Author's response to reviews

Title: Cost Analysis of the Dutch Obstetric System: Home birth compared to short-stay hospital birth - a prospective non-randomised controlled study

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Author's response to reviews: see over
We would like to thank the reviewers for their valuable comments. We found the comments important and useful for the revision of our manuscript. They encouraged us to take another critical look at the presentation and meaning of our results, and to elaborate our discussion and conclusions.

We also adjusted the title of our manuscript. The new title of our manuscript is:
Cost Analysis of the Dutch Obstetric System: low-risk nulliparous women preferring home or short-stay hospital birth - a prospective non-randomised controlled study

Below, we explain how we responded to the reviewers’ comments. The changes in the text are highlighted.
Comments Reviewer Wendy Christiaens:

Reviewer’s report: Minor Revisions
1. Title and abstract
Perhaps Methods should be described with a little more detail in the abstract. First sentence of the Results section of the abstract “…. were transferred to the hospital to an obstetrician.” Could be formulated in a better way.

Response 1.1
We agree with the reviewer and we described the Methods in the abstract in more detail and we revised and updated the sentence (see page 2;12-14).

2. Background
In the background section the authors describe the maternity care system in the Netherlands and argue why the estimation of costs adds to the existing literature.

3. Methods
Methods are described in a proper way. Although a rather complex methodology is used, the authors succeed in making it transparent to the reader. The same accounts for the results section. Sample: “… with independent midwives participated in recruiting the study population.” In my view, study population is not the right wording. Rather ‘respondents” or ‘sample’ are in place. (see also title of table 3).

Response 1.2
We revised these words in the text and the table (see page 8;13).

4. Results

5. Discussion
The most relevant shortcomings are mentioned in the discussion. However some points should be addressed more explicitly. For example the limitations of means substitution are not really mentioned. Also, what about generalisability? Were the 100 midwifery practices selected at random? Authors say “recruitment for the study took place on a national level” (in the Method section), but what does this mean? Does this mean the results are representative for Dutch women intending to give birth at home or with a short stay?

Response 1.3
We added extra information about the recruitment and the consequences for generalisation of the results.

Changes made to the text (page 17;18-21):
The results of this study are representative for the Dutch women intending to give birth at home or in a short-stay hospital setting. One hundred midwives from across the Netherlands were selected at random and participated in the recruitment of the respondents.

In the discussion, authors do not mention policy implications, or implications for the organization of Dutch maternity care. What do the findings mean in the light of the recent tendencies in Dutch maternity care (e.g. declining home births)?

Response 1.4
In the discussion, we added some implications for policy and the organization of the Dutch maternity care (see page 15;10-20)

In general this manuscript offers valuable new information about the Dutch maternity care system. It is well-written and structured in an adequate way.
Comments Reviewer Therese Wiegers:

In general:
1. Maternity care is generally regarded as all care concerning pregnancy, childbirth and the postpartum period. However, the authors use the term ‘maternity care’ as a translation of the Dutch word ‘kraamzorg’. That is not correct. ‘Kraamzorg’ is better translated as ‘maternity care assistance’ or MCA.

Response 2.1
We changed the term ‘maternity care’ in ‘maternity care assistance’, where appropriate.

2. Report of parturition is not a term I am familiar with. I suppose the (LVR-)birth registration form, used by midwives (LVR-1) or by obstetricians (LVR-2) is meant, and not the birth narrative that midwives usually write down in their own dossiers.

Response 2.2
We agree with the reviewer and we changed this in the text.

Step-by-step:
Title
3. You may have set out to compare the costs of home birth and short-stay hospital birth, but what you actually are comparing is preferred home birth with preferred short-stay hospital birth, and that only for nulliparous women, with no pre-existing risk of complications.

Response 2.3
We changed the title of our manuscript into: Cost Analysis of the Dutch Obstetric System: low-risk nulliparous women preferring home or short-stay hospital birth - a prospective non-randomised controlled study.

Abstract
4. The fact that only nulliparous women are included in the study should be mentioned in the abstract.

Response 2.4
We added some extra information in the abstract about the study population, (see page 2;11)

Background
5. Where does the 18% homebirth rate for nulliparae come from? In 2002 that was 32% (TNO-report ‘De thuisbevalling in Nederland 1995-2002’) As far as I know there are no more recent data, because data about birth place are not included in the PRN reports, see [5] and CBS-data on place of birth do not include parity.

Response 2.5
We received this information from the SPRN. So we added a reference (page 4;9).

6. Perinatal mortality rate (page 4 of the pdf) is incorrectly described as mortality rate between 7 days and 22 weeks postpartum, this should be: between 22 weeks of pregnancy and 7 days postpartum. The next sentence is not true, because there are data about 2006: perinatal mortality rate was 9.8%, see [5].

Response 2.6
We agree with the reviewer and we changed this in the text, see page 5;3

7. The reference (Ravelli, 2008) is not included in the reference list.

Response 2.7
We revised the text and we did not use this reference any more. We omitted this reference.
8. At the top of page 5 of the pdf is stated that the costs of home births are expected to be much lower than those of short-stay hospital births. Can you elaborate on that?

Response 2.8
We provided some extra information and references and explained this further.

Changes made to the text (page 5:6-8):
Because short-stay hospital births are known with higher referral rates to the obstetrician during delivery [12-15], it can be expected that this is associated with higher societal costs.

9. In the next paragraph maternity care in the hospital is mentioned. It is not clear to me what exactly you mean by that. Are you referring to a hospital birth, followed by a hospital stay for several days, or are you referring to the postpartum hospital stay only?

Response 2.9
We meant a hospital birth in secondary care. We revised this in the text, page 5:12

10. I would appreciate, here, in the background part of the text, more information about societal costs. Please explain what is included and what is not included in the term ‘societal costs’ and subsequently in the analyses for this article.

Response 2.10
We agreed with the reviewer and we added some extra information about the term ‘societal costs’.

Changes made to the text (page 5:19-23):
A cost analysis from a societal perspective gives insight in the costs of a treatment for the society. This means that not only the health care costs (i.e. costs of care givers, medication and hospitalisation) are included, but also the costs of patients (i.e. out-of-pocket costs, travel expenses), their family (i.e. informal care) and other non health care costs (i.e. productivity losses) [24].

11. The last two sentences here are too much alike, I would suggest you rephrase one of them.

Response 2.11
We rephrased these sentences, page 5:24.

Changes made to the text (page 5:24):
This study sets out to investigate the differences in costs from a societal perspective between low-risk nulliparae preferring to give birth at home and low-risk nulliparae preferring to give birth in a short-stay hospital setting.

Methods
12. It is not clear to me what the difference is between the second step (defining cost categories) and the third step (determine the resources) and I would like to have more information about the different cost categories. For example: what family costs will be taken into account? What are extra costs, made by respondents?

Response 2.12
We explained the difference between the second and third step better and we added some information about the different cost categories and we gave some examples.

Changes made to the text (page 6:16-20):
Contacts with health care professionals, medication, maternity care assistance, medical interventions during delivery, pain control, and hospitalisation were identified as health care costs. Patient and family costs (i.e. informal care during pregnancy and postpartum period), transportation costs, and extra costs made by responders (i.e. costs for antenatal classes) were identified as non health care costs.
13. Preference for place of birth is asked at 16 weeks pregnancy. That is very early. I assume that many women, especially nulliparae, will not yet have made a real choice at that moment, and I would like to know how many of the respondents indicated they had not made up their mind yet.

Response 2.13
None of the respondents had not made up their mind. But we asked the preferred place of birth again in the second questionnaire. So, it can be that some women changed their mind. For this analysis we used the preferences given in questionnaire 1.

Changes made to the text: none

14. I would like more information about the way unit prices for midwifery care were calculated. Primary care midwives receive fixed prices for antenatal, natal and postnatal care, regardless of the time they spend with each client or the number of consultations, but the analyses are based on the number and the length of contacts.

Response 2.14
There is an important difference between price (which is a payment) and actual costs of care. To reflect real opportunity costs we focussed on actual time spend and using a shadow price per hour, thus going beyond a less specific method, using a payment price as mentioned by the reviewer. Using a societal perspective, as in our study, makes it necessary to refrain from using general prices. We received the unit prices of the midwifery care from the Royal Dutch Organization of Midwives. We are familiar with the fixed prices for the midwifery care, but the prices we used are based on price per hour. The cost diary gave us the information about the duration of the contacts.

15. Reference (CBS, 2008) is not included in the reference list.

Response 2.15
We included this reference in the reference list, page 7;24.

16. Sample: here is the first and only place in the text where is mentioned that only nulliparous women are included. There is no information on when the study took place, or whether recruitment was easy or not. How many women were asked and how many declined to participate?

Response 2.16
We agree with the reviewer about the lack of information about the recruitment process. We provided some additional information. However, given the fact that so many care providers were involved in finding couples who were willing to participate in the study, we do not know the exact number of women who where asked but declined to participate.

Changes made to the text (page 8;12,15-16):
Recruitment for the study took place on a national level; 100 practices with independent midwives from across the Netherlands were selected at random and participated in recruiting the respondents. Recruitment was carried out from March 2007 to August 2007.

17. Statistical analysis: Outliers were checked, but how many cases were excluded because of outlying values?

Response 2.17.1
For outliers was checked, but no cases were excluded.

Changes made to the text (page 8:25):
No cases were excluded because of outlying values.
The difference between the base case analysis and the sensitivity analysis is not fully explained. In both analyses missing data on item level were imputed using general mean substitution. However, there is no information about the level of missing data, not on item level and not on cost category level, but only on data source level. Does the overall response of 267 complete cases mean these cases have no missing data?

Response 2.17.2
In the base case analysis missing data were imputed on item level. In this analysis some respondents did not fill in some items in the measurements. In the sensitivity analysis we imputed the costs on case level. For women who did not complete the cost diary at all, the costs were imputed using general mean substitution. In table 2 we added detailed information about the missing data on item level.

Changes made to the text (page 26):
In table 2 we added detailed information about the missing data on item level.

Is it possible that missing data might mean no health care consumption?

Response 2.17.3
No, missing data mean that women did not fill in a question/ item at all. When a woman had no health care consumption she could indicate this in the questionnaire or cost diary.

Changes made to the text: none

How many respondents would remain in the analysis if cases with missing data were excluded?

Response 2.17.4
This is fully dependent of the definition of missing data. The data from the birth registration forms all data were available. On questionnaire level, 24 percent (questionnaire 2) and 29 percent (questionnaire 3) of questionnaires were not returned at all. But of all returned questionnaires, all items were completed. On cost diary level, we provided the number of items which were missing and were imputed using general mean substitution.

What would be the result if you treated missing data as zero?

Response 2.17.5
When missing data were treated as zero, all missing data were treated as ‘no health care consumption’ and the mean costs will decrease. We do not think that will be realistic and we did not perform this analysis.

Changes made to the text: none.

Why is it implied in the sensitivity analysis that respondents with missing data overall consumed more health care costs?

Response 2.17.6
We omitted this sentence and we rephrased this in the text.

Changes made to the text (page 9;7):
It is unclear whether women, who did not fully or partially complete the data sources, have more health care consumption.

Results
18. Participants: the second and third questionnaires are not mentioned anymore. Was that information not relevant for this study?

Response 2.18
We added the response rates on these questionnaires in table 2 (page 26).
19. 62% of nulliparae with a preference for home birth were referred to secondary care and 71% of those with a preference for a short-stay hospital birth. Can you distinguish between a referral before the onset of labour or after? Because those referred before the start of labour clearly no longer had a choice where to give birth, and they would no longer fulfil one of the inclusion criteria: no medical indications for secondary care. Background characteristics may not be different between both groups, but what about this referral rate? Is the difference you found statistically significant?

Response 2.19
This information gives an insight in the pathway of the two different groups. However, the questions above are beyond the scope of this study and are part of another paper. We added figure 1 with the clinical pathways of the study population.

Changes made to the text: none.

20. Cost analysis: women giving birth at home usually receive maternity care assistance during birth (partusassistentie in Dutch) as well as care from a midwife. Are those costs included in the costs of contact with health care professionals?

Response 2.20
Yes, respondents could fill in these contacts in the cost diary. So, these costs are included.

Changes made to the text: none.

21. You mention significant differences and not significant differences, but I cannot see that in the tables. Do you mean (not) statistically significant or do you mean (not) remarkable, or clinically significant?

Response 2.21
We actually mean statistically significant differences. We mentioned this in the tables.

22. What is meant in the sentence at the bottom of page 11 and top of page 12 of the pdf by the words ‘during the period followed’? Do you mean the postpartum period?

Response 2.22
We rephrased this sentence.

Changes made to the text (page 12;9):
period 'week 16-28'

23. By recalculating the data in table 4 I understand that the total costs of contact with health care providers (excluding maternity care assistance in the postpartum period, I presume, because that care is mentioned separately) is about 15% of the overall total costs, but it would be helpful to add a table with the totals of cost categories in addition to the costs per period in tables 4 and 5.

Response 2.23
We added a table with the totals and percentages of each cost category for the sensitivity analysis. It was not possible to add the percentages of each cost category of the results in table 4 (base case analysis). Because the N in each period is different and it is not possible to add the different cost categories.

Changes made to the text (page 31):
We added table 7.
24. By mentioning that all 449 respondents are included in the sensitivity analysis, the question arises how many were excluded in the base case analysis and in how many cases missing data were replaced by the general mean. Why are the total costs in the sensitivity analysis so much higher than in the base case analyses, when in both cases missing data were replaced by general means?

Response 2.24
In table 5 (previous table 4), we added the N for each period. The N is different for each period because not all respondents filled in each period adequately.
For the sensitivity analysis we imputed the missing cases by general mean substitution of the costs. The fact that the total costs in the sensitivity analysis are much higher than in the base case analysis may indicate that women who did not complete the data sources consume more health care costs.

Discussion
25. In the first sentence should be added that this article is about the costs of births for nulliparous women. You could speculate about possible influence of parity on the results, but you cannot ignore it.

Response 2.25
We agree with the reviewer and we added this information.

Changes made to the text (page 13;26):
nulliparous women

26. Halfway page 14 of the pdf it says (in brackets) 0.5% and 2.6% respectively. 0.5% and 2.6% of what?

Response 2.26
On this point, we gave some additional information.

Changes made to the text (page 14:17):
for the short-stay hospital group 0.5% and 2.6% respectively

27. When comparing the costs of the actual place of birth with those of the preferred place of birth, the conclusion is that this may indicate a difference in referral rate. Why so cautious? You already have shown that the referral rates are different (62% vs. 71%).

Response 2.27
We agree with the reviewer and we stated this less cautious.

28. Looking at the cost analysis of the actual place of birth, in theory the main difference is for home births the additional costs for maternity care assistance (during and immediately after birth) and for short-stay hospital births the additional costs of using the hospital facility. Does this explain the difference you found?

Response 2.28
Because we did not analyse the differences for each cost-category (because this was not the main objective of the study) it is difficult to conclude this, but this could be an explanation for the difference.

Changes made to the text: none

29. Intention-to-treat analyses are important to avoid bias, but in this case I am not sure that the right choices are made. I would have preferred a comparison between women without medical indications for secondary care, not only at the beginning of pregnancy, but also at the end. That would also give more insight in the different referral rates between the intended home birth group and the intended short-stay hospital group.

Response 2.29
The analyses of the different referral rates were beyond the scope of this study and will be part of another manuscript. The objective of this study was to investigate whether there are differences in
costs between women intending to give birth at home and women intending to give birth in a short-stay hospital birth.

Changes made to the text: none.

30. Comparison with other studies: again, this study is about costs for nulliparous women only.

Response 2.30
We added this in the text.

31. Limitations: not all women in the study had the same possibilities to choose their place of birth, but they all had the opportunity (or: were asked) to express a preference, early in their pregnancy, even if they might have known that preference would not be realistic.

Response 2.1
We agree with the reviewer and we added this limitation in the text.

Changes made to the text (page 17:21-25):
All women were asked to their preferred place of birth in an early stage of their pregnancy (around 16 weeks of gestation age). All women filled in this question and had, therefore, a choice for their place of birth. It is unknown whether this choice is realistic. In the second questionnaire (around 32 weeks of gestation age) the preferred place of birth was asked again. For this analysis we used the first choice for place of birth.

32. The use of general mean substitution, without any indication of the scope of that use at item level, is unsatisfactory.

Response 2.32
We agree with the reviewer to give an insight in the use of mean substitution. In table 2, we added information about the use of general mean substitution on item level.

Conclusions
33. In the second sentence add information about parity:…two groups of women giving birth for the first time.

Response 2.33
We added this sentence in the text, (page 19:17-28).

34. Third sentence: For some (not in general), the obstetric system is currently (and has been so for a long time) a topic of debate, not despite the high rate of home births in the Netherlands, but because of it.

Response 2.1
We agree with the reviewer and we changed this (page 19:19).

35. Last sentence: If you say there is no difference between the costs for the women in your study, do you really mean the women themselves (for instance the obligatory co-payment for maternity care assistance or for use of the hospital facilities?) or do you mean the costs for the health insurance companies?

Response 2.35
We rephrased this part of the text (page 19:21-22).
Tables
36. Table 1: is a midwife assistant comparable with a GP assistant? If so, then why is the unit price per hour for midwife assistants so much higher than the unit price per hour for GP assistants?

We did not assume that the work of a midwife assistant is not comparable to the work of a GP assistant. We received the information from the Royal Dutch Organization of Midwives and calculated the unit prices for a midwife assistant.

37. Table 2: the response rate on a questionnaire is 76.6%. Is this the first questionnaire, the second, or the third, or all questionnaires combined? I assumed that 449 first questionnaires were returned.

Response 2.37
This is the response rate of the second questionnaire, but we added also the response rate of the third questionnaire in table 2.

38. The overall response of complete cases was 267, was that the number used in the base case analysis?

Response 2.38
No, in the base case analysis we used all cases who completed the database completely or partially. When a respondent filled in the database partially we used general mean imputation to impute the missing items.

39. Tables 4 and 5: Please indicate the N in the analyses.

Response 2.39
We indicated the N in the tables. In table 5 (previous table 4), the N is different for each cost period.

40. The lay-out of this table, as well as the next, is confusing, because of the horizontal lines, that separate the subtotals from the items they are based on (above the line) and give the impression that they are referring to the items below (between the lines).

Response 2.40
We changed the lay-out of the tables.
Comments Reviewer Miranda Mugford:

This paper reports a cost analysis based on two groups of women, who were having their first birth, and were clinically at low risk, i.e., not requiring secondary obstetric care during pregnancy. If they agreed to take part in the study, they were offered a choice to give birth at home or in a gp/midwife delivery provision in hospital (‘short stay hospital setting’). Women completed questionnaires at recruitment and then before and after the birth. They were also asked to complete cost diaries weekly during the study. Data were also extracted from clinical records. Costs per woman were constructed from these data with NL specific unit costs.

The analysis compares the ‘societal costs’ for the two groups, based on initial intended place of delivery and on actual place of delivery. The main finding is that there is no significant difference in costs of the two groups, but that higher costs are incurred where women gave birth in obstetric secondary/tertiary level care.

On the whole this is an original and useful addition to the fairly limited international literature on costs of birth, but there are a few corrections to be made. I would like to see more justification for many statements made.

Major compulsory revisions

Although there are more home births in NL than other EU countries and USA, this is still not a general study of costs of obstetric care. This needs to be a bit clearer.

Response 3.1
We added some information.

More background on how women finance their maternity care in NL would be helpful (to understand incentives for choices).

Response 3.2
We added some information about the way women finance their maternity care in the Netherlands.

Changes made to the text (page 4;21-25):

In the Netherlands, maternity care is financed by health insurers. Women who give birth in a short-stay hospital setting pay an extra out-of-pocket charge for the rent of the maternity room in the hospital. When a woman has a medical indication to give birth in the hospital under supervision of the obstetrician, the out-of-pocket charge expires.

There were some relevant studies in the UK in the 1970s which are comparable to this report, as the home birth rate in UK was then similar to current NL rates, although perinatal mortality and some technologies in low risk pregnancy were different then. I realise that the literature is unlikely to be available to the authors via standard online search methods, and they might be in the Henderson and Petrou review, but I attach some references I have. The judgement that international comparisons ‘cannot be transferred’ to the NL situation is a bit sweeping, and clearer reasons should be given.

Response 3.3
We are grateful for the additional references and we added them in the reference list. We added also some additional information about the transferability of costs. A recent paper of Drummond et al (2009) showed that unit cost prices should be jurisdiction specific because of differences in relative and absolute price levels among jurisdictions.

Changes made to the text (page 5;13-15):

Because of differences in relative and absolute price levels among jurisdictions, the unit cost prices are jurisdiction specific and the results cannot be transferred to the typical Dutch system [23].
The authors claim that this study is from the societal viewpoint, and include some data on informal help at home, but do not include data on productivity loss. They do discuss this, but it is a very partial view of ‘societal costs’.

Response 3.4
We agree with the reviewer that this is a very partial view of ‘societal costs’. But we did not take the productivity losses into account.

Changes made to the text: none

It is good to see the unit costs reported, but it is also recommended (eg BMJ guidelines on economic studies from 1996) that quantity of resource use be presented in economic studies, as it helps readers to judge transferability to their own settings.

Response 3.5
We agree with the reviewer and we think this a valuable comment. However, in the base case analysis we imputed missing data on item level. Besides this, as mentioned previously, every cost period has a different number of respondents (see table 4 and 5). For the sensitivity analysis we imputed on the costs level using general mean imputation, thus going beyond the specific volume measurement. We added an additional table with the volumes of resource use per cost period. However, some of the unit prices are based on price per hour. The total costs are dependent of the time the respondent spent with the caregiver. Reporting the volumes of each item for each measuring instrument, and each time block will lead to enormous tables.

Changes made to the text: additional Table 4

Response rates were quite low for complete data – and so missing data replacement method is used. The authors need to convince me better how the mean value replacement method affects the uncertainty around the final estimates.

Response 3.6
The mean value replacement do not affect the uncertainty because we enlarged the N and this has no influence on the percentiles.

Changes made to the text: none

I don’t understand the term ‘real mean costs’ – this needs clarifying.

Response 3.7
We called this ‘real mean costs’ because we wanted to make the distinction between the bootstrapped mean costs and the mean costs. So, we changed this in ‘mean costs’.

Discussion
The costs of diagnostic tests are stated to be ‘not taken into account’. Would it not be more accurate to state that these tests are part of the hospital resource and are in fact included in the calculation of unit costs of visits? The point is that the difference in use of tests between women in the study is not reflected in the costs as estimated here.

Response 3.8
We agree with the reviewer and we rephrased these sentences.

Changes made to the text (page 18;14-16):
Therefore, the cost of the diagnostic test itself is included in the calculation of unit costs of visits and it is not possible to present the difference in use of diagnostic tests between both groups.
Minor essential revisions
There are some small corrections to language that need to be made before publication. I have not listed these as have not got page or line numbers in the downloaded text.

Given that this journal is international, reference to ‘foreign countries’ feels a bit odd to me.

Response 3.9
We agree with the reviewer and we rephrased these sentences.

Discretionary revisions
This is a cost comparison study, and makes no comparison with outcome data. It would be interesting to readers to know why women were not asked to complete health utility or other benefit/preference measurement instruments for themselves and their child. It is clear that for this study serious adverse outcomes would be rare and the study was not designed to assess this.

Response 3.10
We agree with the reviewer. However, we added this in the discussion.

A diagram, like a flow chart, of the clinical pathways followed by the two groups of women would be helpful.

Response 3.11
We agree with the reviewer that a flowchart helps to visualise the pathway of both groups. We added figure 1, with the clinical pathways of both groups.