Author’s response to reviews

Title: Use of a trigger tool to detect adverse drug reactions in an emergency department

Authors:

Silvana Almeida (silvana.mariadealmeida@gmail.com)

Aruana Romualdo (aruana.romualdo@einstein.br)

Andressa Ferraresi (andressa.ferraresi@einstein.br)

Giovana Zelezoglo (giovana.zelezoglo@einstein.br)

Alexandre Marra (alexandre-rodriguesmarra@uiowa.edu)

Michael Edmond (michael-edmond@uiowa.edu)

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Reviewer reports:

Domenico Motola (Reviewer 1): The manuscript reports the results of a study aimed at identifying ADRs through the use of trigger tools, in particular the use of certain drugs such as glucocorticoids and antihistamines.

The study is interesting because it applies an alternative methodology for identifying ADR, but it also presents some critical aspects listed below.

Authors: We really appreciate your review.

1) Page 3, lines 68-69: Authors' statement is not supported by the evidence mentioned and in any case it is not common opinion that current pharmacovigilance methods are expensive and ineffective. The sentence needs to be changed.

Authors: We have changed it.
2) Page 4, line 91. The authors state that patients were randomly selected. It would be interesting to know what inclusion and exclusion criteria were used.

Authors: We have added it.

3) In the paragraph of the results, it would be advisable to provide some additional details on the type of ADR that the patients showed.

Authors: We have added it.

4) Page 10, line 195. See comment number 1.

Authors: We have changed it.

5) Page 10, line 10. The reference to adverse events is improper as it applies to investigational drugs. Delete.

Authors: We have corrected it.


Authors: We have changed them. Some results we need to show in the discussion to compare with other papers.

7) Among the limits of the study it should be stated that not all ADRs require medicines used as trigger drugs, so in this study such ADRs have not been considered.

Authors: We have added it.
Emanuel Raschi (Reviewer 2): The work by de Almeida et al. estimated the impact of adverse drug reactions (ADRs) on hospital admission in a tertiary care hospital in Brazil.

The article is not new in the literature (and authors properly discussed their data in the light of published surveys), although of interest as it applies a so-called trigger tool (i.e., medications that may be administered in response to ADRs), which might theoretically increase the detection rate, as compared to traditional methods.

Here below, the following concerns are listed:

- TITLE. The authors entitled their work an "active surveillance", although the study was retrospective. Therefore, they should consider to modify the title, for instance by specifying the application of the trigger tool. Moreover, the setting should be specified (i.e., Brazilian tertiary care hospital).

Authors: We have changed it.

- AIM. The study aims to estimate the incidence of ADRs; however, the retrospective nature of the work does not allow to calculate incidence, but instead PREVALENCE. This should be consistently modified in the text.

Authors: We have changed it.

- CONCLUSION. The authors' statement is not supported by the data. In fact, to claim the usefussfulness of the trigger tool, a comparator group is needed, or at least a secondary analysis to evaluate the detection rate through traditional approaches. The limited sample size does not allow to draw firm conclusion. I think that the conclusion should summarize key results and call for additional studies to directly compare the detection rate of different approaches.

Authors: The trigger tool was important to detect the ADRs. The ADRs represented known interactions and are likely to be preventable. That is the most important part of this manuscript to avoid unintended consequences in an emergency department about ADRs and to understand it to treat and to prevent them.

- DISCUSSION. The authors discussed the JAMA paper on US data, but no discussion is provided on the most updated survey of 2016 (quoted in the bibliography). The section on limitations should be strengthened, also by discussing the limited sample size.
Authors: We have corrected it. We believe that the limited sample size is because our study is representing only one year of evaluation of the trigger tool methodology for patients treated at the emergency room of a tertiary care hospital.

- ABSTRACT. Apart from issues related to conclusion and incidence, methods and results should be revised. For instance, the trigger tool should be briefly described, and the sample size provided.

Authors: We have corrected it.

- Minor typos should be corrected (e.g. requir line 157, ARDs line 194).

Authors: We have corrected them.