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

TITLE (PROVISIONAL) | What is important for you? – A qualitative interview study of living with diabetes and experiences of diabetes care to establish a basis for a tailored Patient-Reported Outcome Measure for the Swedish National Diabetes Register.

AUTHORS | Svedbo Engström, Maria; Leksell, Janeth; Johansson, Unn-Britt; Gudbjörnsdottir, Sofia

VERSION 1 - REVIEW

REVIEWER | Julia Frost
             University of Exeter, UK

REVIEW RETURNED | 20-Oct-2015

GENERAL COMMENTS | My primary concern is whether or not this paper adds anything to the voluminous literature regarding what it is like to live with diabetes. As well as the qualitative review by Gomersall, there are many others in existence. See for example:

Similarly, there are many diabetes PROMS already in existence, and the authors do not make clear how their findings will make for a more appropriate PROM than those already in existence:
Bradley C, Lewis KS. Measures of psychological well-being and treatment satisfaction developed from the responses of people with
Bradley C. The Diabetes treatment satisfaction questionnaire (DTSQ): change version for use alongside status version provides appropriate solution where ceiling effects occur. Diabetes Care. 2007. 22. 3. 530-2.

While the above two issues could be addressed by reading and engaging with the existing literature, a further concern is the application of content analysis as a means to analyse the data, and the description provided is not adequate for replication. With such rich data and lofty aims, would another analytical approach not have been more appropriate? Perhaps a greater understanding of PROMS science and the construction of new measures (in terms of both their validity and reliability) would have been helpful.

This paper lacks originality and does not add anything to the existing literature.

**REVIEWER** Katharine Barnard
Bournemouth University, UK

**REVIEW RETURNED** 25-Oct-2015

**GENERAL COMMENTS**
I really like this paper - not because it particularly adds anything exciting to existing literature, but because it continues to highlight the challenges that people face and the lack of currently available measures to effectively assess PROs and address them. This in itself makes it worthy of publication.

It's a good study that would benefit from greater detail in reporting. As such I have made some suggestions below.

Abstract – no comment

Introduction:
There are several diabetes-specific quality of life measures, so greater clarification as to why the authors believe that none of these are currently appropriate would be helpful. I agree with the authors, however believe that as currently worded, they are open to criticism. I suggest adding a sentence stating why current measures are inadequate.

Method:
<table>
<thead>
<tr>
<th>Reviewer 1: Dr Julia Frost, University of Exeter, UK</th>
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</table>
| **Comment 1:1**  
My primary concern is whether or not this paper adds anything to the voluminous literature regarding what it is like to live with diabetes. As well as the qualitative review by Gomersall, there are many others in existence. See for example:  
Ho A, Berggren I, Dahlborg-Lyckhage E (2010) Diabetes empowerment related to Pender’s health... |
promotion model. Nursing and Health Sciences. 12, 259-267.

Our response:
Thank you for this comment and for making suggestions of literature to add. We chose to include the papers by Campbell et al. 2003, Gask et al. 2011, Ho et al. 2010, and Paterson et al. 1998 (pages 1 and 15).

Comment 1:2
Similarly, there are many diabetes PROMS already in existence, and the authors do not make clear how their findings will make for a more appropriate PROM than those already in existence:
Bradley C. The Diabetes treatment satisfaction questionnaire (DTSQ): change version for use alongside status version provides appropriate solution where ceiling effects occur. Diabetes Care. 2007. 22. 3. 530-2.

Our response:
Thank you for this comment and for making us aware of the need to more clearly explain why there is a need for a new PROM that fits the very specific aim of this project, i.e. to work in the context of a register. We agree and have added a clarifying statement, page 1.

There is a large number of questionnaires in existence. Due to this, we chose to refer to reviews describing different questionnaires instead of including a high number of references to individual questionnaires. Gibbons et al, which you refer to, is included. Unfortunately, we just referred to the Patient Reported Outcome Measures Group and did not specify the authors. We have corrected our mistake, page 21.

The earlier instruments are older now and possibly outdated and as we mention many have been developed based on professionals’ views rather than patient perspective, with the risk of not targeting what is important from a patient perspective today. To meet the requirements of the register, we need a questionnaire tailored to a well-working national register that includes about 90 % of all individuals diagnosed with diabetes in Sweden. Furthermore, some of the existing questionnaires focus on a specific area, such as fear of hypoglycemia or empowerment. We argue that a modern quality register needs to be able to assess PRO as an equally important measure when improving diabetes care for the individual.

Comment 1:3
While the above two issues could be addressed by reading and engaging with the existing literature, a
further concern is the application of content analysis as a means to analyse the data, and the
description provided is not adequate for replication. With such rich data and lofty aims, would another
analytical approach not have been more appropriate? Perhaps a greater understanding of PROMS
science and the construction of new measures (in terms of both their validity and reliability) would
have been helpful.

Our response:
Thank you for this comment concerning an important issue. During the planning phase of this study
we discussed our choice of analytical approach within our group and with colleagues and experts in
qualitative research methodology. Our choice of content analysis is based on its benefits to
systematically organize and describe data. In addition, it was deemed as an appropriate approach as
we wanted to keep as much as possible of the verbal phrasing for subsequent item generation.
Another reason for choosing content analysis was the authors’ shared experience and training in this
approach.

Comment 1:4
This paper lacks originality and does not add anything to the existing literature.

Our response:
Thank you for this comment. We have clarified our reasons for a new PROM (Page 1). We hope that
there are readers interested in following challenges still present for people with diabetes and reading
about the initiative of developing a PROM inspired by the Capability Approach to be implemented in a
nationwide quality register.
The Swedish National Diabetes Register (NDR) is a unique nationwide register including very rich
data on validated risk factors for diabetes care and data on socioeconomic factors. Adding PROM is a
unique effort. The rich data set call for a responsibility to get the most adequate information from this
register. In order for the PROM to target what is important from a patient perspective today, qualitative
interviews are an important basis. We acknowledge that there is a voluminous literature regarding
what it is like to live with diabetes. However, given the unique opportunity, we decided to start from
scratch aiming for a PROM suitable for use within the scope of the NDR. The NDR enables
longitudinal registration of PRO in a vast number of people with diabetes and the possibility to merge
the analysis with a large amount of different data. Therefore, we considered the long and thorough
development process worth the effort in order to target the perspective of people living with diabetes.

REVIEWER 2: Prof Katharine Barnard, Bournemouth University, UK

Comment 2:1
I really like this paper - not because it particularly adds anything exciting to existing literature, but
because it continues to highlight the challenges that people face and the lack of currently available
measures to effectively assess PROs and address them. This in itself makes it worthy of publication.

Our response:
Thank you for this comment.

Comment 2:2
It's a good study that would benefit from greater detail in reporting. As such I have made some
suggestions below.

Our response:
Thank you for these suggestions. Please find our responses to each section below.

Comment 2:3
Abstract – no comment

Our response:
No changes made

Comment 2:4
Introduction:
There are several diabetes-specific quality of life measures, so greater clarification as to why the authors believe that none of these are currently appropriate would be helpful. I agree with the authors, however believe that as currently worded, they are open to criticism. I suggest adding a sentence stating why current measures are inadequate.

Our response:
Thank you for this comment and for making us aware of the need to more clearly explain why there is a need for a new PROM that fits the very specific aim of this project, i.e. to work in the context of a register. We agree and have added a clarifying statement, see page 1.

Comment 2:5
Method:
Why was it deemed that 29 participants would be adequate in terms of purposive sampling, particularly as it included T1 and T2 participants which are different diseases? Again, I agree it is probably sufficient, however a sentence explaining this method would be useful for readers who are not experienced in it.

Our response:
Thank you for this comment. We agree an explanation is needed in the methods section. Therefore, we have moved and edited some information on this subject that previously was included in the discussion and instead made some clarifying changes on pages 2-3/Participants and sampling.

Comment 2:6
How did you overcome selection bias? What makes you confident that the participants are representative of the wider clinic population rather than simply those that the nurses/authors thought might be ‘easy’ targets? I am not suggesting that the authors did this, however again, greater clarification of rationale and process is required.

Our response:
Thank you for this comment. We have added some clarifications on page 2-3/Participants and sampling.

Comment 2:7
What reasons were given for non-participation by the other 18 individuals? This is approximately 40% refusal rate so some detail on why would be helpful.

Our response:
Thank you for this comment. We have added clarifying information for non-participation on page 3/participants and sampling for two individuals. However for ethical reasons, an explanation for non-participation was not asked for and approached potential participants were only asked to reply if they consented to participation. However, the assisting diabetes nurses reported that a few potential participants told them that they had declined due to lack of time. In addition, the diabetes nurses experienced that when they, due to lack of time, handed out or sent the study information without offering any additional oral information, it was more likely that they got no response. Furthermore, one diabetes nurse working at an outpatient clinic with a high proportion of patients not born in Sweden
reported difficulty in recruiting participants due to language barriers.

Comment 2:8
Data collection:
How were the interview schedules piloted on potential participants prior to use and amended in line with feedback? The authors say they conducted two pilot interviews and revised the questionnaire order but that their data was included still. Why is that? This does not really qualify as ‘piloting’.

Our response:
Thank you for this comment. As described in the data-collection section/page 4, two pilot interviews were conducted. As is also described, the order the questions were presented was revised after these two pilot interviews. However, these changes were only minor, and this has been clarified in the manuscript. Other than being conducted in private in the participants’ homes instead of at the clinic, the two pilot interviews were conducted in the same manner as the other interviews and they both gave their informed consent. Both of the pilots provided important content describing and reflecting on their experience. They both represented characteristics adding to the heterogeneity, for example by representing long experience of living with diabetes, experience of late complications, and being in contact with diabetes care. In summary, it was deemed an ethical problem not to make use of their contributions.

Comment 2:9
Why were interviews not all conducted in clinic? Were there any differences in duration or content for those conducted elsewhere?

Our response:
Thank you for this comment. Not all interviews were conducted at the clinic due to participant preference and long distances for them to travel to their clinic: approximately 200 km. We have added a clarification on page 4/Data-collection. There were no variations in interview duration or content that was perceived as resulting from the different location.

Comment 2:10
Results:
Were there any differences between results for participants with T1 diabetes and those with T2 diabetes? Why is it felt appropriate that they be analysed together, bearing in mind my comment earlier that they represent two different diseases and management approaches. A sentence explaining this approach is required.

Our response:
Thank you for this comment. We have clarified our intentions in the discussion, page 17. We aim for a PROM suitable for use irrespective of diagnosis, to make it easy to handle for diabetes care and for the NDR. Therefore, it was not our intention to analyse differences between type 1 DM and type 2 DM, but rather to focus on the experience of living with diabetes.

Comment 2:11
Discussion - No comment

Our response:
No changes made except from those described above.

Additional Changes:
• Title page: The affiliation regarding Dalarna University have been corrected.
• Page 3/Participants and sampling: The number of participants invited by the authors has been corrected (wrongly stated as six instead of four).
• Page 13: the word for has been changed to of.
• Pages 12, 17, and 19: the term clinicians has been changed to professionals.

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**GENERAL COMMENTS**

There have been many primary qualitative and secondary review papers about the patient experience of diabetes and this paper does not add anything new. All of the findings replicated previous papers, see for example the work of Julia Lawton and colleagues:

- Elliott J, Rankin D, Jacques RM, Lawton J, Emery CJ, Campbell MJ, Dixon S, Heller SR. (2015) A cluster randomised controlled non-inferiority trial comparing 5 day DAFNE training delivered over 1 week against DAFNE training delivered over 1 day per week for 5 weeks - DAFNE 5 x1 day trial. Diabetic Medicine, 32: 391-398 Link
- Rankin D, Barnard KD, Elliott J, Cooke DD, Heller S, Gianfrancesco C, Taylor CD, Lawton J. (2014). Type 1 diabetes patients' experiences of, and need for, social support after attending a structured education programme: a qualitative longitudinal...


Casey D, Murphy K, Lawton J, Findlay-White F, Dinnen S. (2011). Factors impacting on Diabetic patient's ability to assimilate the Dose Adjustment For Normal Eating (DAFNE) principles into daily living and how these factors change over time. BMC Public Health. 11:672.


Adjustment for Normal Eating (DAFNE) programme for type 1 diabetes patients in the UK. Social Science & Medicine, 71: 486-493. DOI Link


Lawton J, Ahmad N, Douglas M, Hanna L, Bains H, Hallowell N (2008). "We should change ourselves, but we can't": accounts of food and eating practices amongst British Pakistanis and Indians with type 2 diabetes". Ethnicity and Health, 13: 305-319


REVIEWER
Katharine Barnard
Bournemouth University
UK

REVIEW RETURNED
06-Jan-2016

GENERAL COMMENTS
Thank you for the opportunity to review this article entitled "What is important for you? – A qualitative interview study of living with diabetes and experiences of diabetes care to establish a basis for a tailored Patient-Reported Outcome Measure for the Swedish National Diabetes Register."
Overall, the article is informative and interesting. The methodology is sound and conclusions appropriate.
There is a focus on questionnaire development in the introduction, which I suggest can be cut considerably as the article relates to the qualitative phase only. I would reduce this to one or two sentences only so as not to detract from the current study unnecessarily.

VERSION 2 – AUTHOR RESPONSE

REVIEWER 1: Dr Julia Frost, University of Exeter, UK

Comment 1:1
There have ben many primary qualitative and secondary review papers about the patient experience of diabetes and this paper does not add anything new. All of the findings replicated previous papers, see for example the work of Julia Lawton and colleagues: (Dr Julia Frost provides a list of references, omitted here)

Our response:
Thank you for this comment and for providing examples of existing research illuminating the situation of individuals living with diabetes. To better acknowledge previous qualitative research, we have added references to more recent works in addition to the reviews representing earlier publications (pages 1 and 15). Furthermore, we have clarified our purpose to, despite the existing research, conduct qualitative interviews as the basis for the development of a patient-reported outcome measure (PROM) for the Swedish National Diabetes Register (NDR) (page 2). The novelty lies within the thorough and transparent process of developing a comprehensive PROM that is feasible for implementation within a unique nationwide diabetes register containing rich medical data.

REVIEWER 2: Prof Katharine Barnard, Bournemouth University, UK

Comment 2:1
Overall, the article is informative and interesting. The methodology is sound and conclusions appropriate.

Our response:
Thank you for this comment.

Comment 2:2
There is a focus on questionnaire development in the introduction, which I suggest can be cut considerably as the article relates to the qualitative phase only. I would reduce this to one or two sentences only so as not to detract from the current study unnecessarily.

Our response:
Thank you for this comment. Some sentences in the introduction are deleted to clarify that the manuscript is related to the qualitative phase (page 2).

Additional changes

Table 1 (page 4): We recognized a difference in the format of presenting standard deviations. For consistency, all standard deviations are now presented within parenthesis.

VERSION 3 – REVIEW

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Julia Frost</th>
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<td>University of Exeter Medical School, UK</td>
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| REVIEW RETURNED         | 22-Feb-2016            |

| GENERAL COMMENTS        | The authors have attended to previous reviewer comments |

<table>
<thead>
<tr>
<th>REVIEWER</th>
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<tr>
<td>GENERAL COMMENTS</td>
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What is important for you? A qualitative interview study of living with diabetes and experiences of diabetes care to establish a basis for a tailored Patient-Reported Outcome Measure for the Swedish National Diabetes Register

Maria Svedbo Engström, Janeth Leksell, Unn-Britt Johansson and Soffia Gudbjörnsdottir

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