Reviewer’s report

Title: Biphasic Insulin Aspart 30 vs. NPH plus Regular Human Insulin in Type 2 Diabetes Patients; A Cost-Effectiveness Study

Version: 0 Date: 26 Jan 2016

Reviewer: Marcin Czech

Reviewer's report:

Please find my comments below:

1. Please describe a randomisation method

2. How VAS was used as a second method of QALY calculations? Directly? VAS is a part of EQ-5D.

3. How disutilities from hypoglycaemias were calculated?

4. Have you considered using country-specific population utilities (if available)?

5. Don't you think that lack of cost differences in the number of visits is a consequence of a study protocol (the same number of visits in both arms)?

6. What method of indirect costs calculations was used? Human capital approach? Based on GDP per capita or salary lost? Friction cost method?

7. Final utility values from the results section needs more explanations (in discussion?) due to unexpectedly big differences

8. How hypoglycaemias were included in QALY measures?
9. In abstract: the last sentence in methodology section not finished; in the results section-abbreviation FPG and PPG should be introduced; in conclusions: "offers the same glucose control" not supported as it is dose-dependent, the drug was titrated

10. Please decide if HbA1c or A1c is used. Harmonise in the text

11. Spelling / spaces (p-page, l-line)
- p.6 l.29 "clinical of trial". "of" not needed
- p.6 l.48 "estimated" not "Estimated"
- p.9 l.7 space missing after L
- p.9 l.26, l.29 space after full stop and before [..] needed
- p.15 l.26 space after full stop needed
- p.16 l.31 space before [..] needed
- p.16 l.34 space after full stop needed
- p.17 l.29 space after full stop needed
- p.17 l.56 space before [..] needed- p.6 l.29 "clinical of trial". "of" not needed
- p.9 l. 28

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.

Yes
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 recommend additional statistical review

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

Needs some language corrections before being published

Declaration of competing interests  
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below.  
If your reply is yes to any, please give details below.
Ad. 1. In the period of 2007-2015 I was employed at the European Health Economics and Outcomes Research Team of Novo Nordisk. (I have even published in BMC Endocrine Disorders under this affiliation)

Ad. 2. I possess Novo Nordisk shares

I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal