Author’s response to reviews

Title: Effects of auditing patient safety in hospital care: design of a mixed-method evaluation

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Dear Editor,

We wish to thank you for your consideration. In response to your letter of 11 March 2013, we can provide the following information:

1. Ethical approval
The Ethical Committee of the Radboud University Nijmegen Medical Centre (RUNMC) approved the study on 11 July 2011. It conforms to Dutch law and privacy regulations and was judged not to involve human-subject research. We have included a copy of the original approval of the Ethical Committee of the_RUNMC (Appendix 1) and a letter in which the Ethical Committee of the RUNMC declares that this study conforms to the Dutch law and privacy regulations (Appendix 2). Page 14 of the manuscript presents the revised text about ethical approval and principles. We have described the ethical approval in a part of the study protocol. If necessary, the written consent can be verified. We intend to publish the results of this study anonymously.

2. Funding
Our study has not received external funding from any major funding body or commercial organization. This study is being funded with general resources of the Radboud University Nijmegen Medical Centre.

3. A list of manuscripts under submission
There are no manuscripts under submission with other journals based on the study protocol.

4. Registration
Our study is an observational study, so registration is not required. Nevertheless,
the manuscript was registered on 12 March 2012 in the Dutch Trial Registry for clinical trials (Appendix 3). The Dutch Trial Registry adheres to all of the ICMJE guidelines. The Dutch Trial Registration record number for our study is NTR3343.

We hope that we have clarified your concerns adequately and look forward to your response.

Yours sincerely, on behalf of all the co-authors,

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