Reviewer’s report

Title: Characterization and preventability of Adverse Drug Events as cause of Emergency Department visits: a prospective 1-year observational study

Version: 0 Date: 06 Aug 2018

Reviewer: Balamurugan Tangiisuran

Reviewer's report:

General comment:

The aim of this multicentre observational study is to describe the frequency, severity, and preventability of ADEs reported in Emergency Department (ED) over 1 year period in Sicily, Italy. This study is interesting and well-written, despite the fact that we can consider that there is no new original conclusion that could be drawn. Comparison of the current study to other studies that have been published previously in European countries or US studies find that there are no differences in term of the occurrence of ADEs in ED. It is unfortunate that there is no information about outcome of patients (at least deceased or alive). Nevertheless, the information about severity of ADEs and ADEs which have resulted in hospitalization is very useful to describe the outcome at the point of ED visit. A focus on severe and preventable ADEs is interesting and will provide the readers to focus on drug classes that will need special monitoring.

While the author is to be commended for his effort, there are a number of questions remaining to be clarified and are outlined below by section.

Title

The title of the manuscript is concise with information on the main objective and study design.

Abstract

* Suggest to add more information in the method section. Information on case identification process is not stated.

Method

* Page 3, Line 64 - There is lack of information on the case identification process in the method section. It is not clear whether only cases diagnosed by ED physicians were included
based on patient record review or the monitors assess each cases individually to identify any missed cases.

* Page 3, Line 66 - The effective diagnosis of ADE was performed by an independent ED physicians or by the same person? It will be good if another independent reviewer evaluated each of the identified ADEs to increase the reliability of the finding. There are several studies have been published showing the existence of variability between healthcare professionals and also in the method utilised for the identification of ADEs.

* Page 4, Line 104 - It is supposed to be Mann-Whitney U test

* The inclusion statement given is very vague. There is no minimum cut-off age in the inclusion criteria. Does it mean that paediatric patients were included in the study as well?

Results

* Page 4, Line 121 - It will be good to show whether the comparison between the patients with various severity were statistically significant. Statistical analysis using Mann-Whitney U test can be done perform the comparison between the groups.

* Table 3 - Page 16; Line 1: column two should be Types of drug classes.

Discussion

* Page 6, Line 164 - One of the main reason for choosing EDs as a useful setting to identify the occurrence of ADEs should be due to the reason that most of the ADE cases are usually screened and identified in emergency department. Recruitment of patients in the ward will only allow the researcher to identify cases that causing hospitalization.

* Whilst the current study highlights the important issues around the use of medications causing preventable ADEs, there is no recommendation were given to reduce or prevent this problem. The author recommended that appropriate education strategies need to be promoted. However, several strategies have been developed by researchers worldwide in order to reduce the occurrence of ADEs. There are two common strategies that can be used to reduce or prevent the occurrence of ADEs among older people. The first approach is by focusing on the analysis of the process of care, while the second method is through identification of patients who are 'at-risk'. Suggest to include these preventive strategies in the discussion section.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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