Author's response to reviews

Title: Haemorrhagia post partum; an implementation study on the
evidence-based guideline of the Dutch Society of Obstetrics and Gynaecology
(NVOG) and the MOET (Managing Obstetric Emergencies and Trauma-course)
instructions; the Fluxim study

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Author's response to reviews: see over
Subject: Study protocol Haemorrhagia post partum; an implementation study on the evidence-based guideline of the Dutch Society of Obstetrics and Gynaecology (NVOG) and the MOET (Management of Obstetric Emergencies and Trauma-course) instructions; the Fluxim study

Dear Editor,

Thank you for the significant comments of the reviewers Justus Hofmeyer and Malinee Laopiboon on our manuscript. We are very pleased to get an opportunity for adapting the protocol for publication. In the second page you will find the answers on the remarks and questions from the reviewers. In the protocol, the textual adaptations are indicated by track changes.

We hope you will accept this study protocol for online publication in BMC Pregnancy and Childbirth.

Yours sincerely,

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Reviewer: Justus Hofmeyr

Reviewer's report:
This is an interesting and clearly-written protocol which describes the development of a strategy to influence carers to adhere to evidence-based practices for prevention of postpartum haemorrhage. A general limitation of the protocol is the fact that the implementation strategy and the adherence measures will be developed as part of the research, therefore the protocol is presented in very general terms, without being able to define the interventions and outcomes, and how these will be analysed. It will be useful to have an update of the protocol for the feasibility study once the actual care study and the barrier and facilitator studies have been completed.

We totally agree with the reviewer and find the proposal a good idea. After the actual care and barrier studies have been completed, we can be much more specific about the intervention and outcomes. Should the BMC find it useful, we can send an additional study protocol for the second part.

The following major revisions may be useful to readers:

1. It would be useful to have a clearly stated hypothesis for the feasibility study.
We agree with the reviewer and adjusted the text in the design of the feasibility study as follows:

At this moment we have some hypotheses about expecting limitations in actual care. At the level of the guideline/MOET-instructions itself we think that the guideline can be more specific; the description of the desired care is not detailed enough. The desired care can be described in a detailed and structural manner by the development of "bundles". These bundles are defined as a group of interventions related to a disease process that, when executed together, results in better outcome than when implemented individually. A second limitation could be a delayed time interval between events and taken actions, (right actions taken to slowly due to individual decisions or organizational factors)

The solution could also be describing the desired care in bundles in the guideline and on organizational level an improvement process can be undertaken if the exact problem can be identified for example; multidisciplinary clear agreements. At the level of the professionals, a lack of knowledge/insight in own performance can be an impending factor. The installed monitors could be used to constant audit and feedback their performance, both individual and in review conferences and team training could be an intervention.

2. In the initial observational (actual care) study, it will be useful to describe how PPH will be defined and measured.

PPH is defined in the background text as >1000 cc. We will measure the amount of (measured or estimated) blood loss in the actual care study by a medical record search. These data will be supplemented by comments and actions from the recorded images.
3. It will be useful to discuss limitations of the methodology, particularly the inherent limitations of a before-and-after study.

See answer point 4


We are very much aware of the limitations of a before-and-after study. However, our first step in testing the developed implementation strategy is to test the feasibility of it. When the strategy has proven to be feasible, we will perform an RCT to test the effectiveness. However, to get an indication of the effectiveness of the strategy, we will include some effect measures in the feasibility study. We adjusted the text in the outcome and discussion as follows:

**Text outcome**
To get an indication of the effectiveness of the strategy the outcome measure is the adherence to developed quality indicators. Other outcome measures are the experiences of the participants (both professionals and patients) with the elements of the strategy and with the changed care. Also the cost of the tested strategy will be measured.

**Text discussion**
A randomized controlled study is the next step to measure the effectiveness of the implementation of the obtained strategy if the result of this study is that the strategy is feasible in practice, can be implemented with low costs and indicates to be effective.

**Reviewer: Malinee Laopaiboon**

**Reviewer's report:**
The protocol is very interesting. I have some comments as the followings.

1. It would be clear to readers if the authors present all complete steps of methodology for each objective like this

   **Objective 1:**

   **Methods:**

   1) design and study population

   2) outcome measures
3) procedure and data collection with the time of collection, separate for each group of subjects, like patients and clinicians

4) analysis plan

5) Expected results to be used for development of implementation strategy in objective 3

Although in RCT’s the proposed method of describing study protocols is preferable, we believe that in implementation research the method of textual build up is different. However, if the editor wishes it otherwise we are of course willing to adjust the text in an other sequence.

2. It is unclear how the authors will allocate a sample of 320 PPH to the 20 selected hospitals and how many of the 20 hospitals will be selected from academic and non academic hospitals.

We adjusted the text in the ‘study population’ of the actual care study where it states that 4 academic, 8 non academic but teaching and 8 non academic non teaching hospitals will participate (about 16 patients per participating hospital).

3. The recruitments of 320 women in 20 hospitals in 6-9 months in the subheading of 'statistical issues' is not clear whether at the first or third objective.

The subheading of the statistical issues is: Sample size calculation actual care study and feasibility of recruitment. So, it concern the actual care study which is the first objective.

4. For the methods of the third objective, there are some points to make them clear
4.1) why do they implement only in 4 hospitals

This protocol does not describe the implementation of a strategy but only tests the feasibility of a possible strategy. For a feasibility study, 4 hospitals is sufficient.

4.2) how long for implementing the developed strategy

The implementation duration is 9 months. This is adjusted in the text.

4.3) the 100 patients included for measuring feasibility after intervention is not consistent with the number presented in sample size calculation, 320.

As mentioned above, the sample size calculation is performed for the actual care study to calculate how many patients and hospitals we have to include for a precise estimation of the actual care in the Netherlands (320 patients is necessary for a precise estimation). For the feasibility study we want to measure feasibility and costs of the developed strategy by including four hospitals. To get an indication of the effectiveness of the strategy, about 100 patients (about 25 per hospital) is enough.

I finally strong suggest to modify the method as mentioned in 1.