Author's response to reviews

Title: The Incidence of Adverse Events in an Italian Acute Care Hospital. Findings of a Two-stage Method in a retrospective cohort study.

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Version: 3
Date: 22 June 2014

Author's response to reviews: see over
Author's response to reviews

Title: “The Incidence of Adverse Events in an Italian Acute Care Hospital. Findings of a Two-stage Method in a retrospective cohort study”

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Version: 2 Date: 22 June 2014

Author's response to reviews: see over
Dear Editor,

Thank you for your valuable comments regarding our manuscript “The Incidence of Adverse Events in an Italian Acute Care Hospital. Findings of a Two-stage Method in a retrospective cohort study”. We have now revised the manuscript as suggested by the reviewers.

We have stated all the comments from the reviewers with our responses underneath each comment. Please note that the lines that we refer to in the responses to the comments are the ones in the revised manuscript.

The revised paper and the cover letter with comments and responses have been seen and approved by all authors.
We think the changes have improved and increased the quality of the paper and hope that you will consider our paper for publication.

Yours sincerely,

Gianfranco Damiani
Response to the reviewers for the manuscript “The Incidence of Adverse Events in an Italian Acute Care Hospital. Findings of a Two-stage Method in a retrospective cohort study”

Comments to author followed by our responses underneath – reviewer 1 Giovanni Rabito

Minor Essential Revisions

Comment 1
There are some typing errors that need to be corrected
Response
Thank you for your warning, we corrected all typing errors.

Comment 2
Which is the proportions of admissions studied?
Response
The study sample amounts to 7.3% of the overall inpatient admissions in 2008. We have reported this detail in the methods section.

Comment 3
Could you provide the hospital median length of stay for units of discharge considered in the study? Reviewing only the short-stay patients could affect the random nature of the sampling.
Response
As reported in table 1, the median length of stay was: 5 days for Medical Wards, 7 days for Surgical Wards and 18 days for Intensive Care Unit.

Comment 4
The figures mentioned in the Abstract Results should be aligned to the figures in the tables (table n.2 and n.3).
Response
Thank you for your warning. We aligned the figures in the Abstract Results to those in the tables.

Comment 5
Could you provide any explanation about the results obtained by the Charlson Index for the patient sample? Did it reflect the hospital case mix?
Response
Thank you for the comment which allows providing further interpretation of results. The study suggests that Charlson Index is not significantly associated to the occurrence of AEs. This is justifiable because Charlson Index has been used in order to predict mortality (Charlson ME, J Chronic Dis 1987) and very few AEs led to death. As well-known, Charlson Index reflects comorbidities. Furthermore, if clinical coding is accurate, it may be supposed that Charlson Index represents the hospital case mix. This was also suggested by other studies in the literature (Mohammed MA, BMJ 2009).

Comment 6
In the selection of hospital discharges, did you consider readmission within 30 days as trigger?
Response

Largo F. Vito 1, 00168 Roma
In the modular review form for detection of AEs a new unplanned re-admission within 21 days of discharge was one of the screening criteria. Indeed, it was considered as trigger.

Comment 7
Authors used 18 screening criteria (RF1 and RF2) adapted by those of Vincent et al.: details about questionnaire are required in annex or may be as electronic supplement.

Response
Thanks for your suggestion which has allowed us to identify even a small mistake in the text. In fact, the screening criteria of the Review Form 1 (RF1), adapted by those of Vincent et al, were 16 and not 18. On the basis of your advice, we provided the RF1 and RF 2 in annex and also listed them below:

REVIEW FORM 1 (RF1)

1. Was the patient taking any drug?
2. Does the patient have any comorbidity?
3. New unplanned re-admission within 21 days of discharge
4. Injury/fall during the hospital stay
5. Allergic reaction
6. Unplanned transfer from general care to intensive care or higher dependency
7. Unplanned transfer to another acute care hospital
8. Unplanned return to the operating room during the hospital stay
9. Complications during surgery, invasive procedures or delivery
10. Other complications including myocardial infarction, stroke, pulmonary embolism
11. Onset of new neurological deficit
12. Unexpected death
13. Cardio-respiratory arrest
14. Injury or complications related to abortion, labour and delivery including neonatal complications and low Apgar score
15. Hospital acquired infection or sepsis
16. Any other undesirable outcomes (not covered by any of the other criteria)

REVIEW FORM 2 (RF2)

An adverse event has to fulfil all three criteria:
1. an unintended injury or complication
2. temporary or permanent disability and/or increased length of stay or death
3. caused by health care management

Discretionary Revisions

Comment 1
Could you provide information about the average time spent for reviewing clinical records? The experience of hundreds of organisations has shown there is a propensity to review the easier case notes.

**Response**

In our study the time spent for reviewing clinical records was not taken into account but, since the sampling was random, there is no reason to believe that there has been a tendency to review the easier clinical records.

**Comment 2**

The percentage of adverse events (AE) should be reported in the Abstract Results

**Response**

On the basis of your suggestion we reported the percentage of AEs in the Abstract Results.

**Comment 3**

In the methods you could briefly specify if you adopt a specific path in the review process

**Response**

The path of the review process is specified in the Methods of the study, on page 5, from line 151 to 166.

**Comment 4**

Did you assign and collect information about severity of AEs? It should be useful to know severity of AEs related to organizational risk factors.

**Response**

Thank you for the comment. In case, we could focus our attention on this topic in a next study specifically dedicated to assess the association between severity of AEs and organizational risk factors.

**Comment 5**

Which specialities are included in the review? Which is the proportion of inpatient care?

**Response**

All hospital specialties were included in the review (Medical Wards, Surgical Wards and Intensive Care Unit) and the proportion of inpatient care was about 72% of the overall admission in 2008. We have enclosed this information in the amended version of the paper.

**Comment 6**

Did the specialties included in the review reflect the hospital practice?

**Response**

The sample was taken randomly and all the specialties were represented in the final sample. Indeed, the specialties included in the work reflect the hospital practice.

**Comment 7**

In the abstract conclusion, it should be better to empathize the role of organizational factors. There seems to be a small discrepancy between your findings in the abstract conclusion and the discussion. In particular, in the discussion you wrote: “Relative to several intrinsic risk factors, the high frequency of AEs in patients admitted to ICU suggests that patient vulnerability could play a
major role in generating AEs [18,19,30,14,3]. However, our study doesn’t show any association with comorbidity assessed by the Charlson Index. ....In conclusion on the basis of our results, it appears that organizational characteristics, taking into account the adjustment for comorbidity, are the main factors responsible for AEs while patient vulnerability played a minor role.” In the abstract conclusion, you wrote “high frequency of AEs in patients admitted to ICU suggests that patient vulnerability could play a major role in generating AEs, as well as the organizational context.”

Response
Thank you for pointing out the need of clarification of the role of organizational factors also in the abstract. On the basis of your suggestion we clarified this issue in the abstract conclusion.

Comments to author followed by our responses underneath – reviewer 2  Maria Giuliana Solinas

Comment
I have only a question (the authors are free to explain) regarding the role of confounding pattern in multivariable model. If it is possible, to explain.

Response
In order to control for confounding variables, we based our analysis on an additive regression model, using the value of 0.25 as cut off for the selection and inclusion of variables in the logistic model. The detail about the model (additive) was enclosed in the text.