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Editorial Board Member of *World Journal of Clinical Cases*, Ahmed Mohamed Ahmed Al-Emam, PhD, Associate Professor, Department of Pathology, King Khalid University, Abha 62521, Saudi Arabia. amalemam@kku.edu.sa

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The primary aim of *World Journal of Clinical Cases* (*WJCC, World J Clin Cases*) is to provide scholars and readers from various fields of clinical medicine with a platform to publish high-quality clinical research articles and communicate their research findings online.

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E-mail: bpgoffice@wjgnet.com https://www.wjgnet.com
Observational Study

Psychological needs of parents of children with complicated congenital heart disease after admitting to pediatric intensive care unit: A questionnaire study

Ji-Hua Zhu, Chen-Di Jin, Xiao-Min Tang

BACKGROUND

Parents of children with complicated congenital heart disease (CHD) have different needs after surgery. Little literature reports the impact factors for psychological needs of parents of children with complicated CHD.

AIM

To investigate the status quo of the needs of parents of children after surgery for complex CHD, and analyze the influencing factors, in order to provide a theoretical basis for formulating corresponding nursing countermeasures.

METHODS

A modified Chinese version of the Critical Care Family Needs Inventory (M-CCFNI) was used to select 200 parents of children with complex CHD after surgery within 72 h after admission to the intensive care unit in our hospital to conduct an online questionnaire survey. The aim was to understand the needs of parents in relation to the following five aspects: The support from medical staff, comfort of the parents themselves, the acquisition of information, their closeness to the children, and assurance of the child’s condition.

RESULTS

Parents of children with complex CHD had a higher degree of demand, especially in terms of condition assurance, acquisition of information, and closeness to the children. The age, education level, and residence of the parents were related to the five dimensions of the needs of parents of children with complex CHD who had undergone surgery.
CONCLUSION
In practice, nurses should formulate corresponding nursing strategies based on the different cultural and social backgrounds of parents of children after complex CHD surgery to meet their different needs, and improve satisfaction. These findings provide a theoretical basis for constructing a family participatory nursing model for children in the intensive care unit in the future.

Key Words: Congenital heart disease; Family participation; Psychological needs; Nursing model; Pediatric intensive care unit

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Core Tip: In the treatment and nursing of children with complicated congenital heart surgery, nursing staff should also pay attention to the mood changes of the caregiver, relieve and guide the bad mood, and help the caregiver establish a correct attitude and confidence in overcoming the disease, which can reduce the burden of caregivers through a variety of ways.

INTRODUCTION
According to relevant data[1-3], approximately 150000-200000 newborns in China suffer from congenital heart disease (CHD) each year, accounting for about 0.8% of all live births. CHD is the most common birth defect in China, and there are more and more complicated CHDs with any combination of “ventricular septal defect, atrial septal defect, patent ductus arteriosus, and simple pulmonary stenosis”. Studies have shown that due to improvements in medical standards, surgical correction is the only way to cure complex CHDs. Due to the complexity of the operation, extracorporeal circulation and a long time period are required for anesthesia, postoperative close monitoring in the intensive care unit (ICU), and assisted supportive treatment of cardiopulmonary function to survive the most dangerous postoperative stage. The relatively closed ICU environment, long period of separation, lack of knowledge of the disease, and other factors make the psychological pressure on parents far greater than on parents of children with other diseases[4-6]. The unhealthy psychological problems of the parents of these children not only affect the rehabilitation of children, but can also cause conflict between the doctor and patient, and tension between the doctor and the parents[7]. In this study, the parents of children with complicated CHD who underwent surgery were surveyed to understand their psychological needs, analyze influencing factors, identify major sources of stress, and explore intervention strategies to improve the medical care service model, nursing quality and satisfaction, and patient care.

MATERIALS AND METHODS
Building the survey
This study obtained authorization from Xia and Yan[8], the original author of the modified Chinese version of the Parental Needs Inventory for Critically Ill Children (M-CCFNI) and consulted the relevant national and international literature on the needs of parents of critically ill children. The current psychological needs of the parents of children with heart disease were evaluated. The basic information (general demographic and social data) of the parents included the parents’ gender, age, relationship to the child, cultural level, occupation, monthly family income, family residence, and other related data. The M-CCFNI scale has five dimensions and a total of 37 items which include the support of medical staff (Support Scale), parents’ own comfort (Comfort Scale), access to information (Information Scale), the need to be close to the children (Proximity Scale), and the Assurance Scale. The scale uses the Likert 4-point system for scoring. This study investigated the parents of children with CHD who had undergone surgery within 72 h after admission to the pediatric ICU (PICU).
### Table 1 General information on parents of the children

<table>
<thead>
<tr>
<th>Measurement index</th>
<th>Variable</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>≤ 25</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>26-35</td>
<td>120</td>
</tr>
<tr>
<td></td>
<td>≥ 36</td>
<td>52</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>137</td>
</tr>
<tr>
<td>Relationship to the child</td>
<td>Mother</td>
<td>137</td>
</tr>
<tr>
<td></td>
<td>Father</td>
<td>61</td>
</tr>
<tr>
<td></td>
<td>Grandparents</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Babysitter</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td>Education level</td>
<td>Junior high school and below</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>Technical secondary school or high school</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>College or undergraduate</td>
<td>91</td>
</tr>
<tr>
<td></td>
<td>Master degree and above</td>
<td>6</td>
</tr>
<tr>
<td>Occupation</td>
<td>Medical staff</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Enterprise but not medical staff</td>
<td>47</td>
</tr>
<tr>
<td></td>
<td>Unemployment</td>
<td>33</td>
</tr>
<tr>
<td></td>
<td>Freelancer</td>
<td>78</td>
</tr>
<tr>
<td></td>
<td>Farming</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>19</td>
</tr>
<tr>
<td>Monthly family income (RMB)</td>
<td>Below 3000</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>3000-5999</td>
<td>85</td>
</tr>
<tr>
<td></td>
<td>&gt; 6000-10000</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>More than 10000</td>
<td>48</td>
</tr>
<tr>
<td>Home</td>
<td>City</td>
<td>69</td>
</tr>
<tr>
<td></td>
<td>Rural area</td>
<td>87</td>
</tr>
<tr>
<td></td>
<td>Town</td>
<td>44</td>
</tr>
<tr>
<td>The only child</td>
<td>Yes</td>
<td>83</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>117</td>
</tr>
<tr>
<td>Religious beliefs</td>
<td>Yes</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>117</td>
</tr>
</tbody>
</table>

### Table 2 Scores of items in the M-CCFNI scale

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Item content</th>
<th>Score (mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical staff support</td>
<td>1 Hope that before I enter the ICU for the first time, the medical staff can introduce me to the ICU</td>
<td>3.62 ± 0.58</td>
</tr>
<tr>
<td></td>
<td>4 Hope to be guided by medical staff when visiting the ICU</td>
<td>3.63 ± 0.52</td>
</tr>
<tr>
<td></td>
<td>6 Hope that medical staff will take the initiative to inform parents of the child’s condition and current situation</td>
<td>3.76 ± 0.46</td>
</tr>
<tr>
<td></td>
<td>12 When the condition changes, someone can call the parents in time</td>
<td>3.82 ± 0.39</td>
</tr>
<tr>
<td></td>
<td>15 Hope to know other experts who can solve children’s problems</td>
<td>3.53 ± 0.66</td>
</tr>
</tbody>
</table>
23. Hope to provide spiritual and psychological support  3.61 ± 0.58
24. Hope that medical staff treat patients as relatives and sincerely care and take care of patients  3.78 ± 0.44
28. I hope to talk to the ICU medical staff about my bad emotions, such as guilt, anger, etc.  2.97 ± 1.02
29. Hope that medical staff will help like friends  3.54 ± 0.67
30. Hope that medical staff can patiently explain, comfort and psychologically counsel  3.59 ± 0.63
36. Sometimes family members are emotionally upset for the patient, and I hope the medical staff can understand  3.53 ± 0.63

Parents’ own comfort
8. Hope that family members have comfortable rest facilities in the waiting room  3.12 ± 0.89
13. Hope that there is a special waiting room for parents outside the ICU  3.00 ± 1.05
19. Hope that there will be a special waiting room for family members outside the ICU  3.48 ± 0.71
26. Hope that the hospital has humanized management and handles the relationship between doctors and patients’ family members  3.67 ± 0.51

Getting information
3. Hope to communicate with the doctor every day  3.69 ± 0.52
7. Can understand the general information of the patient’s doctor in charge and responsible nurse, such as job title, experience, level, etc.  3.52 ± 0.67
9. I hope to communicate with the same nurse every day to understand the patient’s condition  3.53 ± 0.66
14. Needs for understanding disease-related knowledge  3.63 ± 0.54
16. Know what kind of information needs to be asked of staff  3.56 ± 0.63
17. When you cannot go to the hospital to visit, you can call the responsible nurse or doctor to ask about the child’s condition  3.59 ± 0.62
22. Know every treatment the child is currently receiving  3.78 ± 0.45
25. Medical staff do not avoid the condition of the disease, and can talk to me about the possibility that the child’s treatment effect is not significant  3.75 ± 0.46
27. Be informed when planning to change the treatment plan  3.76 ± 0.49
34. Know the purpose of a certain treatment for the patient  3.75 ± 0.48
35. I hope to receive dietary guidance and activity guidance for children with various diseases  3.72 ± 0.49

The need to be close to the child
18. When parents have special circumstances, they hope to adjust the visiting time flexibly  3.57 ± 0.60
32. Hope to be able to accommodate and increase visitation opportunities in special circumstances  3.65 ± 0.58
33. Get information about the patient’s condition every day  3.76 ± 0.47
37. I hope the doctor can make an appointment to explain the child’s condition  3.60 ± 0.62

Condition assurance
2. Hope that the medical staff can explain the condition easily and understandably  3.69 ± 0.52
5. The medical staff can answer my questions truthfully  3.75 ± 0.45
10. Feel the care of medical staff for patients  3.69 ± 0.49
11. Let me understand the prognosis of the child  3.81 ± 0.40
20. Hope that medical staff will do their best and be responsible  3.82 ± 0.42
21. Can feel the condition is expected to improve  3.80 ± 0.41
31. Can know the specific circumstances of the change  3.75 ± 0.47

ICU: Intensive care unit.

**Methods of investigation**

This survey involved completing a questionnaire online. First, the researcher adopted the domestic mature electronic questionnaire system design to form the electronic version of the questionnaire, and used repeated tests to ensure that the content of the electronic version of the questionnaire was completely consistent with the paper questionnaire. Then, the research team used the WeChat electronic version of the questionnaire to create a QR code for the questionnaire, and the survey participants used the mobile terminal to scan the code to complete the questionnaire. Each terminal was restricted to completing the questionnaire only once. This questionnaire survey adopted an anonymous method, and the parents were able to truly express their opinions without being affected by other factors. A
Table 3 M-CCFN1 scores of various dimensions and total score of parents of children with complicated congenital heart disease

<table>
<thead>
<tr>
<th>Demand dimension</th>
<th>Score (mean ± SD)</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition assurance</td>
<td>3.76 ± 0.46</td>
<td>1</td>
</tr>
<tr>
<td>Get information</td>
<td>3.66 ± 0.56</td>
<td>2</td>
</tr>
<tr>
<td>The need to be close to the child</td>
<td>3.65 ± 0.57</td>
<td>3</td>
</tr>
<tr>
<td>Support from medical staff</td>
<td>3.58 ± 0.65</td>
<td>4</td>
</tr>
<tr>
<td>Parents' own comfort</td>
<td>3.31 ± 0.86</td>
<td>5</td>
</tr>
<tr>
<td>Total score</td>
<td>3.62 ± 0.62</td>
<td></td>
</tr>
</tbody>
</table>

Table 4 Scores of top 5 needs of parents of children with complicated congenital heart disease

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Entry</th>
<th>Score (mean ± SD)</th>
<th>“Very important” proportion/%</th>
<th>Sort</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS</td>
<td>Hope that medical staff will do their best and be responsible</td>
<td>3.82 ± 0.42</td>
<td>83.3</td>
<td>1</td>
</tr>
<tr>
<td>SS</td>
<td>When the condition changes, someone can call the parents in time</td>
<td>3.82 ± 0.39</td>
<td>81.9</td>
<td>2</td>
</tr>
<tr>
<td>AS</td>
<td>Allow me to understand the prognosis of the child</td>
<td>3.81 ± 0.40</td>
<td>81.9</td>
<td>3</td>
</tr>
<tr>
<td>AS</td>
<td>Can feel the condition is expected to get better</td>
<td>3.80 ± 0.41</td>
<td>80.9</td>
<td>4</td>
</tr>
<tr>
<td>IS</td>
<td>Know every treatment the child is currently receiving</td>
<td>3.78 ± 0.45</td>
<td>76.5</td>
<td>5</td>
</tr>
</tbody>
</table>

AS: Assurance scale; SS: Support scale; IS: Information scale.

RESULTS

General information on parents of the children with complicated CHD is shown in Table 1. The needs of parents of children with complicated CHD are shown in Tables 2-4. Influencing factors on the needs of parents of children with complicated CHD are shown in Table 5.

DISCUSSION

The results of this study showed that the needs of parents of children with complex CHD after surgery are multifaceted, with a higher degree of demand as shown in Tables 3 and 4, with an average score of (3.62 ± 0.62). In this study, single factor analysis of the needs of parents of children with CHD is shown in Table 5. It was found that age, educational level, and place of residence of the parents were correlated with the five dimensions of the needs of parents of these children. Therefore, more attention should be paid to the parents of children with complicated CHD who are admitted to the ICU and try to meet their needs.

This study showed that condition assurance is the most important requirement for parents of children with complicated CHD after surgery, which is consistent with the findings in other studies [9,10]. And three of the first five needs of parents are disease assurance needs. In this study, the score of "Hope that medical staff will do their best and be responsible" was the highest (3.82 ± 0.42), and 83.3% of the parents thought that this demand was very important. Within 72 h after admission to ICU, the patient's condition is still in an unstable state. Parents are most concerned about whether the child can be treated effectively to ensure that the child can pass through the critical period safely. It is suggested that medical staff should focus on meeting the disease guarantee needs of children's parents, including ensuring that children get the best treatment, and truthfully answer parents' questions, so that they can tell them about the progress of the disease. In the actual clinical work, when the child is sick, the family can only rely on the treatment and care of the medical staff, and often have high expectations for the treatment and prognosis of the child. When the treatment outcome of the child is not satisfactory, it is difficult for the family to understand and accept it. It is very easy to produce doctor-patient conflicts. Therefore, ICU medical staff should not only make the family members of patients feel the hope of
Table 5 Single factor analysis of demand scores of parents of children with congenital heart disease

<table>
<thead>
<tr>
<th>Influencing factors</th>
<th>Dimension 1: Medical staff support</th>
<th>Dimension 2: Parents’ own comfort</th>
<th>Dimension 3: Getting information</th>
<th>Dimension 4: Close to the needs of children</th>
<th>Dimension 5: Condition assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Demand score</td>
<td>F value</td>
<td>P value</td>
<td>Demand score</td>
<td>F value</td>
</tr>
<tr>
<td>Age (yr)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 35</td>
<td>22.40 ± 2.22</td>
<td>1.635</td>
<td>0.202</td>
<td>9.320</td>
<td>0.003b</td>
</tr>
<tr>
<td>&gt; 35</td>
<td>21.94 ± 2.21</td>
<td></td>
<td></td>
<td>6.96 ± 0.99</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>0.637</td>
<td>0.426</td>
<td></td>
<td>1.304</td>
<td>0.255</td>
</tr>
<tr>
<td>Male</td>
<td>22.10 ± 2.08</td>
<td>7.43 ± 9.3</td>
<td></td>
<td>7.19 ± 1.01</td>
<td>0.93</td>
</tr>
<tr>
<td>Female</td>
<td>22.37 ± 2.28</td>
<td>7.36 ± 0.94</td>
<td></td>
<td>6.26 ± 2.32</td>
<td>0.57</td>
</tr>
<tr>
<td>Parents</td>
<td>1.307</td>
<td>0.254</td>
<td></td>
<td>1.694 ± 0.195</td>
<td>0.05</td>
</tr>
<tr>
<td>Father</td>
<td>22.02 ± 2.06</td>
<td>7.17 ± 1.01</td>
<td></td>
<td>26.17 ± 2.67</td>
<td>0.14</td>
</tr>
<tr>
<td>Mother</td>
<td>22.40 ± 2.28</td>
<td>7.37 ± 0.94</td>
<td></td>
<td>26.63 ± 2.33</td>
<td>0.14</td>
</tr>
<tr>
<td>Education</td>
<td>2.532</td>
<td>0.113</td>
<td></td>
<td>2.359</td>
<td>0.126</td>
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<tr>
<td>Below college</td>
<td>22.04 ± 2.46</td>
<td>7.20 ± 1.03</td>
<td></td>
<td>26.04 ± 2.78</td>
<td>0.14</td>
</tr>
<tr>
<td>College degree and above</td>
<td>22.54 ± 1.91</td>
<td>7.41 ± 0.88</td>
<td></td>
<td>26.96 ± 1.93</td>
<td>0.14</td>
</tr>
<tr>
<td>Monthly income</td>
<td>1.704 ± 1.19</td>
<td>0.193</td>
<td></td>
<td>1.443</td>
<td>0.231</td>
</tr>
<tr>
<td>≤ 6000 yuan</td>
<td>22.10 ± 2.39</td>
<td>7.23 ± 1.03</td>
<td></td>
<td>26.23 ± 2.62</td>
<td>0.14</td>
</tr>
<tr>
<td>&gt; 6000 yuan</td>
<td>22.52 ± 1.95</td>
<td>7.40 ± 0.86</td>
<td></td>
<td>26.84 ± 2.14</td>
<td>0.14</td>
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<td>Place of residence</td>
<td>5.213</td>
<td>0.023a</td>
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<td>1.515</td>
<td>0.220</td>
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<td>Rural area</td>
<td>22.02 ± 2.29</td>
<td>7.24 ± 1.01</td>
<td></td>
<td>26.21 ± 2.59</td>
<td>0.14</td>
</tr>
<tr>
<td>City</td>
<td>22.77 ± 2.01</td>
<td>7.42 ± 0.86</td>
<td></td>
<td>27.00 ± 2.04</td>
<td>0.14</td>
</tr>
<tr>
<td>Only child</td>
<td>0.075 ± 0.785</td>
<td>0.193</td>
<td></td>
<td>2.557 ± 0.111</td>
<td>0.054</td>
</tr>
<tr>
<td>No</td>
<td>22.32 ± 2.10</td>
<td>7.21 ± 1.01</td>
<td></td>
<td>26.55 ± 2.28</td>
<td>0.14</td>
</tr>
<tr>
<td>Yes</td>
<td>22.23 ± 2.39</td>
<td>7.43 ± 0.89</td>
<td></td>
<td>26.40 ± 2.66</td>
<td>0.14</td>
</tr>
<tr>
<td>Religious belief</td>
<td>0.711</td>
<td>0.400</td>
<td></td>
<td>0.054 ± 0.816</td>
<td>0.000</td>
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</table>
improvement of the patient's condition, but also let the family members correctly understand the prognosis of the patients, and form a correct and reasonable psychological expectation of the prognosis of the patients, so as to reduce the conflict between doctors and patients.

In addition, the demand for information was also relatively high. Nurses must provide parents with information about the child, such as the child’s recovery from the disease, medication use, and mental state while the child’s condition is stable. In this study, the need to get close to the child was slightly lower than the need to obtain information. In a study of the needs of parents of newborns in the ICU by Thomi et al.[11], “being with the child” was the most important need. The children and their parents are prone to developing unhealthy emotions such as separation anxiety, which is not conducive to the children’s early rehabilitation and nurse-patient communication. Therefore, when the child or the parent has special circumstances, the nursing staff should adjust the visiting time and frequency in a timely manner. It is also important to keep in touch with the parents of the child in a variety of ways, so that they can understand the changes in the child’s condition dynamically and in real time, meet the psychological needs for the child’s closeness, and relieve nervousness. At the same time, the establishment of a semi-closed or fully open PICU management model or family participatory nursing model can be explored.

This study found that parents of children with complex CHD place too much emphasis on the treatment of children, and they neglect to pay attention to themselves. Gramszlo et al.[12] believe that the concept of centering on the parents should be integrated into the ICU’s child-centered medical care service model. In 2019, Golfenshtein et al.[13] showed that if the needs of parents of ICU children can be effectively met, this can reduce their anxiety, provide a good social support system for children, and promote their recovery. This also suggests that nursing staff should pay attention to providing psychological support services to parents of children during the nursing process.

**CONCLUSION**

With the continuous renewal of nursing concepts, the importance of child- and parent-centered concepts and family support therapy in the treatment process has been increasingly recognized by hospital administrators and clinical nursing staff. In the treatment and nursing process of children who undergo complicated surgery for CHD, nursing staff should also pay attention to the mood changes of the caregivers, relieve and guide their emotions, and help them establish the correct attitude and confidence to overcome the disease which can reduce the burden of caregivers in a variety of ways[14], in order to provide more and better positive support to children and promote their recovery. On the other hand, satisfying the reasonable psychological needs of the parents of these children can improve satisfaction and help build a harmonious nurse-patient relationship.
ARTICLE HIGHLIGHTS

Research background
Parents of children with complicated congenital heart disease (CHD) have different needs after surgery. Little literature reports the impact factors for psychological needs of patents of children with complicated CHD.

Research motivation
To investigate the status quo of the needs of parents of children after surgery for complex CHD, and analyze the influencing factors, in order to provide a theoretical basis for formulating corresponding nursing countermeasures.

Research objectives
To provide a theoretical basis for formulating corresponding nursing countermeasures.

Research methods
A modified Chinese version of the Critical Care Family Needs Inventory (M-CCFNI) was used to select 200 parents of children with complex CHD after surgery within 72 h after admission to intensive care unit (ICU) in our hospital to conduct an online questionnaire survey. The aim was to understand the needs of parents in relation to the following five aspects: The support from medical staff, comfort of the parents themselves, the acquisition of information, their closeness to the children, and assurance of the child’s condition.

Research results
Parents of children with complex CHD had a higher degree of demand, especially in terms of condition assurance, acquisition of information, and closeness to the children. The age, education level, and residence of the parents were related to the five dimensions of the needs of parents of children with complex CHD who had undergone surgery.

Research conclusions
In practice, nurses should formulate corresponding nursing strategies based on the different cultural and social backgrounds of parents after complex CHD surgery to meet their different needs, and improve satisfaction. These findings provide a theoretical basis for constructing a family participatory nursing model for children in the intensive care unit in the future.

Research perspectives
How to provide psychological intervention for parents of children admitted to ICU after complex CHD should be further explored in the future.

FOOTNOTES

Author contributions: Zhu JH, Jin CD and Tang XM designed the research study; Jin CD performed the research; Zhu JH and Tang XM analyzed the data and wrote the manuscript; all authors have read and approved the final manuscript.

Institutional review board statement: The study was reviewed and approved by the Medical Ethics Committee of Children’s Hospital Affiliated to Zhejiang University School of Medicine.

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Conflict-of-interest statement: All the authors report no relevant conflicts of interest for this article.

Data sharing statement: No additional data are available.

STROBE statement: The authors have read the STROBE Statement-checklist of items, and the manuscript was prepared and revised according to the STROBE Statement-checklist of items.

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