Author’s response to reviews

Title: Systematic literature review of use of blood glucose monitoring in phase III clinical studies of insulin analogs

Authors:

Kaisa Miikkulainen (kaisa.miikkulainen@gmail.com)
Antonio Caruso (antonio.caruso@roche.com)
Oliver Mast (oliver@familie-mast.de)
Rongrong Zhang (rongrong.zhang@synergus.com)
Oleg Borisenko (oleg.borisenko@synergus.com)

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Response to reviewer’s comments for the manuscript

"Systematic literature review of use of blood glucose monitoring in phase III clinical studies of insulin analogs"

(Ms# BEND-D-15-00121)

Reviewer #2

Comment 1: A statement should be included in the introduction, why is the role of SMBG discussed controversly? State the issue of conceptional problem with assessment of SMBG efficacy since SMBG per se is a diagnostic procedure and not an intervention.

Response: We agree with the comment.

Actions: The following was added to the Introduction section: “Another contributing factor to complexity of assessment of efficacy of SMBG is that is it a diagnostic measure, not a treatment intervention.”

Comment 2: Furthermore a statement in the discussion should be added regarding the importance of a SMBG-based disease management strategy.

Response: We already have two paragraphs in the Discussion section, focused on the role of SBMG in the overall management of diabetes, however additional comment was made.
Actions: The following was added to the Discussion section: “And SMBG is only helpful, if it results in therapeutic consequences. To achieve that SMBG shall be placed in the center of the disease management for diabetic patients, including appropriate training of structured testing, as mentioned above.”

Editorial comments

Comment: Ethics: If your study involves humans, human data or animals, then your article should contain an ethics statement which includes the name of the committee that approved your study. If ethics was not required for your study, then this should be clearly stated and a rationale provided.

Response: Our study does include any patient’s data and thus does not require ethical approval.

Actions: The following statement was added to the methods section: “Study did not require ethical approval, as it did not include any patient’s data”.

Comment: Consent: If your article is a prospective study involving human participants then your article should include a statement detailing consent for participation. If individual clinical data is presented in your article, then you must clarify whether consent for publication of these data was obtained.

Response: Our study is not a prospective study involving human participants, so obtaining consent was not relevant.

Actions: Not required.

Comment: BioMed Central strongly encourages all data sets on which the conclusions of the paper rely be either deposited in publicly available repositories (where available and appropriate) or presented in the main papers or additional supporting files, in machine-readable format whenever possible. Authors must include an Availability of Data and Materials section in their article detailing where the data supporting their findings can be found. The Accession Numbers of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript must be provided and include the corresponding database name.

Response: Our study includes published studies or Clinical Study Reports, which can be obtained from the European Medicines Agency, according to Regulation (EC) No 1049/2001. All information, required to interpret results of the study is provided in the Tables 1 and 2.

Actions: The following section was added: “Availability of data and materials: All information, required to interpret results of the study is provided in the Tables 1 and 2 of the article”

Comment: Authors Contributions: Your 'Authors Contributions' section must detail the individual contribution for each individual author listed on your manuscript.
Response: The section already exists in the manuscript.

Actions: Not required.