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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Dear Sirs and Madams’

We respectfully request your consideration of our manuscript “Severe Hypoglycemia in ACCORD: symptoms, participant behaviors, immediate consequences and association with glycemia medication usage” for publication in BMC Medicine. This manuscript reports the results of post-hoc analyses of the antecedents and consequences of hypoglycemic events in the ACCORD trial and their association with classes of glycemia medications. This paper compares these events within and across ACCORD glycemia study arms.

Many health care providers perceive that hypoglycemia is not a significant problem in patients with type 2 diabetes. However, we found clinically serious consequences in both the standard control and the intensive control participants. Additionally, practitioners may believe that analog insulins will reduce the risk of hypoglycemia, yet we found episodes of severe hypoglycemia despite analog use. Finally, while it is known that a caloric or carbohydrate decrease my lead to hypoglycemia, the extent to which this contributes to severe hypoglycemia is not widely known. Publication of these may provide a framework to change clinical practice and alert practitioners to be more watchful of hypoglycemia and to focus on carbohydrate/food causes and solutions as an early step in prevention.

This manuscript is not under consideration by another journal. The on-line version of the ACCORD protocol has been referenced in the Methods section of the paper and can be found at the following address:

The authors declare the following conflict of interest:
Bonds, Miller, Dudl, Feinglos, Malozowski, Seaquist, Simmons: No Conflicts of Interest
Sood: Consultancies: Pfizer, Abbott, Medtronic (All one time only, 2005-2008), Honoraria for public speaking: Pfizer, Novartis (All one time only, 2006)
Ismail-Beigi: Consultant, Eli Lilly Corporation

Please do not hesitate to contact me if I can be of any assistance. My telephone number is 301-435-0379 and my email is bondsde@nhlbi.nih.gov.

Sincerely,

Denise E. Bonds, MD, MPH
Medical Officer