthened by clarifying the interrelationships between the design characteristics. Based on the results of this study, the researcher found a direct relationship between objectives, problem-solving, and debriefing; with objectives directly driving the design of the problem-solving situation and both objectives and student problem-solving behaviors informing the structure of debriefing. The design characteristics of fidelity and student support directly impact problem-solving, in that changes in fidelity or student support impact the complexity of the problem-solving. In addition, fidelity and student support are connected with student support being used to overcome barriers to fidelity, and fidelity impacting the content and timing of when student support is provided. With these changes, the design characteristics portion of the model would be depicted in relationship rather than in a list (see Figure 1).

![Figure 1. Proposed relationships between design characteristics](image)

Figure 1. Rectangles denote the design characteristics. One-way arrows show directional relationship. Two-way arrows show a reciprocal relationship.

Visualizing the design characteristics in this manner could provide added guidance to designers and faculty interested in methods to align problem-solving
and guided reflection with the objectives, as well as considering the ways in which changes in fidelity and student support impact the complexity of problem-solving.

**Implications**

The Jeffries model is useful for guiding clinical scenario design, implementation, and evaluation in an acute care setting with the use of supplemental resources to inform both student preparation and guided reflection. Within this context, the researcher found that learner analysis should include prior experience with simulation-based learning and expectations related to those experiences. Assuring environmental fidelity to the extent possible was helpful to participants during the clinical scenario. In the acute care setting, access to a version of either the paper or electronic health record is important to reinforce student use of these resources. Attention should be paid to the quality of debriefing, as participants identify this phase of the simulation to be the most helpful in their learning.

**Limitations**

There are a few limitations to this study which must be acknowledged. First, the researcher also served as the designer which may introduce bias into the study. Triangulation of data from other sources was used to minimize this effect, but the potential exists. Related to this is the effect of designer expertise on the decisions made in using the model. It is quite likely that another designer would have made different decisions that would affect student achievement and participant satisfaction.
Second, faculty expertise influenced implementation of the course. Although faculty had experience in facilitating simulation-based education, this was the first time these scenarios were used with students. It is the nature of simulation-based learning to evoke variable responses from students and flexibility in faculty response is expected (Jeffries & Rogers, 2007). Concerns regarding adhering to the script may have limited faculty flexibility during the course. Also, facilitating guided reflection is a key component in student learning and is a difficult skill to master. The dynamic of student engagement and peer interaction during the discussion influences outcomes.

A third limitation was using a single setting and a single course with a small number of participants. This limits the ability to broadly generalize the findings beyond the context described in the study.

**Future Research**

There are several areas where further research would contribute to a greater understanding of the Jeffries model and its components. Investigation of the interrelationships between the design characteristics might enhance understanding of each characteristic and improve decision making when designing and implementing clinical simulations.

It is important to gain a better appreciation of how faculty provides student support in both designing and implementing simulation-based education. Discomfort with knowing how to strike the balance between assisting the learner
when difficulties arise without taking the responsibility for problem-solving away from the learner was a common theme among faculty and the designer.

Another area would be investigating what types of fidelity matter in terms of student achievement and satisfaction. Current literature has focused on the mannequin or task trainer used, expanding this research to include environmental fidelity would provide guidance in how to best invest limited resources without compromising student learning.

Further research on optimal group size for engagement in learning would be of benefit. This area would include investigations into the effect of being observed by peers during a clinical simulation on student performance and satisfaction as well as methods for engaging observers if they are present.

Research on methods for learner analysis and approaches to preparing students from diverse educational backgrounds for simulation-based learning would be of benefit for designers working with new graduate nurses in the acute care setting. New graduate nurses represent a unique subset of learners who have likely experienced simulation-based learning in their undergraduate program but have not yet assimilated the culture of the workplace.

Summary

The findings from this study supported the validity of the design characteristics in the Jeffries Framework for designing, implementing and evaluating clinical simulation. The combined findings of student participant achievement and satisfaction, coupled with faculty satisfaction with the course
provide evidence that using this model is feasible and beneficial for educators in the acute care setting. Although there are areas that could be strengthened, supplementing the model with evidence-based recommendations is a practical approach. Further examination of the interrelationships among the design characteristics will benefit nurse educators using the model in their setting.
References


Demographic Data: Designer

Age:  Gender:  Ethnicity:

Education:

What degrees do you hold in nursing?

What degrees do you hold outside of nursing?

Have you participated in any formal education specific to simulation-based education?

If so, please explain:

Describe your experience as an instructional designer:

Number of years:

Primary responsibilities:

Describe your experience in designing and using simulation-based education:

Number of years:

Approximate number of simulation-based courses/coursees per year:

Number of different courses/coursees:

For each course, describe your role in designing, developing, implementing and evaluating the course. (e.g. wrote objectives, wrote scenarios, programmed high-fidelity human patient simulator (HPS), operated HPS, faculty role during implementation of the scenario, debriefing)
<table>
<thead>
<tr>
<th>Date</th>
<th>General Activity</th>
<th>Model Use</th>
<th>Other Tools/Resources Used</th>
<th>Decision Made</th>
<th>Reactions/Lessons Learned</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/22/10</td>
<td>Writing Course Objectives</td>
<td>Details of model recommendations</td>
<td>Textbooks, taxonomies</td>
<td>Selecting level of objectives and outcomes expected</td>
<td>This would be reflection on the activities once they are completed</td>
</tr>
</tbody>
</table>
APPENDIX A3

DEMOGRAPHIC DATA: FACULTY
Demographic Data: Faculty

Study Code: _____

Age: Gender: Ethnicity:

Education:

What degrees do you hold in nursing?

What degrees do you hold outside of nursing?

Have you participated in any formal education specific to simulation-based education?

If so, please explain:

Describe your experience as an educator:

Number of years:

Primary responsibilities:

Describe your experience in using simulation-based education:

Number of years:

Approximate number of simulation-based courses/courses per year:

Number of different courses/courses:

For each course, describe your role in designing, developing, implementing and evaluating the course. (e.g. wrote objectives, wrote scenarios, programmed high-fidelity human patient simulator (HPS), operated HPS, faculty role during implementation of the scenario, debriefing)
<table>
<thead>
<tr>
<th>Date</th>
<th>General Activity</th>
<th>Utility of Instructor Guide</th>
<th>Problems or Confusion Encountered</th>
<th>Alterations Made</th>
<th>Reactions/ Lessons Learned</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/22/10</td>
<td>Dry run Program</td>
<td>Program Flowchart</td>
<td>Scenario stuck in initial frame</td>
<td>Requested changes</td>
<td>This would be reflection on the activities once they are completed</td>
</tr>
<tr>
<td>EXAMPLE 0930</td>
<td>0930</td>
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<td>1230</td>
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</table>
APPENDIX A5

SCENARIO AND DEBRIEFING OBSERVATION SHEET
Scenario Observation Sheet

Key to Type of Support:

A  Faculty via voice of the patient (e.g. re-emphasizing primary problem)
B  Faculty via voice of the provider (e.g. requesting additional information)
C  Faculty via another student (coaching student to deliver specific cue)
D  Faculty via direct communication with student (overhead, entering room)
E  Environmental cues (e.g. change in vital signs, alarms, lab reports)
F  Other (Specify)

<table>
<thead>
<tr>
<th>Time</th>
<th>Type of Support</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>00:15</td>
<td>A</td>
<td></td>
</tr>
<tr>
<td>00:45</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>

Debriefing Observation Sheet

Amount of time spent in debriefing on:

<table>
<thead>
<tr>
<th>Topic of Discussion</th>
<th>Time Spent – rounded to nearest minute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recap of what happened</td>
<td></td>
</tr>
<tr>
<td>Collecting objective and subjective assessment data</td>
<td></td>
</tr>
<tr>
<td>Performing focused assessment</td>
<td></td>
</tr>
<tr>
<td>Selecting and organizing data to be reported to the provider</td>
<td></td>
</tr>
<tr>
<td>Selecting recommendations</td>
<td></td>
</tr>
<tr>
<td>Using write down/ read back</td>
<td></td>
</tr>
<tr>
<td>Appropriate nursing interventions</td>
<td></td>
</tr>
<tr>
<td>Application of learning to practice</td>
<td></td>
</tr>
</tbody>
</table>
Faculty Interview Schedule: Day 1

Introduction: I would like to talk to you about how you felt the course went today overall and then focus on some of the common decisions that need to be made during the course. I will be videotaping our discussion, which we talked about before you agreed to participate. Are you still comfortable with that? Remember your participation is completely voluntary, if there is a question you don’t want to answer, that is fine. Also, we can end the interview at any point. Are you ready?

1. What are your overall impressions of how the course went today?

2. What are your observations regarding the level of realism or fidelity built into the scenarios? (design characteristic: fidelity)

3. What are your observations regarding the complexity of the scenarios?
   a. In your view, did the complexity match the learner’s needs?  
      (design characteristic: complexity/problem solving)

4. I want you to think about when you were running the actual scenarios. How do you decide when to provide extra information or support to students in the scenario? (design characteristic: student support/cues)

5. Now, I want to talk about the debriefings today. How did you plan what feedback to give as you moved from observing to debriefing? (design characteristic: debriefing/feedback)

6. How did you feel the debriefing went?
   a. What would you have done differently during the debriefing?

7. What changes would you make to improve the course?
Faculty Interview Schedule: Day 2

1. What are your overall impressions of how the course went today?

2. What adjustments did you make in your teaching based on your experience with the course two days ago?

3. What differences in the level of realism (fidelity) did you notice today compared to two days ago?

4. In your view, did the complexity match the learner’s needs today?

5. What do you feel the new graduates learned from the experience?

6. Any differences in how running the scenarios went today?

7. How did you feel the debriefing went today?
   a. What would you have done differently during the debriefing?

8. Based on this new experience, what changes would you make to improve the course?
Demographic Data: Students

Study Code: ________

Age:  Gender:  Ethnicity:

Education:

What is the highest degree you hold in nursing?

What degrees do you hold outside of nursing?

Experience:

Other than as a nursing student, what other clinical experience have you had (either employment or volunteer)?

Did you participate in clinical simulations during your nursing program?

If yes, approximately how many per semester?

Please rate your agreement with the statement: Overall, participating in clinical simulations has been helpful in learning to provide nursing care.

Strongly Agree  Agree  Neither Agree  Disagree  Strongly Disagree

neither Agree  nor Disagree  Disagree
APPENDIX A8

PRETEST AND POSTTEST
Pretest

Directions: This pretest is based on the patient assessment videotape. Please fill in each section of the SBAR report you would provide to the patient’s physician/provider based on the information in the videotape. Assume that the physician/provider is NOT familiar with the patient.

You may use any notes you took while viewing the videotape, but no other resources. Please write legibly. You have 10 minutes to complete the pretest.

1. Situation:

2. Background:

3. Assessment:

4. Recommendation:
Posttest

Directions: This posttest is based on the patient assessment videotape. Please fill in each section of the SBAR report you would provide to the patient’s physician/provider based on the information in the videotape. Assume that the physician/provider is NOT familiar with the patient.

You may use any notes you took while viewing the videotape, but no other resources. Please write legibly. You have 10 minutes to complete the posttest.

1. Situation:

2. Background:

3. Assessment:

4. Recommendation:
APPENDIX A9

SCORING RUBRIC
<table>
<thead>
<tr>
<th>Scoring Rubric</th>
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<tbody>
<tr>
<td><strong>Situation</strong></td>
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<tr>
<td>Right sided chest pain on inspiration Rated 6/10 New onset SOB</td>
</tr>
<tr>
<td><strong>Background</strong></td>
</tr>
<tr>
<td>70 year old Admitted for CHF Decreased activity Type II DM Recent colon resection Hx of MI</td>
</tr>
<tr>
<td><strong>Assessment</strong></td>
</tr>
<tr>
<td>Oriented Afebrile Heart rate increased from 92 to 118 and irregular Resp increased from 14 to 24 Resp labored and shallow Oxygen sats 93% on RA BP 115/78 Non-pitting edema L &gt;R Pain on palpation L &gt;R + pedal pulses Equal strength both LE</td>
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<tr>
<td>Recommendation</td>
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<tr>
<td>ABG</td>
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<td>CXR</td>
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<td>Chest CT</td>
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<td>Coag labs</td>
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<tr>
<td>Missing only one recommendation</td>
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<td>Missing more than one recommendation or recommend a dangerous intervention</td>
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<td>TOTAL</td>
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APPENDIX A10

NLN SIMULATION DESIGN SCALE
Simulation Design Scale (Student Version)

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Use the following rating system when assessing the simulation design elements:

1 - Strongly Disagree with the statement
2 - Disagree with the statement
3 - Undecided - you neither agree or disagree with the statement
4 - Agree with the statement
5 - Strongly Agree with the statement
NA - Not Applicable; the statement does not pertain to the simulation activity performed.

<table>
<thead>
<tr>
<th>Item</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>1</th>
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<tbody>
<tr>
<td><strong>Objectives and Information</strong></td>
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<tr>
<td>1. There was enough information provided at the beginning of the simulation to provide direction and encouragement.</td>
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<td>2. I clearly understood the purpose and objectives of the simulation.</td>
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<td>3. The simulation provided enough information in a clear manner for me to problem-solve the situation.</td>
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<td>4. There was enough information provided to me during the simulation.</td>
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<td>5. The cues were appropriate and geared to promote my understanding.</td>
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<td><strong>Support</strong></td>
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<td>6. Support was offered in a timely manner.</td>
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<td>7. My need for help was recognized.</td>
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<td>8. I felt supported by the teacher's assistance during the simulation.</td>
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<td>Item</td>
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<td><strong>Problem Solving</strong></td>
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<td>9. I was supported in the learning process.</td>
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<td>10. Independent problem-solving was facilitated.</td>
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<td>11. I was encouraged to explore all possibilities of the simulation.</td>
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<td>12. The simulation was designed for my specific level of knowledge and skills.</td>
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<td>13. The simulation allowed me the opportunity to prioritize nursing assessments and care.</td>
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<td>14. The simulation provided me an opportunity to goal set for my patient.</td>
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<td><strong>Feedback/Guided Reflection</strong></td>
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<td>15. Feedback provided was constructive.</td>
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<td>16. Feedback was provided in a timely manner.</td>
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<td>17. The simulation allowed me to analyze my own behavior and actions.</td>
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<td>18. There was an opportunity after the simulation to obtain guidance/feedback from the teacher in order to build knowledge to another level.</td>
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<tr>
<td><strong>Fidelity (Realism)</strong></td>
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<td>19. The scenario resembled a real-life situation.</td>
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<tr>
<td>20. Real life factors, situations, and variables were built into the simulation scenario.</td>
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</table>
APPENDIX A11

POST-COURSE SURVEY: STUDENTS
Post-Course Survey: Students

1. What actions (if any) were taken by your teachers that supported you in learning about interprofessional communication today?
2. What feedback (if any) did you receive that was helpful to your learning?
3. Were there actions taken by either your teachers or your fellow students that were not helpful to your learning or made you uncomfortable? Please explain.

Please rate the following:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Neither Agree nor Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>The simulation rooms were set up in a way that was helpful to my learning</td>
<td></td>
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<tr>
<td>The audiovisuals available in the simulation classroom were helpful to my learning</td>
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<tr>
<td>The seating arrangement in the classroom was helpful to my learning</td>
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<tr>
<td>The class schedule was convenient for me</td>
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</table>

Any other comments you wish to share?
APPENDIX A12

STUDENT SATISFACTION AND CONFIDENCE IN LEARNING
This questionnaire is a series of statements about your personal attitudes about the instruction you receive during your simulation activity. Each item represents a statement about your attitude toward your satisfaction with learning and self-confidence in obtaining the instruction you need. There are no right or wrong answers. You will probably agree with some of the statements and disagree with others. Please indicate your own personal feelings about each statement below by marking the numbers that best describe your attitude or beliefs. Please be truthful and describe your attitude as it really is, not what you would like for it to be. Please use the following code to answer the questions.

1 = STRONGLY DISAGREE with the statement 2 = DISAGREE with the statement
3 = UNDECIDED - you neither agree or disagree with the statement 4 = AGREE with the statement 5 = STRONGLY AGREE with the statement

<table>
<thead>
<tr>
<th></th>
<th>1=SD</th>
<th>2=D</th>
<th>3=UN</th>
<th>4=A</th>
<th>5=SA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The teaching methods used in this simulation were helpful and effective</td>
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<tr>
<td>2</td>
<td>The simulation provided me with a variety of learning materials and activities to promote my learning</td>
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<tr>
<td>3</td>
<td>I enjoyed how my instructor taught the simulation</td>
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<tr>
<td>4</td>
<td>The teaching materials used in this simulation were motivating and helped me to learn</td>
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<tr>
<td>5</td>
<td>The way my instructor(s) taught the simulation was suitable to the way I learn</td>
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<tr>
<td>6</td>
<td>I am confident that I am mastering the content of the simulation activity that my instructors presented to me</td>
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<td>7</td>
<td>I am confident that this simulation covered critical content necessary for the mastery of structured communication</td>
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<td>8</td>
<td>I am confident that I am developing the skills and obtaining the required knowledge from this simulation to perform necessary tasks in a clinical setting</td>
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<td>9</td>
<td>My instructors used helpful resources to teach the simulation</td>
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<td>10</td>
<td>It is my responsibility as the student to learn what I need to know from this simulation activity</td>
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<td>11</td>
<td>I know how to get help when I do not understand the concepts covered in the simulation</td>
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<td>12</td>
<td>I know how to use simulation activities to learn critical aspects of these skills</td>
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<td>13</td>
<td>It is the instructor’s responsibility to tell me what I need to learn of the simulation activity content during class time</td>
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Revised December 22, 2004
APPENDIX B
PERMISSION TO USE NLN TOOLS
Permission to Use NLN Questionnaires

It is my pleasure to grant you permission to use the "Simulation Design Scale" and “Student Satisfaction and Self-Confidence in Learning” NLN/Laerdal Research Tools. In granting permission to use the instruments, it is understood that the following assumptions operate and "caveats" will be respected:

1. It is the sole responsibility of (you) the researcher to determine whether the NLN questionnaire is appropriate to her or his particular study.
2. Modifications to a survey may affect the reliability and/or validity of results. Any modifications made to a survey are the sole responsibility of the researcher.
3. When published or printed, any research findings produced using an NLN survey must be properly cited as specified in the Instrument Request Form. If the content of the NLN survey was modified in any way, this must also be clearly indicated in the text, footnotes and endnotes of all materials where findings are published or printed.

I am pleased that material developed by the National League for Nursing is seen as valuable as you evaluate ways to enhance learning, and I am pleased that we are able to grant permission for use of the "Simulation Design Scale" and “Student Satisfaction and Self-Confidence in Learning” instruments.

Alyss Doyle  | Coordinator of Educational Programming | National League for Nursing | www.nln.org
adoyle@nln.org | Phone: 800-669-1656 x145 | Fax: 212-812-0391 | 61 Broadway | New York, NY 10006
APPENDIX C1

ARIZONA STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD

EXEMPT STATUS
To: Debra Hegler
NHL:2

From: Mark Roosa, Chair
Soo Bah IRB

Date: 01/28/2011

Committee Action: Exemption Granted

IRB Action Date: 01/28/2011

IRB Protocol #: 1101035020

Study Title: A Model Validation Study for Instructional Design of Clinical Simulation-Based Education

The above-referenced protocol is considered exempt after review by the Institutional Review Board pursuant to Federal regulations, 45 CFR Part 46.101(b)(1).

This part of the federal regulations requires that the information be recorded by investigators in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. It is necessary that the information obtained not be such that if disclosed outside the research, it could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation.

You should retain a copy of this letter for your records.
APPENDIX C2

MAYO CLINIC INSTITUTIONAL REVIEW BOARD

EXEMPT STATUS

132
Principal Investigator Notification:

From: Mayo Clinic IRB

To: Rebecca Wilson

CC: Rebecca Wilson

Re: IRB Application #: 10-008687

Title: A Model Validation Study for Instructional Design of Clinical Simulation-Based Education

IRBe Protocol Version: 0.01
IRBe Version Date: 1/5/2011 9:49 AM

IRB Approval Date: 1/12/2011
IRB Expiration Date:

The above referenced application is determined to be exempt (45 CFR 46.101, item 1) from IRB review. Continued IRB review of this study is not required as it is currently written. However, any modifications to the study design or procedures must be submitted to the IRB to determine whether the study continues to be exempt. The Reviewer approved waiver of HIPAA authorization in accordance with applicable HIPAA regulations.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY:

(1) Submission to the IRB of any modifications and supporting documents for review and approval prior to initiation of the changes.

(2) Submission to the IRB of all unanticipated problems involving risks to subjects or others (UPIRTSO).

(3) Compliance with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer