

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Characterizing Common Challenges Faced by Parental Caregivers of Children with Type 1 Diabetes Mellitus in Mainland China: A qualitative study
<b>AUTHORS</b>	Tong, Huijuan; Qiu, Feng; Fan, Ling

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Odeh, Rasha The University of Jordan
<b>REVIEW RETURNED</b>	06-Mar-2021

<b>GENERAL COMMENTS</b>	<p>This is a qualitative study that aims to examine perceptions of common challenges among parental caregivers of children with T1DM in Mainland China.</p> <p>In general, the study fulfills the requirements of qualitative studies in terms of methodology . However, the manuscript requires some English language editing.</p> <p>The key words on the BMJ open front page are not identical with the ones in the manuscript which are more representative of the manuscript.</p> <p>Background:</p> <ol style="list-style-type: none"><li>1. As you are describing financial burdens on the parents of patients with T1DM from China, it would be helpful to provide some information on insurance coverage of these patients in your region and its limitations ( if any).</li><li>2. In the same context, it would be also helpful to provide information on where your region lies in terms of gross national income per capita according to the world bank to get a sense of the financial burden.</li><li>3. Page 5 line 56 : it is better to use severe hypoglycemic events rather than deadly hypoglycemic events</li></ol> <p>Results:</p> <ol style="list-style-type: none"><li>1. page 10 line 45 : (10.6±2.45) this age range is obviously for children with T1DM and does not fit in the context of the sentence.</li><li>2. page 10 line 49 : please use insulin pumps instead of islet pumps</li><li>3. page 16 line 49: it would be clearer if you provide the equivalent of this expenditure example in another currency like Euros or US dollars for comparison.</li><li>4. page 16 line 59 : "Lack of Limited Social Activities" , you mean limited social activities?</li></ol> <p>references:</p> <ol style="list-style-type: none"><li>1. reference 6 does not match with the context</li><li>2. reference 30 does not match with the context</li></ol> <p>Table 2 page 32 : Monthly Income (CNY) : as mentioned above, it is better to have an equivalent in another currency for comparison.</p>
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<b>REVIEWER</b>	Gawel, Wladyslaw Medical University of Silesia
<b>REVIEW RETURNED</b>	21-Mar-2021

<b>GENERAL COMMENTS</b>	<p>The paper is of great value and certainly adds to the scope of the journal. However, minor language editing is needed e.g. line 36 "who rely"</p> <p>line 68 why is the age 13? I was not able to find this information in the cited article</p> <p>line 77 children in childhood</p> <p>line 78 are the adverse effects caused by the blood glucose control e.g. pricking the finger or are caused by the unsatisfactory blood glucose control?</p> <p>line 92 may instead of man</p> <p>line 125 I would like to ask why did the authors choose the age of 14 when in introduction the age of intense caring by caregivers was 13?</p> <p>line 130 to require</p> <p>line 132 to communicate</p> <p>line 385 repeatedly</p> <p>I would like to congratulate authors on their work. After the slight edition the article will add a valuable insight to the journal.</p>
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<b>REVIEWER</b>	Haslund-Thomsen, Helle Aalborg University Hospital
<b>REVIEW RETURNED</b>	22-Mar-2021

<b>GENERAL COMMENTS</b>	Thank you for you paper, it is an interesting study and interesting also that across countries it is still stressfull and a burden
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### VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Rasha Odeh, The University of Jordan

Comments to the Author:

This is a qualitative study that aims to examine perceptions of common challenges among parental caregivers of children with T1DM in Mainland China.

In general, the study fulfills the requirements of qualitative studies in terms of methodology . However, the manuscript requires some English language editing.

The key words on the BMJ open front page are not identical with the ones in the manuscript which are more representative of the manuscript.

Background:

1. As you are describing financial burdens on the parents of patients with T1DM from China, it would be helpful to provide some information on insurance coverage of these patients in your region and its limitations ( if any).

Response: Thank you for your comment. The insurance situation in the region for most of the cases is that all expenses are covered while the child is in hospital, but once the child is discharged, the expenses are paid by parents/guardians. Insulin medication is also partly covered by health insurance, and the reimbursement rate may vary depending on the type of health insurance (for example, with municipal health insurance 90% is reimbursed). We added the brief description of the insurance situation into discussion section (page 21, lines 473-477).

2. In the same context, it would be also helpful to provide information on where your region lies in terms of gross national income per capita according to the world bank to get a sense of the financial burden.

Response: Thanks for this suggestion. According to the world bank report, China has been classified among Upper-Middle-Income Economies, but per capita income significantly differs between regions. We hope this information will help you understand this study better.

3. Page 5 line 56 : it is better to use severe hypoglycemic events rather than deadly hypoglycemic events

Response: Thank you for your comment. The corresponding part has been changed according to your suggestion (page 4, line 71).

#### Results:

1. page 10 line 45 : (10.6±2.45) this age range is obviously for children with T1DM and does not fit in the context of the sentence.

Response: Thank you for your comment. Yes, it was the mean age of the children whose parents participated in the study. The corresponding part has been changed to "included 7 fathers and 13 mothers (gender roles were self-identified by the interviewee), aged 30 to 53 years, with their children mean age of 10.6±2.45 years" (page 9, line 188-190).

2. page 10 line 49 : please use insulin pumps instead of islet pumps

Response: Thank you for your comment. The corresponding part has been changed according to your suggestion (page 9, line 191).

3. page 16 line 49: it would be clearer if you provide the equivalent of this expenditure example in another currency like Euros or US dollars for comparison.

Response: Thank you for your comment. We added the corresponding amounts in USD, according to the approximate exchange rate during the study period (page 15, line 340-343).

4. page 16 line 59 : "Lack of Limited Social Activities" , you mean limited social activities?

Response: Thank you for your comment. Yes, this subtitle was meant to discuss "Limited social activities". The corresponding part has been changed according to your suggestion (page 16, line 347).

#### references:

1. reference 6 does not match with the context

2. reference 30 does not match with the context

Response: We thank you for your comment. Although cited papers are not directly linked to the T1DM management in pediatric practice, they discussed points relevant to our study. After careful consideration, we have changed some of the sources (including 6 and 30), using most recent works.

Table 2 page 32 : Monthly Income (CNY) : as mentioned above, it is better to have an equivalent in another currency for comparison.

Response: Thank you for your comment. We added the corresponding amounts in USD, according to the approximate exchange rate during the study period (Table 2, page 32, line 640).

#### Reviewer: 2

Dr. Wladyslaw Gawel, Medical University of Silesia

#### Comments to the Author:

The paper is of great value and certainly adds to the scope of the journal. However, minor language editing is needed e.g. line 36 "who rely"

line 68 why is the age 13? I was not able to find this information in the cited article

line 77 children in childhood

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line 125 I would like to ask why did the authors choose the age of 14 when in introduction the age of intense caring by caregivers was 13?

line 130 to require

line 132 to communicate

line 385 repeatedly

I would like to congratulate authors on their work. After the slight edition the article will add a valuable insight to the journal.

Response: We thank reviewer for all comments and suggestions. We have carefully checked the article again, in order to improve the language. Regarding the age of children, according to the age division of children in China, children are defined as those who under 14 years old.

As this study was limited by the time of interviews, the exact nature of the adverse effects caused by the blood glucose monitoring, mentioned by parents, sometimes wasn't clarified. The cited source was referring to "adverse health effects due to invasive procedures or ineffective blood glucose control" (which has been clarified in the introduction section). Our general impression is that the process of invasive glucose monitoring itself was linked to the negative emotions in many cases. But as we didn't include this parameter during data processing, it can't be discussed in the current article. However, we will most certainly consider this suggestion in our future works.

Reviewer: 3

Dr. Helle Haslund-Thomsen, Aalborg University Hospital

Comments to the Author:

Thank you for you paper, it is an interesting study and interesting also that across countries it is still stressfull and a burden

Characterizing Common Challenges Faced by Parental Caregivers of Children with Type 1 Diabetes Mellitus in Mainland China: A qualitative study

It is an interesting paper, that reflects a relevant study. There are however some concerns that needs to be addressed and elaborated before publication.

There seems not to be a sufficiently clearly stated aim, which generates a focus that is less consistent in analysis, findings and discussion.

The focus on transition to more autonomy in treatment seems to be a point of interest in the article but is not as such included in the interview guide.

I also would like to know if there were differences across the data on the children that were treated with daily injections, and those who were not. And if there were differences between mothers and fathers, as well as differences in the results according to education and socioeconomic status.

Response: Thank you for your comments. Due to the small sample size, there were no significant age or sex differences between the injected and non-injected children. Regarding caregivers, since it is more specific for traditional Chinese culture, majority of the caregivers were mothers, but still, due to the qualitative nature of the study, sample size was not powered to demonstrate the statistical differences.

Abstract:

It is unclear which agegroup of children that is included in the study and if they are newly diagnosed with diabetes or have had it for how long?. And it is unclear how many interviews that were conducted, and with whom more specifically. It is not clear what main and subthemes are in the results section.

Response: Thank you for your comment. Abstract section has been edited to clarify the number of participants, their age and other relevant information, according to your suggestion.

Strengths and limitations of this study:

No 1: That sentence is unclear, what is meant by the real condition of young children?

Response: Thank you for your comment. Sentence in question has been changed to: "This is the first study, which describes the conditions and consequences of young children with T1DM relying on parental caregivers for disease management in China" (page 3, line 34-35).

Background:

Line 57- 59: However, communities in China generally have less 58 resources and fewer T1DM cases outside of urban centers, which can increase the strain 59 on Chinese parental caregivers. Thus, examining the situation of middle- and low60 income parents of children with T1DM in China is essential to improving resources for 61 T1DM care and long-term outcomes. This sentence has an unclear meaning and the argument is difficult to follow for a broader non-Chinese audience .

Response: Thank you for your comment. Sentence in question has been changed to: "However, rural communities in China generally have fewer resources and growing number of T1DM cases outside of urban centers would eventually increase the strain on Chinese parental caregivers", in order to make point clearer (page 4, line 56-58).

Line 72-73: These responsibilities place immense psychological financial stress on....Here I would prefer, that a word as presumably or another could soften this claim, and I also wonder if it is both a psychological AND a financial stress – or if they are connected.....

Response: Thank you for your suggestions. Sentence in question has been accordingly changed to: "These responsibilities presumably place immense psychological and financial stress on parental caregivers" (page 5, line 72-73).

Line 77: many children in child still experience – something is missing here.

Response: Thank you for your suggestions. Sentence in question has been accordingly changed to: "Despite improvements in T1DM medications and treatment technologies, many children still experience adverse health effects due to invasive procedures or ineffective blood glucose control" (page 5, line 76-79).

Final section of Background: It is unclear why this study focusses on the transition period – this has not been argued clearly for in the background section and therefore seems to be introduced as bit surprisingly in the end. There is not stated a clear aim, which seems to be mission throughout the paper as a structuring tool for analysis and discussion.

Socio-ethnographic study – why is this term used ? How does that differ from a qualitative study design.

Response: We thank the reviewer for the comment. Theme of "Transition from Parental Management to Self-Management" emerged after the data analysis, and we are planning to discuss it further in the future studies. Regarding the terminology, after final edition of the manuscript it was decided not to mention "Socio-ethnographic study" in order to avoid confusion (page 6, line 106).

Methods:

Line 184: Could you elaborate on how the translation process of the interviews and quotes was performed. Were authorized translators involved?

A more general comment to the findings section is that the very large number of themes makes some of them be less robust and there is some overlap also, where it could be considered to integrate some of them in other themes, and make more nuanced themes that could be more supported by quotes.

Response: Thank you for your comment. We have amended the findings, in order to make this section clearer and easier to read. The authors of the paper translated the chosen quotes word by word, while all analyses were performed in the local language of the interview (Mandarin Chinese).

Line 211: I think it would strengthen transparency in the interpretations and analysis if the quotes were used when certain analytical points were described. To have them in the end of the theme without direct connection to the text makes it less transparent which quote that is an illustration of which point/argument. And as this subtheme is quite broad the empirical ground on which the analysis is based is not clear for each perspective in the theme.

Response: Thank you for your comment. The structure of the article was chosen by authors in accordance with the general format of qualitative research, aiming for gradual introduction of the theme, description, and interview content in that manner, for some of the parts might be omitted by faster readers. After carefully considering the suggestions of reviewers, we additionally amended this section of the paper in order to make the link between quotes and discussed topics clearer (page 10, line 200-364).

Line 273: "Now I rarely focus my energy on the company [I work for], just get 274 off work as soon as possible. I used to leave early and return late to make money. Now 275 I quit my job and found a new one that can make a living while taking care of my child. 276 When she is on vacation, so am I." This quote is an example on changed everyday life and should be considered in the theme below:

Challenges in Daily Management Theme

Response: Thank you for your comment. The quote indeed describes the challenges in daily management, however, the emphasis here was put on a change in the role function, shifting from earning money to the care of the affected child. We hope these explanation will help you support our ideas better.

Line 298 - It seems to me like the two themes Emotional Regulation and managing parent-child conflict are very closely connected and overlapping. It could be considered if these two could be put together in one, in order to make a more robust theme.

Response: Thank you for your suggestion, which is very sound and was supported by all authors. Those two sections were combined under the title: "Emotional Regulation and Managing Parent-Child Conflict" (page 13, line 295).

Line 322: However, premature transfer of diabetes management tasks to children with T1DM is now considered a factor leading 324 to poor blood glucose control. This statement seems not to be supported by data and it is unclear on what grounds this claim is made.

The transition theme is a bit short and says that it is hard to find the right timing, which is not elaborated in dept. Has the timing to do with the child's age or the time the child has had the diagnosis ?

Response: Thank you for your comments. The timing of the transition was related to the child's age and self-management ability. From the interviews, it was clear that premature transfer of diabetes management tasks to children with type 1 diabetes can cause poor glycemic control.

Line 351: In particular, mothers in the interview often left their employment, changed careers, or reduced hours to allow for caregiving for their child with T1DM. This has already been said in the theme above.

Response: Thank you for your comments. The focus here was shifted to the fact that the social circle of the Caregiver became smaller in the process of taking care of children due to resignation, which breaks away from the original social interaction and causes social limitation.

Discussion:



A broader comment on the discussion. The discussion as a whole is not sufficiently framed and clear on what is discussed. That there is not stated a clear aim in the beginning is a problem also in the discussion, as the results should be discussed related to the study aim and with contributions from other studies or theory.

Response: Thank you for your comment. We amended the section according to your suggestions (page 16, line 367-374).

Line 389: These findings are 389 consistent with other quantitative psychological studies demonstrating posttraumatic 390 stress disorder (PTSD) symptoms in caregivers<sup>20,22-24</sup>; That your study shows that caregivers have PTSD is not clear from the results – and should be elaborated further.

Response: Thank you for your comment. We amended the section according to your suggestions (page 17, line 385-406).

Line 416: social standing, in some cases going so far as to hide their child's to avoid perceived 417 discrimination – there is a word missing here.

Response: Thank you for your suggestions. Sentence in question has been accordingly changed to: "in some cases going so far as to hide their child's condition to avoid perceived discrimination" (page 18, line 413).

Line 430: Through analyzing interviews, this study found that the psychological burden 431 of parents primarily derives from the following courses: (1) Pressure of blood glucose 432 management in children, especially in diet management; (2) Children's physical and mental pain caused by insulin injections, blood glucose monitoring, and diet restrictions; (3) Mood changes in children due to illness; and (4) The impact of the disease on the future of the children. These insights can be used to design integrated patient management programs that consider both parental caregiver emotional health and the medical condition of the T1DM child. It is not quite clear if these are new themes or how they are represented in the presented themes presented in the findings section. Further the sentence on how these insights can be used if rather concerning implications to practice, and not so much discussion as such.

Response: Thank you for your comment. These are discussions from the findings of the interviews, which have summarized to be four reasons to illustrate the sources of psychological burden of parents. We try to provide these possible reasons to help to use to design integrated patient management programs in the future.

Line 447. While technology has improved T1DM care through the use of insulin pumps and continuous blood glucose monitoring, often young children may not have access to these technologies or compliance may not be possible <sup>30</sup>. The reference used seems not to be relevant (elderly). I suggest you look at: H, LA, B. Parental Experience of Continuous Glucose Monitoring in Danish Children with Type 1 Diabetes Mellitus. J doi: Epub 2020 Mar 31. PMID: 32245681

Response: We thank you for your comment and suggestion. Although cited paper is not directly linked to the T1DM management in pediatric practice, it discussed points relevant to our study. After careful consideration, we have changed some of the sources (including <sup>30</sup>), using most recent works.

Line 485: China has currently has a lack.....the number two has should be had.

Line 489: Therefore, we propose that we should, as a healthcare system, selectively learn from the successful experience of other countries and gradually implement training for school personnel and other personnel 492 who come into contact with diabetic children to improve the social support system for 493 children with diabetes. Are these effects documented? There is a reference needed here to support this claim. And in line with an earlier comment – this is rather an implication to practice and not so much a discussion.

Response: We thank you for your comments. Effects of appropriate and consistent training, as well as support from health services and children's diabetes specialist services on the management of disease and disease-related mental burden have been reported before with the different degree of evidence. We have added relevant references to support our point (page 21, line 487&493).