Reviewer's report

Title: Severe hypoglycemia symptoms, antecedent behaviors, immediate consequences and association with glycemia medication usage: secondary analysis of the ACCORD Clinical Trial data

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Reviewer: Rattan Juneja

Reviewer's report:

Overall this is a well written manuscript. It addresses a very important -and often less emphasized aspect of hypoglycemia; its antecedent causes. Although in clinical practice, root cause analysis of the reasons for hypoglycemia is the accepted norm both in patient teaching and physician evaluation, in clinical trials, data such as collated in this study are rarely presented. One is then left wondering if a particular drug was associated with increase in hypoglycemia or if there were other factors such as dietary changes, exercise etc. a contributing factor. With this study the autors have clearly shown that non-drug related factors do indeed matter and need to be taken into consideration in any clinical trial reporting hypoglycemia. As such I see this study as an important milestone in perhaps setting the stage for future clinical trials (including those designed for regulatory approval for a drug) incorporating such reporting. I complement the authors on taking on this important analysis.

The only revision I would recommend it to clarify language both in the abstract and body of the document where the term INT and STD are used without a clear explanation that they mean INTERVENTION Group and STANDARD treatment.

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

No Competing interests