Author's response to reviews

Title: Understanding and meeting the needs of those using growth hormone injection devices

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Author's response to reviews: see over
Re: MS 1991757280986305. Understanding and meeting the needs of those using growth hormone injection devices.

Herve Dumas, Paris Panayiotopoulos, Dorothy Parker and Vincent Pongpairochana.

Dear Dr Fairservice

Thank you for sending us the review comments on the above manuscript. First of all, may we point out that the second reviewer, Dr Zvonko Milicevic, is an employee of Eli Lilly, which is a rival company to Serono. Dr Milicevic works with, and has published on, potentially competing injection devices developed by Eli Lilly (1), including the HumatroPen®, which is mentioned as one of the electronic device comparators in our manuscript. We do not, therefore, feel that Dr Milicevic’s review is impartial.

We will address the points made below by Dr Milicevic, but we feel that, due to his conflict of interest, the points made by him under minor essential revisions are there just to cause delay and inconvenience rather than to increase the accuracy and value of our manuscript. We are also very concerned that Dr Milicevic seems to have the power of veto over publication of our manuscript (his comment under “What next?” – “Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions”). We trust that if we have dealt appropriately with the suggestions under Revisions, there will be no obstacle to publication or that another, independent, reviewer will be allowed to arbitrate.

We would be grateful if, for future manuscripts we may submit to BMC Endocrine Disorders, you would not send them for review to employees of companies in direct competition with Serono.

Requested Formatting Changes

Ethics - Experimental research that is reported in the manuscript must have been performed with the approval of an appropriate ethics committee.

We did not need ethics committee approval as this survey was conducted as a marketing research project under the codes of conduct of the relevant ethical professional bodies: MRS, BHBIA, EphMRA/ESOMAR and PBRIG (USA).
Major Compulsory Revisions

1. Result section: With regard to the statement that the electronic device prototype is better accepted than others, it is unclear how this conclusion was reached (based on what kind of comparison). What statistical procedure was used?

   Our manuscript is based upon qualitative research which, by definition, does not lend itself to in-depth statistical analysis. The findings were the respondents’ expressed personal choices and the results of individual self-completion scoring sheets.

2. Methods: How was the list of 19 attributes validated? This is a crucial question.

   The participants in the survey first spontaneously identified the key device attributes that were important for them. These attributes were then compared with a pre-existing list and the participants were free to add extra attributes from this list, if they wished. The participants were then asked to score each of the selected attributes for importance. In other words, users of injection devices themselves were asked to rate the most important things they look for. The text has been amended to make this clearer.

3. Results: It seems that the patients had different opinion versus the other 3 groups of participants. Please, provide data in this section and comment in the Discussion section.

   This is a misunderstanding on the part of the reviewer. The patients, i.e. children, did not complete the self-completion scoring sheets, as these were felt to be inappropriate for children. The children’s views were expressed spontaneously and key aspects were probed for, e.g. views on ease of use, size etc. However, only the views of those who completed the self-completion scoring sheets (parents, nurses and physicians) are reported. This was already explained under methods, but the text has been revised to emphasise this point.

4. Figure 3 is pretty complex. I propose to find an easier way to compare various devices. An average reader may have problems to get the message.

   A new version of Figure 3 has been substituted.
Minor Essential Revisions

1. **Background, pg 3:** It is important to elaborate more precisely on how devices are impacting compliance and which other factors are involved. Please, provide some data on who is injecting the drug (parents, pts, nurses). This is different for different patient subgroups. It is an important question, but not elaborated in the introduction.

   This point is already covered in the section under “Methods” headed “Participants”: “Participants included prescribing physicians …… with recent experience of treating patients aged <18 years with r-hGH, nurses involved in patient training and support, teenage patients self-injecting r-hGH using a delivery device, and parents injecting their children (aged <14 years) with r-hGH”.

2. **Discussion: How the list of 5 most important attributes compare with the literature?**

   We do not feel this question is relevant. The purpose of our manuscript is not to review the literature on injection device attributes, but rather to present the opinions of a group of device users on what they consider to be the most important device attributes.

3. **Discussion: Please provide some analysis on why the outcomes were different in the pt subgroups versus health care professionals and parents.**

   This is a misunderstanding on the part of the reviewer, see under Point 3 in Major Compulsory Revisions, above.

   We hope the above comments and revisions to the manuscript have addressed all the required revisions. We look forward to hearing from you.

Yours sincerely

Hervé Dumas
References