Reviewer’s report

Title: Hypoglycaemic events in Patients with Type 2 Diabetes in the United Kingdom: Associations with Patient-Reported Outcomes and Self-Reported HbA1c

Version: 3 Date: 10 October 2013

Reviewer: Linda Gonder-Frederick

Reviewer’s report:

This is a well-written and well-organized report on the impact of hypoglycemic episodes on individuals with type 2 diabetes in the U.K. The authors have taken a comprehensive perspective and investigated a broad range of outcome variables ranging from quality of life to clinical status, which adds to the significance of the paper as a contribution to the hypoglycemia literature. There are, however, several questions that need to be addressed to improve the manuscript and help the reader understand the study and findings.

Major Compulsory Revisions

1. As the authors note, the study was planned as a longitudinal prospective project, with participants completing outcome measures on six separate occasions. Compliance to the longitudinal protocol was poor and by the sixth assessment, only 34% of participants responded, with only 9% of participants completing all six assessments. While the authors note this as problematic, they have chosen to report the findings on the 9% of participants who completed the protocol as a guide to future research. Although this is the prerogative of the authors, what is missing is methodological detail on how the follow-up assessments were conducted, and this needs to be included in the Methods section. For example, what type of reminders did participants receive and how many? What was the level of contact with participants for follow-up data collection? Why do the authors think that the compliance rate for the entire protocol was so low? This type of information is needed to evaluate the study methods/findings and to help other researchers planning similar longitudinal studies. The other alternative the authors could consider is leaving out the follow-up data, although this may not be appropriate given that several statistically significant findings emerged even with the reduced power.

Related to this point, the Results section (paragraph 1) needs to describe the number of respondents who completed each follow-up assessment

2. The method for soliciting potential respondents is also unclear, even though the authors do go to a great deal of trouble to describe this in detail. However, several issues remain unclear. For example, what is the purpose of the SEU NHWS survey? Why were respondents who indicated that a family member had type 2 diabetes invited to participate in the study? How many of the potential respondents did have type 2 diabetes and of these how many declined to participate?
3. Table 2 should be described as “Clinical” characteristics and not “Patient” characteristics in the first paragraph of the Results section.

4. In the fourth paragraph of the discussion, the statement regarding individuals who maintain low blood glucose who are “closer to hypoglycemia” should be rewritten to reflect that individuals with lower glycosylated hemoglobin measures are indeed at higher risk for hypoglycemia according to several studies and give representative references.

5. What do the authors think are the clinical implications of their findings?

**Level of interest:** An article of importance 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:**

My research program has received licensing fees from Eli Lilly for the use of the Hypoglycemia Fear Survey-II.