Author's response to reviews

Title: Hospital deaths and adverse events in Brazil

Authors:

Mônica Martins (martins@ensp.fiocruz.br)
Claudia MR Travassos (claudia.maria.travassos@gmail.com)
Walter Mendes Jr (wmendes@ensp.fiocruz.br)
Ana Luiza B Pavão (analuizabp@yahoo.com.br)

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Author's response to reviews: see over
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Editors of BMC Health Services Research
BioMed Central Ltd
Floor 6, 236 Gray’s Inn Road
London, United Kingdom
WC1X-8HB

Dear Editors,

We would like to submit the second version of manuscript “Hospital death and adverse events in Brazil” for publication in BMC Health Services Research. The content of this version was reviewed considering major and minor recommendations of the two reviewers. The answer for each remark is on next pages of this letter, it is done in red colour. The yellow highlights in the document were included to indicate the changes. This new version was reviewed by a professional reviewer.

Yours sincerely,

Mônica Martins
National Schools of Public Health (Brazil)

Correspondence address:
Rua Leopoldo Bulhões 1480, sala 725.
Manguinhos -- Rio de Janeiro RJ.
21041-210
BRAZIL
tel.: +55 (21) 2598 2851
fax: + 55 (21) 2290 0993
E-mail: martins@ensp.fiocruz.br
http://www.ensp.fiocruz.br
Answers at reviewer’s requirements

Report of first reviewer: Zaina Qureshi

Major Compulsory Revisions
1. Reference for the first sentence of background is needed.
   This was considered in the second version of manuscript

2. The third sentence in the background section leads us to believe that there may be numerous studies regarding the association of adverse events with hospital care but only one reference is provided.
   We had included only one reference because that one provides a summary table with the classic studies on the topic. In this table #6 of the paper by Zegers et al, 12 studies were included. Anyway, we also included a systematic review done by De vries et al.2008.

3. The third paragraph on page 3 in the background section requires references for the first and second sentence.
   It was included.

4. In the second paragraph on page 5, the methodology used for random sampling needs more clarification. Whether each university hospital had equal number of patients to choose from? Which seems unlikely seeing as the total number of patients was 27,350. If there were unequal numbers then was the sampling random within each institution or was this not considered?
   Details of sampling were included. The hospitals had not the same inpatients' volume. The random sample process was applied for each hospital, considering the parameters from Canadian study and an estimated loss rate.

5. Please include the reason for excluding patients admitted under the age of 18.
   The main reason was follow the design of Canadian study, whose tools were adapted for using in Brazil. On the other hand, we can argue that tools driven for youngest population would deserve a further calibration.

6. One of the variables considered by the authors was preventable adverse events, while this is an extremely important variable, a definition, be it standard or operationalized to the study, needs to be included.
   It was included at the end of the first paragraph in Method.

7. Table 2 the formula for % deaths should be reversed from \( \frac{A}{B} \times 100 \) to \( \frac{B}{A} \times 100 \).
   We apologized for this mistake, it was corrected.

8. The first paragraph of the discussion is a reiteration of the results, which can be eliminated to provide more space for discussion if the reason for a short discussion was space limitations.
   Considering the high volume of publication on Patient Safety, we opted for a sorter and synthetic discussion. However, we have included some new points.

9. The second sentence in principal study limitations on page 11, that states that “Importantly, the study population was limited to admissions to three public
university hospitals in a single State of Brazil, which could partially explain the results” – requires further clarification. Which part of the results in particular is the author referring to here and what would be the implication of this limitation?

Our concerns are related at the hospital supply and country characteristics. Brazil has more than 5,000 hospitals; there is heterogeneity in terms of facilities, human resources, and of course quality of care. In fact in the three hospitals sampled the medical records are proper and teaching activities are developed, among others. Because of this aspect, the results showed must be better in these hospitals than in the others. So we consider that the numbers obtained could be underestimated for Brazilian reality.

We included a paragraph about this content on page 11.

Minor Essential Revisions

1. While the second sentence of the background attempts at building an argument for the study, it is vague and would benefit from some clarification from the text of the IOM report regarding the specific causes of mortality rather than stating “principal causes of mortality”.
   
   It was done.

2. There are many different views every author has regarding writing style and the concept of smooth transitioning between each sentence/paragraph to provide a convincing line of reasoning for the study, and I believe that this paper has room for improvement both in terms of language and flow.
   
   We tried to improve the flow. The language was reviewed by a professional reviewer.

3. Please include the start date and the ending date of the study i.e. All patient admitted to each of the hospitals between January 1, 2003 to December 31, 2003.
   
   It was included

4. In Table 2 the reference category for age is not highlighted with an asterisk.
   
   It was included.

5. The text states that the variables surgical procedure and clinical specialty were included in the second model but were excluded in the final model due to lack of statistical significance. On the other hand Table 3 shows that the second model did not include those variables either. The addition or deletion of the variables needs to be made clear in the text and the table either ways.
   
   We reorganized this section in order to become clearer.

6. Overall document needs to be assessed for appropriate grammar and other minor errors like on page 3, the third paragraph 1st line – Few studies have analyzed the presence of “an” association…
   
   The document was again reviewed by a professional reviewer.
Report of second reviewer: Hillegonda Maria Dutilh Novaes

Major Compulsory Revisions
1) General comment: The data source for this study was a previous, pioneer and successful, study on the occurrence of adverse events in 3 university hospitals in Rio de Janeiro, Brazil in 2003, based on the utilization of a Canadian methodology, and testing its utility in Brazilian hospitals was also an objective. For this study no new patient data were produced, and the discussions concerning the methodological dilemmas of the identification of adverse events and their classification in preventable or not should be mentioned but are at this point not a central issue in this paper. The main contribution of this study is the development of a statistical model with in-hospital mortality as the dependent variable and the occurrence of an adverse event, including its preventability, as the main independent variable, with the inclusion of other variables known to be related to hospital death (patient and process of care characteristics). In order to emphasize this contribution, in the background section a synthetic analysis of the literature concerning in-hospital mortality models in general and those including adverse events should be mentioned, since the main topic of interest is the (statistical)importance of adverse events, and its behaviour when controlling for case severity, or other variables which may influence the model results. Abstract and background should be revised considering this perspective. A recent article may be helpful to insert the hospitals of this study in a frame of reference for brazilian public hospitals (annex).

Considering all important points posed above, we felt necessity to clarifying some assumptions applied in the construction of our approach. In fact the main motivation of this analysis was the debate posed by Hayward & Hofer in the beginning of 00’ decade. These authors highlighted there be an overestimation of preventable deaths in part due to the overlook the underlying prognostic factors of patients that died. On the other hand, as the hospital mortality models have been developed since 80’s, we believe that our paper have not a new contribution on this issue. However, we have not found articles using modeling to understand the relationship between death and adverse event considering risk adjustment. The papers that have searched to study deaths related with adverse event have used descriptive approaches. Only two papers, cited in our manuscript, tried to focus deeper on death and adverse events (Zegers and Garcia-Martin). For this analytical proposal we review all deaths case sampled in stage one of screening during the baseline study.

2) Methods and results are well written, but more details of the model should be presented, with less emphasis on the different ways of calculating the prevalence of AE in general and preventable AE, they are important but of less interest in this article, except for the influence their high frequency may have on the model results. Details of modeling process were included. We tried not to put too focus on prevalence rates.
The justifications for the size of the sample (4% of the hospitalizations in these hospitals in 2003) should be presented.

Details of sampling were included.

3) Discussion: The statistical strategies should be emphasized, valued and their effect on the results discussed more explicitly. And a return to the main discussion in the background should be included.

As we opted for a sorter discussion, we included the risk adjustment and statistical approach as a positive point in conclusion and abstract.

Language revision:

The language problem was reviewed by a professional reviewer.