Reviewer's report

Title: Mild Traumatic Brain Injury with CT scan abnormality: which patients are safe for discharge? A protocol for the development of a prediction model in a retrospective cohort

Version: 0 Date: 08 Feb 2018

Reviewer: Vanesa Bellou

Reviewer's report:

This manuscript is a protocol of a retrospective study based on hospital records with an aim to develop a clinical prediction model. The population in interest is patients presenting with traumatic brain injury in the emergency department and admitted in the hospital. They focus on patients with a high Glasgow Coma Scale (13-15). The clinical endpoint is a composite outcome entailing multiple adverse outcomes and the goal is to identify those patients who will deteriorate and need hospitalization.

In general this is a well written protocol, on a clinically significant topic. Traumatic brain injury is a very common cause of attendance in the emergency department and the authors raise a valid research topic. I would like to propose a few edits to amend the protocol

1) In the inclusion criteria please elaborate on the definition of traumatic brain injury. Be more specific about the mechanism of trauma and the CT findings that were deemed eligible. Also you mention in the exclusion criteria that you excluded spontaneous intracranial hemorrhage. How was that ascertained? Moreover, please give more details on which type of pre-existing brain pathologies you excluded.

2) In the study outcome you mention as part of the composite endpoint "intravenous therapy whilst an inpatient". Please clarify what type of treatment that includes eg antibiotics, antiepileptic medication

3) Page 8, line 2 : you mention that predictors that you will retain in the multivariate model prediction having great clinical relevance. Do you mean that this is true even if they don't fulfill the p-value criterion? What is your rationale for that?

4) You mention that according to your sample size and the expected prevalence of the outcome that allows the model to include 20 variables. However this is a very big number of variables for a model to allow application in acute care settings. A prediction model
that is intended for use in the emergency department should include a small number of factors, that are easily and quickly measured

5) Please specify the method you will use for imputation of missing values

6) If you have access in the Italian cohort why not perform external validation then? Why did you decide to compare results only?

7) Page 10, paragraph 2nd of limitations please rephrase the paragraph, it is very difficult to comprehend

8) Figure 1: I would propose one column with the factors and group them by source of inclusion

9) Comment on midline shift and size of bleed are two factors that suffer greatly from lack of interobserver agreement. How will this be assessed, qualitatively or quantitatively?

10) When you mention CT head report as a factor what do you mean? How is that assessed?

11) GCS as a variable in the final model is dependent on the eligibility criteria you set and has low variability. I would propose to omit it as a variable.

12) Please add in table 1 for each candidate factor how it will be handled (as a categorical or continuous variable)

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