

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Organizational Challenges of Pain Management in Neonatal Intensive Care Unit: A Qualitative Study
AUTHORS	neshat, hanieh; hassankhani, hadi; jabraeili, mahnaz; Negarandeh, Reza

VERSION 1 – REVIEW

REVIEWER	Alinejad-Naeini, Mona Iran University of Medical Sciences, Neonatal and pediatric
REVIEW RETURNED	25-Mar-2023

GENERAL COMMENTS	<p>My comments after the initial review of the article are as follows:</p> <ol style="list-style-type: none">1- It is better to add neonatal intensive care unit instead of intensive care unit in the title.2- In the introduction, it was well stated about pain, its results on the neonate and the system, but you did not write anything about the role of the nurse in pain control and its importance, which led to the creation of a research question in you. Please explain in one paragraph about the role of the nurse and the challenges of managing infant pain.3- In the Ethical Consideration section, please mention more things that are considered in qualitative research.4- In the Setting section, please explain more about the NICU level (II or III). Because when sampling from only one center, it is important to describe the setting well.5- Explain about maximum variation in sampling.6- In the Data Collection section, explain how you chose the doctor after choosing the nurses and when and on what basis you ended the interviews.7- In the Data Collection section, explain the study method in more detail, for example, how long did the study last? Were the nonverbal behaviors of participants also considered? How were the interviews conducted? And other details...8- Your references are very old, please use more recent qualitative research that has been done in the neonatal intensive care unit and in your context.
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REVIEWER	Aiton, Neil Brighton and Sussex University Hospital NHS Trust, Neonatology
REVIEW RETURNED	04-Apr-2023

GENERAL COMMENTS	<p>This study attempts to answer the challenges in addressing the management of pain within a NICU setting using an appropriate descriptive methodology.</p> <p>The objective starts with the pretext that management of neonatal pain is both important as well as challenging to implement</p>
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	<p>successfully. The justification of the importance is discussed and referenced, but it would be helpful to add some explanation/references which relate to gaps/reality regarding implementation.</p> <p>The limitations should probably include some reference to cultural background, as although the hierarchical nature of medical environments is widespread internationally, there are differences between different cultures.</p> <p>The conclusion should be given greater depth of thought: yes these were the factors which were found, but perhaps more about why those factors impacted on adequate pain management.</p> <p>The results are potentially generaliseable to the experience of many neonatal units, and underline the complexity of making change in real life: sometimes, having the evidence available, as well as a protocol, and providing training are not enough! Some increased acknowledgement and discussion of this complexity of interaction might strengthen the paper further (although a full evaluation of the 'implementation of change' literature would be beyond the remit of this paper).</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Mona Alinejad-Naeini, Iran University of Medical Sciences, Iran University of Medical Sciences

Comments to the Author:

My comments after the initial review of the article are as follows:

Thank you so much for your time and kindness and your valuable suggestions. We have used your useful guidance and improved our manuscript according to your comments. The manuscript is modified, and we hope that the revised manuscript will satisfy you.

1- It is better to add neonatal intensive care unit instead of intensive care unit in the title.

Response: It is modified.

Title: "Organizational Challenges of Pain Management in Neonatal Intensive Care Unit: A Qualitative Study"

2- In the introduction, it was well stated about pain, its results on the neonate and the system, but you did not write anything about the role of the nurse in pain control and its importance, which led to the creation of a research question in you. Please explain in one paragraph about the role of the nurse and the challenges of managing infant pain.

Response: Thank you so much. We added it. We must respectfully say that due to the centrality of the organization's role in the management of infant pain, we behaved cautiously in this matter.

Line 81-82: "Pain management of neonates is one of the most important caring tasks of care providers. Especially nurses, play a significant role in pain management due to spending more time at the patient's bedside"

3-In the Ethical Consideration section, please mention more things that are considered in qualitative research.

Response: We completed Ethical Consideration section.

Line 112-114: "All participants were assured that they could withdraw from the study at any time without giving any reason."

Line 117-119: "The interviews were voice-recorded after obtaining the participants' consent. The place and time of the interview were chosen according to the participants' preference and their privacy was respected during the interview."

4- In the Setting section, please explain more about the NICU level (II or III). Because when sampling from only one center, it is important to describe the setting well.

Response: We explained more about the study setting.

Line 123-130: "The study was conducted in a NICU (level III) in Tabriz, East Azerbaijan province in the northwest of Iran. The NICU was a referral center for term and preterm neonates with various medical and surgical disease. The physical space of the NICU included three large halls equipped with 27 warmers. The average ratio of nurse to patient was 1:3. In this ward, different types of painful interventions are performed according to the neonates' needs. The ward has a special accommodation for mothers, which includes kitchen, toilet, bathroom and a large hall with multiple beds and wardrobes. Mothers can stay in the ward and with their infant 24 hours a day."

5- Explain about maximum variation in sampling.

Response: We explained it.

Line 133-136: "The purposive sampling was used to achieve the maximum variation. For this purpose, we selected the interested participants (nurses and physician) with various age range, educational level, work experience, organizational position, and profession for either individual or focus interviews."

6- In the Data Collection section, explain how you chose the doctor after choosing the nurses and when and on what basis you ended the interviews.

Response: Thank you for your consideration. Doctors were chosen at the same time as nurses. We talked to all of them and they accept participation, kindly. We added some details in this regard.

Line 110-111: " The first author explained the purpose of the research to the NICU staff (nurses and physicians), and answered their questions."

Line 148-149: "when no new information emerged of the individual interviews..."

7- In the Data Collection section, explain the study method in more detail, for example, how long did the study last? Were the nonverbal behaviors of participants also considered? How were the interviews conducted? And other details...

Response: We added some details. Respectfully, the research team prepared to considered nonverbal behaviors of participants using filed note, but the discussion sessions were completely professional and expert opinions were presented. No significant non-verbal behaviors that could contribute to the richness of our data were found.

Line 139: "Data were collected from February 2021 to January 2022"

Line 142-144: "The first author led the individual interviews using a semi-structured interview guide that focused on participants' experiences of neonatal pain management in NICU (Table 2)."

Line 148-153: "In order to achieve a broader and richer range of information when no new information emerged of the individual interviews, three focus groups were conducted by the first author in a conference hall of the center. Integrating individual and focus interviews makes a productive process and enriches data to conceptualize the phenomenon 19. The focus group sessions began by providing information about the study, and the questions asked were similar to the individual interviews. The first author handled the focus groups."

8- Your references are very old, please use more recent qualitative research that has been done in the neonatal intensive care unit and in your context.

Response: We modified them.

Reviewer: 2

Dr. Neil Aiton, Brighton and Sussex University Hospital NHS Trust

Comments to the Author:

This study attempts to answer the challenges in addressing the management of pain within a NICU setting using an appropriate descriptive methodology.

We thank you so much for your insightful and helpful comments. The manuscript has benefited from your valuable guidance. The manuscript is modified, and we hope that the revised manuscript will satisfy you.

1- The objective starts with the pretext that management of neonatal pain is both important as well as challenging to implement successfully. The justification of the importance is discussed and referenced, but it would be helpful to add some explanation/references which relate to gaps/reality regarding implementation.

Response: Thank you so much. We added it.

Line 78-80: "Evidence suggests that the rate of routine pain assessment in NICU can be as low as 6-10% and only 7.1% of care providers always take interventions to reduce neonates' pain."

2- The limitations should probably include some reference to cultural background, as although the hierarchical nature of medical environments is widespread internationally, there are differences between different cultures.

Response: We added it in the main text and bullets.

Line 58-59: "Potential for missing some information due to the hierarchical nature of the setting that discourage the voicing of opinions."

"Limitation

Our study was conducted in the NICU of a government teaching hospital, which may have a different environment from other clinical settings and limit the representativeness of the findings. Although qualitative research is usually not generalizable and its emphasis is on in-dept exploration of an issue. Another limitation is related to the hierarchical nature of the medical environment, which although widespread internationally, is exacerbated in developing countries. Medical hierarchical power structures have been linked to negative impacts by creating environments that discourage the voicing of opinions and sharing information freely. To deal with this issue, we emphasized on maintaining the confidentiality of the participants in different stages of the study. Also, in order to control the effect of the nurse/physician power imbalance, which increased the possibility of marginalization of nurses, the focus groups of the nurses and physicians were held separately."

3- The conclusion should be given greater depth of thought: yes these were the factors which were found, but perhaps more about why those factors impacted on adequate pain management.

Response: We modified it.

"Conclusion

This study showed the organizational factors affecting the gap between the level of expected neonatal pain management in the NICU and the care provided. The non-encouraging organizational culture and its hierarchical nature caused the loss of communication channels between health team members and their insufficient interaction. Poor interprofessional collaboration led to inconsistency in care, missed opportunities to relieve the neonate's pain, and repeated painful procedures. The weakness of the FCC principles and the power imbalance between care providers and parents caused the low participation of parents in the management of their neonate's pain. An unresponsive organizational structure and lack of a clear policy on the quality of neonatal pain management were associated with care provider discretion and, in some cases, suboptimal pain management. Work overload caused care providers to give priority to the tasks that seemed more necessary in the setting. In addition, insufficient educational resources caused lack of knowledge and further marginalization of infant pain management."

4- The results are potentially generalizable to the experience of many neonatal units, and underline the complexity of making change in real life: sometimes, having the evidence available, as well as a

protocol, and providing training are not enough! Some increased acknowledgement and discussion of this complexity of interaction might strengthen the paper further (although a full evaluation of the 'implementation of change' literature would be beyond the remit of this paper).

Response: Thank you for your valuable comment. We added some interaction between the findings in our setting and suggested it for further researches. Respectfully, this study is ongoing with the change process, and these connections will be discussed in more detail in future studies

Line 357-359: "High workload and lack of time cause accumulation of staff's duties. This issue, along with the non-supportive organizational structure and lack of care providers' knowledge about the importance of neonates' pain management can cause priority of some care that was necessary for the newborn's survival and restrict the pain management. Rochefort et al. suggests that staffing constraints and non-supportive work environments result in the rationing of nursing interventions in NICU 47. "

Line 384-388: "However, knowledge -practice gap is a global issue. Sometimes there is knowledge about protocols, standard procedures or guidelines, but they are ignored in practice 51. It is necessary to facilitate the use of knowledge along with its promotion. Some of facilities can include respect for teamwork and coordination in providing care which was discussed previously. Also, reducing work overload can provide the time needed to use of knowledge in relieving the neonate's pain. It seems, there are some interactions between the study findings that emphasize the complexity of making change and can be a basis for further studies. "

VERSION 2 – REVIEW

REVIEWER	Alinejad-Naeini, Mona Iran University of Medical Sciences, Neonatal and pediatric
REVIEW RETURNED	27-May-2023

GENERAL COMMENTS	The corrections requested in the previous version were done well, and in my opinion, the article is suitable for publishing. Just please edit the English of text by a native person.
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REVIEWER	Aiton, Neil Brighton and Sussex University Hospital NHS Trust, Neonatology
REVIEW RETURNED	13-Jun-2023

GENERAL COMMENTS	<p>Commendation to the authors in producing a paper looking at a fairly universal issue, and attempting to investigate some of the reasons why implementing and addressing management of neonatal pain is so challenging. I do suspect that the issues raised in this paper are perhaps more generalisable than perhaps they give credit for. The paper reads much better than the initial submission.</p> <p>Some very minor suggested "tweaks" on this re-review: L84 Substitute ' Nurses in particular play...' for 'especially' L 98 the words "in them" are not necessary I think the METHOD section requires more detail, and that the following should be part of the method section (either with or without their current subheadings): L 138-141 Data collection section L143-159 Data analysis L164-169 Trustworthiness L172 - 180</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Dr. Mona Alinejad-Naeini, Iran University of Medical Sciences, Iran University of Medical Sciences

Comments to the Author:

The corrections requested in the previous version were done well, and in my opinion, the article is suitable for publishing. Just please edit the English of text by a native person.

Response: We thank you for your thoughtful consideration. The paper was edited by an English editing company. The changes was highlighted in the manuscript.

Reviewer: 2

Dr. Neil Aiton, Brighton and Sussex University Hospital NHS Trust

Comments to the Author:

Commendation to the authors in producing a paper looking at a fairly universal issue, and attempting to investigate some of the reasons why implementing and addressing management of neonatal pain is so challenging. I do suspect that the issues raised in this paper are perhaps more generalisable than perhaps they give credit for. The paper reads much better than the initial submission.

Response: We thank you for your time and considerations.

Some very minor suggested "tweaks" on this re-review:

L84 Substitute ' Nurses in particular play...' for 'especially'

L 98 the words "in them" are not necessary

Response: The items were modified.

Line 82: "Nurses in particular play a significant role in pain management due to spending more time at the patient's bedside."

Line 95: "However, there is a belief that the NICU context in developed countries may differ in developing countries, leading to different pain management challenges."

I think the METHOD section requires more detail, and that the following should be part of the method section (either with or without their current subheadings):

L 138-141

Data collection section L143-159

Data analysis L164-169

Trustworthiness L172 – 180

Response: We thank you for your thoughtful suggestion. We reorganized the method section and added items to its subsections.

Methods

The interpretive descriptive method was used to evaluate the perceptions of health professionals on organizational pain management challenges in the NICU. Descriptive qualitative research helps to describe or discover a phenomenon or a problem, and the researcher can use it to examine a wide range of topics related to people's experiences, perceptions, and perspectives 18. The Ethics Committee of Tabriz University of Medical Sciences approved the study (code: IR.TBZMED.REC.1398.985).

The study was conducted in a NICU (level III) in Tabriz, East Azerbaijan province in the northwest of Iran. The NICU was a referral center for term and preterm neonates with various medical and surgical diseases. The physical space of the NICU included three large halls equipped with 27 warmers. The average ratio of nurse to patient was 1:3. In this ward, different types of painful interventions are

performed according to the neonates' needs. The ward has a accommodation for mothers, which includes a kitchen, toilet, bathroom and a large hall with multiple beds and wardrobes. Mothers can stay in the ward and with their infant 24 hours a day.

Participants and recruitment

Interviews were conducted with 26 nurses and 5 physicians who had at least 6 months of experience in the NICU. In order to make an informed decision of staff about whether to participate, the first author went to the NICU and explained the purpose of the research to them (potential participants). All were given the opportunity to ask questions. The first author also informed them about the voluntary nature of the participation, their right to privacy and confidentiality. All participants were assured that they could withdraw from the study at any time without giving any reason. Then, staff were offered an interview by the first author and no one declined to take part. Volunteered participants received, and studied written information. They completed the consent form and expressed their willingness to participate in the individual or focus interviews. The purposive sampling was used to achieve the maximum variation. For this purpose, we selected the participants with various age ranges, educational levels, work experiences, organizational positions, and professions for either individual or focus interviews (Table1).

Patient and public involvement

No patient involved.

Data Collection

Data were collected from February 2021 to January 2022 through 11 individual interviews and three focus group discussions with 7-, 8-, and 5-participants, respectively. The place and time of the interview were chosen according to the participants' preference and their privacy was respected during the interview. The interviews were voice-recorded after obtaining the participants' consent. The individual interviews lasted an average of 42 minutes (range: 23–65min). All of them were performed in the coffee room, according to the preference of the participants. The first author, who had a clinical and research background in neonatal care, led the individual interviews. She used a semi-structured interview guide that focused on participants' experiences of neonatal pain management in NICU (Table 2).

Table 2. Interview Guide

Main questions:

It's very valuable for me to know about your experiences of managing infant pain in your NICU.

Please talk about them if you wish.

What are health care services provided to manage the infant pain in your NICU?

What are the problems in managing infant pain in your NICU?

What organizational factors are effective in managing the neonatal pain?

Probing questions:

Could you explain more?

What do you mean?

Can you give an example to clarify further?

In order to achieve a broader and richer range of information when no new information emerged from the individual interviews, three focus groups were conducted by the first author in a conference hall of the center. Integrating individual and focus interviews makes a productive process and enriches data to conceptualize the phenomenon 19. The focus group sessions began by providing information about the study, and the questions asked were similar to the individual interviews. The first author transferred the topics from one to another and, if necessary, extracted the meaning of the participants' answers and elicited more details.

Data Analysis

We began coding before data collection had finished. This allowed us to reflect on how questions were asked during interviews and learn more about topics of relevance to the research aims. The audio-recorded interviews were transcribed verbatim and were double-checked for anonymity and accuracy. Conventional content analysis was used to interpret the transcripts. In this approach, inductive codes, sub-themes, and themes emerged from the transcripts. We used Graneheim and Lundman algorithms to analyze the data 20. MAXQDA10 software was used for data analysis. The data analysis steps was presented in Table 3.

Table 3. The Steps of Data Analysis

- A- The first author transcribed each interview and read it several times to obtain a comprehensive view.
- B- Sentences, and paragraphs considered meaning units were condensed according to their content.
- C- The condensed meaning units were abstracted and labeled with codes (852 codes).
- D- A group of 4 researchers (HN, HH, MJ, and RN) reviewed and discussed condensed meaning units and codes once more to resolve any conflicts in the concept of one code or any possible similarities in several codes.
- E- They sorted the codes based on their similarities and differences with sub-themes.
- F- Finally, themes were formulated from the classification of sub-themes.