

Study protocol

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Developing patient safety standards for health-care quality promotion in neonatal intensive care units: A mixed-methods Protocol

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Abstract:

BACKGROUND: Neonatal intensive care unit (NICU) is one of the accident-prone settings in the health-care system. There is a series of structural and process threats to the safety of infants hospitalized in this unit, which can be prevented by taking the right actions. For this purpose, developing standards based on current knowledge, available resources, and the context that provides care can determine patient injury prevention requirements. Likewise, it can be a source for national development and application of related guidelines and protocols. This study aims to develop patient safety standards in the NICUs of Iran.

MATERIALS AND METHODS: This mixed-methods study will apply the exploration, preparation, implementation, and sustainment framework to develop patient safety standards. In each phase of this framework, a set of activities take place. Exploration is based on the world health organization model to develop standards. Determining the validity and applicability of standards will be done in Phase 2 (Preparation) and Phase 3 (Implementation), respectively. Since the long-term effects are not desired, the fourth phase (Sustainment) will not be considered.

DISCUSSION: Patient safety standards from this study will contribute to efficient and effective, equitable, and high-quality health-care delivery. The application of them will further promote patient safety and the quality of medical care in Iranian NICUs.

Keywords:

Health-care quality promotion, Iran, neonatal intensive care unit, patient safety, standards

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Introduction

Safety is one of the basic human needs, and patient safety is an essential component of health-care quality.^[1] Since the publication of the report "To Err is Human: Building a Safer Health System," patient safety has turned into a global priority. It has also led to some movements throughout the world.^[2] These movements prompt the health-care systems to work to reduce incidents and errors and build a safe environment together with providing health-care services.

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Neonatal intensive care unit (NICU) is one of the accident-prone settings in the health-care system for the provision of special care, equipment complexity, need for specialized knowledge and skills, and high vulnerability of infants.^[3-6] Here, errors occur eight times more than in other units.^[7] In addition, the rate of unexpected incidents is more than 74 incidents per 100 infants.^[8] Many other factors can also threaten the safety of hospitalized infants.

Infant safety in a NICU may include a wide range of structures and practices of health-care professionals and family

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involvement. Poorly designed care processes and environments, lack of facilities, and human resources can endanger patient safety.^[4,9] Furthermore, stressors such as light and noise, infection, unplanned removal of the endotracheal tube, and implementing invasive procedures can increase the risk of infant injury and affect the growth and neurodevelopmental outcomes.^[10-15] Conversely, improving the work environment,^[16,17] teamwork, safety climate,^[6] and quality promotion efforts^[18] may be a promising strategy to achieve safer settings for at-risk newborns. Thus, processes and structures should be in such a way as to provide safe care for the infants hospitalized in NICUs and promoted expected outcomes.

Investigations on the processes and structures in the NICUs of the Islamic Republic of Iran have reported low quality of care, as well as neonatal nutritional support^[19,20] and discharge processes in NICUs.^[21] Moreover, developmental care is not yet pervasive,^[22] and there is a need to standardize the physical space^[23] of units and equipment to achieve the expected neurodevelopmental outcomes.^[24,25] Taking proper and correct actions prevent these problems in the two areas of structure, process, and promote quality of care.^[26]

Improving the health-care quality for women and children is a World Health Organization (WHO) priority for reducing preventable maternal, newborn, and child deaths.^[27] Some countries such as England, Scotland, and Wales have developed national standards for understanding and meeting safety needs based on their unique conditions. Other organizations such as the British Association of Perinatal Medicine^[28] and the National Institute for Health and Care Excellence^[29] have developed standards that can be used across the UK. In addition, the European Foundation for the Care of Newborn Infants has proposed interdisciplinary reference standards in 11 main areas covering the most significant issues related to preterm birth and neonatal complications.^[30] Therefore, considering the needs of each context and available resource, the development of patient safety standards based on valid evidence is part of every health-care system for quality promotion.

Designing and developing evidence-based standards is considered one of the most important aspects of modern management in the health sector. Iran's Ministry of Health and Medical Education (MOHME) has established accreditation programs. Furthermore, it has planned to implement the standards of the safety-friendly hospitals of the WHO, too. However, the need to develop an integrated set of evidence-based standards to promote the safety of hospitalized infants has still existed due to specific characteristics of NICU and the need to adapt to global conditions and scientific developments.

Current knowledge, available resources, and the environment in which care is provided help to develop standards to determine the requirements for preventing patient injury. Moreover, these standards can be a source for the formulation and application of guidelines, agreements, and protocols across the country. Likewise, development of such these standards will help improve the efficiency and effectiveness of structures and processes, increase outcomes, facilitate appraisal and evaluation, and provide fair and high-quality services. Hence, the present study was designed to establish patient safety standards in Iranian NICUs. We believe that the development of such these standards will help provide high-quality services.

Materials and Methods

This sequential three-phase mixed methods study applies the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework. EPIS is a prospective model for identifying the external context (at the system level) and internal context (service providers and patient organizations) that may affect the implementation of innovations in the clinical environment.^[31] It is anticipated 24 months for study. Since the long-term effects have not been investigated, the fourth phase (Sustainment) will not be considered.

A key component within the EPIS framework, which is an essential implementation strategy in this study, considers the organizational relationships between stakeholders and entities. The study represents it through a community-academic partnership^[32] to improve inter-university cooperation and facilitate the translation of research from theory to practice.^[33] Accordingly, the present research was planned in the form of a dissertation proposal for the Doctor of Philosophy (PhD) in nursing.

The Neonatal Health office (NHO) of Iran's MOHME proposed the initial study idea, and Isfahan University of Medical Sciences funded it. Furthermore, other stakeholders, including various health-care professionals working in NICUs (neonatologist, nurses, managers, policy-makers, and developers of neonatal clinical guidelines) will participate in various meetings during the study through the interdisciplinary training group affiliated with this Office and will discuss on the findings.

The phases of the study and activities in each phase are described in the following sections [Table 1]. Activities in each phase seek to achieve the aims of the study. The first aim is to identify patient safety scopes in NICU, standard topics, and a standard template and the second one is to develop patient safety standards in NICUs.

Validation of developed standards and examines the feasibility of standards are the third and fourth aims of the study, respectively.

Phase 1: Exploration

Phase 1 (Exploration) seeks to achieve the first and second aims of the study. According to the WHO model,^[27] this phase includes activities for scoping based on the theoretical model, deciding on the standard topic, developing the standard template, peer review, stakeholders review, and developing and drafting patient safety standards in NICUs.

Scoping based on the theoretical model, deciding on the standard topic, and developing the standards template

In Phase 1, for the first to third activities, a range of national and international guidelines and standards in scientific databases and libraries will be searched using the desired keywords [Table 2]. In addition, organizations that may have patient safety standards and websites of standards development institutions are visited. Publication date (from 2011 to 2021) and language (English and Persian) limitations are applied. Excluded findings are that their full texts inaccessible or irrelevant to patient safety in the NICU.

Peer review

The standard development team (research team) will check the entirety of searching and evaluate the related literature, databases, and websites. Moreover, they will agree on the scope, standard topics, and standard templates.

Stakeholders review

The results of the peer review sessions will be reviewed in a meeting with neonatal health-care stakeholders (Neonatologist, neonatal nurses, managers, and health policy-makers) from all over the country. All participants are informed and given their written consent to record the session. All opinions and comments will be carefully reviewed after transcribing. Important points will be identified. Then, to feedback to the standard development team for decision-making, a report of the main findings and recommendations will be prepared and presented.

Developing and drafting patient safety standards in neonatal intensive care units

The development of patient safety standards is based on evidence. All national and international clinical guidelines and standards in the last 10 years, available in full text, will be collected and appraised based on each standard topic. The initial draft of patient safety standards in NICUs will be prepared and validated in

Table 1: The phases of study and activities of each phase

Phases of study	Activities
Phase 1: Exploration	Scoping based on the theoretical model Deciding on the standard topic Developing the standards template Peer review Stakeholders review Developing patient safety standards in NICUs Drafting patient safety standards in NICUs
Phase 2: Preparation	Reviewing the initial draft of patient safety standards in NICUs Developing the final version of patient safety standards in NICUs
Phase 3: Implementation	Examining the applicability of patient safety standards in NICUs from the users' view

NICUs=Neonatal intensive care unit

Table 2: Desired keywords

(Guideline) OR (instruction) OR (qualit not qualitative) OR (evidence based) OR (standard) OR (clinical pathway) OR (indicator) OR (metric)
AND
(Patient safety) OR (risk management) OR (neonatal safety)
AND
(Intensive care units, neonatal) OR (intensive care, neonatal)

phase two (Preparation). The standards development team will edit the initial draft of the proposed standards, before starting the second phase.

Phase 2: Preparation

This phase includes two activities, reviewing the initial draft of standards and developing the final version of patient safety standards in NICUs.

Study design and setting

In this phase, the RAND/UCLA Appropriateness Method (RAM) will be used.^[34] To do this, a group of experts will validate the developing draft of the patient safety standards in NICUs. The research setting is Neonatal Health Office (NHO) of MOHME of Iran.

Study participants and sampling

According to the instruction for using RAM, 9–15 nurses and neonatologists with at least 10 years of experience working in NICU and a willingness to participate in the study will be purposefully selected and invited to participate in two rounds.^[34,35]

Data collection tool and technique

The first round of rating is via e-mail. For this purpose, the facilitator (first investigator) will contact the panelists individually to explain the RAM procedure and clarify any questions. Then, the panelists e-mailed the draft of standards and asked to offer their opinions on the target and user groups, goal, statement, and rationale for each

standard within 1 month. Also, they will be asked to assess the usefulness, clarity, relevance, and applicability and rate the appropriateness of the components of each standard on a 9-point Likert scale (nine being the most appropriate).^[34]

The median scores will be calculated and the number of panelists' ratings outside the median tertile will be recorded. Following the RAM guidelines, the components will be classified and agreed to as valid based on the median rating of appropriateness and the degree of panel agreement (dispersion). Accordingly, the classification of components with a median panel score in the top tertile^[7-9] without disagreement is "appropriate," median ratings in the bottom tertile^[1-3] without disagreement are "inappropriate," and median scores between 4 and 6 or any median with disagreement are neither "appropriate" nor "appropriate," rather they are "uncertain." The second round is face to face for allowing the members to discuss their judgments and reaching a consensus on the components in the "uncertain" category among panelists.^[34]

To develop the final version of patient safety standards in the NICUs, the research team will review all standards. Corrections will be done according to the panelists' opinions. The final version will enter the next phase (Implementation).

Phase 3: Implementation

Study design and setting

Studies have indicated that service providers' perceptions of evidence-based initiatives can prevent or facilitate their acceptance and implementation.^[36] Thus, this phase examines the feasibility of standards from the users' view in a descriptive manner. The research setting includes NICUs in Iran.

Study participants and sampling

Forty-three health-care professionals including neonatal nurses and neonatologist of Iran, having at least 5 years of experience working in NICU, not participating in the first and second sessions of this research, and willing to cooperate, will be selected by convenience sampling method.

Data collection tool and technique

A two-part questionnaire will be applied to collect information. The first part consists of demographic data (age, gender, level of education, the field of study, and length of employment), and the second part includes the 20-item Perceived Characteristics of Intervention Scale. This scale measures evidence-based interventions that are valid according to the experts based on the ten characteristics of relative advantage, compatibility, complexity, trialability, observability,

potential for reinvention, task issues, nature of knowledge, augmentation-technical support, and risk. Health-care service providers will examine these characteristics using a 5-point Likert scale.^[36]

After corresponding with the questionnaire designer, obtaining permission, and receiving the questionnaire along with its user guide, it will be translated from English to Persian to determine its reliability and validity. Finally, a skillful fluent person in English will revise the questionnaire. Next, the face validity and content validity of the questionnaire will be determined. The internal consistency of the questionnaire will be measured using the Cronbach's alpha coefficient. SPSS V. 16 Software (IBM., Armonk, NY). SPSS Inc. Released 2007. SPSS for Windows, Version 16.0. Chicago, SPSS Inc. and descriptive statistics methods. Finally, experts will review the results.

Ethical consideration

We will obtain informed consent from the study participants and ensure their complete anonymity and their right to withdraw from the study at any point. Before initiating and recording conversations in panel sessions, all attendees will be informed and consent will be obtained.

Discussion

Development of evidence-based standards and guidelines is an example of knowledge management in the health-care system. Policy-makers use them to meet the needs of patients and the community. The aim is to evaluate health-care services, promote quality, and achieve goals. Standards are necessary for health-care quality promotion to achieve the best health-care outcomes.^[37] Besides, the need for them has become more apparent due to the increasing technologies and evidence in the health-care area, the need to manage current knowledge about the available resources, and the context in which the health-care services are provided.

Developing evidence-based standards is a dynamically scientific process that can promote the quality of health care. The relationship between safety and quality is so strong that cannot be distinguished from safety.^[38] Therefore, considering the priority of patient safety in the health system and its application as an indicator of quality promotion,^[4] improving patient safety standards based on evidence can play an important role in continuous quality improvement.

The development of patient safety standards can determine the minimum requirements and lead to coordinated and integrated efforts by different individuals and organizations to improve safety.

Also, they can establish a purposeful system for planning, promotion, and evaluation if they develop consistent with the nature of services, the specific characteristics of the population admitted to NICU, and the different partnership of stakeholder. It can further prevent the wastage of available resources.^[39,40] In addition, considering the triangle relationship between availability, quality, and cost, they will encourage managers and decision-makers to do their best to improve patient safety based on valid and scientific evidence based on context.

Significance and priority need for a comprehensive scientific collection of valid actions to improve patient safety in NICUs at the national level. Suggestions made by the NHM of MOHME have committed the researchers to design a protocol for developing applicable standards. These standards will be developed systematically based on an appropriate theoretical view on patient safety that is a comprehensive guide for stakeholders. Besides, what makes this study unique is planning for stakeholders' participation from across the country, using interdisciplinary research teams and experts and paying due attention to the parents' role in infant care. These characteristics and valid evidence can enable standards to improve the efficiency and effectiveness of structures and processes, promote health-care outcomes, and provide conditions for progress toward equitable and high-quality health care. They can also improve the transformation of knowledge and the development of evidence-based practices.

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Conflicts of interest

There are no conflicts of interest.

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