



Research and Applications

Designing and testing clinical simulations of an early warning system for implementation in acute care settings

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Abstract

Objectives: Conducting simulation testing with end-users is essential for facilitating successful implementation of new health information technologies. This study designed a standardized simulation testing process with a system prototype prior to implementation to help study teams identify the system's interpretability and feasibility from the end-user perspective and to effectively integrate new innovations into real-world clinical settings and workflows.

Materials and Methods: A clinical simulation model was developed to test a new Clinical Decision Support (CDS) system outside of the clinical environment while maintaining high fidelity. A web-based CDS prototype, the "CONCERN Smart Application," which leverages clinical data to measure and express a patient's risk of deterioration on a 3-level scale ("low," "moderate," or "high"), and audiovisual-integrated materials, were used to lead simulation sessions.

Results: A total of 6 simulation sessions with 17 nurses were held to investigate how nurses interact with the CONCERN Smart application and how it influences their critical thinking, and clinical responses. Four themes were extracted from the simulation debriefing sessions and used to inform implementation strategies. The strategies include how the CDS should be improved for practical real-world use.

Discussion and Conclusions: Standardized simulation testing procedures identified and informed the necessary CDS improvements, the enhancements needed for real-world use, and the training requirements to effectively prepare end-users for system go-live.

Lay Summary

For the successful integration of new health information technologies in clinical settings, it is important to assess the system's interpretability and feasibility from the perspective of end-users. In this study, we designed a standardized simulation testing process to evaluate a new Clinical Decision Support (CDS) system, the CONCERN Smart Application, which leverages clinical data to predict patients' risk of deterioration. The application displays patient's degree of risk on a 3-level scale ("low," "moderate," or "high"). To facilitate high-fidelity simulation testing outside of a clinical environment, we developed a prototype of CONCERN Smart Application. A series of 6 simulation sessions were conducted with 17 nurses to explore how nurses interactions with the CONCERN Smart application and its influence to nurses critical thinking, and clinical responses. From the simulation debriefing sessions, 4 themes were extracted and it were utilized to guide implementation strategies. Additionally, our study highlighted the necessary improvements and enhancements to the CDS for real-world use and outlined the training requirements to effectively prepare end-users for go-live.

Key words: simulation training; clinical decision support systems; nursing informatics; feasibility studies; early warning system.

Introduction

Health information technology (HIT) use in clinical settings has rapidly increased over the past few decades. ^{1,2} With the rise in HIT adoption, the majority of hospitals have transitioned to electronic health record (EHR) systems with integrated clinical decision support (CDS) to aid clinicians in providing higher quality care to patients. ^{3,4} CDS has evolved from tools with simple functions, such as capturing medication prescription errors in computerized prescriber orderentry (CPOE) documentation, to meticulously designed

predictive models capable of recognizing early indications of negative outcomes. ⁵⁻¹³ As the use of CDS diversifies and the operating logic becomes more complex, there is greater emphasis on the end-user's ease of use. Focusing design efforts on system interpretability and feasibility from the end-users' perspective is essential for facilitating successful adoption and producing desired outcomes with the technology. ^{14–16} It is therefore imperative to involve prospective end-users in the CDS design phase to ensure the system is user-friendly and complements established workflows. As

part of this process, simulation testing can be conducted to assess the usability and acceptability of the CDS before its implementation into clinical practice. Tone approach is to develop a system prototype using de-identified, real patient data validated by clinicians to simulate real-life interactions. Our team designed a standardized simulation that not only offers high fidelity but also aims to enhance participant engagement by providing simulation options, such as choosing the location for simulation testing and the flexibility of participating individually or as a group in the simulation testing.

Previous work

This study is part of the larger CONCERN (Communicating Narrative Concerns Entered by RNs) study which aimed to develop the CONCERN smart application. ²³ The application leverages nurses' EHR documentation patterns to predict patients' risk of deterioration. The application displays patient degree of risk ("CONCERN Level") as a colored circle with a 3-level scale in the EHR patient list as follows: Green—"Low risk for deterioration," Yellow—"Increased risk for deterioration," and Red—"Showing signs of deterioration." Specifically, green indicates that patient's condition is stable, while the yellow circle is meant to enhance nurses' surveillance of the patient by indicating an escalating risk for deterioration. Red indicates that the patient is already in a high-risk state. Clicking on the colored circle launches the CONCERN app and displays the features that contribute to the overall CONCERN level and its associated temporal trends.

The goal of the CONCERN Smart Application is to increase inter-professional situational awareness of patients at risk of deterioration among care team members and to support clinicians' decision-making processes to ultimately decrease preventable adverse events, such as mortality, rapid response, and sepsis that often require escalation of care.

Objectives

The purpose of this study is to design and test simulation testing procedures to be used before the application is implemented in health care systems. Our goals were: (1) to investigate the feasibility of the CONCERN application in the context of nursing workflow, (2) to identify a system design that is easy for end users to use and understand and useful to increase situational awareness between nurses and physicians, and (3) to identify how the CONCERN Smart application use varies.

Methods

This study employed user-centered design efforts in development and implementation of a CDS-based application. A simulation testing process with nursing role-specific clinical scenarios was created. Simulations were comprised of 2 principal materials: a web-based CONCERN Smart application prototype and an audiovisual (A/V)-integrated Microsoft PowerPoint presentation that were developed for use in each session. Overall simulation testing was developed through a multidisciplinary collaboration with registered nurses, physicians, graphic designers, computer programmers, and a nurse with experience in designing and operating simulations. Portable devices, such as laptops and tablets were used to ensure

that the simulation sessions could be performed in any location that was convenient for participants (eg, hospital units, conference rooms).

We recruited simulation participants by sending a recruitment email to practice councils and nursing leaders. To maximize the number of participants, simulation sessions were conducted as part of a scheduled group session or individually at participant's convenience. Mass General Brigham Institutional Review Board approved this study (IRB protocol 2015P002472).

The CONCERN smart application prototype

The CONCERN Smart application prototype mimicked the study hospital EHR (Figure 1) by using screenshots of the EHR user interface demonstrating the CONCERN level for 6 simulated patients on a mockup of the EHR's patient list that displayed real, de-identified data. The CONCERN Smart application design and its location within the EHR were determined through iterative, participatory approaches, such as user-centered design sessions and focus groups from a previous study.¹⁴

As noted earlier, the CONCERN levels were represented by 3 colored symbols: Red, Yellow, or Green, corresponding with the patient's risk for deterioration. The prototype functionality allowed participants to click the CONCERN symbols and view detailed clinical information captured by the application, including the features that contribute to the overall CONCERN level and the trends demonstrating how the CONCERN level has changed over time. To ensure realistic scenarios, the CONCERN levels for the mock patients were calculated by applying our study's risk prediction algorithm to real, de-identified patient data.

Audiovisual—guided simulation design

Audio/visual (A/V)-integrated slides containing pictures and voiceovers guided participants through the simulation. Each session began with a brief introduction, then guided participants through a 2-phased mock clinical scenario which required them to use the prototype (Figure 2). After each phase, participants were presented with a set of questions. Simulations concluded with a debriefing session. Total runtime was 45 minutes; the introduction took approximately 5 minutes, running through mock scenarios took about 30 minutes, and debriefing took around 10 minutes.

Simulation testing scenarios

The scenario was designed to observe how participants interact with the prototype and how their clinical perceptions were affected by the CONCERN Smart application display and corresponding EHR data across 2 phases designed to simulate patient deterioration over time.

The first of the 2 scenario phases involved the nurse assessing a mock patient who is in stable condition with no complaints or worrisome signs and symptoms. At that time, the patient's CONCERN level is displayed as green in the EHR patient list to communicate low risk for deterioration. The second phase, set 18 hours later, demonstrated a change in the mock patient's CONCERN level from green to yellow, signifying that the patient's risk of deterioration had increased. The mock patient communicated her subjective symptoms, stating that something was wrong, despite her physiological parameters being within normal range.



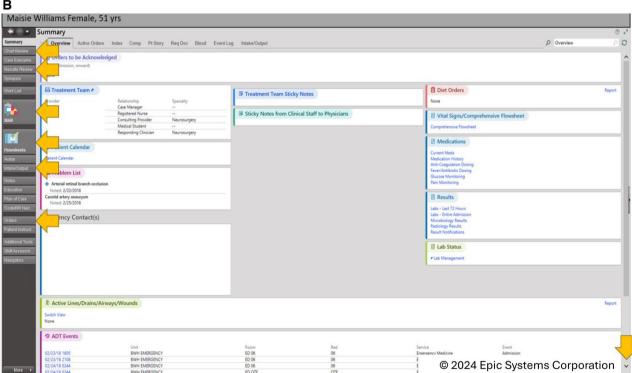
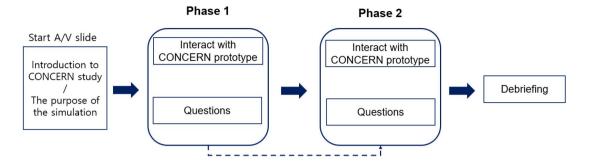


Figure 1. Screenshots of CONCERN Smart application prototype| Epic screen shot used with approval by 2024 Epic Systems Corporation. © 2024 Epic Systems Corporation. (A) A mock EHR patient list containing 3 simulated CONCERN levels. The arrow is clickable and links to an additional screen that provides features contributing to the overall CONCERN level and the trends in how the CONCERN level has changed over time. (B) One mock patient chart (Modified on Epic® screen). The arrows are clickable and link to additional screens that provide more detailed information (e.g., Chart Review, Results Review, MAR (Medication Administration Record), Flowsheets, Intake/Output, Orders, and scrolling down the screen).



Changes:

- 18 hours passed: scenario patient begun to deteriorate
 - Mock patient spells out something is wrong
 - In prototype, CONCERN level changed from Green to Yellow

Figure 2. Simulation testing process.

Development of 2 question sets

A total of 2 different question sets were developed for this study (Supplementary 1). One question set was developed based on the existing Situation Awareness Global Assessment Technique (SAGAT) tool, designed to measure shared situational awareness among the participants via 3 aspects: perception, comprehension, and projection.²⁴ The other question set was used in the debriefing session. It was developed by the research team based on prior qualitative work to investigate how the CONCERN Smart application can be incorporated into clinician workflow and its potential clinical applications. All the answers provided by simulation participants were transcribed by 3 researchers and the thematic analysis was conducted after each debriefing session.

Debriefing and dissemination

The debriefing responses obtained from the simulation participants were subjected to thematic analysis based on Braun and Clarke's Six Phases of Thematic Analysis. 25,26 Three researchers who participated in the simulation sessions transcribed the content. Subsequently, the transcribed data was coded and analyzed to establish themes by identifying meaningful patterns (important or recurring responses corresponding to the questions). Through team consensus, the appropriateness of the derived themes were verified, and themes were named. Themes were used to identify how CDS could be improved for practical real-world use and to inform implementation strategies. Strategies for CDS improvement and implementation were refined and finalized through collaborative discussions within the research team and then shared with the hospital information system team who made technical changes in the EHR system. Implementation strategies were also incorporated into training materials.

Results

In 2020, a total of 17 nurses participated in 6 simulation sessions, which exceeded the expected number of 10-12 nurses. Of these sessions, 5 were individual simulations, each session featuring different nurses. The group simulation session included a group of 12 nurses. Through these sessions, our study gained adequate saturation for thematic analysis. The average age of nurses was 35.56 ± 7.38 years. Nurse

participants were 94.12% female. Most nurses worked 6-10 years (41%), (Table 1).

Table 2 summarizes nurses' responses to the SAGAT questions that were asked during scenario phases 1 and 2. The majority of participants agreed that the CONCERN level aligned with the patient condition. When the CONCERN level increased in phase 2, the nurses' surveillance of the mock patient increased even if the patient was considered to be in stable condition based on their physiological data.

During the debrefing sessions 4 themes were extracted. (1) education and training strategies for users, including methods to educate nurses and locations for posting materials; (2) potential uses of the CONCERN Smart application; (3) software changes, focusing on how to alert CONCERN levels and where to display them; and (4) system sensitivity to future users. These thems were further deveoped to guide implementation strategies, which each theme containing 2-4 sub-themes (Table 3).

Discussion

Conducting a usability and feasibility evaluation of CDS with end-users is an essential element for successful implementation of new technology. 17-22,27,28

Users' perspectives on CONCERN smart application

The CONCERN Smart application algorithm is designed to predict when patients are at risk of deterioration especially before physiological decline. Through the SAGAT questions, we were able to investigate how participants understand the application and use it in clinical situations.²⁹

Analysis of responses from the "Projections" section revealed that when the CONCERN level changed from green to yellow, the application had the intended effect of increasing nursing surveillance of the patient. During the clinical scenario, nurses reported increased concern for the mock patient, and in response they paged the physician.

Four themes and implementation strategies

Four themes extracted through the simulation debriefing sessions became fundamental for developing implementation strategies. These strategies were applied when the

CONCERN Smart application was implemented in the clinical setting.

"Educating and Training" strategies that could be applied in the clinical settings were discussed. In addition to holding training sessions for nurses, we also recruited volunteer nursing staff as champions to provide special training. They served as a bridge between the developers (ie, study team) and the end users (ie, nurses). The Champions provided training to other nurses and addressed practical issues raised in their units. If they received suggestions from the end users, they delivered the feedback to our study team. With Champions, we maintained a close connection with the clinical site.

Through the "Potential Uses" theme, we were able to investigate how participants perceive that they will use the CONCERN Smart application in practice. Clinicians reported that the CONCERN Smart application could be used as a tool for patient prioritization and helping charge nurses make the patient assignments. However, since each unit has a different workflow, the potential uses varied by

Table 1. General characteristics of simulation participants.

		Nurses (N = 17, n (%))
Age		35.56 ± 7.38
Gender	Female	16 (94.12%)
	Male	1 (5.88%)
Highest professional degree	BS/BA ^a	9 (52.94%)
	MA/MS ^b	7 (41.18%)
	AD^{c}	1 (5.88%)
	Doctoral degree	_
Years working in current	<1 year	_
profession	1-5 years	3 (17.65%)
	6-10 years	7 (41.18%)
	11-15 years	4 (23.53%)
	15> years	3 (17.65%)

- ^a BS/BA = Bachelor of Science/Bachelor of the Arts.
- b MA/MS = Master of Arts/Master of Science.
- AD = Academic Degree.

unit. The Champions were encouraged to describe which potential uses made sense for their unit's workflow. Unit-specific potential uses were introduced by the champions in training sessions.

Most of the suggestions for the "Software Changes" theme were incorporated into the official CONCERN Smart application prior to go-live. For example, CONCERN was programmed to calculate a patient's risk level every hour, and when the color changes, the indicator is displayed on the screen to let participants know that the level has changed.

Through the "System Sensitivity" theme, it was agreed that the CONCERN algorithm's yellow level of sensitivity must be very carefully determined. If the application was too sensitive, clinicians would find it untrustworthy, or if clinicians attended to the CONCERN Smart application and the patient did not ultimately deteriorate, they might consider it a false alarm. Participants reported that repeated false alarms would lead to lack of trust in the CDS and limit participant use of the CONCERN Smart application, even if its usability and functionality are continuously improved. The recommendation was that the distribution of yellow patients should be carefully configured based on both statistical and human factors evaluations.

Designing simulation testing model

Simulation centers in academic medical institutions primarily focus on training clinical techniques and problem-solving skills, ^{30–34} and for assessing the usability of new systems. ^{20–22,28,35} However, the integration of CDS into the simulation center's EHR training system may not be readily available. Accordingly, we developed a web-based prototype resembling the EHR system in use on clinical units. In this process, we devised simulations using computers, laptops, and mobile devices offering enhanced flexibility regarding the location of the simulation sessions.

For the group discussion, each participant was provided with an individual device (eg, tablet), allowing participating

Table 2. Nurses' answers to questions based on SAGAT method.

SAGAT question ^a	Nurses' answers	
Phase 1: The mock patient's CONCER	N level was green	
Perception	Overall, the patient seems stable (session 1-6)	
Comprehension	Green CONCERN level means patient is low risk; this score seems appropriate based on the patient's chart (sessions 1-6)	
Projection	Patient seems stable, no immediate intervention is needed. Continue to monitor the patient (sessions 1-6)	
Phase 2: The mock patient's CONCER	N level changed from green to yellow	
Perception	 Patient is declining because the patient stated she was declining. Participant would be concerned that the patient is declining (session 1, 3) 	
	 Patient's complaint is something new, potentially a sign of something negative to come. Increased nurse concern for patients noted. However, the patient still seems stable (sessions 2, 4, 5) 	
	 Breakdown of CONCERN score revealed vital signs were being taken more frequently, meaning the nurse increased surveillance of patient (session 6) 	
Comprehension	 The score was demonstrating increased nursing concern that patient was at higher risk of deterioration than before (sessions 1, 3, 5, 6) 	
	• The yellow score signifies that the patient's anxiety is not unwarranted. There is something going on that might not be clearly definable yet (session 2)	
	 Yellow score response would be to increase close monitoring and contact with the team to establish or adapt a care plan (session 4) 	
Projection	 Increased frequency of monitoring/checks (More frequent checks, neuro checks, vital signs, and medications) (sessions 1-5) 	
	• Page the doctor/contact the team (sessions 1, 2, 4, 5, 6)	

^a SAGAT: Situation Awareness Global Assessment Technique.

Table 3. Implementation strategies driven by 4 themes.

Themes	Details from debriefing sessions	Implementation strategies
Education and training	Educate nurses	Run training sessions
	 Run training sessions 	 Recruit volunteered nursing staffs (eg,
	 Having special trained nurses 	Champions) for special training
	 Introduce in emails, practice councils, 	 Displaying posters on unit wall
	unit orientations	 Provide nurses with pocket card
	 Place materials in common areas 	
Potential uses	 Patient prioritization tool 	 Champions were encouraged to describe
	 Patient assignment tool 	which uses made sense for their workflow
	 Nurse staffing tool 	 Protentional uses of App were introduced
	 Communication tool to other clinicians 	in training sessions
Software changes	 Alert when CONCERN level changes (by pop-up, indicator) 	 Indicator displays in the patient list when CONCERN level changes
	 Appropriate place in the patient list or add in Sticky Note section/Summary tab in the patient chart 	• Keep the App display in the EHR patient list
System sensitivity	 Patient distribution is important The system's high sensitivity is difficult to interpret 	 Adjust the App algorithm to distribute patient's level based on statistical and human factors
	 Repeated false alarms would lead to low 	 Explain how the App algorithm works
	trust	Explain the irrelevance of backdating to
	 Documentation backdating may negatively impact temporal accuracy 	CONCERN levels

individuals to simultaneously interact with the prototype. Study team members were actively involved in this session to support the technical issues encountered by participants in using the prototype. Offering group simulation session not only increased the accessibility for participants to enroll in the session as a group but also facilitated dynamic discussions during the debriefing session. We observed a rich discussion with diverse feedback building on individual opinions and comments. Moreover, among peers, individuals were encouraged to participate in the discussion.³⁶

One limitation of this study is that the simulation focused mostly on nurses' use of the CDS, even though the CON-CERN Smart application can be used by both nurses and physicians. However, given that this study was conducted in the early days of the COVID pandemic, recruiting clinicians was challenging given their time and resource constraints. Despite this limitation, our study team gleaned important findings from simulation testing by nurses that enabled improvements and enhancements to the CDS that were necessary for real-world use and to inform the training needed to effectively prepare end-users for go-live.

Conclusion

This study designed a standardized simulation testing process to evaluate nurses' perceptions of and experiences with an early warning CDS, the CONCERN Smart application which predicts when patients are at risk for deterioration prior to implementation in the healthcare system.

By applying the system prototype to scenarios that represent real and probable clinical situations, it was possible to investigate how nurses interact with the CONCERN Smart application and how it influences their critical thinking and clinical actions. Our methods also informed us what improvements and enhancements to the CDS were necessary for real-world use and to inform training requirements to effectively prepare end-users for go-live.

Author contributions

Kenrick D. Cato, Patricia C. Dykes, Sarah C. Rossetti initiated study design. Min-Jeoung Kang, Graham Lowenthal, Patricia C. Dykes conducted simulation testing and data analysis. Li Zhou provided model input used for the study. Kumiko O. Schnock contributed to interpreting the results. Christopher Knaplund managed the study process. All authors contributed to the final version of this manuscript. All authors are accountable for the integrity of this work.

Supplementary material

Supplementary material is available at JAMIA Open online.

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Conflicts of interest

Authors have no competing interests to declare.

Data availability

The data underlying this article will be shared on request to the corresponding author.

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