Author's response to reviews

Title: The development and application of a new tool to assess the adequacy of antenatal care based on content and timing of care.

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Author's response to reviews: see over
We would like to thank the reviewers for their extensive reading and detailed suggestions. We are grateful for their critical and interesting comments and remarks.

We ordered the comments into the major, minor and discretionary revisions. First the comments of reviewer one are considered, followed by those made by reviewer two. The questions and comments are repeated in black and our answer is written underneath, in blue.

**REVIEWER 1:**

**Major Compulsory Revisions**

**R1.1** In general I found the paper a little confusing. I think it would help if you more clearly articulated which part of your program of work this particular paper addresses.

- For example in the abstract the following statement could be used – second sentence; This study builds on previous work by further refining a tool that considers both the content and timing of antenatal care. The conceptualisation of the CTP tool has not been described before. Our pilot study was used as training set to test the algorithm of the tool. As we did not report the pilot study in a previous paper due to the very low number of women included (n=102), we think it is difficult to talk about previous work as we cannot refer to this. Therefore we’re under the impression that we can speak about ‘development’ in this paper, because we describe for the first time how we developed the tool.

- This issue also leads onto a query I have about how you have used the word ‘conceptualisation’. Using it as you have, for example in the title, suggests that the study is perhaps a literature review that has, as an end point, a recommended design for a new tool. However you have gone much further than this – this paper is refining an already developed tool that has undergone some initial testing. Or is this incorrect? Indeed the pilot study was used as training set. In line with our answer to the previous comment, we can say that the subject of this paper is to describe the steps we made to develop the tool and that we apply it on our study sample and compare it with a currently used index. Therefore we suggest to use the word ‘development’ instead of ‘conceptualisation’ in the title and add the word ‘application’ to the title, referring to the use of the tool in our final sample. We suggest the following title: ‘The development and application of a new tool to assess the adequacy of antenatal care based on content and timing of care.’

- The heading Methods on page 5 should be removed. This section should be incorporated into your introduction. When explaining our tool development, we aimed to describe the method we used to construct the tool. Hence, we believe that the description of the tool development is part of the ‘Methods’ and should be incorporated in the Method’s section. We took other articles in BMC Health Services Research as examples. Other articles that describe the development of new tools in BMC Health Services Research also start the Method’s section with a description of the ‘tool development’. By doing so, the structure of our paper is conform current practice in the journal.

Examples we found are: BMC Health Services Research 2009, 9:234 / 2009, 9:142/ 2008, 8:172

http://www.biomedcentral.com/content/pdf/1472-6963-9-234.pdf
- Clearly write aim of the study outlined in this paper. There is confusion with what this study is doing as opposed to the earlier pilot work - referenced to 46

Where you have made reference to the first study then stated (method see data collection) – this should actually be referenced to your first publication – reference 46

Reference 46 does not refer to our pilot study that was used as training set to test the algorithm of the CTP tool. Ref 46 describes the method of data collection we used and therefore was mentioned here. At no point Ref 46 describes content of care received in pregnancy or the CTP tool. This study only concludes that such a tool is necessary. We decided not to refer to the previous study to explain the data collection, first in order to avoid any confusion and second, because reviewer two asked to document in detail the method we used instead of referring to a previous publication.

R1.2 Heading - Conceptualisation of content and timing of care pregnancy tool (CTP)

As stated this section does not really make sense to me.

You seem to be saying that the CTP was designed in another study? Or do you mean that the tool was conceptualised as a result of this first study into care received during pregnancy? The conceptualisation of the CTP tool is a result of our findings that no tool existed to measure content of care in pregnancy. We developed the tool as a result of this finding. We did a pilot study to test our method of data collection on care during pregnancy (In Belgium no routine information about care in pregnancy existed).The pilot study was also used as training set to test our algorithm.

Besides describing the development of our tool, the aim of the manuscript was to apply the CTP tool on data about antenatal care use gathered in our main study.

- Selection of indicators – 4th paragraph – the phrase ‘between countries’ needs clarification – which countries? We focused on European countries that provide recommendations for routine antenatal care as well as on the American guidelines and those from the World Health Organization. We provided these details in our text, we changed the sentence as follows: ‘To check if these components had widespread support as effective components of antenatal care, we looked at differences in current practices between European countries as well as the recommendations of the World Health Organisation and American guidelines.’ P7

- The phrase ‘the procedure of conceptualisation of the CTP tool included 3 dimensions..’ does not make sense and is not linked to the above paragraph? Should it be something like...
The next step was to detail the classification system. Based on ?????... Three categories were chosen, inadequate, intermediate and sufficient.... you then need to define these much more clearly for the reader. This is really important given the results are all about these classifications.

3rd paragraph under this heading (page 8) the sentence commence ‘A woman is followed sufficiently.... doesn’t make sense.

This paragraph was re-written in order to make more clear how the CTP was composed providing insight in the reasoning that was followed. We refer to p8 and 9

Furthermore in order to clearify the differences between the four categories, we added the definition for each category to figure one that provides a schematic overview.

R1.3 Heading Data Collection page 8 - The heading ‘Methods’ should precede this Then you need the sentence. ‘We conducted a prospective observational study...’

- This needs to be followed by text under the following headings

  Setting /Participants /Recruitment procedure / Data collection/ Data analysis /Ethical considerations

- The statement ‘data were analysed with SPSS 17.0' is not sufficient. You need to detail your analysis of the data. For example Chi analysis etc.

This section was completely re-written taking into account the considerations. We refer to p10/11 in our manuscript.

R1.4 RESULTS – Comparison (page 10)

- APNCU categories need defining earlier in the paper. Then here you can talk about the differences

  After the composition of CTP is explained, we address the categories of the APNCU index.

- Consider the use of tables to present some of the results

  We made the description of the results in the Results section shorter, as they are presented in the table.

R1.5 DISCUSSION

From my reading of the paper it appears that this work is about ‘refining’ / testing?? a tool that attempts to account for content and timing of care rather than visits alone? Does this by comparing the new tool to the APNCU index????
Yes indeed, the APNCU index only considers the number of visits, corrected for gestational age. Both measures have the same structure (4 category ordinal scale) and both measure the adequacy of the antenatal care trajectory. Therefore they lent to be compared.

- Re over consumption of care – yes refining necessary but perhaps also need to make comment about the high number of US as an example? Do you think tools of this nature might actually perpetuate over use of technologies that should only be used after assessment of the woman’s individual situation needs?

Taking into account woman’s individual situation needs would be the ideal. It can be suggested to provide a risk assessment score that could be taken into account to evaluate overconsumption.

In order to provide an answer to this comment, we added the following text and example on p15/16:

... Although the tool does account for the adverse effect of overprovision of some aspects of care when there is underprovision of other aspects (in the second iteration of the process) it does not yet account for overuse where other aspects are provided at the minimum level. This aspect would also need to be calibrated against clinical need for higher risk women. In our study for example, half of the women received at least five ultrasounds, while recommendations for evidence based practice only advise two ultrasounds. A risk assessment score could be introduced to further fine-tune the CTP tool... ...

Minor essential revisions

R1.6 Referencing inconsistency also need attention.

We checked all references and provided consistency eg p 6 and 15

R1.7 Please consider defining / or clarifying the phrase ‘follow-up pregnancy’ or perhaps whether this term is most suitable. I’m presuming you mean ‘ongoing antenatal care’.

Yes we agree with the term ‘ongoing antenatal care’ instead of ‘follow-up’.

R1.8 Introduction: 3rd paragraph, 3rd sentence... replace ‘will’ with ‘are likely to..’

We agree with this remark and changed the phrasing

R1.9 Selection of indicators

- 1st paragraph – last sentence – replace the 1st ‘better’ with ‘superior’ and the second with ‘carefully monitoring blood pressure improves the diagnosis and successful treatment of preeclampsia. We agree that rephrasing this sentence improves the quality of it

- 4th paragraph – try ‘In addition to accounting for....’ Rtehr than ‘besides taking into account...’ This part of the text was re-written
- 5th paragraph – 1st sentence too long. Full stop after ‘US screening. Then ‘This was based on...’ This part of the text was completely re-written.

- 5th paragraph – 2nd last sentence - clarify phrase ‘the tool in the study was...’ what study? This part of the text was completely re-written.

R1.10 Be mindful of your language – for example 3rd paragraph under the conceptualisation heading (page 8) – please consider using ‘Women are classified to the ‘appropriate category’ where they have received ...This section has been completely re-written

R1.11 Page 12 – ‘Women assigned to the APNCU categories of....’ This has been changed

R1.12

- Conclusion – 1st sentence – replace ‘obviously’ with ‘appears to have..” We changed this in line with the suggestion

- Wording - Make a different to the health and wellbeing of childbearing women and their offspring We adjusted this sentence in our text.

Discretionary Revisions

R1.13 Abstract: you have stated that the CTP comprises four categories and reflects care that is needed in ‘every’ pregnancy (my emphasis). I guess I’m asking you to consider your language here and in the rest of the paper – for example does every woman ‘need’ an ultrasound? There would be many healthy pregnant women who would not consider an ultrasound particularly necessary or needed! Certainly having nearly 6 U/S in a healthy pregnancy is a terrible waste of resources and not evidenced based practice. This issue if also worthy of some debate perhaps in your discussion.

We agree with this comment. Therefore we changed the phrasing in the abstract into ‘recommended’ instead of ‘need’. We changed this throughout our manuscript.

The issue of overuse of care is considered in the discussion part, I refer to comment 1.5.

REVIEWER 2:

Major Compulsory Revisions

R2.1 Many sections of this paper, and in particular the discussion, are written very well, are clear, coherent, and easy to understand. However, I struggled with the abstract and found it unclear and poorly representative of the work later described in the paper.

In order to clarify the abstract, it was re-written.
The aim of the study is unclear. The aim is stated as providing ‘a first step in the development of a more refined tool in which content and timing of antenatal care are considered.’ What is this first step specifically? That is likely to identify more precisely the aim of the study. The authors mention the development of ‘a first classification system reflecting content of care’. Clarity is needed on what this is and how it is developed. Later it is stated that ‘The Content and Timing of care during Pregnancy tool (CTP) was designed in a pilot study prior to this study’ suggesting that the instrument was already designed. The discussion notes that ‘In this study we attempted to develop a tool for assessing antenatal care use’. To me, the study is about comparing two instruments measuring aspects (and perhaps different constructs) of antenatal care. If this is the case, or whatever might be the case, the paper needs to be revised throughout to reflect the aim.

We described the aim of our manuscript more precisely, avoiding confusion with the pilot study to which we referred in the manuscript. In this way we believe that the aim of our study is clear for the reader.

For both reviewers the reference to our pilot study seems to create confusion about our instrument. We interpret their comments as they were under the impression that the instrument would already have been designed earlier. This however is incorrect. We provide some more details about the pilot study for clarification. As no data on antenatal care is routinely collected in Belgium, we needed to test our method of prospective data collection in a pilot study. Due to the rather small sample (n=102) we did not publish these data. As the evaluation of the method of data collection was positive we used the data training set to initially test the algorithm of the CTP tool.

We have the idea that mentioning the pilot study as we did in the original version, leads to confusion and hinders the intelligibility of the manuscript. Therefore we decided to restructure the paper and to refer to the pilot study in the data-collection section where we describe the aim of the pilot study (testing the method of data collection and use this as training set for our algorithm); By doing so, the aim of this study is more clear and the construction of the manuscript is made more logical and in line with the journal’s guidelines. (see remark 3 of reviewer one)

Minor essential revisions

R2.3. Further justification of the importance of measuring beyond the frequency and timing of antenatal care consultations would be helpful.

We added the next sentences in the background section: ...Furthermore, there is no consensus about the quantity of care a woman should receive [20], especially because one can receive the same content of care in a smaller number of visits [21].

R2.4. Section ‘Selection of indicators to measure content of antenatal care’ jumps from discussing weight gain to screening for diabetes and preeclampsia and back to weight gain again in terms of international practice/recommendations. This reads rather disjointedly. I suggest that all components of each specific indicator e.g. weight gain are addressed together and separately for each indicator.
The conceptualisation of our CTP tool is based on two major steps: analyses of the evidence of the clinical importance of different interventions during the routine antenatal care and secondly on the how these routine interventions are recommended in different guidelines. To make these two steps clear to the reader, we decided to describe each step in a separate paragraph. We added a brief introductionairy sentence to make distinction in both steps.

This part of the text was re-written starting on p6 of the manuscript

‘ In order to decide which elements of content of care should be considered, we determined that they needed to be easily and unambiguously identifiable and measurable, and based on the existing evidence for the clinical components of antenatal care that are currently used in many countries and settings. To assess the latter, we looked at the evidence for the following commonly used measures and interventions in pregnancy: ......’

And P7

.... To check if these components had widespread support as effective components of antenatal care, we looked at differences in current guidelines between European countries as well as the recommendations of the World Health Organisation and American guidelines....

R2.5. States that the ‘procedure of the conceptualisation of the CTP tool includes three dimensions...’

Clarity is needed as to how this conceptualisation was arrived at (i.e. the procedure). I found it difficult to understand the schema in figure 1 and its narrative in the text (p.7-8). This needs to be clearer and would be helped I think by giving examples from practice and how women might map to the schema given.

This section was completely re-written, (cfr comment 2.2) explaining more in detail the reasoning behind the composition of the tool and providing some examples in the text. Figure one was adapted in order to make it more understandable.

R2.6. Data collection states ‘we conducted a prospective observational study in nine out of eleven medical centres that provide antenatal care in the Brussels Metropolitan Region’. What was the purpose of this study? How does this link with the intended aim of the paper? (I am assuming that whatever this study seeks to do is the overall paper aim).

The purpose of the study was to provide insight in the differences in antenatal care trajectories women have. In order to say something about the adequacy of the care trajectories, detailed data on antenatal care use was needed. In this way the conceptualised CTP tool could be applied and compared with the APNCU index. (which indeed is the overall aim of the paper)

We started the description of the data collection in the method’s section as follows: ‘In order to map antenatal care use, a prospective observational study was conducted in nine out of eleven...’ to make this clearer

R2.7. It would be helpful if inclusion criteria (referred to as given previously in another paper) were synopsised here.

We described all the inclusion criteria in the method section.
R2.8. States ‘For each visit the women were asked to document received health care during their pregnancy by answering the six same multiple choice questions as described for the pilot study.’ It would helpful to explain what this consisted of.

The explanation about the questions we asked was incorporated in the methods section. In this way all information about data collection is pooled and will make things clear.

R2.9. Further justification of decision to focus instrument on blood pressure, blood screening, and ultrasound screening beyond guidelines recommending their use would be helpful.

This part was re-written. The last paragraph on p 8 provides background about our decision of the selection of elements to be incorporated in our tool.

‘The previous steps indicted that, despite being nominally based on current best evidence, many of the guidelines did not agree with each other. However, after weighing up the clinical evidence and the guideline recommendation congruence, we confirmed the decision to focus on blood pressure (BP), blood screening (BS) and ultrasound screening (US) as valid clinical components for the first iteration of the CTP. We are aware that future iterations of the tool will require a further scrutiny of this evidence, and that this future work would benefit from consensus methods such as a Delphi study among relevant stakeholders. This study is designed to test the feasibility of using such a tool in principle, before undertaking these refinements in future.’

R2.10. Please explain what is meant by the following sentence ‘In order to compare the CTP classification with the APNCU index, we adapted the number of antenatal visits for a given gestational age to the Belgian guidelines.’ I think this may mean that the APNCU was adapted from the number of visits recommended by the ACOG to the recommended number of visits within Belgian guidelines.

The reviewers interpretation is correct. We changed the phrasing in our text accordingly.

R2.11. It would be helpful is there was further clarity on which instrument was being referred to in sentence beginning ‘2.4% of the women were followed inadequately....’

We agree with this comment and made this clearer in the text.

Discretionary Revisions

R2.12 Given the purpose of the study, consider replacing ‘a more refined tool’ with ‘a more comprehensive tool’.

We followed this suggestion and replaced ‘refined’ with ‘comprehensive’.
R2.13. Stated in methods that ‘The aim of our tool is to reflect a minimum care package needed in every pregnancy, regardless of parity or risk status.’ This reads more as a desire to create consensus or best practice around the content and timing of antenatal care, which is different to creating an instrument to measure its presence or absence.

We indeed wanted to create an instrument to measure presence of a minimal care package, recommended in every pregnancy. Based on the existing evidence we developed the CTP tool. The algorithm enables to classify women into one of the four categories evaluating if minimal recommended care was provided or not.

In order to avoid confusion we changed the sentence into: The tool aims to reflect if women received a minimum care package recommended in every pregnancy, regardless of parity or risk status (p8)

14. There are a number of sentences/sub sentences that are somewhat cumbersome. I think the authors may wish to consider rewriting: These are:

a. The selection of indicators to form a new tool (Content and Timing of care in Pregnancy (CTP)) is based on clinical relevance to follow-up pregnancy and recommendations in international guidelines.

b. Bimonthly follow-up was foreseen to record all the received interventions.

c. The existing Adequacy of Prenatal Care Index (APNCU) as well as the proposed CTP tool were applied and compared.

d. Antenatal care use of 333 pregnant women was registered.

e. The new timing of care element was particularly influential in the distribution between the CTP categories.

f. An ultrasound scan in the second trimester (18 to 23 weeks) is effective to detect structural anomalies [27-29].

g. Visits to other than the regular health care provider in the hospital are not registered in the antenatal records.

As the abstract was re-written, sentences A to E have changed. In sentence F, we added the word ‘method’ and G was removed.