

# Clinical Guideline for Nursing Care of Children with Head Trauma (HT): Study Protocol for a Sequential Exploratory Mixed-Method Study

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**Background:** Head trauma is a major health problem. Its primary complications happen at the time of trauma and are inevitable; thus, head trauma management is focused on the prevention and management of secondary complications. A clear clinical guideline for head trauma care can help nurses effectively prevent and manage secondary complications. This study aims to develop the clinical guideline for nursing care of children under 18 years with head trauma hospitalized in emergency departments, critical care units, and neurosurgery wards.

**Methods:** This sequential exploratory mixed-method study will be conducted in three main phases as follows: qualitative, systematic review, and integration phases. In the qualitative phase, semi-structured interviews will be conducted to determine the care-related needs of children with head trauma. In the systematic review phase, a systematic review will be performed to find and then to review the most relevant articles, books, and the appropriate clinical guidelines. The quality of the retrieved guidelines will be assessed using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument. In the integration phase, the findings of the qualitative and systematic review phases were integrated, the draft of the guideline will be prepared, which will then be revised and validated through a nationwide Delphi survey.

**Discussion:** The guideline for nursing care of children with head trauma can help to more effectively prevent, reduce, and manage the secondary complications of head trauma. Moreover, it reduces disability and mortality rates, improves nursing care quality, decreases healthcare costs, shortens hospital stay, and makes more rational clinical decisions.

**Keywords:** head trauma, nursing care, children, clinical guideline

## Background

Trauma is considered as the first leading cause of disability among the active population in developing countries<sup>1</sup> and is the second leading cause of death in both genders. Its mortality rate in the world and in Iran is 99 and 58 cases per 100,000 people, respectively.<sup>2</sup>

With a prevalence of 39.7%, head trauma (HT) is the most common type of trauma among children,<sup>3</sup> which is known as the first leading cause of disability and death among children with age range between 1 and 14 years.<sup>4</sup> Estimations show that 57 million people in the world are annually hospitalized due to one or more HTs.<sup>6</sup> Every year 600,000 children under the age of 18 are admitted to the emergency department because of HT which is also a cause of 7400 deaths in the

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world.<sup>7,8</sup> HT prevalence among children in Iran is poorly known. A study in Tehran, Iran, showed that the prevalence of HT was 295 cases per 100,000 people and with a death rate of 19%.<sup>9</sup>

HT is associated with different health, familial, and financial consequences. It usually causes two main types of brain injuries, including primary and secondary.<sup>11</sup> During secondary injuries, brain cells are injured, and hence, brain ischemia or edema may happen and result in late mortality.<sup>5</sup> Besides, HT victims experience different neurologic and mental disorders such as personality changes, anger, depression, and sense of insufficiency, all of which can exert negative effects on patients, families, and societies. Moreover, because of different disabilities, HT victims may need long-term care; so that this issue imposes heavy costs on healthcare systems.<sup>13</sup>

Given the different personal, familial, financial, and social consequences of HT, afflicted patients need emergency care services with high quality. Also, quality healthcare delivery necessitates using clear and explicit guidelines.<sup>15</sup> Clinical guidelines are statements, which are systematically developed based on the best accessible evidence in order to help nurses and patients make decisions about the most appropriate nursing care in clinical situations. In this regard, clinical guidelines explain the practical steps of clinical care, prevent non-standard caring activities,<sup>16</sup> reduce care diversity, improve coordination among healthcare providers, shorten hospital stay, and reduce disability and mortality rates.<sup>17</sup> The use of clinical guidelines for patients with HT also helps to prevent or minimize secondary brain injuries and thereby, reduces disability and mortality rates.<sup>18</sup> A study performed in Saudi Arabia showed that using clinical guidelines for patients with severe traumatic brain injuries has significantly reduced hospital mortality and also improved survival rate without increasing the healthcare-related costs.<sup>28</sup> Another study revealed that using nursing care protocols for care delivery to patients with a moderate HT was significantly effective on reducing all the HT-related systemic complications, disability, and mortality through a significant improvement of respiratory function, arterial blood gas levels, hemodynamic status, neurologic function, skin integrity, and body temperature.<sup>5</sup> Accordingly, these studies confirm that developing and use of clinical guidelines for nursing care of children with HT can reduce the burden of care delivery, decrease disability and mortality rates, improve patients' quality of life, shorten their hospital stay time, and reduce or prevent

secondary brain injuries. Moreover, developing and using these guidelines can improve nursing care quality, promote public health, improve coordination among different healthcare providers, and also help nurses to make wiser clinical decisions based on the patients' clinical conditions.

Contrarily, the lack of such guidelines in adjacent with heavy workload of nurses, nursing staff shortage, and poor coordination among healthcare providers can reduce care quality. A study in Iran reported that, the quality of airway management provided to patients with moderate to severe HTs, was moderate.<sup>19</sup> Another study performed in Iran also reported the low quality of care services for patients with HT.<sup>20</sup>

Despite the importance of clinical guidelines for providing quality healthcare delivery and the poor status of nursing care for HT victims in Iran, our literature search showed that there was no culturally adapted clinical guideline for nursing care of children with head trauma in Iran. So, the present study attempt to address this gap. The aim of the study is to develop the clinical guideline for nursing care of children under 18 years with head trauma hospitalized in emergency departments, critical care units, and neurosurgery wards.

## Primary Objective

- Develop the clinical guideline for nursing care of children with head trauma hospitalized in emergency departments, critical care units, and neurosurgery wards.

## Secondary Objectives

- Determining care-related needs of children with HT hospitalized in emergency departments, critical care units, and neurosurgery wards from the perspectives of their families and healthcare providers;
- Identifying the most appropriate clinical guidelines and the most relevant articles and books on nursing care for children with HT;
- Preparing the draft of clinical guideline for nursing care of children with HT hospitalized in emergency departments, critical care units, and neurosurgery wards; and
- Validation of the draft of clinical guideline for nursing care of children with HT hospitalized in emergency departments, critical care units, and neurosurgery wards through a nationwide Delphi survey and developing the final guideline.

## Methods

This sequential exploratory mixed-method study will be conducted based on the pragmatism paradigm in three main phases as follows:

1. Phase I (the qualitative phase): Exploration and prioritization of the care-related needs of children with HT;
2. Phase II (the systematic review phase): systematically reviewing the exiting literature to find the most appropriate clinical guidelines and the most relevant articles and books. Also, the quality of the retrieved guidelines will be assessed using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument.
3. Phase III (the integration phase): Integration of the findings of the two previous phases to prepare the draft of the clinical guideline, validation, and revision of the guideline by a panel of experts, and preparation of the final guideline.

### Phase I: The Qualitative Phase Design

A qualitative study will be done to explore and prioritize the care-related needs of children under 18 years with HT hospitalized in emergency departments, critical care units, and neurosurgery wards.

#### Participants

Participants will be the family members of children under 18 years with HT as well as physicians and nurses who work in emergency departments, critical care units, and neurosurgery wards in Isfahan, Iran. Inclusion criteria are the experience of caregiving to children with HT (for all participants), willingness for participation (for all participants), and working in emergency departments, critical care units, and neurosurgery wards (for healthcare providers). Participants who choose to withdraw from the study will be excluded. Study setting will be the emergency departments, critical care units, and neurosurgery wards of hospitals affiliated to Isfahan University of Medical Sciences, Isfahan, Iran, in which children with HT are hospitalized for HT management. Sampling will be done purposefully and with maximum variation concerning eligible participants' age, gender, educational level, socioeconomic status, and geographic place of residence.

#### Data Collection

Data will be collected through in-depth semi-structured interviews. Interviews will be held in the workplace of the first author or the workplace of participants, depending on their own preferences. The length and the number of interviews with each participant will also depend on the intended participant's information and conditions. Interview will be recorded and notes will be made during interviews. Data collection will keep on up to data saturation. The following questions will be used to guide the interviews: "What needs and problems do you experience in relation to caregiving to your patient?" "In your opinion, what are the reasons for these problems?" "In your opinion, has your patient ever had needs which have been neglected during the course of treatment?"

#### Data Analysis

Data will be analyzed concurrently with data collection through the conventional content analysis approach proposed by Graneheim and Lundman. The six steps of this approach are deciding on the level of analysis, selecting the unit of analysis, selecting meaning units, generating condensed meaning units, generating primary codes, and generating categories.<sup>21</sup>

#### Trustworthiness

Trustworthiness will be ensured using the credibility, dependability, confirmability, and transferability criteria.<sup>22</sup> To ensure credibility, techniques such as prolonged engagement with the data, holding in-depth interviews in different sessions, member checking, and sampling with maximum variation will be used. Dependability will be ensured through a detailed description of the study process. Confirmability will be maintained through reporting all steps of the study with details and also through peer checking by several experienced qualitative researchers who will be provided with the data and the findings and will be asked to confirm the accuracy of the coding process. For transferability, a clear description of the study process will be provided to help the application of the findings to other settings.

### Phase II: The Systematic Review Phase Design

A systematic literature review will be performed to find the most appropriate clinical guidelines and the most relevant articles and books related to nursing care of children with HT. The quality of the retrieved guidelines will be assessed using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument.

## Data Collection

A systematic literature search will be done in online databases such as CINAHL, Cochrane library, Springer, Ovid, Elsevier, PubMed, SID, Irandoc, and Magiran as well as in the websites related to clinical guidelines such as the websites of the National Institute for Health and Care Excellence (NICE), the Scottish Intercollegiate Guidelines Network (SIGN), and the National Guideline Clearinghouse (NGC). Study population will be all accessible articles, books, and clinical guidelines related to nursing care of children with HT. Inclusion criteria are relevance to nursing care of children with HT, accessible full-text, and publication in English or Persian between 2000 and 2019. The quality of the retrieved guidelines will be assessed using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument. Accordingly, a neurosurgery specialist, an anesthesiologist, and four nursing instructors with PhD degree will be invited to appraise the quality of the guidelines using the AGREE II instrument. Updated guidelines with a score of more than 50% for the AGREE II instrument will be included.<sup>23</sup>

## Data Analysis

Data will be analyzed through a narrative review. Accordingly, eligible guidelines, articles, and books will be assessed to find the most important care measures related to nursing care of children with HT. Relevant items will be extracted and included in the guideline.

The quality of the retrieved guidelines will be evaluated using the Appraisal of Guidelines for Research & Evaluation Instrument (AGREE II). Accordingly, a neurosurgery specialist, an anesthesiologist, and four nursing instructors with PhD degree will be invited to appraise the quality of the guidelines using the AGREE II instrument. Updated guidelines with a score of more than 50% standardized score for the AGREE II instrument will be included.<sup>23</sup>

AGREE II instrument: The AGREE II tool encompasses 23 items in six domains:

1. Scope and purpose (3 items),
2. Stakeholder involvement (3 items),
3. Rigor of development (8 items),
4. Clarity of presentation (3 items),
5. Applicability (4 items), and
6. Editorial independence (2 items).

Each item is rated from 1 (strongly disagree) to 7 (strongly agree). Detailed criteria for each item are available within the AGREE II tool to assist the appraiser.<sup>24</sup> The appraisers were asked to provide their comments to justify their rating. They also gave an overall assessment of the guideline from 1 (lowest) to 7 (highest) and were asked to state if they would recommend the guideline, recommend it with modifications or not. Average appraisal scores were calculated for each appraiser by taking the average rating<sup>25</sup> for all items of a single guideline. Percentages for each domain were then calculated will be done by adding all six appraiser ratings of items in a single domain (obtained score) and scaling to the maximum and minimum possible domain scores and converting to a percentage.

## Phase III: The Integration Phase Design

In this phase, the findings of the first and the second phases will be integrated and the draft of the guideline for nursing care of children with HT will be developed based on the needs of Iranian children with HT. Then, a nationwide Delphi survey will be performed to validate the guideline and develop its final version.

## Data Collection

The findings of the first and the second phases will be integrated by the research team and the draft of the guideline for nursing care of children with HT will be developed based on the needs of Iranian children with HT. The face and the content validity the draft of the guideline will be assessed by the research team in terms of criteria such as item quality, wording, and content. Then, a nationwide Delphi survey will be performed to validate the guideline and develop its final version.

## Participants of the Delphi Survey

The participants of the Delphi survey will be nursing instructors who are experienced in neurosurgery or intensive nursing care, neurosurgery specialists, emergency medicine specialists, critical care anesthesiologists, and nurses from emergency departments, critical care units, and neurosurgery wards in Iran. Inclusion criteria are the experience of caregiving to children with HT (for all participants), willingness for participation (for all participants), and working in emergency departments, critical care units, and neurosurgery wards (for healthcare providers). Participants who choose to withdraw from the study will be excluded.

## Data Analysis

The participants of the Delphi survey will be provided with a checklist containing care measures extracted from the primary draft of the guideline and will be asked to prioritize the care measures on a 5-point Likert scale with respect to their cost-effectiveness, applicability, quality, and necessary amount of time for completion. Moreover, they will be asked to add any other care measure or recommendation which is not included in the checklist. Finally, their rating scores will be used to calculate the essentiality, usefulness, readability, and plausibility scores of each care measure. Accordingly, care measures with an agreement above 70% will be kept in the guideline, and care measures with less than 70% will be discussed and then decided on in a panel of experts.

## Participants of the Expert Panel

The participants of the Expert panel will be nursing instructors who are experienced in neurosurgery or intensive nursing care, neurosurgery specialists, emergency medicine specialists, critical care anesthesiologists, and nurses from emergency departments, critical care units, and neurosurgery wards in Isfahan, Iran.

## Ethical Considerations

This study was approved by the Ethics Committee of Isfahan University of Medical Sciences, Isfahan, Iran (code: IR.MUI.RESEARCH.REC.1398.422). Written informed consent will be obtained from all participants and they will be informed about their freedom to voluntarily withdraw from the study.

## Discussion

The aim of this study is to develop the clinical guideline for nursing care of children with HT hospitalized in emergency departments, critical care units, and neurosurgery wards. The sequential exploratory mixed-method design will be used in this study because the process of guideline development is multiphasic and entails data collection from different sources. Integration of qualitative and systematic review designs can help develop a clearer guideline for nursing care of hospitalized children with HT.

Since the essential aspects of providing quality care are the involvement of service providers in the provision of clinical guidance, disregarding the viewpoint and needs of the users of the guideline, despite the proper implementation of the formulation process, may lead to the rejection of the guidance provided by them.<sup>26</sup> Therefore, this study will use a qualitative approach to identify the care needs of

patients from the perspective of family, nurses and physicians. Then, we will integrate the qualitative and review data, so that we can develop a more obvious guideline for nursing care of hospitalized children with HT. A clear guideline provides nurses with the latest data on patient care and enables them to provide patients with fair and standard care.<sup>27</sup>

A study by Goneim et al (2012) entitled “The Impact of Nursing Care Implementation on the Consequences of Patients with moderate Head Injuries in the Intensive Care Unit” was conducted in semi-experimentally design. The samples were easily selected and then divided into two groups each one containing 30 subjects, including the control group, which were managed according to the routine of the special management department, and the study group, which were cared in terms of the instructions. Patients’ mortality rate in the control group (56.7%) was higher than the study group (26.7%) after 2 weeks of admission. Also, 73% of patients in the study group were transferred to the neurology department, while in the control group, this rate was 43%. Accordingly, the results of this study revealed that the application of nursing care guidelines in patients with moderate head injury have the best effect on reducing the incidence of all systemic complications, mortality, and disability. Using nursing care guidelines, respiratory function, arterial blood gases, hemodynamic status, neural function, liver function tests, hemoglobin, intestinal motility, urinary excretion, mucosal membrane integrity, and skin and temperature of the body have significantly improved. Therefore, it is essential that simple and practical booklets, including nursing care guidelines for patients with traumatic brain injury, should be provided to all nurses in the intensive care unit.

Griesdale et al (2014) conducted a study entitled “Adherence to clinical guidelines for managing cerebral blood pressure and its consequence in patients with severe traumatic brain injury.” The aim of this study was to determine the degree of compliance with clinical guidelines related to cerebral blood flow pressure as well as indicating the relationship between this compliance and the mortality rate of patients with severe traumatic brain injury. The study was conducted as a retrospective cohort based on data obtained from all 127 patients who were admitted to an intensive care unit at Vancouver General Hospital between 2006 and 2012. The hospital used guidelines for managing patients with traumatic brain injury in terms of the clinical guidelines from the Brain Trauma Institute. The results of the study showed that, in total,

100 of the 127 patients examined were discharged from the hospital. The rate of compliance with the clinical guidelines in this hospital was low, and contrary to the recommendations of this guide that determined the range of cerebral blood flow pressure between 50 and 70 mm Hg, this amount was higher than 70 mm Hg in most of the cases. As a result, pressures more than 70 mm were associated with the reduced mortality and pressures lower than 50 mm Hg were associated with the increased mortality.

A study in Saudi Arabia showed that using clinical guidelines for patients with severe traumatic brain injuries significantly reduced hospital mortality and improved survival without increasing healthcare-related costs.<sup>28</sup> Another study revealed that using nursing care protocols for care delivery to patients with moderate HT was significantly effective in reducing all HT-related systemic complications, disability, and mortality through significant improvement of respiratory function, arterial blood gas levels, hemodynamic status, neurologic function, skin integrity, and body temperature.<sup>5</sup> All these studies confirm that developing and use of clinical guidelines for nursing care of children with HT can reduce the burden of care delivery, decrease disability and mortality rates, improve patients' quality of life, shorten their hospital stay, and reduce or prevent secondary brain injuries. Moreover, developing and using guidelines can improve nursing care quality, promote public health, improve coordination among different healthcare providers, and help nurses to make wiser clinical decisions based on patients' clinical conditions.

## Abbreviations

HT, head trauma; AGREE II, Appraisal of Guidelines for Research and Evaluation II.

## Ethics Approval and Consent to Participate

Written informed consent was taken from each Participant. The Ethics Committee of the Isfahan University of Medical Sciences in Isfahan, Iran. The protocol of this study was approved (code Number: IR.MUI.REC.1398. 422).

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## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

Authors have declared that there are no competing interests.

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