Reviewer’s report

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

Version: 0 Date: 10 Feb 2016

Reviewer: Gerlies Treiber

Reviewer’s report:

Miikkulainen et al performed a systematic literature review and reported the proportion of blood glucose monitoring in phase III clinical studies of insulin analogs.

I completely agree that SMBG is a mandatory component of effective therapy in patients with diabetes who are on insulin. SMBG is an integral part of patient self-management, enabling patients to adjust the dosage of their insulin according to their food intake and physical activity. However, the measures to be taken by individual patients on the basis of measurement results are often not governed by any algorithms or guidelines. SMBG is only helpful when it results in therapeutic consequences. The knowledge required for this can be gained by means of training courses. SMBG measurement frequency depends on several individual factors like type of diabetes, treatment targets, risk of hypoglycemia, stability of metabolic control, patients motivation and so on. Having said that, SMBG is an essential part of an intensified insulin treatment protocol.

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

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

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes
Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I am able to assess the statistics

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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