

Developing Patient Safety Standards for Quality Improvement in the NICUs: A Mixed-Methods Protocol

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Study Protocol

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Abstract

Background

Neonatal intensive care unit is one of the accident-prone environments in the health care system. A range of structural and process factors threaten hospitalized infant safety in this unit. These factors are prevented by identifying safety needs and taking the right actions. In this regard, some countries in the world have developed standards. Developing standards based on current knowledge, available resources, and context that provide care, determine patient injury prevention requirements. Likewise, it can be a source for national development and application of guidelines, protocol, and laws. This study aims to develop patient safety standards in the Neonatal intensive care units of the Islamic Republic of Iran.

Methods

This mixed methods study will apply the Exploration, Preparation, Implementation, Sustainment framework to develop patient safety standards. The first three phases are the focus of this study. Due to investigating the long-term effects, it doesn't consider Phase 4(Sustainment). In each of these phases, a set of activities takes place. Designing Phase 1 (Exploration) is based on the World health organization model to develop standards. Determining the validity and applicability of developing standards will be done in Phase2 (preparation) and Phase 3 (implementation), respectively.

Discussion

Patient safety standards from this study are developed based on valid evidence and a comprehensive theoretical view. Additionally, considering parents' roles and the interdisciplinary experts' views in the neonatal intensive care unit. In this regard, determining the minimum requirements to maintain patient safety and developing evidence-based practice will be improved efficiency and effectiveness and contributed to equitable and higher quality health care delivery. The application of developing standards will be improving patient safety and quality of health care in the neonatal intensive care units of Iran.

Background

Safety is one of the basic human needs, and patient safety is an essential component of health care quality (1). Since "To Err is Human: Building a Safer Health System report" was published, it has been considered a significant health approach that led to some movements in the world (2). These movements prompted every health care system to work to reduce incidents and errors and build a safe environment, in addition to providing health care services. The neonatal intensive care unit (NICU) is one of the accident-prone environments in the health care system due to the provision of special care, equipment complexity, need for specialized knowledge and skills, and high vulnerability of infants (3–5). In this environment, errors occur eight times more than in others (6). Also, the rate of unexpected incidents is

more than 74 incidents per 100 infants (7), and many factors can be threatening the hospitalized infant safety.

Infant safety in the NICU includes the wide range of structures and practices of health care professionals and family involvement. Poorly designed care processes, not the well-designed environment, lack of facilities and human resources can endanger patient safety (8, 9). Also, stressors like light and noise, Infection, Sudden endotracheal tube extubation, and implementing invasive procedures increase the risk of infant injury and affect the growth and neurodevelopmental outcomes (10–15). Thus, organizational processes and structures should be designed in such a way as to provide safe care for hospitalized infants in the NICU and improved expected outcomes (16).

Investigations on the processes, structures, and expected outcomes in the NICUs of the Islamic Republic of Iran (IRI) reported low quality of care. They have shown that neonatal nutritional support processes (17) and discharge processes have low quality in the NICU (18). Likewise, developmental care has not widespread yet (19). Moreover, need to standardize the physical space of units and equipment to achieve the expected neurodevelopmental outcomes (21).

Expected outcomes such as infant developmental status, time to start oral feeding, breastfeeding, weight gain, and length of hospital stay, family satisfaction, and infant cognitive development in the future (22) play a role in assessing the effects of structures and processes and evaluating the degree of achieving to goals in the NICU. However, some problems in documenting hospitalized infant information, such as uncertainty about the validity and reliability of data, lack of supervisory authority on the accuracy of completing and information, and lack of access to information in the patient's subsequent visits, make it difficult to assess the expected outcomes. Identifying safety needs and taking proper and correct actions prevent the mentioned factors in the three areas of structure, process, and outcome (23).

Some countries have developed standards for understanding and meeting safety needs. National standards of England, Scotland, and Wales were developed based on unique conditions. Besides, other organizations such as the British Association of Perinatal Medicine (BAPM) (24) and the National Institute for Health and Care Excellence (NICE) (25) have developed standards that can use across the UK. Reference standards in eleven main areas covering the most significant issues related to preterm birth and neonatal complications have been developed interdisciplinary by the European Foundation for the Care of Newborn Infants (EFCNI) (26). Therefore, considering the needs of each context and available resources, the development of standards based on valid evidence is part of the health care system.

Designing and developing evidence-based standards is considered one of the most important aspects of modern management in the health sector. In the IRI, The Ministry of Health, and Medical Education (MOHME) has established accreditation programs and has planned to implement the standards of the safety-friendly hospitals of the World Health Organization (WHO), too. But, barriers to implementation standards, lack of adequate attention to safe care processes, limited resources, specific characteristics, and conditions of each health care center, and the need to adapt and update to global conditions and developments on the other hand, as well as the lack of comprehensive attention to the main factors in

standards development such as health care professionals, infant, family, and other stakeholders, lack of consideration of differences, and critical characteristics of NICUs, increases the need to develop an integrated set of evidence-based standards focused on these characteristics to improve the hospitalized infant safety.

Developing standards based on current knowledge, available resources, and context that provide care, determine patient injury prevention requirements. Also, it can be a source for the development and national application of guidelines, protocols, and laws. Therefore, designing a study to develop patient safety standards in the NICU. Using the developing standards may increase the efficiency and effectiveness of structures and processes, improve outputs, facilitate assessment and evaluation, and provide equitable and high-quality services.

Method And Design

This study is a sequential three-phase mixed methods study approved by the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.RESEARCH.REC.1399.496). The study applies the Exploration, Preparation, Implementation, Sustainment (EPIS) framework. This model is a prospective framework that identifies outer context (at the system level) and inner context (service provider and patient organization) factors that may influence the implementation of innovations in a clinical environment (27). The first three phases are the focus of this study. The fourth phase(sustainment) is not considering due to investigating the effects in the long term.

A key component within the EPIS framework and is an essential implementation strategy within this study considers the organizational relationships between stakeholders and entities. Our study represents it through community-academic partnership (28) To improve inter-university cooperation and facilitate the translation of research from university to practice field (29). In this regard, planning the research in the form of a thesis proposal for the Doctor of Philosophy (Ph. D) in nursing is provided.

The neonatal Health Department (NHD) of the MOHME proposed the study idea, and Isfahan University of Medical Sciences funded it. Also, other stakeholders, including various health care professionals related to the NICU (physicians, nurses, lower, middle, and upper-level managers, policymakers, and developers of neonatal clinical guidelines) will participate in various meetings during the study through the interdisciplinary training group affiliated with this department and will discuss on the findings. The phases and activities in each Phase are in the following sections (Table 1).

Phase 1: Exploration

Planning Phase 1 (Exploration) activities are to achieve the first and second aims of the study. These aims are identifying the structure and process needs and developing structure and process patient safety standards and the expected outcomes in the NICU. According to the WHO model (30), this phase includes activities for scoping based on the theoretical model, determining operational definitions, deciding on the

standard topic, developing the standard template, peer review, stakeholders review, and developing and drafting patient safety standards in the NICU.

In Phase One, for first to fourth Activities, searching and appraising a range of national and international guidelines and standards in scientific databases, domestic and foreign sites, and libraries are done, using the desired keywords (Table 2). Also, 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. To determine the Theoretical model, decide on the standard topic, and develop the standard template, all evidence and findings are reviewed and appraised.

The standards development team (research team) will check the entirety of searching and evaluate literature, databases, and websites. Also, team members will agree on scoping, operational definitions, the standards topic, and the Standard template for the s. The results of the peer review sessions will review in a meeting with neonatal health care stakeholders (physicians, nurses, managers, and health policymakers in the area of neonates) from all over the country. All participants are informed and given their consent to record the session. All opinions and comments will review carefully according to the objectives after transcribing. Important points will identify. Then, to feedback to the standard development team for decision-making, a report of the main findings and recommendations is prepared and presented (31).

Developing the Patient Safety Standards is based on evidence. National and international clinical guidelines and standards in the last ten years, in which their full text is available, will be collected and appraised based on each standard topic. The initial draft of patient safety standards in the NICU will be prepared and validated in "Stage 2: Preparation". The standards development team will edit the initial draft of the proposed Standards, Before the second phase.

Phase 2: Preparation

This phase included two activities, reviewing the initial draft of standards and developing the final version of the Patient Safety Standards in the NICU. First, a group of experts will validate the developing draft of the Patient Safety Standards in the NICU. To this end, the RAND/UCLA Appropriateness Method (RAM) will be used (32). According to the instruction for using RAM, 9 to 15 health care system professionals from different specialties will be purposefully selected and invited to participate in two rounds (32, 33).

The first round of rating is via email. For this purpose, the facilitator (ZSH) will contact each panelist to explain the RAM procedure and clarify any questions. Then, the panelists are emailed the draft of standards and asked to offer their opinions on the target and users, goal group, statement, and rationale for each Standard within one month. Also, they will assess usefulness, clarity, relevance, and applicability and rate the appropriateness for components of each standard on a Likert scale of 1 to 9 (nine being the most appropriate) (32).

Following the RAM guidelines, median scores are calculated, and the number of panelists rating outside the median tertile is recorded. The components are 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 as “appropriate”, median ratings in the bottom tertile (1–3) without disagreement is as “inappropriate”, and median scores between 4 and 6 or any median with disagreement is as neither appropriate nor appropriate but as “uncertain”. The second round is face-to-face for allowing members to discuss their judgments. Reaching a consensus on the components in the "uncertain" category among panelists (32).

To develop the final version of Patient Safety Standards in the NICU, the standards development team reviews all standards. Requiring corrections will be done according to the panelists' opinions. The final version enters the next Phase (Phase three, implementation).

Phase 3: Implementation

Studies have indicated that service providers' perceptions of evidence-based initiatives can prevent or facilitate their acceptance and implementation (34). Thus, this phase examines the feasibility of standards from the users' view in a descriptive design. For this purpose, 43 health care professionals, who have at least five years of experience working in the NICU and are not participants in the first and second sessions of experts of this research and are willing to cooperate, will be selected by stratified sampling method.

A questionnaire will be applied to collect information. It consists of demographic data (Age, Gender, Level of education, The field of study, and the length of employment) and the 20-item Perceived Characteristics of Intervention Scale (PCIS). This scale measures evidence-based interventions that are valid according to the experts based on ten characteristics of relative advantage, compatibility, complexity, trialability, the potential for reinvention, task issues, nature of knowledge, augmentation-technical support, and risk from health care service providers' view on a 5-point Likert scale (34).

After corresponding with the questionnaire designer, obtaining permission, and receiving the questionnaire along with its user guide, the questionnaire will be translated from English to Persian to determine its reliability and validity. Finally, a skillful fluent person in English revises the questionnaire. The face validity and content validity of the questionnaire are determined. The internal consistency of the questionnaire is measured using Cronbach's alpha coefficient. Data will be analyzed using SPSS-16 software and descriptive statistics methods. Experts will review the results.

Discussion

Evidence-based standards and guidelines development are examples of knowledge management in the health care system. To meet the needs of people and the community, Policymakers using them. They use them to evaluate healthcare services, improve quality, and achieve goals. Standards are necessary for health care quality improvement to achieve the best health outcomes (35). 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 considering the available resources, and the context where provided the health care services.

Developing evidence-based standards is a dynamically scientific process that can be improving the quality of health care. The strong relationship between safety and quality is so strong that providing high-quality care cannot be distinguished from safety (36). Therefore, considering the priority of patient safety in the health system and its application as an indicator of quality improvement (9), improving patient safety based on evidence-based standards can play an important role in continuous quality improvement.

Developing patient safety standards determines minimums and leads to coordinated and integrated efforts of different individuals and organizations to promote safety. Also, they can cause a purposeful system for planning, improvement, and evaluation if they develop consistent with the nature of services, the specific characteristics of the population admitted to the NICU, and the different stakeholders' partnership. It can prevent the waste of available resources. (37). Besides, they cause managers and policymakers to do their best for patient safety improvement based on valid scientific evidence based on the context, considering the triangle of availability, quality, and cost.

Significance and priority need for a comprehensive scientific collection valid actions to improve patient safety in the NICUs at the national level, and suggestion of the Neonatal health department (NHD) of MOHME made Researchers 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 that, what makes this study unique is planning for stakeholder participation from across the country, using interdisciplinary research teams and experts, and paying attention to the parents' roles in infant care. Along with the valid evidence, these characteristics can cause the standards to increase the efficiency and effectiveness of structures and processes, improve outcomes, and provide the conditions to move toward equitable and high-quality health care. Also, they can facilitate translating knowledge and developing evidence-based practice.

List Of Abbreviations

NICU

Neonatal Intensive Care Unit

IRI

Islamic Republic of Iran

MOHME

Ministry of Health and Medical Education

WHO

World Health Organization

EPIS

Exploration, Preparation, Implementation, Sustainment
Ph. D
Doctor of Philosophy
NHD
Neonatal Health Department
RAM
RAND/UCLA Appropriateness Method
PCIS
Perceived Characteristics of Intervention Scale
SPSS V. 16
Statistical Package for the Social Sciences software, Version 16

Declarations

Ethics approval and consent to participate

The ethics committee affiliated with Isfahan University of Medical Sciences, Isfahan, Iran (IR.MUI.RESEARCH.REC.1399.496) approved the study. 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.

All information (questionnaires and recorded files) will be coded by a unique identifier number and stored in a secure password protected file that will be kept by investigator (ZSH).

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

As a funding body, this protocol has been reviewed and approved by Isfahan University of Medical Sciences, Isfahan, Iran (grant agreement number 399464 and the total budget of 93,386,03 Rial). Additionally, the Neonatal health department of the Ministry of Health and Medical Education in the Islamic Republic of Iran provide project operational support. Head of the Neonatal health department and department Manager of the educational group affiliated to that, "MH", is the project counselor.

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Authors' contributions

The present study protocol was the research priority of the NHD of MOHME in the IRI. ARI is the Head of the research team.

ARI, ZSH, SJM, and MH were involved in the study design. They have developed the framework of the work. ZSH wrote the first draft of this manuscript. ARI, SJM, and MH reviewed and worked on subsequent drafts of the protocol and manuscript. All authors read and approved the final manuscript.

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Tables

Due to technical limitations, table 1 is only available as a download in the Supplemental Files section.

Table 2: Keywords

<i>[Guideline] OR [Instruction] OR [Qualit NOT Qualitative] OR [Evidence Based] OR [Standard] OR [Clinical pathway] OR [Indicator] OR [Metric]</i>
AND
<i>Patient Safety] OR [Risk Management] OR [Neonatal Safety]</i>
AND
<i>[Intensive Care Units, Neonatal] OR [Intensive Care, Neonatal]</i>

Supplementary Files

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