Title: Women’s experiences of a diagnosis of gestational diabetes mellitus: a systematic review

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Author’s response to reviews:

Reviewer reports:

Eran Hadar, MD (Reviewer 1): Craig et al. preformed a qualitative systemic review of 41 available studies, on the psychological impact of GDM diagnosis. I find the 2 previous reviews were quite thorough in their assessment, and overall, I think have contributed to the quality of the paper. I do have some minor suggestions, that once addressed will allow publications

1) The only major remark is that I disagree with the conclusion: "HCPs might carefully re-consider the current definition of GDM." As you explored the diagnosis of GDM, unrelated to its diagnostic methodology, lowering the threshold would still have an impact, and it is not in line with the pathological-physiological studies which have explored this. I would suggest to consider GDM diagnosis as the watershed line - your research is beyond that point and I would avoid discussing the issue of GDM diagnosis which is not in the scope of your study. Also, it seems you disregard your own findings of the positive behavioral effect of GDM diagnosis, which are important and valuable to a women's health, even if this causes "responsibility" and "financial investment", as it had important beneficial health effects. The appropriate conclusion would be to offer support to women with GDM and to reduce their numbers by altering the evidence-based diagnosis.

Response: We respect this conclusion was tangential to the aim of the systematic review and has been modified.
Change: The conclusion has now been changed to the following on Page 14, Lines 441-444. ‘The findings of this review highlight the need for HCPs to consider the implications that a GDM diagnosis may have on a women and to ensure that those women receive consistent evidence-based information and ongoing psychological and social support.’

Some minor remarks:

2) "...BGL threshold associated with the risk of adverse infant outcomes (such as risk of macrosomia, excess infant adiposity and neonatal hyperinsulinemia)". The cutoff was actually set according the ORs for LGA and not for other risks. Please amend.

Response: A combination of the primary outcomes of the HAPO study data were used as the basis for the GDM definition recommended by the International Association of Diabetes and Pregnancy Groups (IADPSG). The IADPSG recommended definition of GDM is based on a 1.75 odds of the risk of multiple adverse perinatal outcomes based on the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study [1].

Change: No changes have been made.

3) "There is currently no globally accepted testing or diagnostic process…” - this sentence seems to be a redundant repetition. I suggest to omit it.

Response: We agree that this sentence does not add to the existing paragraph.

Change: We have now omitted this sentence from Page 3.

4) "...which led to the anomalous position that two women in two countries with exactly the same glucose levels may or may not be...." - I fail to see how this is relevant to your study, as its scope is not the methods to diagnose GDM. Many health-related differences exist between countries.

Response: We believe that between country variation is important. The studies included in our review had participants of varying cultures sampled from countries with different GDM definitions. However, there appeared no difference in the qualitative outcomes between studies/countries. In our review, the experiences of women diagnosed with GDM suggest psychosocial harms appear to outweigh the qualitative benefits and quantitative studies that report prevalence changes in GDM when the definition change [2,3] report minimal change to maternal and infant physical outcomes.
Change: To explain our findings in relation to the country differences described in the sentence you reference in the Introduction, we have now added the above explanation to the discussion on P12, Line 376-381. “The studies included in our review had participants of varying cultures sampled from countries with different GDM definitions. However, there appeared no difference in the qualitative outcomes between studies/countries. In our review, the experiences of women diagnosed with GDM suggest psychosocial harms appear to outweigh the qualitative benefits and quantitative studies that report prevalence changes in GDM when the definition change [72,73] report minimal change to maternal and infant physical outcomes.”

5) Please explain: “included pregnant women awaiting GDM screening or women with a current diagnosis or history of GDM” - it seems that awaiting GDM screening and History of GDM is not an appropriate inclusion criteria - rather only those with a diagnosis of GDM should be included

Response: Thank you for the careful reading and highlighting this inconsistency. The initial version of the protocol stated this inclusion criteria, however, the research group subsequently agreed that the review should only contain studies that included women with a diagnosis of GDM. The text from the initial protocol used to draft this paper was not updated which explains the error.

Change: We have now removed ‘pregnant women awaiting GDM screening’ and the criterion on Page 4, Line 107 now reads ‘Included pregnant women with a current diagnosis or women with a history of GDM’

Giovana Vesentini (Reviewer 3): This manuscript is a systematic review of papers investigating the psychosocial experiences of the diagnosis of gestational diabetes on women during pregnancy and postpartum period. There is a wide range of studies considering the risk of GDM for both mother and newborn, however, it’s very important to consider the psychosocial consequences for this population.

The authors have been very attentive for the other reviewer comments and I believe the manuscript is much clearer now. However, I have minor comments for the manuscript:

Background:

1) Please correct the definition of gestational diabetes (page 3 line 1): elevated blood glucose with onset during pregnancy;

Response: Thank you, we have made that change
Change: Page 3 lines 50-52 now read “Gestational diabetes mellitus (GDM) is diagnosed by elevated blood glucose with onset during pregnancy though the definition has changed repeatedly since its first description in the 1960’s. [1, 2]”

2) Add reference for the first and second sentence of the background

Change: We have added three references to support these two sentences.

3) In the objective, the authors state: ".... we aim to synthesise the evidence on the psychosocial experiences a diagnosis of GDM has on women and their families during pregnancy" How they evaluated the families experiences? I suggest delete "families".

Response: The findings of the review do include some experiences relating to family members such as communication, family support and the impact that changes in diet and lifestyle healthy eating had on other family members. However, we agree that the focus is on the women with no direct reports from family members.

Change: We have now removed the word ‘families’ on Page 4, Line 101.

Methods

4) Please state if the authors used any software during the selection of studies.

Response: We have now added the software that was used to manage the references and used during the selection process.

Change: Page 5, Line 129-130 is now as follows – ‘A single reviewer (LC) screened the titles and abstracts of retrieved references using Endnote Version X7.7.1’

Discussion

5) page 13 line 379 the population of the included studies are women of different demographic characteristics. However, the majority of included studies are from high-income countries. This limitation should be addressed in this section.

Response: Thank you for highlighting this limitation.
Change: We have now incorporated the following into the limitation section on Page 13, Lines 416-419 – “Furthermore, although the data were collected from diverse populations the majority of the countries in which research were conducted in were high-income countries which could be considered to have more established and evidence-based healthcare systems than low-income countries.”

6) Figure 1: The numbers of the PRISMA flowchart don't match, please check the number of full-text assessed for eligibility (records screened - records excluded = 87). Please add the overall number of full-text excluded.

Response: Thank you for highlighting this error.

Change: We have reviewed our Endnote database and have corrected the records excluded to n=701 not n=702. Therefore, the numbers now add up i.e. 789-701=88

7) Strong point of this paper is a very good methodological approach. Topic is original with a high number of included studies for the qualitative synthesis. Selection of papers appears appropriate, quality assessment and qualitative synthesis are complete. Conclusions can be useful for clinical practice.

Response: Thank you

Pantaleo Greco, MD (Reviewer 4):

1) Abstract/ Background: sentence: "The aim of this qualitative systematic review was to identify the psychosocial experiences a diagnosis of GDM has on women during pregnancy and the postpartum period". Instead of "has" I would rather use the word "causes".

Response: Thank you for your suggestion. We would prefer not to use the word cause which infers causation which we cannot infer. The terms causation and association are terms not readily used in qualitative/experiential data.

Change: No changes have been made.

2) Abstract/Results: sentence: "Women commented about the added responsibility (eating regimens, appointments), financial constraints (expensive food, medical bills) and conflicts with their cultural (alternative eating, lack of information about traditional food)". Instead of "cultural" I would use "culture".
Response: Thank you.

Change: We have now changed the word cultural to “culture practices” on Page 2, Line 39.

3) Background. Pag.3 row 59: sentence "ill-health and increased surveillance". I would rather write "ill-health and requiring increased surveillance".

Response: We believe that adding the word ‘requiring’ provides a sense that surveillance is needed whilst this is contrary to the initial point regarding that pregnancy is a natural process.

Change: No changes have been made.

4) Background. Pag.3 row 64-65: sentence "Some of this is due to the increasing age of women becoming pregnant, more women being overweight, more testing, and better recording.". Please rewrite this sentence more clearly.

Response: Thank you for highlighting that this sentence is unclear.

Change: We have now changed this sentence to the following – ‘Some of this is due to the increasing age at which women are becoming pregnant, an increase in overweight and obesity amongst women, more testing during pregnancy, and better recording during pregnancy.’ (page 3, lines 78-80)

5) Background. Pag.3-4 row 66 to 71: sentence "However, much of the rise has occurred since 2013 when some countries adopted the new IADPSG criteria and testing regimen for gestational diabetes, which led to the anomalous position that two women in two countries with exactly the same glucose levels may or may not be diagnosed with GDM depending on the country's definition, greatly altering the pregnancy experience. Caution was raised that the new IADPSG definition would increase prevalence of women diagnosed with GDM by two-to-three-fold.". Please rewrite the sentence to make it clearer.

Response: Thank you for the suggestion.
Change: This section has been divided into shorter sentences to make clearer. Page 3-4, Lines 80-86 now read -‘However, much of the rise has occurred since 2013 when some countries adopted the new International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria and testing regimen for gestational diabetes. This resulted in the anomalous position that two women in two countries with exactly the same glucose levels may or may not be diagnosed with GDM depending on the country’s definition. Caution had been previously raised that the new IADPSG definition would increase prevalence of women diagnosed with GDM by two-to-three-fold.[17]’

6) Results. Pag 7 row 169 to 170: sentence "As the purpose of all the studies was to explore or gain knowledge levels, opinions or attitudes about GDM the qualitative methods that were employed in all the studies was appropriate". Instead of "was appropriate" I would use "were appropriate".

Response: Thank you.

Change: We have made this change.

7) Results. Pag 8 row 218: sentence "Some women stated that they would have preferred to have been more prepared to have received the diagnosis and have early knowledge about the testing for diabetes.". I would rather write "Some women stated that they would have preferred to be more prepared to receive the diagnosis and have early knowledge about the testing for diabetes."

Response: Thank you for your suggestion.

Change: We have now incorporated your suggested change and the sentence on Page 8, Line 231-233 now reads- ‘Some women stated that they would have preferred to be more prepared to receive the diagnosis and have early knowledge about the testing for diabetes’

8) Results. Pag 9 row 260-261: sentence "Women prioritised the health of the baby and were willing to do anything so as not to comprise that, with women reporting that the baby's health took precedence over their own." Please rewrite this sentence in a clearer way.

Response: Thank you for highlighting that this sentence is unclear.

Change: We have now re-written this on Page 9, Line to 274-275 ‘Women prioritised the health of the baby over their own health and were willing to do anything to ensure that the health of their baby was not compromised.’
9) Discussion. Pag 12 row 360: sentence "seems to dissipate after birth most likely due to the driver to protect their unborn child is no longer there." Please rewrite this part of the sentence.

Response: We have made a minor change to this sentence which we believe improves readability.

Change: Page 12, Line 374 now reads - ‘dissipate after birth possibly because the driver to protect their unborn child is no longer there’.

10) Conclusion: in the conclusions of this study the Authors suggest that, considering the rising incidence of GDM and the "potential minimal clinical improvements" and on the other hand the range of psychosocial experiences identified in the study, HCPs might reconsider the current definition of GDM. In my opinion this conclusion is maybe not completely fitting in this kind of study. Considering that this review focused on the psychosocial aspects of GDM and not on its maternal and fetal medical complications, I would focus the conclusions on the improvements that should be achieved in psychological and social management and in counselling rather than on changes in GDM definition and diagnostic criteria.

Response: Thank you for this insight and in light of reviewer 1’s similar comment about the focus on the conclusions we have made the appropriate changes.

Change: The conclusion on Page 14, Lines 441-444 have now been changed to the following – “The findings of this review highlight the need for HCPs to consider the implications that a GDM diagnosis may have on a women and to ensure that those women receive consistent evidence-based information and ongoing psychological and social support”

11) I think it should be more emphasized the fact that the population in exam is not homogeneous, as the studies considered in this review have samples from many populations which differ in ethnicity, habits, BMI, etc… and this kind of differences have a strong impact on blood glucose values, required dietary changes and GDM consequences in later life.

Response: In response to Reviewer 3’s comment we have highlighted the diversity of populations included in the study. However, we can make no inferences on dietary changes due to differences of blood glucose levels in women as these are unknown.

Change: Page 13 Lines 416-419, “Furthermore, although the data were collected from diverse populations the majority of the countries in which research were conducted in were high-income countries which could be considered to have more established and evidence-based healthcare systems than low-income countries.”
12) I suggest a review of the English from an English-speaking language reviewer.

Response: Thank you. We acknowledge some grammatical errors which have been corrected.

Kimberly Kovach Trout, PhD (Reviewer 5): The current edited version heeded the comments of the previous reviewers. The resultant manuscript is an excellent contribution to the literature concerning women's psychosocial experiences of receiving a GDM diagnosis if some substantive changes are made.

Response: Thank you for the kind compliment.

1) There is a clear bias exhibited by the authors against the clinical utility of the diagnosis and treatment of GDM, despite evidence from multicenter trials that support the benefits of treating even "mild" forms of GDM (the ACHOIS study by Crowther, et al.; the MFMU network study in the US, etc.). These were well-executed randomized controlled trials and yet, the authors of this manuscript counter such evidence with citations of "pre/post studies" (a very weak research design) and a qualitative report of 19 women who viewed "treatment for their borderline condition 'unnecessary". I am not saying that the views of the women from this citation are not important, but such qualitative data does not support the refutation of quantitative outcome studies; rather, the objectives of such a qualitative study are completely different.

Response: We believe that we have reported these findings transparently and in context of the level of evidence that the findings are based upon i.e. pre/post design and qualitative design. The randomised controlled trial that you refer to evaluates interventions for women with a diagnosis of GDM which is not within the scope of our review. However, we are agree our conclusion had drifted from the scope of the study and we have made changes to ameliorate this.

Change: We have amended the conclusion of this paper to more closely align with the aims of the systematic review. Page 14 Lines 441-444, now read “The findings of this review highlight the need for HCPs to consider the implications that a GDM diagnosis may have on a women and to ensure that those women receive consistent evidence-based information and ongoing psychological and social support.”
2) The qualitative synthesis performed by the authors is very well done, with the exception of conclusions made that are not warranted by the qualitative data. The authors state conclusions concerning methods of diagnosis and manner of treatment that is NOT the focus of this study. If they would stick to the focus of their study and make conclusions based on this focus, this manuscript would be well worth publishing. In the conclusion, they cite outdated literature (for example, Goer, 1996) that is not original research or even from a journal that is peer-reviewed. If the authors would stick to making conclusions about their own data, this article has great potential.

Response: Thank you. We agree that our conclusion should be based directly on the findings of our study and have made these changes as described previously.

Change: The conclusion has now been changed on Page 14, Lines 441-444.

References:

