Author's response to reviews

Title: Reduction of late stillbirth with the introduction of fetal movement information and guidelines - a clinical quality improvement

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Author's response to reviews: see over
Authors’ cover letter for the second submission and response to reviewers’ comments

Title: “Reduction of late stillbirth with the introduction of fetal movement information and guidelines – a clinical quality improvement.”

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Version: 2 Date: 20th of May 2009

Dear Editors,

Please find enclosed the manuscript entitled “Reduction of late stillbirth with the introduction of fetal movement information and guidelines - a clinical quality improvement.”

Thank you for reviewing our manuscript and for the valuable evaluation and comments. The manuscript has been revised in compliance with the reviewers’ suggestions, which we consider to have improved the paper significantly. We appreciate the positive feedback and useful comments from the reviewers.

There have been no changes in authorship during revision. We confirm that all authors fulfil all conditions required for authorship. None of the authors have reported any conflicts of interest.

We hope editors and referees will find our revisions satisfactory, and that our revised manuscript present important information highly relevant to the readers of BMC Pregnancy and Childbirth.

We will be grateful to be contacted if you have any queries about our revisions or our manuscript.

On behalf of the authors,
Yours sincerely,

Julie V. Holm Tveit, MD
J. Frederik Frøen, MD, PhD
The manuscript has been revised in the following ways (all comments from referees in bold, authors’ responses in italic):

**Referee #1**

**Minor essential revisions:**

1. **Introduction section consisted of 8 paragraphs. Please shorten this part:**
   
   The text has been revised and shortened as suggested by reviewer #1:

   - The paragraph regarding Grant et al’ study has been moved to the discussion part (page 10, lines 23-26 and page 11, lines 1-2 in the revised manuscript) as also suggested by referee #2.

   - The paragraph regarding fetal movement counting has been revised and the main part of the section has been moved to the discussion part (page 10, lines 14-23 in the revised manuscript).

   - The part regarding the agreement of the hospital and the mother has been moved to the methods section and described in a revised form (page 6, lines 7-11 in the revised manuscript).

2. **Page 6, line 4 from the bottom: reference of Femina**

   Reference of Femina has been inserted (reference #2). Even though this publication is in Norwegian and published in the Journal of the Norwegian Medical Association we hope editors and reviewers will find this satisfactory.

3. **Discussion section:**

   Please indicate that 5th paragraph is a new paragraph

   This section is the 4th paragraph in the revised manuscript, the text has been revised.

   The 2nd paragraph deals with limitation/weakness of this study. Please move this paragraph to the latter part of the discussion part.

   We agree and have moved the paragraph dealing with limitations of the study to the latter part of the discussion part. The strength of the study appears as the 2nd paragraph, followed by Grant et al’s study (reference # 40 in the revised manuscript). The limitations of the study appears as the second paragraph to the last of the discussion followed by the last paragraph and the conclusion part.

   The text has been revised and shortened as suggested by reviewer #1. However; as other parts of the text has been revised and moved to this section (i.e., the part describing Grant et al’s study as suggested by reviewer #1, the part regarding
maternal movement counting suggested by referee #2 etc.) we still end up with seven paragraphs. We believe that the text is more readable with the remaining seven paragraphs and hope editors and reviewers will find this satisfactory.

4. A comma in page 12, line 8 from the bottom:

A comma has been inserted, the text has been revised.

Referee # 2

Major compulsory revisions:

1. The design and method described in the background and in the results:

   The text has been revised as suggested by referee #2 and all parts regarding the background and methods have been moved to the methods part.

   - The part regarding the background of the intervention (on pages 5 and 6 in the old manuscript) has been moved to the methods part (page 5, lines 21-26 and page 6, lines 1-6).
   - The part regarding inclusion and exclusion of cases (page 9 in the old manuscript) has been substituted with a flow chart in the revised manuscript, figure 1.

a) How maternity care is arranged in Norway

   A part describing details on how maternity care is arranged in Norway has been added on page 5, lines 2-10. We are happy to supply further information if the referee so wish.

b) Description of the 14 centers and the number of pregnancies and (still) birth at each hospital

   Unfortunately, we are not able to describe the number of births and stillbirth at each of the 14 hospitals. When we included the 14 hospitals in our study, we made an agreement with each hospital emphasizing confidentiality of all data from each hospital. This is also in accordance with our study protocol which has been approved by The Regional Committees for Medical Research Ethics.

c) The total number of births in Norway and the frequencies of stillbirth over five to ten years.

   Details on the frequencies of births and stillbirths in Norway over a five years period (1999-2004) have been added (Page 7, lines 13-17 in the revised manuscript).
To address the question of variations in mortality rates that could explain the entire effects observed (although far more prevalent outcomes than deaths are included), we have added a figure presenting the mortality rates in a Statistical Process Control (SPC) chart (figure 2). The included figure shows that there is only normal variation in the number of deaths from month to month both before and after the intervention; the only significant change in the number of deaths is the intervention. The arrow indicates when the change was significant (after seven months) according to SPC statistics. Not in one single month thereafter the mortality was over the mean of the pre-intervention period. The three highest rates per month occurred before the intervention, and the twelve lowest rates were after. It also shows what is known in QI-projects: the effect is gradually diminishing over time.

1. Use a very exact language when referring to your different populations.

The text has been revised. We hope editors and reviewers will find this satisfactory.

2. Maternal obstetric risk data are lacking for comparisons between groups

A table illustrating maternal obstetric risk data before and during the intervention has been embedded in the manuscript (table 2).

Minor essential revisions:
1. The questions or aims could be better defined both in the abstract and in the background part.

The text has been revised as suggested by referee #2.

- The aim in the abstract is defined in the following way:” We intended to examine two cohorts of women with DFM before and during two consensus-based interventions aiming to improve care through: 1) written information to women about fetal activity and DFM, including an invitation to monitor fetal movements, 2) guidelines for management of DFM for health-care professionals.

- The aim in the background part has been defined in the following way:” We intended to examine two cohorts of women with DFM before and during a quality improvement intervention by implementing guidelines for management of DFM and uniform information on fetal activity to women.

2. Discussion: put detailed information of different managements of FM counting to the discussion part
The paragraph describing ways of FM counting has been moved to the discussion part as suggested by referees’ # 1 and 2 (page 10, lines 14-23 in the revised manuscript).

3. References:
It is not OK to use a submitted study as a reference i.e., nr 4.

The text has been revised as suggested by referee #2. Reference #4 in the old manuscript has been omitted from the text and substituted with reference #2 in the revised manuscript: Frøen JF, Saastad E, Tveit JV, Børdahl PE, Stray-Pedersen B: [Clinical practice variation in reduced fetal movements]. Tidsskr Nor Laegeforen 2005, 125: 2631-2634.

4. Dictionary revisions: Language improvements and some instances shorter sentences:

The text has been revised throughout the manuscript. We hope editors and reviewers will find this satisfactory and that this has improved the readability of the text.
Referee # 3

Minor essential revisions:

1. In the US there is also a 1-hour count approach: this should be included in the list of counting methods:

The purpose of our intervention was not to study and evaluate the use of a kick chart per se. The intervention intended to provide consistent written information to women about fetal activity and DFM, including an invitation to monitor fetal movements. Our manuscript does therefore only include the two main groups of counting methods and does not discuss further details on fetal movement counting. The 1-hour count approach used in the US is therefore not added in the text. For more details discussing fetal movement counting we have given references to three of our previous publications: Heazell AE, Frøen JF: Methods of fetal movement counting and the detection of fetal compromise. [Review] [66 refs]. Journal of Obstetrics & Gynaecology 2008, 28: 147-154, Frøen JF, Heazell AE, Tveit JV, Saastad E, Fretts RC, Flenday V: Fetal movement assessment. Seminars in Perinatalogy 2008, 32: 243-246, and Frøen JF: A kick from within - fetal movement counting and the cancelled progress in antenatal care. J Perinat Med 2004, 32: 13-24).

1. Page 5, 3nd paragraph, refer to the large multi-centered RCT, reference 31, as Grant, Valentine, Elbourne & Alexander for clarity.

The text has been revised and cited as suggested by referee # 3 and moved to the discussion part as suggested by referee # 1 (page 10, line 25-26 and page 11, line 1, reference #40 in the revised manuscript).

Discretionary revisions:

1. “Thumb rules to recognize DFM”. Could those be included in a table in this article?

A table of our study’s “rules of thumb” are illustrated on page 3 in the “kicks count” folder. We have suggested a hyperlink to these rules in the text (page 6, line 26). We hope referee #3 will find this satisfactory.
Additional comment by the authors:

1) Page 6, lines 24-25; the following sentence has been added "In addition to Norwegian, the brochure was available in Somali, Urdu, English, Turkish, and Arabic".

2) Page 12, lines 1-7 in the revised manuscript: Paragraph 7 in the original manuscript has been shortened and revised.

3) Page 12, lines 6-7 in the revised manuscript: A new sentence has been added

4) "... and consistent with the evidence for antepartum testing in other risk pregnancies"

5) Page 12, line 7 in the revised manuscript: Four new references have been added #12, 45-47.

6) In addition to the previously submitted English version of the Kicks Count folder, the Norwegian, Urdu, Somali and Turkish versions of the folder have been added as additional files with this submission.

7) A new table (Table 2) has been included in the manuscript (as suggested by referee #2).

8) A new figure (Figure 1) has been provided as a separate file (as suggested by referee #2).

9) A new figure (Figure 2) has been provided as a separate file.

10) The manuscript has been revised according to the journal style. Please do not hesitate to contact us if there are any revisions not correctly formatted.

11) The language in the manuscript has been revised and improved (as suggested by referee #2). We hope editors and referees find our revisions satisfactory.