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Organizational Challenges of Neonatal Pain Management in Intensive Care Unit: Perception of Health Professionals

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3 **1 Title**
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5 2 Organizational Challenges of Neonatal Pain Management in Intensive Care Unit: Perception
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8 3 of Health Professionals
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3 26 **Organizational Challenges of Neonatal Pain Management in Intensive Care Unit:**
4
5 27 **Perception of Health Professionals**
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8 28

9
10 29 **Abstract**
11

12 30 **Objectives:** Despite credible evidence, managing neonates' pain in the neonatal intensive care
13
14 31 unit is a challenging issue. In this regard, the organizational context is an important factor. The
15
16 32 existing challenges vary depending on the context and investigating them can help to improve
17
18 33 the quality of services. The study aimed to explore organizational challenges to neonates' pain
19
20 34 management in the neonatal intensive care unit.
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23
24 35 **Methods:** This qualitative study included 31 nurses and physicians in the neonatal intensive
25
26 36 care unit of Children's Hospital. Data collection was done through individual and focus group
27
28 37 interviews. For data analysis, we used conventional content analysis.
29

30
31 38 **Results:** The identified challenges included organizational culture (poor interprofessional
32
33 39 collaboration and low parental participation), organizational structure (lack of unified approach
34
35 40 in relieving pain and limited supervision for pain management), and organizational resources
36
37 41 (lack of time due to high workload and inadequate educational programs).
38
39

40 42 **Conclusions:** Many organizational factors consistently affect the neonatal pain management.
41
42 43 Adopting some approaches to enhance the cooperation of treatment team members, holding
43
44 44 educational programs, proper organizational supervision, and implementing a unified neonatal-
45
46 45 based pain management program could improve neonatal pain management.
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51 47 **Strengths and limitations**
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53
54 48 Strengths are:
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3 49 • The exclusive focus on the organizational challenges of neonatal pain management in
4
5 50 the clinical setting of developing country, which has been less addressed in other
6
7 51 studies.
8
9
10 52 • The inclusion of a range of health professionals across different caring situations,
11
12 53 educational levels, and work experiences.
13
14 54 • Triangulation in data collection (individual interviews and focus groups) which
15
16 55 increases the trustworthiness of the findings.
17
18 56 • Providing strategies in the discussion that can be useful for solving challenges and
19
20 57 improving the quality of practice in settings of developing countries.
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24 58 Limitation is:

- 25
26 59 • Sampling of single NICU and lack of organizational diversity.
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31 61 **Background**

32
33 62 Nowadays, the survival rate of neonates admitted to the neonatal intensive care unit (NICU)
34
35 63 has increased. Therefore, it is essential to optimize the NICU care and reduce the complications
36
37 64 of survived cases. In this regard, proper neonates' pain control is a priority. Despite the
38
39 65 misconceptions in the past, scientists have proved the neonates' perception of pain in recent
40
41 66 decades ¹.
42
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45 67 Pain can increase the demand in the cardiovascular system and endanger the hemodynamic
46
47 68 status of the neonate by increasing the heart rate and decreasing the arterial oxygen saturation.
48

49 69 It also increases the risk of intraventricular hemorrhage by increasing blood pressure in the
50
51 70 germinal matrix. The weak immune system and increased risk of infections are other problems
52
53 71 related to pain tolerance in neonates. Anxiety, abnormalities in processing pain (hypo- or hyper
54
55 72 sensitivity to pain), and developmental problems are some long-term effects of inappropriate
56
57 73 pain management in neonates ². Studies show that the prevention of pain in the neonate is not
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1
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3 74 only ethically essential, but it is also necessary for preventing short-term and long-term
4
5 75 complications and developmental disorders in neonates^{3,4}.

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8 76 Although there have been theoretical advances and clinical guidelines related to pain
9
10 77 management in the NICU, it is still a severe challenge in complex care conditions ⁵ and needs
11
12 78 further research ⁶. According to previous studies, the lack of knowledge in service providers is
13
14 79 the significant barriers to optimal pain management^{7,8}. The evidence shows that the knowledge
15
16 80 of care providers and their perceived responsibility for managing pain is significantly related
17
18 81 to the organization's policies ⁹. Nowadays, health care accreditation centers consider the
19
20 82 optimal management of pain as one of the indicators for evaluating the quality of care. They
21
22 83 extend patient pain management from an individual issue to an organizational issue and
23
24 84 emphasize the importance of the organization in providing safe care. Hence, the researchers
25
26 85 are trying to understand the role of organization in this area ¹⁰.

27
28
29 86 Evidence suggests that differences in service quality may be due to organizational differences
30
31 87 ¹¹. In this regard, a study examined the role of organizational factors (culture, structure,
32
33 88 resources, capabilities, skills, and policies) in the NICU pain management of a developed
34
35 89 country and discussed the existing challenges ¹². However, there is a belief that the NICU
36
37 90 context in developed countries may be different from developing countries, leading to different
38
39 91 pain management challenges in them ¹³.

40
41
42 92 Although some studies have evaluated pain management in the NICU, limited studies have
43
44 93 focused on organizational challenges in developing countries. Accordingly, the present
45
46 94 descriptive qualitative study aimed to investigate the organizational challenges of NICU pain
47
48 95 management in Tabriz, Iran.

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52 53 54 55 56 97 **Methods**

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3 98 Interpretive descriptive method was used to evaluate the perceptions of health professionals
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5 99 on organizational pain management challenges in the NICU. Descriptive qualitative research
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7
8 100 helps to describe or discover a phenomenon or a problem, and the researcher can use it to
9
10 101 examine a wide range of topics related to people's experiences, perceptions, and perspectives
11
12 102 ¹⁴.

103

104 **Ethical Considerations**

105 The Ethics Committee of Tabriz University of Medical Sciences approved the study (code:
106 IR.TBZMED.REC.1398.985). The first author explained the purpose of the research to the
107 NICU staff, and answered their questions. She also informed them about the voluntary nature
108 of the participation, their right to privacy, confidentiality and to withdraw from the study at any
109 time without given any reason. Then, staff were asked to participate in the study by the first
110 author. Volunteered participants received, and studied written information. They completed the
111 consent form and also expressed their willingness to participate in the individual or focus
112 interviews.

113

114 **Setting and Participants**

115 This study was carried out in the NICU of Children Hospital in Tabriz. The NICU has 27 beds
116 in three levels of care that admit full-term and premature neonates with various diseases. In
117 this unit, different types of painful interventions are performed according to the newborns'
118 needs. The participants included 31 nurses and physicians in the NICU (Table1).

119 Table 1. Demographic Characteristics of Participants

Participants (N=31)	Age (Year)	Marital status Married/Single	Educational status	Organizational position	Work experience (Year)
Nurse (N=26)	30-44	23 / 3	MSc =1 BSc =25	Clinical Supervisor=1	5-20

				Educational Supervisor=1 Head Nurse=2 Nurse=22	
Physician (N=5)	35-48	5 / 0	Neonatologist=4 Fellowship of neonatology=1	Academic Member=2 Clinical Physician=2 Assistant=1	4-18

120

121 The purposive sampling was used and interested participants with different ages, educational
 122 levels, work experiences, and organizational positions were selected for either individual or
 123 focus interviews.

124

125 Data Collection

126 Data were collected during 11 individual interviews and three focus group discussions with 7-,
 127 8-, and 5-participants, respectively. The individual interviews lasted an average of 42 minutes
 128 and were performed in the coffee room, according to the preference of the participants. The
 129 interviews were voice-recorded after obtaining the participants' consent. We also used the
 130 focus group discussions to gain a deeper understanding of neonates' pain management.
 131 Integrating individual and focus interviews makes a productive process and enriches data to
 132 conceptualize the phenomenon ¹⁵. The first author led the individual and focus interviews using
 133 a semi-structured interview guide (Table 2). After 11 individual and three focus interviews,
 134 data saturation was obtained.

135 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?

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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?

136

137 **Patient and public involvement**

138 No patient involved.

139 **Data Analysis**

140 Conventional content analysis was used to interpret the transcripts. In this approach, inductive

141 codes, sub-themes, and themes emerged from the transcripts. We used Graneheim and

142 Lundman algorithms to analyze the data ¹⁶. MAXQDA10 software was used for data analysis.

143 The data analysis steps were presented in Table 3.

144 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 as the meaning units were condensed according to their content.

C- The condensed meaning units were abstracted and labeled with 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 that may exist in the concept of one code or any possible similarities in several codes.

E- They sorted the codes based on their similarities and differences to sub-themes.

F- Finally, themes were formulated from the classification of sub-themes.

145

146

147 **Trustworthiness**

148 We used Guba and Lincoln's criteria to assess trustworthiness ¹⁷. Credibility was enhanced

149 through purposive sampling with the principle of maximum variation to select the participants.

150 In addition to individual interviews, we used focus groups to collect data. Also, to verify the

151 data and the extracted codes, the member check was used. The researchers were familiar with

152 the NICU department, and they were experienced in qualitative research. For the study's

153 dependability, we tried to clearly describe the research steps taken from the beginning of the

154 research project to the development and reporting of findings. We also used the probing

155 questions to increase dependability. In addition, the process of data collection and findings

156 were audited by experts, which helped promote confirmability.

157

158 **Results**

159 Three main themes and six sub-themes that explained the organizational challenges to optimal

160 neonates' pain management in the NICU were identified (Table 4).

161 Table 4. Themes and Sub-themes

Themes	Sub-themes
Organizational culture	Poor interprofessional collaboration
	Low parental participation
Organizational structure	Lack of unified approach to pain relief
	Limited supervision for pain management
Organizational resources	Lack of time due to high workload

	Inadequate educational programs
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162

163 **Organizational Culture**

164 *Poor interprofessional collaboration*

165 According to the participants, individual decision-making on doing tasks and poor coordination
166 among team members led to such problems as repetitive manipulations of the neonates,
167 disorganization, and limited opportunities to relieve the neonates' pain. Also, the staff did not
168 talk to each other about the pain management of the neonates and no suggestions were
169 exchanged between them. Although the nurses talked to physicians about the need to control
170 neonates' pain and made suggestions in some cases, they were usually dismissed by the
171 physicians because they had more decision-making power.

172

173 *"Staff just want to do their job. For example, the doctor comes and says: 'I want to do an LP*
174 *on the infant.' Without coordinating the things related to managing the neonate's pain with the*
175 *nurse!"* (Participant 3)

176

177 *Low parental participation*

178 Although the parents were present in the ward, they were not considered as the members of the
179 care team, and were not often consulted. The participants believed that the staff was usually
180 controlling the parents, and the parents acted according to the staff's wishes. Usually, parents
181 are given limited information about their neonate's pain and how to participate and relieve it.
182 This led to a one-way and non-interactive relationship between family and the staff. As a result,
183 they were unable to play a fully effective role in activities such as relieving their neonate's
184 pain.

185

186 *“In our ward, usually we do not involve the parents in controlling the baby’s pain. Most of the*
187 *times, the staff asks the parents to go out and come back after managing the neonate’s pain.*
188 *This is a quite acceptable behavior in the ward.”* (Participant 21)

189

190 **Organizational structure**

191 *Lack of unified approach in relieving pain*

192 According to the participants, there were no predefined and specific policy for pain control in
193 the ward. As a result, no positive atmosphere and clear expectations in terms of pain-relieving
194 actions were created. This caused a lack of strong support for the implementation of evidence
195 in practice. Although several health care professionals working in the NICU did things to
196 relieve the neonates’ pain based on their personal preference, credible pain assessment tools
197 and pain prevention and management policies were not used abundantly. Thus, there were
198 disagreements and arbitrary pain management in the ward. The participants believed that
199 introduction of specific protocols could help to improve outcomes and develop optimal pain
200 management practices in the NICU, leading to the uniformity of the performance among
201 different professions and clinicians.

202

203 *“Currently, it is not clear what we should do to control the pain in different situations. For*
204 *example, we don’t know what exactly to do to control the pain of a neonate after surgery. The*
205 *internal medicine and surgery team members have different opinions on this issue, and their*
206 *lack of understanding sometimes causes the neonate not to be given painkillers at all.”*
207 (Participant 1)

208

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3 209 “We have different neonatologists with different methods of practicing; some of them prescribe
4
5 210 painkillers more commonly than others. Perhaps we could have some predefined instructions
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7 211 for a variety of methods or painful pain management because some care-providers might think
8
9 212 that a specific method is not very painful.” (Participant 13)
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13 213

14 214 *Limited supervision for pain management*

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16
17 215 There is little demand from the organization regarding the neonatal pain management. Also,
18
19 216 the staff’s performance regarding neonatal pain management is not supervised. The participants
20
21 217 explained that the Hospital Quality Assurance Committee had no policies on assessing the
22
23 218 quality of neonatal pain management. Also, the patients’ pain management was not explicitly
24
25 219 mentioned in the job description of the staff, and the neonates’ pain management was not
26
27 220 examined in the monthly and annual performance evaluations of the staff. Thus, the
28
29 221 performance of health professionals regarding the use of analgesics was not often questioned.
30
31 222 However, in some cases, verbal warning were delivered to some health professionals highly
32
33 223 inattentive to the patients’ pain. Furthermore, there were no clear policies to encourage health
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35 224 professionals who performed well in managing the neonates’ pain. Accordingly, appropriate
36
37 225 management of the neonates’ pain was not considered a professional value.
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45 227 “Nobody asks staff about the quality of their performance in relieving infant’s pain. We feel
46
47 228 we’re not evaluated or monitored in this regard; and we are completely free to do it or not.”
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49 229 (Participant 10)
50

51 230

52 53 54 231 **Organizational Resources**

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57 232 *Lack of time due to high workload*
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3 233 According to the participants, a high workload was another challenge to appropriate pain
4
5 234 management in the NICU. In most cases, the health professionals did not have a good
6
7
8 235 performance in relieving the neonates' pain due to lack of time and work overload. Care-
9
10 236 providers mentioned the large number of patients as a challenge for pain management. They
11
12 237 believed that high workload resulted in limited attention to the neonates' pain and not using
13
14 238 analgesics before the procedures. Also, some nurses believed that less pain during the
15
16
17 239 procedure required two nurses, but the lack of time made it impossible for them to help their
18
19 240 colleagues during the painful procedure.
20
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23
24 242 *"A nurse with three patients may admit another one. This workload makes pain management*
25
26 243 *difficult. She/he only thinks of doing their duties quickly and finishing the shift."* (Participant
27
28 244 25)
29
30

31 245 32 33 246 *Inadequate educational program*

34
35 247 According to the participants, the lack of effective training programs and consequently
36
37 248 insufficient knowledge caused the staff not to know the benefits and importance of controlling
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39
40 249 the neonates' pain. Some of the educational needs mentioned by the participants included
41
42 250 gaining knowledge and skills in using pain assessment tools and pain management techniques
43
44 251 appropriate for different situations and procedures, as well as using analgesics. From the
45
46
47 252 participants' point of view, attending in-service training courses for managing the neonates'
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49 253 pain and participation in research projects or quality improvement activities could increase the
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51 254 health professionals' awareness of the neonates' pain and its treatment benefits.
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3 256 *“There is no training program for the NICU staff about the importance and methods of*
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5 257 *relieving pain in neonates. Since the treatment team members know little about this issue, we*
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7 258 *should not expect them to perform well.”* (Participant 24)
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14 260 **Discussion**

16 261 According to our results, organizational factors, including cultural, structural, and resource
17
18 262 issues, can affect the optimal control of neonates' pain in the NICU.

21 263 Organizational culture is the model of group's prevalent assumptions, which develops through
22
23 264 a shared history, experiences, and learning ¹². The health professionals who participated in our
24
25 265 study believed that the low participatory culture and poor collaboration of health team members
26
27 266 threatened the optimal management of the neonates' pain. This issue has caused such problems
28
29 267 as over-stimulation of the neonates, inconsistencies in providing services, and losing
30
31 268 opportunities in relieving the pain. Interprofessional collaboration is a way in which different
32
33 269 health care professionals interact with each other to make clinical decisions after considering
34
35 270 each other's knowledge. In this way, the specialists undertake complementary roles and get
36
37 271 involved in problem-solving and decision-making processes to develop and implement patient
38
39 272 care programs ¹⁸. Participants in the study cited the clinical dominance of physicians over
40
41 273 nurses as a barrier to appropriate collaboration. Power imbalances in clinical practice are a key
42
43 274 barrier to joint decision-making, which can affect the quality of care ¹⁹. The findings of our
44
45 275 study are supported by the other literature. Mirlashari et al. showed that the power imbalance
46
47 276 between physicians and nurses in Iranian NICUs leads to insufficient team collaboration in
48
49 277 providing care ²⁰. In studies conducted in developed countries, proper communication and
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51 278 interprofessional collaboration in complex care settings such as the NICU was considered the
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53 279 vital element of effective practice on pain ^{12,21,22}. According to studies, finding communication
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3 280 channels between the health care members can reduce power imbalance and improve their
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5 281 ability to negotiate about pain management approaches ²³. In contrast of our study finding,
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7 282 Tavernier et al. identified team collaboration as a contextual factor to optimal pain management
8
9 283 in U.S. hospitals. They acknowledged that interprofessional educational programs have
10
11 284 improved communication between the disciplines and supported collaborative relationships ²⁴.
12
13 285 This strategy can be used in countries such as Iran, where insufficient communication and
14
15 286 collaboration of health professionals is considered as a challenge in the quality of care. The
16
17 287 users of educational programs of Iranian health institutions are traditionally all from the same
18
19 288 discipline. Also, evidence-based strategies, such as interprofessional practice teams, can
20
21 289 improve the interprofessional collaboration ²⁵.
22
23
24 290 The findings of this study indicate insufficient parent-health professional collaboration in the
25
26 291 neonates' pain management. Organizational culture did not adequately support parental
27
28 292 involvement, and relationships between parents and professionals was affected by power
29
30 293 imbalances. Parents often did not receive sufficient information and their participation in the
31
32 294 decision making and service providing was not considered in the practice. Although few
33
34 295 parental care involvement research is done in developing countries such as Iran, this finding is
35
36 296 supported by other Iranian study ^{20,26}. Khajeh et al. found that families in Iranian medical fields
37
38 297 are considered non-participating visitors ²⁷. Other studies in Finland, Sweden, the United States
39
40 298 and China showed that the level of parental involvement in the management of neonatal pain
41
42 299 varies, from parental absence to their full collaboration ^{28,29}. However, The participation of the
43
44 300 patients' family members and health care professionals is essential to provide optimal care ³⁰.
45
46 301 There are positive effects of parental involvement in the literature of developed countries, such
47
48 302 as reducing parental stress ³¹, facilitating parent/ infant attachment ³², and more effectively
49
50 303 manage neonatal pain ³³. Axelin et al. pointed out that when the health professionals
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52 304 relationship with the parents is paternalistic, parents were usually absent or passive in
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3 305 managing their neonate pain. They believed that implication of Family-Centered Care (FCC)
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5 306 approach had a positive effect on information sharing and parental involvement in neonatal
6
7 307 pain management ²⁸. Mirlashari et al. also acknowledged that the low parental involvement in
8
9 308 Iranian NICUs is due to the marginalized FCC ²⁰. In the FCC model, the family is an essential
10
11 309 member of the health care team and has a close relationship with staff. In this model the parents
12
13 310 are the most influential contributors to caring for their neonates in the NICU ³⁴. Some studies
14
15 311 showed that the implementation of FCC model could increase the parents' participation in
16
17 312 neonates' pain management ^{22,35}. Evidence highlights the role of the organization in creating
18
19 313 instructions to change the context and provide the optimal parental involvement in neonatal
20
21 314 care ²¹.

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25
26 315 The lack of clear policy and supervising the health professionals' performance in relieving the
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28 316 neonates' pain are the main challenges related to organizational structure. This increases the
29
30 317 evidence-practice gap and causes the staff to use analgesics based on their individual opinions
31
32 318 and knowledge, which can lead to improper neonates' pain management. This finding is
33
34 319 supported by some studies in Iran ³⁶ and other developing countries ^{37,38}. Studies often
35
36 320 conducted in developed countries emphasize the facilitation of optimal pain management with
37
38 321 clear organizational protocols and quality improvement policies ^{12,24}. A longitudinal study in
39
40 322 Sweden showed that the development of the program about the neonatal pain management and
41
42 323 stay on it increased the rate of the using of pain assessment tools 80% since 1993 to 2008 ³⁹.
43
44 324 Nowadays, reputable institutions and neonatal pain specialists recommend that the NICUs
45
46 325 should have evidence-based step-by-step protocol and continuous auditing program to optimal
47
48 326 neonates' pain management ⁴⁰. The American Academy of Pediatrics (AAP) listed the
49
50 327 components of the neonates' pain management protocol that include strategies to minimize the
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52 328 number of performed painful procedures, routine pain assessment programs, and
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54 329 pharmacological and non-pharmacological treatments for pain management during surgery and
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3 330 procedures⁴¹. Stevens et al. used the evidence-based Practice for Improving Quality method
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5 331 and implemented a multifaceted intervention to improve pain management in Canadian
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7 332 pediatric hospitals that can be used in other settings. After examining the unit's base-line pain
8
9 333 practices and reviewing evidence of pain assessment and management in a participatory
10
11 334 process, they identified their protocol and improved the level of pain management with step-
12
13 335 by-step interventions including educational sessions, reminders, audit and feedback⁴².

16 336 Organizational resources include the supplies and time necessary to meet work demands.
17
18 337 Achieving this organizational feature requires sufficient staff with the appropriate expertise to
19
20 338 be able to balance the job demands, workload, and time. In our study, some nurses raised time
21
22 339 management concerns more frequently than addressing their concerns about the neonates' pain
23
24 340 management. High workload and lack of time can restrict the introduction of new practices,
25
26 341 such as the neonates' pain management. Moreover, a high workload can cause physical and
27
28 342 mental fatigue in staff and negatively affect their performance. Work overload and lack of time
29
30 343 are the international challenge in health institutions that affect in quality of care. Similar to our
31
32 344 finding, the studies that conducted in in Iran⁴³ and other countries such as the US, England,
33
34 345 and China^{24,29,44} mentioned high workload as a barrier to optimal management of patient pain.
35
36 346 Although part of the high workload is due to the nurse shortage, which requires interventions
37
38 347 at the international and national levels, nevertheless, some solutions such as reducing indirect
39
40 348 care time by supplies availability, providing enough off-duty hours, and more payments for
41
42 349 extra work hours can motivate nurses and improved the quality of neonatal pain management
43
44 350 in busy settings.

45
46 351 Inadequate training programs on the neonates' pain management was another problem related
47
48 352 to organizational resources. According to the participants, the knowledge about various areas
49
50 353 of pain management was at a low level due to inadequate training. Although Cong et al.
51
52 354 concluded that care providers' knowledge of neonatal pain has changed dramatically in recent
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3 355 decades²⁹, there is still a need to improve it. Studies in developed and developing countries
4
5 356 have reported insufficient knowledge of health professionals in patient pain management
6
7 357 ^{23,24,36,45}. In this regard, international organizations and specialists stated that improvement the
8
9 358 knowledge of the health professionals by providing educational resources is an important factor
10
11 359 for appropriate pain management in the NICU ^{41,46}. Nowadays, pain management is one of the
12
13 360 topics of continuing education programs in developed settings. A study cited the use of
14
15 361 numerous training forums and seminars as a factor in promoting pain management in US
16
17 362 hospitals ²⁴. In addition, other educational methods have been mentioned in studies that can be
18
19 363 used based on the facilities and conditions of each setting. For an example Rajasoorya
20
21 364 acknowledge that clinical rounds are a great opportunity to gain knowledge, and if performed
22
23 365 well, they can create unique learning opportunities and improve the quality of patient care ⁴⁷.
24
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29 366

30 367 **Conclusion**

31
32
33 368 Since the challenge of pain management vary depending on the context, the present study
34
35 369 indicated the organizational challenges to optimal pain management in an NICU in a
36
37 370 developing country. According to the participants' opinions, many organizational factors
38
39 371 consistently affected neonatal pain management. These challenges included: culture (e.g., low
40
41 372 collaboration and communication between health care team members), lack of organizational
42
43 373 protocols and supervision as a formal structure, and inadequate resources such as the lack of
44
45 374 time and educational programs.
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49 375

50 376 **How might this information affect in practice?**

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52
53 377 It seems that new strategies are needed for improving NICU pain management. Promoting
54
55 378 interprofessional collaboration as well as parent-care providers' interactions can increase
56
57 379 neonatal pain management. Moreover, to achieve optimal pain management, developing and
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3 380 implementing an evidence-based pain management protocol is necessary. An integrated
4
5 381 clinical performance can be achieved through administrative supervision and frequent auditing.
6
7 382 Due to the inadequate knowledge in the health care team, practical training is essential in such
8
9
10 383 areas as control of environmental stimuli, pharmacological and non-pharmacological pain-
11
12 384 relieving methods, and using pain assessment tools. Also, heavy workload can decrease the
13
14 385 quality of staff performance about the management of neonatal pain. Reducing the workload
15
16 386 in health care organizations is complex and multifaceted, but fulfilling the physical and
17
18 387 emotional needs of the care team can improve their performance.
19
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23 24 389 **Acknowledgements**

25
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27
28 391 interviewed.
29

30 31 392 **Contributorship statement**

32
33 393 H.N: Conceptualization, Methodology, software, Data Curation, Project administration,
34
35 394 Formal analysis, Writing- original draft, Writing-review and editing. H.H: Conceptualization,
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37 395 Methodology, Supervision, Formal analysis, Writing-review and editing. M.J:
38
39 396 Conceptualization, Methodology, Validation, Formal analysis, Writing-review and editing.
40
41
42 397 R.N: Methodology, Formal analysis, Validation.
43

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46
47 399 None declared.
48

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51
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53

54 55 402 **Data sharing statement**

56
57 403 Data are available upon reasonable request.
58

59 60 404 **Ethics approval statement**

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3 405 The Ethics Committee of Tabriz University of Medical Sciences approved the study (code:
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5 406 IR.TBZMED.REC.1398.985). Participants gave informed consent to participate in the study
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7
8 407 before taking part.
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408

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COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

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Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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

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2
3 1 **Title**

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5 2 Organizational Challenges of Pain Management in Neonatal Intensive Care Unit: A Qualitative
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8 3 Study

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3 26 **Organizational Challenges of Pain Management in Neonatal Intensive Care Unit: A**
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5 27 **Qualitative Study**
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10 29 **Abstract**

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12 30 **Objectives:** Despite credible evidence, managing neonates' pain in the neonatal intensive care
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14 31 unit is a challenging issue. In this regard, the organizational context is an important factor. The
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16 32 existing challenges vary depending on the context and investigating them can help to improve
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18 33 the quality of services. The study aimed to explore organizational challenges to neonates' pain
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20 34 management in the neonatal intensive care unit.

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22 35 **Methods:** This qualitative study included 31 nurses and physicians in the neonatal intensive
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24 36 care unit of Children's Hospital, Tabriz, Iran. Data collection was done through individual and
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26 37 focus group interviews. For data analysis, we used conventional content analysis.

27
28 38 **Results:** The identified challenges included organizational culture (poor interprofessional
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30 39 collaboration and low parental participation), organizational structure (lack of unified approach
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32 40 in relieving pain and limited supervision for pain management), and organizational resources
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34 41 (lack of time due to high workload and inadequate educational programs).

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36 42 **Conclusions:** Many organizational factors consistently affect the neonatal pain management.
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38 43 Adopting some approaches to enhance the cooperation of treatment team members, holding
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40 44 educational programs, proper organizational supervision, and implementing a unified neonatal-
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42 45 based pain management program could improve neonatal pain management.
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47 47 **Strengths and limitations**

48 48 Strengths are:
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3 49 • The exclusive focus on the organizational challenges of neonatal pain management in
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5 50 the clinical setting of developing country, which has been less addressed in other
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8 51 studies.
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10 52 • The inclusion of a range of health professionals across different caring situations,
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12 53 educational levels, and work experiences.
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14 54 • Triangulation in data collection (individual interviews and focus groups) which
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16 55 increases the trustworthiness of the findings.
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19 56 Limitations are:

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22 57 • Sampling of single NICU and lack of organizational diversity.
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24 58 • Potential for missing some information due to the hierarchical nature of the setting that
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26 59 discourage the voicing of opinions.
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31 **Background**

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33 62 Nowadays, the survival rate of neonates admitted to the neonatal intensive care unit (NICU)
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35 63 has increased. Therefore, it is essential to optimize the NICU care and reduce the complications
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37 64 of survived cases. In this regard, proper neonates' pain control is a priority. Despite the
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39 65 misconceptions in the past, scientists have proved the neonates' perception of pain in recent
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41 66 decades ¹.
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45 67 Pain can increase the demand in the cardiovascular system and endanger the hemodynamic
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47 68 status of the neonate by increasing the heart rate and decreasing the arterial oxygen saturation.
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49 69 It also increases the risk of intraventricular hemorrhage by increasing blood pressure in the
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51 70 germinal matrix. The weak immune system and increased risk of infections are other problems
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53 71 related to pain tolerance in neonates. Anxiety, abnormalities in processing pain (hypo- or hyper
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55 72 sensitivity to pain), and developmental problems are some long-term effects of inappropriate
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57 73 pain management in neonates ². Studies show that the prevention of pain in the neonate is not
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3 74 only ethically essential, but it is also necessary for preventing short-term and long-term
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5 75 complications and developmental disorders in neonates^{3,4}.

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8 76 Although there have been theoretical advances and clinical guidelines related to pain
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10 77 management in the NICU, it is still a severe challenge in complex care conditions ⁵ and needs
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12 78 further research ⁶. Evidence suggests that the rate of routine pain assessment in NICU can be
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14 79 as low as 6-10% ^{7,8} and only 7.1% of care providers always take interventions to reduce
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16 80 neonates' pain ⁹.

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19 81 Pain management of neonates is one of the most important caring tasks of care providers.
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21 82 Especially nurses, play a significant role in pain management due to spending more time at the
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23 83 patient's bedside ¹⁰. According to previous studies, the lack of knowledge in care providers is
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25 84 the significant barriers to optimal pain management^{11,12}. The evidence shows that the
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27 85 knowledge of care providers and their perceived responsibility for managing pain is
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29 86 significantly related to the organization's policies ¹³. Nowadays, health care accreditation
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31 87 centers consider the optimal management of pain as one of the indicators for evaluating the
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33 88 quality of care. They extend patient pain management from an individual issue to an
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35 89 organizational issue and emphasize the importance of the organization in providing safe care.
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37 90 Hence, the researchers are trying to understand the role of organization in this area ¹⁴.

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40 91 Evidence suggests that differences in service quality may be due to organizational differences
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42 92 ¹⁵. In this regard, a study examined the role of organizational factors (culture, structure,
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44 93 resources, capabilities, skills, and policies) in the NICU pain management of a developed
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46 94 country and discussed the existing challenges ¹⁶. However, there is a belief that the NICU
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48 95 context in developed countries may be different from developing countries, leading to different
49
50 96 pain management challenges in them ¹⁷.

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53 97 Although some studies have evaluated pain management in the NICU, limited studies have
54
55 98 focused on organizational challenges in developing countries. Accordingly, the present

1
2
3 99 descriptive qualitative study aimed to investigate the organizational challenges of NICU pain
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5
6 100 management in Tabriz, Iran.
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10 102 **Methods**

11
12 103 Interpretive descriptive method was used to evaluate the perceptions of health professionals
13
14 104 on organizational pain management challenges in the NICU. Descriptive qualitative research
15
16
17 105 helps to describe or discover a phenomenon or a problem, and the researcher can use it to
18
19 106 examine a wide range of topics related to people's experiences, perceptions, and perspectives
20
21 107 ¹⁸.
22
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24 108

25
26 109 **Ethical Considerations**

27
28 110 The Ethics Committee of Tabriz University of Medical Sciences approved the study (code:
29
30 111 IR.TBZMED.REC.1398.985). The first author went to the NICU and explained the purpose of
31
32
33 112 the research to the NICU staff (nurses and physicians), and answered their questions. She also
34
35 113 informed them about the voluntary nature of the participation, their right to privacy and
36
37 114 confidentiality. All participants were assured that they could withdraw from the study at any
38
39 115 time without giving any reason. Then, staff were asked to participate in the study by the first
40
41 116 author. Volunteered participants received, and studied written information. They completed the
42
43 117 consent form and also expressed their willingness to participate in the individual or focus
44
45 118 interviews. The interviews were voice-recorded after obtaining the participants' consent. The
46
47 119 place and time of the interview were chosen according to the participants' preference and their
48
49 120 privacy was respected during the interview
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56 122 **Setting and Participants**

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124 The study was conducted in a NICU (level III) in Tabriz, East Azerbaijan province in the
 125 northwest of Iran. The NICU was a referral center for term and preterm neonates with various
 126 medical and surgical disease. The physical space of the NICU included three large halls
 127 equipped with 27 warmers. The average ratio of nurse to patient was 1:3. In this ward, different
 128 types of painful interventions are performed according to the neonates' needs. The ward has a
 129 special accommodation for mothers, which includes kitchen, toilet, bathroom and a large hall
 130 with multiple beds and wardrobes. Mothers can stay in the ward and with their infant 24 hours
 131 a day. The participants included 26 nurses and 5 physicians (Table1).

132 Table 1. Demographic Characteristics of Participants

Participants (N=31)	Age (Year)	Marital status Married/Single	Educational status	Organizational position	Work experience (Year)
Nurse (N=26)	30-44	23 / 3	MSc =1 BSc =25	Clinical Supervisor=1 Educational Supervisor=1 Head Nurse=2 Nurse=22	5-20
Physician (N=5)	35-48	5 / 0	Neonatologist=4 Fellowship of neonatology=1	Academic Member=2 Clinical Physician=2 Assistant=1	4-18

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

138

139 **Data Collection**

140 Data were collected from February 2021 to January 2022 through 11 individual interviews and
 141 three focus group discussions with 7-, 8-, and 5-participants, respectively. The individual

1
2
3 142 interviews lasted an average of 42 minutes and were performed in the coffee room, according
4
5 143 to the preference of the participants. The first author, who had a clinical and research
6
7 144 background in neonatal care, led the individual interviews. She used a semi-structured
8
9 145 interview guide that focused on participants' experiences of neonatal pain management in
10
11 146 NICU (Table 2).
12
13
14
15 147
16
17 148 Table 2. Interview Guide
18

19 Main questions:

20
21 It's very valuable for me to know about your experiences of managing infant pain in your
22
23 NICU. Please talk about them if you wish.
24

25
26 What are health care services provided to manage the infant pain in your NICU?
27

28
29 What are the problems in managing infant pain in your NICU?
30

31
32 What organizational factors are effective in managing the neonatal pain?
33

34 Probing questions:

35
36 Could you explain more?
37

38
39 What do you mean?
40

41
42 Can you give an example to clarify further?
43

44
45 149 In order to achieve a broader and richer range of information when no new information
46
47 150 emerged of the individual interviews, three focus groups were conducted by the first author in
48
49 151 a conference hall of the center. Integrating individual and focus interviews makes a productive
50
51 152 process and enriches data to conceptualize the phenomenon¹⁹. The focus group sessions began
52
53 153 by providing information about the study, and the questions asked were similar to the individual
54
55 154 interviews. The first author handled the focus groups.
56
57
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2
3 **157 Patient and public involvement**
4

5 158 No patient involved.
6

7
8 **159 Data Analysis**
9

10 160 Conventional content analysis was used to interpret the transcripts. In this approach, inductive
11
12 161 codes, sub-themes, and themes emerged from the transcripts. We used Graneheim and
13
14 162 Lundman algorithms to analyze the data ²⁰. MAXQDA10 software was used for data analysis.
15
16
17 163 The data analysis steps were presented in Table 3.
18

19 164 Table 3. The Steps of Data Analysis
20

21
22 A- The first author transcribed each interview and read it several times to obtain a
23
24 comprehensive view.
25

26 B- Sentences, and paragraphs considered as the meaning units were condensed
27
28 according to their content.
29

30 C- The condensed meaning units were abstracted and labeled with codes (852 codes).
31

32 D- A group of 4 researchers (HN, HH, MJ, and RN) reviewed and discussed condensed
33
34 meaning units and codes once more to resolve any conflicts that may exist in the
35
36 concept of one code or any possible similarities in several codes.
37
38

39 E- They sorted the codes based on their similarities and differences to sub-themes.
40
41

42 F- Finally, themes were formulated from the classification of sub-themes.
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49 **167 Trustworthiness**
50

51 168 We used Guba and Lincoln's criteria to assess trustworthiness ²¹. Credibility was enhanced
52
53 169 through purposive sampling with the principle of maximum variation to select the participants.
54
55
56 170 In addition to individual interviews, we used focus groups to collect data. Also, to verify the
57
58 171 data and the extracted codes, the member check was used. The researchers were familiar with
59
60

172 the NICU department, and they were experienced in qualitative research. For the study's
 173 dependability, we tried to clearly describe the research steps taken from the beginning of the
 174 research project to the development and reporting of findings. We also used the probing
 175 questions to increase dependability. In addition, the process of data collection and findings
 176 were audited by experts, which helped promote confirmability.

177

178 **Results**

179 Three main themes and six sub-themes that explained the organizational challenges to optimal
 180 neonates' pain management in the NICU were identified (Table 4).

181 Table 4. Themes and Sub-themes

Themes	Sub-themes
Organizational culture	Poor interprofessional collaboration
	Low parental participation
Organizational structure	Lack of unified approach to pain relief
	Limited supervision for pain management
Organizational resources	Lack of time due to high workload
	Inadequate educational programs

182

183 **Organizational Culture**

184 *Poor interprofessional collaboration*

185 According to the participants, individual decision-making on doing tasks and poor coordination
 186 among team members led to such problems as repetitive manipulations of the neonates,
 187 disorganization, and limited opportunities to relieve the neonates' pain. Also, the staff did not
 188 talk to each other about the pain management of the neonates and no suggestions were
 189 exchanged between them. Although the nurses talked to physicians about the need to control

1
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3 190 neonates' pain and made suggestions in some cases, they were usually dismissed by the
4
5 191 physicians because they had more decision-making power.
6
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9
10 193 *"Staff just want to do their job. For example, the doctor comes and says: 'I want to do an LP*
11
12 194 *on the infant.' Without coordinating the things related to managing the neonate's pain with the*
13
14 195 *nurse!"* (Participant 3)
15
16

17 196

18 19 20 197 *Low parental participation*

21
22 198 Although the parents were present in the ward, they were not considered as the members of the
23
24 199 care team, and were not often consulted. The participants believed that the staff was usually
25
26 200 controlling the parents, and the parents acted according to the staff's wishes. Usually, parents
27
28 201 are given limited information about their neonate's pain and how to participate and relieve it.
29
30 202 This led to a one-way and non-interactive relationship between family and the staff. As a result,
31
32 203 they were unable to play a fully effective role in activities such as relieving their neonate's
33
34 204 pain.
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39
40 206 *"In our ward, usually we do not involve the parents in controlling the baby's pain. Most of the*
41
42 207 *times, the staff asks the parents to go out and come back after managing the neonate's pain.*
43
44 208 *This is a quite acceptable behavior in the ward."* (Participant 21)
45
46

47 209

48 49 50 210 **Organizational structure**

51 211 *Lack of unified approach in relieving pain*

52
53 212 According to the participants, there were no predefined and specific policy for pain control in
54
55 213 the ward. As a result, no positive atmosphere and clear expectations in terms of pain-relieving
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2
3 214 actions were created. This caused a lack of strong support for the implementation of evidence
4
5 215 in practice. Although several health care professionals working in the NICU did things to
6
7 216 relieve the neonates' pain based on their personal preference, credible pain assessment tools
8
9
10 217 and pain prevention and management policies were not used abundantly. Thus, there were
11
12 218 disagreements and arbitrary pain management in the ward. The participants believed that
13
14 219 introduction of specific protocols could help to improve outcomes and develop optimal pain
15
16 220 management practices in the NICU, leading to the uniformity of the performance among
17
18 221 different professions and clinicians.
19
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22

23
24 223 *“Currently, it is not clear what we should do to control the pain in different situations. For*
25
26 224 *example, we don't know what exactly to do to control the pain of a neonate after surgery. The*
27
28 225 *internal medicine and surgery team members have different opinions on this issue, and their*
29
30 226 *lack of understanding sometimes causes the neonate not to be given painkillers at all.”*
31
32
33 227 (Participant 1)
34
35
36

37
38 229 *“We have different neonatologists with different methods of practicing; some of them prescribe*
39
40 230 *painkillers more commonly than others. Perhaps we could have some predefined instructions*
41
42 231 *for a variety of methods or painful pain management because some care-providers might think*
43
44 232 *that a specific method is not very painful.”* (Participant 13)
45
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47

48
49 234 *Limited supervision for pain management*
50
51 235 There is little demand from the organization regarding the neonatal pain management. Also,
52
53 236 the staff's performance regarding neonatal pain management is not supervised. The participants
54
55 237 explained that the Hospital Quality Assurance Committee had no policies on assessing the
56
57 238 quality of neonatal pain management. Also, the patients' pain management was not explicitly
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1
2
3 239 mentioned in the job description of the staff, and the neonates' pain management was not
4
5 240 examined in the monthly and annual performance evaluations of the staff. Thus, the
6
7
8 241 performance of health professionals regarding the use of analgesics was not often questioned.
9
10 242 However, in some cases, verbal warning were delivered to some health professionals highly
11
12 243 inattentive to the patients' pain. Furthermore, there were no clear policies to encourage health
13
14 244 professionals who performed well in managing the neonates' pain. Accordingly, appropriate
15
16 245 management of the neonates' pain was not considered a professional value.
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19 246

20
21 247 *“Nobody asks staff about the quality of their performance in relieving infant's pain. We feel*
22
23 248 *we're not evaluated or monitored in this regard; and we are completely free to do it or not.”*
24
25
26 249 (Participant 10)
27

28 250

251 **Organizational Resources**

252 *Lack of time due to high workload*

253 According to the participants, a high workload was another challenge to appropriate pain
254 management in the NICU. In most cases, the health professionals did not have a good
255 performance in relieving the neonates' pain due to lack of time and work overload. Care-
256 providers mentioned the large number of patients as a challenge for pain management. They
257 believed that high workload resulted in limited attention to the neonates' pain and not using
258 analgesics before the procedures. Also, some nurses believed that less pain during the
259 procedure required two nurses, but the lack of time made it impossible for them to help their
260 colleagues during the painful procedure.

261

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2
3 262 “A nurse with three patients may admit another one. This workload makes pain management
4
5 263 difficult. She/he only thinks of doing their duties quickly and finishing the shift.” (Participant
6
7
8 264 25)

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10 265
11
12 266 *Inadequate educational program*

13
14 267 According to the participants, the lack of effective training programs and consequently
15
16 268 insufficient knowledge caused the staff not to know the benefits and importance of controlling
17
18 269 the neonates’ pain. Some of the educational needs mentioned by the participants included
19
20 270 gaining knowledge and skills in using pain assessment tools and pain management techniques
21
22 271 appropriate for different situations and procedures, as well as using analgesics. From the
23
24 272 participants’ point of view, attending in-service training courses for managing the neonates’
25
26 273 pain and participation in research projects or quality improvement activities could increase the
27
28 274 health professionals’ awareness of the neonates’ pain and its treatment benefits.
29
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35
36 276 “There is no training program for the NICU staff about the importance and methods of
37
38 277 relieving pain in neonates. Since the treatment team members know little about this issue, we
39
40 278 should not expect them to perform well.” (Participant 24)
41
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44 279

47 280 **Discussion**

48
49 281 According to our results, organizational factors, including cultural, structural, and resource
50
51 282 issues, can affect the optimal control of neonates’ pain in the NICU.

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53 283 Organizational culture is the model of group’s prevalent assumptions, which develops through
54
55 284 a shared history, experiences, and learning¹⁶. The health professionals who participated in our
56
57 285 study believed that the low participatory culture and poor collaboration of health team members
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3 286 threatened the optimal management of the neonates' pain. This issue has caused such problems
4
5 287 as over-stimulation of the neonates, inconsistencies in providing services, and losing
6
7 288 opportunities in relieving the pain. Interprofessional collaboration is a way in which different
8
9
10 289 health care professionals interact with each other to make clinical decisions after considering
11
12 290 each other's knowledge. In this way, the specialists undertake complementary roles and get
13
14 291 involved in problem-solving and decision-making processes to develop and implement patient
15
16 292 care programs²². Participants in the study cited the hierarchical nature and clinical dominance
17
18 293 of physicians over nurses as a barrier to appropriate collaboration. Power imbalances in clinical
19
20 294 practice are a key barrier to joint decision-making, which can affect the quality of care²³. The
21
22 295 findings of our study are supported by the other literature. Mirlashari et al. showed that the
23
24 296 power imbalance between physicians and nurses in Iranian NICUs leads to insufficient team
25
26 297 collaboration in providing care²⁴. In studies conducted in developed countries, proper
27
28 298 communication and interprofessional collaboration in complex care settings such as the NICU
29
30 299 was considered the vital element of effective practice on pain^{16,25,26}. According to studies,
31
32 300 finding communication channels between the health care members can reduce power
33
34 301 imbalance and improve their ability to negotiate about pain management approaches²⁷. In
35
36 302 contrast of our study finding, Tavernier et al. identified team collaboration as a contextual
37
38 303 factor to optimal pain management in U.S. hospitals. They acknowledged that interprofessional
39
40 304 educational programs have improved communication between the disciplines and supported
41
42 305 collaborative relationships²⁸. This strategy can be used in countries such as Iran, where
43
44 306 insufficient communication and collaboration of health professionals is considered as a
45
46 307 challenge in the quality of care. The users of educational programs of Iranian health institutions
47
48 308 are traditionally all from the same discipline. Also, evidence-based strategies, such as
49
50 309 interprofessional practice teams, can improve the interprofessional collaboration²⁹.
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3 310 The findings of this study indicate insufficient parent-health professional collaboration in the
4
5 311 neonates' pain management. Organizational culture did not adequately support parental
6
7 312 involvement, and relationships between parents and professionals was affected by power
8
9 313 imbalances. Parents often did not receive sufficient information and their participation in the
10
11 314 decision making and service providing was not considered in the practice. Although few
12
13 315 parental care involvement research is done in developing countries such as Iran, this finding is
14
15 316 supported by other Iranian study^{24,30,31}. Khajeh et al. found that families in Iranian medical
16
17 317 fields are considered non-participating visitors³². Other studies in Finland, Sweden, the United
18
19 318 States and China showed that the level of parental involvement in the management of neonatal
20
21 319 pain varies, from parental absence to their full collaboration^{33,34}. However, The participation
22
23 320 of the patients' family members and health care professionals is essential to provide optimal
24
25 321 care³⁵. There are positive effects of parental involvement in the literature of developed
26
27 322 countries, such as reducing parental stress³⁶, facilitating parent/ infant attachment³⁷, and more
28
29 323 effectively manage neonatal pain³⁸. Axelin et al. pointed out that when the health professionals
30
31 324 relationship with the parents is paternalistic, parents were usually absent or passive in
32
33 325 managing their neonate pain. They believed that implication of Family-Centered Care (FCC)
34
35 326 approach had a positive effect on information sharing and parental involvement in neonatal
36
37 327 pain management³³. Mirlashari et al. also acknowledged that the low parental involvement in
38
39 328 Iranian NICUs is due to the marginalized FCC²⁴. In the FCC model, the family is an essential
40
41 329 member of the health care team and has a close relationship with staff. In this model the parents
42
43 330 are the most influential contributors to caring for their neonates in the NICU³⁹. Some studies
44
45 331 showed that the implementation of FCC model could increase the parents' participation in
46
47 332 neonates' pain management^{26,40}. Evidence highlights the role of the organization in creating
48
49 333 instructions to change the context and provide the optimal parental involvement in neonatal
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51 334 care²⁵.

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3 335 The lack of clear policy and supervising the health professionals' performance in relieving the
4
5 336 neonates' pain are the main challenges related to organizational structure. This increases the
6
7 337 evidence-practice gap and causes the staff to use analgesics based on their individual opinions
8
9
10 338 and knowledge, which can lead to improper neonates' pain management. This finding is
11
12 339 supported by some studies in Iran ⁴¹ and other developing countries ⁴². Studies often conducted
13
14 340 in developed countries emphasize the facilitation of optimal pain management with clear
15
16 341 organizational protocols and quality improvement policies ^{16,28}. A longitudinal study in Sweden
17
18 342 showed that the development of the program about the neonatal pain management and stay on
19
20 343 it increased the rate of the using of pain assessment tools 80% since 1993 to 2008 ⁴³. Nowadays,
21
22 344 reputable institutions and neonatal pain specialists recommend that the NICUs should have
23
24 345 evidence-based step-by-step protocol and continuous auditing program to optimal neonates'
25
26 346 pain management ⁴⁴. The American Academy of Pediatrics (AAP) listed the components of the
27
28 347 neonates' pain management protocol that include strategies to minimize the number of
29
30 348 performed painful procedures, routine pain assessment programs, and pharmacological and
31
32 349 non-pharmacological treatments for pain management during surgery and procedures ⁴⁵.
33
34 350 Stevens et al. used the evidence-based Practice for Improving Quality method and implemented
35
36 351 a multifaceted intervention to improve pain management in Canadian pediatric hospitals that
37
38 352 can be used in other settings. After examining the unit's base-line pain practices and reviewing
39
40 353 evidence of pain assessment and management in a participatory process, they identified their
41
42 354 protocol and improved the level of pain management with step-by-step interventions including
43
44 355 educational sessions, reminders, audit and feedback ⁴⁶.
45
46
47 356 Organizational resources include the supplies and time necessary to meet work demands.
48
49 357 Achieving this organizational feature requires sufficient staff with the appropriate expertise to
50
51 358 be able to balance the job demands, workload, and time. In our study, some nurses raised time
52
53 359 management concerns more frequently than addressing their concerns about the neonates' pain
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3 360 management. High workload and lack of time cause accumulation of staff's duties. This issue,
4
5 361 along with the non-supportive organizational structure and lack of care providers' knowledge
6
7 362 about the importance of neonates' pain management can cause priority of some care that was
8
9 363 necessary for the newborn's survival and restrict the pain management. Rochefort et al. suggests
10
11 364 that staffing constraints and non-supportive work environments result in the rationing of
12
13 365 nursing interventions in NICU ⁴⁷. Moreover, a high workload can cause physical and mental
14
15 366 fatigue in staff and negatively affect their performance. Work overload and lack of time are the
16
17 367 international challenge in health institutions that affect in quality of care. Similar to our finding,
18
19 368 the studies that conducted in in Iran ⁴⁸ and other countries ^{28,34} mentioned high workload as a
20
21 369 barrier to optimal management of patient pain. Although part of the high workload is due to
22
23 370 the nurse shortage, which requires interventions at the international and national levels,
24
25 371 nevertheless, some solutions such as reducing indirect care time by supplies availability,
26
27 372 providing enough off-duty hours, and more payments for extra work hours can motivate nurses
28
29 373 and improved the quality of neonatal pain management in busy settings.
30
31 374 Inadequate training programs on the neonates' pain management was another problem related
32
33 375 to organizational resources. According to the participants, the knowledge about various areas
34
35 376 of pain management was at a low level due to inadequate training. Although Cong et al.
36
37 377 concluded that care providers' knowledge of neonatal pain has changed dramatically in recent
38
39 378 decades³⁴, there is still a need to improve it. Studies in developed and developing countries
40
41 379 have reported insufficient knowledge of health professionals in patient pain management
42
43 380 ^{27,28,41,49}. In this regard, international organizations and specialists stated that improvement the
44
45 381 knowledge of the health professionals by providing educational resources is an important factor
46
47 382 for appropriate pain management in the NICU ⁴⁵. Nowadays, pain management is one of the
48
49 383 topics of continuing education programs in developed settings. A study cited the use of
50
51 384 numerous training forums and seminars as a factor in promoting pain management in US
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3 385 hospitals²⁸. In addition, other educational methods have been mentioned in studies that can be
4
5 386 used based on the facilities and conditions of each setting. For an example Rajasoorya
6
7 387 acknowledge that clinical rounds are a great opportunity to gain knowledge, and if performed
8
9 388 well, they can create unique learning opportunities and improve the quality of patient care⁵⁰.
10
11
12 389 However, knowledge-practice gap is a global issue. Sometimes there is knowledge about
13
14 390 protocols, standard procedures or guidelines, but they are ignored in practice⁵¹. It is necessary
15
16 391 to facilitate the use of knowledge along with its promotion. Some of facilities can include
17
18 392 respect for teamwork and coordination in providing care which was discussed previously. Also,
19
20 393 reducing work overload can provide the time needed to use of knowledge in relieving the
21
22 394 neonate's pain. It seems, there are some interactions between the study findings that emphasize
23
24 395 the complexity of making change and can be a basis for further studies.
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29 396

30 397 **Limitation**

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32
33 398 Our study was conducted in the NICU of a government teaching hospital, which may have a
34
35 399 different environment from other clinical settings and limit the representativeness of the
36
37 400 findings. Although qualitative research is usually not generalizable and its emphasis is on in-
38
39 401 dept exploration of an issue. Another limitation is related to the hierarchical nature of the
40
41 402 medical environment, which although widespread internationally, is exacerbated in developing
42
43 403 countries. Medical hierarchical power structures have been linked to negative impacts by
44
45 404 creating environments that discourage the voicing of opinions and sharing information freely.
46
47 405 To deal with this issue, we emphasized on maintaining the confidentiality of the participants in
48
49 406 different stages of the study. Also, in order to control the effect of the nurse/physician power
50
51 407 imbalance, which increased the possibility of marginalization of nurses, the focus groups of the
52
53 408 nurses and physicians were held separately.
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410 **Conclusion**

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

425 **How might this information affect in practice?**

426 It seems that new strategies are needed for improving NICU pain management. Promoting
427 interprofessional collaboration as well as parent-care providers' interactions can increase
428 neonatal pain management. Moreover, to achieve optimal pain management, developing and
429 implementing an evidence-based pain management protocol is necessary. An integrated
430 clinical performance can be achieved through administrative supervision and frequent auditing.
431 Due to the inadequate knowledge in the health care team, practical training is essential in such
432 areas as control of environmental stimuli, pharmacological and non-pharmacological pain-
433 relieving methods, and using pain assessment tools. Also, heavy workload can decrease the
434 quality of staff performance about the management of neonatal pain. Reducing the workload

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3 435 in health care organizations is complex and multifaceted, but fulfilling the physical and
4
5 436 emotional needs of the care team can improve their performance.
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9
10 438 **Acknowledgements**

11
12 439 We would like to acknowledge all the participants who so willingly gave their time to be
13
14 440 interviewed.
15

16
17 441 **Contributorship statement**

18
19 442 H.N: Conceptualization, Methodology, software, Data Curation, Project administration,
20
21 443 Formal analysis, Writing- original draft, Writing-review and editing. H.H: Conceptualization,
22
23 444 Methodology, Supervision, Formal analysis, Writing-review and editing. M.J:
24
25 445 Conceptualization, Methodology, Validation, Formal analysis, Writing-review and editing.
26
27 446 R.N: Methodology, Formal analysis, Validation.
28
29

30
31 447 **Competing interests**

32
33 448 None declared.
34

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36
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38
39

40 451 **Data sharing statement**

41
42 452 Data are available upon reasonable request.
43
44

45 453 **Ethics approval statement**

46
47 454 The Ethics Committee of Tabriz University of Medical Sciences approved the study (code:
48
49 455 IR.TBZMED.REC.1398.985). Participants gave informed consent to participate in the study
50
51 456 before taking part.
52
53

54 457

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56 458 **References**
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COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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

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5 2 Organizational Challenges of Pain Management in Neonatal Intensive Care Unit: A Qualitative
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8 3 Study

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3 26 **Organizational Challenges of Pain Management in Neonatal Intensive Care Unit: A**
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5 27 **Qualitative Study**
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10 29 **Abstract**
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12 30 **Objectives:** Despite credible evidence, optimal neonates' pain management in the neonatal
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14 31 intensive care unit is a challenging issue. In this regard, the organizational context is an
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16 32 essential factor. The existing challenges vary depending on the context, and investigating them
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18 33 can help to improve the quality of care. The study aimed to explore organizational challenges
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20 34 to neonates' pain management in the neonatal intensive care unit.
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24 35 **Methods:** This qualitative study included 31 nurses and physicians in the neonatal intensive
25
26 36 care unit of Children's Hospital, Tabriz, Iran. Data collection was done through individual and
27
28 37 focus group interviews. For data analysis, we used conventional content analysis.
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31 38 **Results:** The identified challenges included organizational culture (poor interprofessional
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33 39 collaboration and low parental participation), organizational structure (lack of unified approach
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35 40 in relieving pain and limited supervision for pain management), and organizational resources
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37 41 (lack of time due to high workload and inadequate educational programs).
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40 42 **Conclusions:** Many organizational factors consistently affect neonatal pain management.
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42 43 Adopting some approaches to enhance the cooperation of treatment team members, holding
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44 44 educational programs, proper organizational supervision, and implementing a unified neonatal-
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46 45 based pain management program could improve neonatal pain management.
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51 47 **Strengths and limitations**
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54 48 Strengths are:
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3 49 • The exclusive focus on the organizational challenges of neonatal pain management in
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5 50 the clinical setting of a developing country, which has been less addressed in other
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7 51 studies.
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10 52 • The inclusion of a range of health professionals across different caring situations,
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12 53 educational levels, and work experiences.
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15 54 • Triangulation in data collection (individual interviews and focus groups) which
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17 55 increases the trustworthiness of the findings.
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19 56 Limitations are:

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22 57 • Sampling of single NICU and lack of organizational diversity.
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24 58 • Potential for missing some information due to the hierarchical nature of the setting that
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26 59 discourages the voicing of opinions.
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31 61 **Background**

32
33 62 Nowadays, the survival rate of neonates admitted to the neonatal intensive care unit (NICU)
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35 63 has increased. Therefore, it is essential to optimize the NICU care and reduce the complications
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37 64 of survived cases. In this regard, proper neonates' pain control is a priority. Despite the
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39 65 misconceptions in the past, scientists have proved the neonates' perception of pain in recent
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41 66 decades (1).
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45 67 Pain can increase the demand in the cardiovascular system and endanger the hemodynamic
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47 68 status of the neonate by increasing the heart rate and decreasing the arterial oxygen saturation.
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49 69 It also increases the risk of intraventricular hemorrhage by increasing blood pressure in the
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51 70 germinal matrix. The weak immune system and increased risk of infections are other problems
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53 71 related to pain tolerance in neonates. Anxiety, abnormalities in processing pain (hypo- or hyper
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55 72 sensitivity to pain), and developmental problems are some long-term effects of inappropriate
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57 73 pain management in neonates (2). Studies show that the prevention of pain in the neonates is
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3 74 not only ethically essential, but it is also necessary for preventing short-term and long-term
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5 75 complications and developmental disorders (3,4).
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8 76 Although there have been theoretical advances and clinical guidelines related to pain
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10 77 management in the NICU, it is still a severe challenge in complex care conditions (5) and needs
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12 78 further research (6). Evidence suggests that the rate of routine pain assessment in NICU can be
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14 79 as low as 6-10% (7,8) and only 7.1% of care providers always take interventions to reduce
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16 80 neonates' pain (9).

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19 81 Pain management of neonates is one of the most important tasks of care providers. Nurses in
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21 82 particular play a significant role in pain management due to spending more time at the patient's
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23 83 bedside (10). According to previous studies, the lack of knowledge in care providers is the
24
25 84 significant barrier to optimal pain management (11,12). The evidence shows that care
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27 85 providers' knowledge of pain management and their perceived responsibility is significantly
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29 86 related to the organization's policies (13). Nowadays, health care accreditation centers consider
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31 87 the optimal management of pain as one of the indicators for evaluating the quality of care. They
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33 88 extend patient pain management from an individual issue to an organizational issue and
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35 89 emphasize the importance of the organization in providing safe care. Hence, the researchers
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37 90 are trying to understand the role of organization in this area (14).
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42 91 Evidence suggests that differences in service quality may be due to organizational differences
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44 92 (15). In this regard, a study examined the role of organizational factors (culture, structure,
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46 93 resources, capabilities, skills, and policies) in the NICU pain management of a developed
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48 94 country and discussed the existing challenges (16). However, there is a belief that the NICU
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50 95 context in developed countries may differ in developing countries, leading to different pain
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52 96 management challenges (17).
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56 97 Although some studies have evaluated pain management in the NICU, limited studies have
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58 98 focused on organizational challenges in developing countries. Accordingly, the present
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3 99 descriptive qualitative study was conducted with the aim of investigating the organizational
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5 100 challenges of NICU pain management in Tabriz, Iran.
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10 102 **Methods**

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12 103 The interpretive descriptive method was used to evaluate the perceptions of health
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14 104 professionals on organizational pain management challenges in the NICU. Descriptive
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16 105 qualitative research helps to describe or discover a phenomenon or a problem, and the
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18 106 researcher can use it to examine a wide range of topics related to people's experiences,
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20 107 perceptions, and perspectives (18). The Ethics Committee of Tabriz University of Medical
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22 108 Sciences approved the study (code: IR.TBZMED.REC.1398.985).
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26 109 The study was conducted in a NICU (level III) in Tabriz, East Azerbaijan province in the
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28 110 northwest of Iran. The NICU was a referral center for term and preterm neonates with various
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30 111 medical and surgical diseases. The physical space of the NICU included three large halls
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32 112 equipped with 27 warmers. The average ratio of nurse to patient was 1:3. In this ward, different
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34 113 types of painful interventions are performed according to the neonates' needs. The ward has an
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36 114 accommodation for mothers, which includes a kitchen, toilet, bathroom and a large hall with
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38 115 multiple beds and wardrobes. Mothers can stay in the ward and with their infant 24 hours a
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40 116 day.
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47 118 **Participants and recruitment**

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49 119 Interviews were conducted with 26 nurses and 5 physicians who had at least 6 months of
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51 120 experience in the NICU. In order to make an informed decision of staff about whether to
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53 121 participate, the first author went to the NICU and explained the purpose of the research to them
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55 122 (potential participants). All were given the opportunity to ask questions. The first author also
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57 123 informed them about the voluntary nature of the participation, their right to privacy and
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124 confidentiality. All participants were assured that they could withdraw from the study at any
 125 time without giving any reason. Then, staff were offered an interview by the first author and
 126 no one declined to take part. Volunteered participants received, and studied written information.
 127 They completed the consent form and expressed their willingness to participate in the
 128 individual or focus interviews. The purposive sampling was used to achieve the maximum
 129 variation. For this purpose, we selected the participants with various age ranges, educational
 130 levels, work experiences, organizational positions, and professions for either individual or
 131 focus interviews (Table1).

132 Table 1. Demographic Characteristics of Participants

Participants (N=31)	Age (Year)	Marital status Married/Single	Educational status	Organizational position	Work experience (Year)
Nurse (N=26)	30-44	23 / 3	MSc =1 BSc =25	Clinical Supervisor=1 Educational Supervisor=1 Head Nurse=2 Nurse=22	5-20
Physician (N=5)	35-48	5 / 0	Neonatologist=4 Fellowship of neonatology=1	Academic Member=2 Clinical Physician=2 Assistant=1	4-18

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3 135 **Patient and public involvement**
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5 136 No patient involved.
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10 138 **Data Collection**
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12 139 Data were collected from February 2021 to January 2022 through 11 individual interviews and
13
14 140 three focus group discussions with 7-, 8-, and 5-participants, respectively. The place and time
15
16 141 of the interview were chosen according to the participants' preference and their privacy was
17
18 142 respected during the interview. The interviews were voice-recorded after obtaining the
19
20 143 participants' consent. The individual interviews lasted an average of 42 minutes (range: 23–
21
22 144 65min). All of them were performed in the coffee room, according to the preference of the
23
24 145 participants. The first author, who had a clinical and research background in neonatal care, led
25
26 146 the individual interviews. She used a semi-structured interview guide that focused on
27
28 147 participants' experiences of neonatal pain management in NICU (Table 2).
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35 149 Table 2. Interview Guide
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38 Main questions:

39
40 It's very valuable for me to know about your experiences of managing infant pain in your
41
42 NICU. Please talk about them if you wish.
43

44 What are health care services provided to manage the infant pain in your NICU?
45

46 What are the problems in managing infant pain in your NICU?
47

48 What organizational factors are effective in managing the neonatal pain?
49

50 Probing questions:
51

52 Could you explain more?
53

54 What do you mean?
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Can you give an example to clarify further?

150

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

158

159 **Data Analysis**

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

167 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.

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169

170 **Trustworthiness**

171 We used Guba and Lincoln's criteria to assess trustworthiness (21). Credibility was enhanced
172 through purposive sampling with the principle of maximum variation to select the participants.

173 In addition to individual interviews, we used focus groups to collect data. Also, to verify the
174 data and the extracted codes, the member check was used. The researchers were familiar with
175 the NICU department, and they were experienced in qualitative research. For the study's
176 dependability, we tried to clearly describe the research steps taken from the beginning of the
177 research project to the development and reporting of findings. We also used probing questions
178 to increase dependability. In addition, the process of data collection and findings were audited
179 by experts, which helped promote confirmability.

180

181 **Results**

182 Three main themes and six sub-themes that explained the organizational challenges to optimal
183 neonates' pain management in the NICU were identified (Table 4).

184 Table 4. Themes and Sub-themes

Themes	Sub-themes
Organizational culture	Poor interprofessional collaboration

	Low parental participation
Organizational structure	Lack of unified approach to pain relief
	Limited supervision for pain management
Organizational resources	Lack of time due to high workload
	Inadequate educational programs

185

186 **Organizational Culture**

187 *Poor interprofessional collaboration*

188 According to the participants, individual decision-making on doing tasks and poor coordination
 189 among team members led to such problems as repetitive manipulations of the neonates,
 190 disorganization, and limited opportunities to relieve the neonates' pain. Also, the staff did not
 191 talk to each other about the pain management of the neonates and no suggestions were
 192 exchanged between them. Although the nurses talked to physicians about the need to control
 193 neonates' pain and made suggestions in some cases, they were usually dismissed by the
 194 physicians because they had more decision-making power.

195

196 *"Staff just want to do their job. For example, the doctor comes and says: 'I want to do an LP*
 197 *on the infant.' Without coordinating the things related to managing the neonate's pain with the*
 198 *nurse!"* (Participant 3)

199

200 *Low parental participation*

201 Although the parents were present in the ward, they were not considered members of the care
 202 team, and were not often consulted. The participants believed that the staff usually controlled
 203 the parents, and the parents acted according to the staff's wishes. Usually, parents are given

1
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3 204 limited information about their neonate's pain and how to participate and relieve it. This led to
4
5 205 a one-way and non-interactive relationship between family and the staff. As a result, they could
6
7
8 206 not play a fully effective role in activities such as relieving their neonate's pain.
9

10 207

11
12 208 *"In our ward, usually we do not involve the parents in controlling the baby's pain. Most of the*
13
14 209 *time, the staff asks the parents to go out and come back after managing the neonate's pain.*

15
16
17 210 *This is quite acceptable behavior in the ward."* (Participant 21)
18

19 211

20 212 **Organizational structure**

21 213 *Lack of unified approach in relieving pain*

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23
24 214 According to the participants, there were no predefined and specific policy for pain control in
25
26 215 the ward. As a result, no positive atmosphere and clear expectations in terms of pain-relieving
27
28 216 actions were created. This caused a lack of strong support for the implementing of evidence in
29
30 217 practice. Although several health care professionals working in the NICU did things to relieve
31
32 218 the neonates' pain based on their personal preference, credible pain assessment tools and pain
33
34 219 prevention and management policies were not used abundantly. Thus, there were
35
36 220 disagreements and arbitrary pain management in the ward. The participants believed that
37
38 221 specific protocols could help to improve outcomes and develop optimal pain management
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40 222 practices in the NICU, leading to the uniformity of performance among different professions
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42 223 and clinicians.
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51 225 *"Currently, it is unclear what we should do to control the pain in different situations. For*
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53 226 *example, we don't know what exactly to do to control the pain of a neonate after surgery. The*
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55 227 *internal medicine and surgery team members have different opinions on this issue, and their*
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3 228 *lack of understanding sometimes causes the neonate not to be given painkillers at all.*"

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5 229 (Participant 1)

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10 231 *"We have neonatologists with different methods of practicing; some of them prescribe*

11
12 232 *painkillers more commonly than others. Perhaps we could have some predefined instructions*

13
14 233 *for a variety of methods or painful pain management because some care-providers might think*

15
16 234 *that a specific method is not very painful.*" (Participant 13)

17
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19 235

20
21 236 *Limited supervision for pain management*

22
23 237 There is little demand from the organization regarding the neonatal pain management. Also,

24
25 238 the staff's performance regarding neonatal pain management is not supervised. The participants

26
27 239 explained that the Hospital Quality Assurance Committee had no policies on assessing the

28
29 240 quality of neonatal pain management. Also, the patients' pain management was not explicitly

30
31 241 mentioned in the job description of the staff, and the neonates' pain management was not

32
33 242 examined in the monthly and annual performance evaluations of the staff. Thus, the

34
35 243 performance of health professionals regarding the use of analgesics was not often questioned.

36
37 244 However, in some cases, verbal warnings were delivered to some health professionals highly

38
39 245 inattentive to the patients' pain. Furthermore, there were no clear policies to encourage health

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41 246 professionals who performed well in managing the neonates' pain. Accordingly, appropriately

42
43 247 managing of the neonates' pain was not considered a professional value.

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48 249 *"Nobody asks staff about the quality of their performance in relieving infant's pain. We feel*

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50 250 *we're not evaluated or monitored in this regard; and we are completely free to do it or not.*"

51
52 251 (Participant 10)

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253 **Organizational Resources**

254 *Lack of time due to high workload*

255 According to the participants, a high workload was another challenge to appropriate pain
256 management in the NICU. In most cases, the health professionals did not perform well in
257 relieving the neonates' pain due to lack of time and work overload. Care-providers mentioned
258 the large number of patients as a challenge for pain management. They believed that the high
259 workload resulted in limited attention to the neonates' pain and not using analgesics before the
260 procedures. Also, some nurses believed that less pain during the procedure required two nurses,
261 but the lack of time made it impossible for them to help their colleagues during the painful
262 procedure.

263

264 *"A nurse with three patients may admit another one. This workload makes pain management*
265 *difficult. She/he only thinks of doing their duties quickly and finishing the shift."* (Participant
266 25)

267

268 *Inadequate educational program*

269 According to the participants, the lack of adequate training programs and consequently
270 insufficient knowledge caused the staff not to know the benefits and importance of controlling
271 the neonates' pain. Some of the educational needs mentioned by the participants included
272 gaining knowledge and skills in using pain assessment tools and pain management techniques
273 appropriate for different situations and procedures, as well as using analgesics. From the
274 participants' point of view, attending in-service training courses for managing the neonates'
275 pain and participation in research projects or quality improvement activities could increase the
276 health professionals' awareness of the neonates' pain and its treatment benefits.

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3 278 *“There is no training program for the NICU staff about the importance and methods of*
4
5 279 *relieving pain in neonates. Since the treatment team members know little about this issue, we*
6
7 280 *should not expect them to perform well.”* (Participant 24)
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14 282 **Discussion**

16 283 According to our results, organizational factors, including cultural, structural, and resource
17
18 284 issues, can affect the optimal control of neonates' pain in the NICU.

21 285 Organizational culture is the model of group's prevalent assumptions, which develops through
22
23 286 a shared history, experiences, and learning (16). The health professionals who participated in
24
25 287 our study believed that the low participatory culture and poor collaboration of health team
26
27 288 members threatened the optimal management of the neonates' pain. This issue has caused such
28
29 289 problems as over-stimulation of the neonates, inconsistencies in caring, and losing
30
31 290 opportunities to relieve the pain. Interprofessional collaboration is a way in which different
32
33 291 health care professionals interact with each other to make clinical decisions after considering
34
35 292 each other's knowledge. In this way, the specialists undertake complementary roles and get
36
37 293 involved in problem-solving and decision-making processes to develop and implement patient
38
39 294 care programs (22). Participants in the study cited the hierarchical nature and clinical
40
41 295 dominance of physicians over nurses as a barrier to appropriate collaboration. Power
42
43 296 imbalances in clinical practice are a crucial barrier to joint decision-making, which can affect
44
45 297 the quality of care (23). The findings of our study are supported by the other literature.
46
47 298 Mirlashari et al. showed that the power imbalance between physicians and nurses in Iranian
48
49 299 NICUs leads to insufficient team collaboration in providing care (24). In studies conducted in
50
51 300 developed countries, proper communication and interprofessional collaboration in complex
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53 301 care settings such as the NICU was considered the vital element of effective practice on pain
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3 302 (16,25,26). According to studies, finding communication channels between the health care
4
5 303 members can reduce power imbalance and improve their ability to negotiate pain management
6
7 304 approaches (27). In contrast to our study finding, Tavernier et al. identified team collaboration
8
9 305 as a contextual factor in optimal pain management in U.S. hospitals. They acknowledged that
10
11 306 interprofessional educational programs have improved communication between the disciplines
12
13 307 and supported collaborative relationships (28). This strategy can be used in countries such as
14
15 308 Iran, where insufficient communication and collaboration among health professionals is
16
17 309 considered a challenge in the quality of care. The users of educational programs in Iranian
18
19 310 health institutions are traditionally all from the same discipline. Also, evidence-based strategies,
20
21 311 such as interprofessional practice teams, can improve interprofessional collaboration (29).
22
23 312 The findings of this study indicate insufficient parent-health professional collaboration in
24
25 313 neonates' pain management. Organizational culture did not adequately support parental
26
27 314 involvement, and relationships between parents and professionals was affected by power
28
29 315 imbalance. Parents often did not receive sufficient information and their participation in the
30
31 316 decision making and service providing was not considered in practice. Although few parental
32
33 317 care involvement research is done in developing countries such as Iran, this finding is supported
34
35 318 by other Iranian study (24,30,31). Khajeh et al. found that families in Iranian medical fields are
36
37 319 considered non-participating visitors (32). Other studies in Finland, Sweden, the United States
38
39 320 and China showed that the level of parental involvement in the management of neonatal pain
40
41 321 varies, from parental absence to their full collaboration (33,34). However, The participation of
42
43 322 the patients' family members and health care professionals is essential to provide optimal care
44
45 323 (35). There are positive effects of parental involvement in the literature of developed countries,
46
47 324 such as reducing parental stress (36), facilitating parent/ infant attachment (37), and more
48
49 325 effectively managing neonatal pain (38). Axelin et al. pointed out that when the health
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51 326 professionals' relationship with the parents is paternalistic, parents were usually absent or
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3 327 passive in managing their neonate pain. They believed that the implication of the Family-
4
5 328 Centered Care (FCC) approach had a positive effect on information sharing and parental
6
7 329 involvement in neonatal pain management (33). Mirlashari et al. also acknowledged that the
8
9 330 low parental involvement in Iranian NICUs is due to the marginalized FCC (24). In the FCC
10
11 331 model, the family is an essential member of the health care team and has a close relationship
12
13 332 with staff. In this model the parents are the most influential contributors to caring for their
14
15 333 neonates in the NICU (39). Some studies showed that the implementation of FCC model could
16
17 334 increase the parents' participation in neonates' pain management (26,40). Evidence highlights
18
19 335 the role of the organization in creating instructions to change the context and provide the
20
21 336 optimal parental involvement in neonatal care (25).

22
23
24 337 The lack of clear policy and supervising the health professionals' performance in relieving the
25
26 338 neonates' pain are the main challenges related to organizational structure. This increases the
27
28 339 evidence-practice gap and causes the staff to use analgesics based on their individual opinions
29
30 340 and knowledge, which can lead to improper neonates' pain management. This finding is
31
32 341 supported by some studies in Iran (41) and other developing countries (42). Studies often
33
34 342 conducted in developed countries emphasize the facilitation of optimal pain management with
35
36 343 clear organizational protocols and quality improvement policies (16,28). A longitudinal study
37
38 344 in Sweden showed that the development of the program about neonatal pain management and
39
40 345 staying on it increased the rate of the use of pain assessment tools by 80% from 1993 to 2008
41
42 346 (43). Nowadays, reputable institutions and neonatal pain specialists recommend that the NICUs
43
44 347 should have evidence-based step-by-step protocol and continuous auditing program for
45
46 348 optimal neonates' pain management (44). The American Academy of Pediatrics (AAP) listed
47
48 349 the components of the neonates' pain management protocol that include strategies to minimize
49
50 350 the number of performed painful procedures, routine pain assessment programs, and
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52 351 pharmacological and non-pharmacological treatments for pain management during surgery and
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3 352 procedures (45). Stevens et al. used the evidence-based Practice for Improving Quality method.
4
5 353 They implemented a multifaceted intervention to improve pain management in Canadian
6
7 354 pediatric hospitals that can be used in other settings. After examining the unit's baseline pain
8
9 355 practices and reviewing evidence of pain assessment and management in a participatory
10
11 356 process, they identified their protocol. They improved the level of pain management with step-
12
13 357 by-step interventions including, educational sessions, reminders, audit and feedback (46).
14
15 358 Organizational resources include the supplies and time necessary to meet work demands.
16
17 359 Achieving this organizational feature requires sufficient staff with the appropriate expertise to
18
19 360 balance the job demands, workload, and time. In our study, some nurses raised time
20
21 361 management concerns more frequently than addressing their concerns about the neonates' pain
22
23 362 management. High workload and lack of time cause accumulation of staff's duties. This issue,
24
25 363 along with the non-supportive organizational structure and lack of care providers' knowledge
26
27 364 about the importance of neonates' pain management can cause priority of some care necessary
28
29 365 for the newborn's survival and restrict the pain management. Rochefort et al. suggest that
30
31 366 staffing constraints and non-supportive work environments result in the rationing of nursing
32
33 367 interventions in NICU (47). Moreover, a high workload can cause physical and mental fatigue
34
35 368 in staff and negatively affect their performance. Work overload and lack of time are the
36
37 369 international challenge in health institutions that affect in quality of care. Similar to our finding,
38
39 370 the studies conducted in Iran (48) and other countries (28,34) mentioned high workload as a
40
41 371 barrier to optimal management of patient pain. Although part of the high workload is due to
42
43 372 the nurse shortage, which requires interventions at the international and national levels,
44
45 373 nevertheless, some solutions such as reducing indirect care time by supplies availability,
46
47 374 providing enough off-duty hours, and more payments for extra work hours can motivate nurses
48
49 375 and improve the quality of neonatal pain management in busy settings.
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3 376 Inadequate training programs on the neonates' pain management was another problem related
4
5 377 to organizational resources. According to the participants, the knowledge about various areas
6
7 378 of pain management was at a low level due to inadequate training. Although Cong et al.
8
9 379 concluded that care providers' knowledge of neonatal pain has changed dramatically in recent
10
11 380 decades (34), there is still a need to improve it. Studies in developed and developing countries
12
13 381 have reported insufficient knowledge of health professionals in patient pain management
14
15 382 (27,28,41,49). In this regard, international organizations and specialists stated that
16
17 383 improvement the knowledge of the health professionals by providing educational resources is
18
19 384 an important factor for appropriate pain management in the NICU (45). Nowadays, pain
20
21 385 management is one of the topics of continuing education programs in developed settings. A
22
23 386 study cited numerous training forums and seminars as a factor in promoting pain management
24
25 387 in US hospitals (28). In addition, other educational methods have been mentioned in studies
26
27 388 that can be used based on the facilities and conditions of each setting. For example Rajasoorya
28
29 389 acknowledges that clinical rounds are a great opportunity to gain knowledge. If performed well,
30
31 390 they can create unique learning opportunities and improve the quality of patient care (50).
32
33 391 However, knowledge-practice gap is a global issue. Sometimes there is knowledge about
34
35 392 protocols, standard procedures or guidelines, but they are ignored in practice (51). It is
36
37 393 necessary to facilitate the use of knowledge along with its promotion. Some facilities can
38
39 394 include respect for teamwork and coordination in providing care which was discussed
40
41 395 previously. Also, reducing work overload can provide the time needed to use knowledge to
42
43 396 relieve the neonate's pain. It seems, there are some interactions between the study findings that
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45 397 emphasize the complexity of making change and can be a basis for further studies.
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56 399 **Limitation**

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3 400 Our study was conducted in the NICU of a government teaching hospital, which may have a
4
5 401 different environment from other clinical settings and limit the representativeness of the
6
7 402 findings. Although qualitative research is usually not generalizable and its emphasis is the in-
8
9 403 depth exploration of an issue. Another limitation is related to the hierarchical nature of the
10
11 404 medical environment, which although widespread internationally, is exacerbated in developing
12
13 405 countries. Medical hierarchical power structures have been linked to negative impacts by
14
15 406 creating environments that discourage the voicing of opinions and sharing information freely.
16
17 407 To deal with this issue, we emphasized maintaining the confidentiality of the participants at
18
19 408 different stages of the study. Also, in order to control the effect of the nurse/physician power
20
21 409 imbalance, which increased the possibility of marginalization of nurses, the focus groups of the
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23 410 nurses and physicians were held separately.
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412 **Conclusion**

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33 413 This study showed the organizational factors affecting the gap between the level of expected
34
35 414 neonatal pain management in the NICU and the care provided. The non-encouraging
36
37 415 organizational culture and its hierarchical nature caused the loss of communication channels
38
39 416 between health team members and their insufficient interaction. The poor interprofessional
40
41 417 collaboration led to inconsistent care, missed opportunities to relieve the neonate's pain, and
42
43 418 repeated painful procedures. The weakness of the FCC principles and the power imbalance
44
45 419 between care providers and parents caused the low participation of parents in the management
46
47 420 of their neonate's pain. An unresponsive organizational structure and lack of a clear policy on
48
49 421 the quality of neonatal pain management were associated with care provider discretion and, in
50
51 422 some cases, suboptimal pain management. Work overload caused care providers to prioritize
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53 423 tasks that seemed more necessary in the setting. In addition, insufficient educational resources
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55 424 caused a lack of knowledge and further marginalization of infant pain management.
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6 426 **How might this information affect in practice?**
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8 427 It seems that new strategies are needed to improve NICU pain management. Promoting
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10 428 interprofessional collaboration and parent-care providers' interactions can increase neonatal
11
12 429 pain management. Moreover, developing and implementing an evidence-based pain
13
14 430 management protocol is necessary to achieve optimal pain management. An integrated clinical
15
16 431 performance can be achieved through administrative supervision and frequent auditing. Due to
17
18 432 the inadequate knowledge in the health care team, practical training is essential in such areas
19
20 433 as control of environmental stimuli, pharmacological and non-pharmacological pain-relieving
21
22 434 methods, and using pain assessment tools. Also, a heavy workload can decrease the quality of
23
24 435 staff performance in managing of neonatal pain. Reducing the workload in health care
25
26 436 organizations is complex and multifaceted, but fulfilling the physical and emotional needs of
27
28 437 the care team can improve their performance.
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36
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38
39 441 interviewed.
40
41
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43
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45
46 444 Formal analysis, Writing- original draft, Writing-review and editing. H.H: Conceptualization,
47
48 445 Methodology, Supervision, Formal analysis, Writing-review and editing. M.J:
49
50 446 Conceptualization, Methodology, Validation, Formal analysis, Writing-review and editing.
51
52 447 R.N: Methodology, Formal analysis, Validation.
53
54
55
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57
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59
60

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2
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4
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6
7 452 **Data sharing statement**

8
9 453 Data are available upon reasonable request.

10
11 454 **Ethics approval statement**

12
13 455 The Ethics Committee of Tabriz University of Medical Sciences approved the study (code:
14
15 456 IR.TBZMED.REC.1398.985). Participants gave informed consent to participate in the study
16
17 457 before taking part.
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23
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COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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