Author’s response to reviews

Title: Outcome measures for oral health based on clinical assessments and claims data. Feasibility evaluation in practice

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Author’s response to reviews:

Re: OHEA-D-16-00510R1. “Outcome measures for oral health based on clinical assessments and claims data. Feasibility evaluation in practice.”

Dear Mrs. Symmons,

Thank you very much for your decision that our manuscript is potentially acceptable for publication in BMC Oral Health after minor revisions. We respond point by point on the next pages, and are confident that we addressed all items raised.

We look forward to hearing from you in very due time. We would be glad to respond to any further questions and comments that you may have.
On behalf of all authors,

Yours sincerely,

Riët Hummel

1. In the Ethics approval and consent to participate section of the Declarations please confirm whether your study was submitted to and approved by your institutional ethics committee. Please also ensure that the full name of your ethics committee is included in this statement. If the need for ethics approval was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation.

This study concerns a Health Services Research project which under the Medical Research Involving Human Subjects Act (WMO) is not considered as medical-scientific research. (www.ccmo.nl/en/non-wmo-research http://www.ccmo.nl/en/types-of-research) And as such, neither is ethics clearance from a Medical Ethics Research Board, nor is individual consent of patients required.

A Trusted Third Party has taken care of handling, processing and analyzing data in a secure, anonymous and privacy protected manner. We have thereby taken due care that data cannot be traced back to individuals, while during the data analyses confidentiality was maintained by data coding.

We added this to the ‘Ethics approval and consent to participate’ section of the ‘Declarations’ section (page 22, line 4).

2. We note that you accessed databases from both Dutch healthcare organizations and international organizations in your study to select and develop measures. Please could you clarify whether access to these databases is open or closed. If some of these databases are not publically available please clearly state in the Ethics approval and consent to participate section who you obtained permission from to access and use these databases.
All databases were open at the time of the search in December 2012. Up to date, we noticed that not all websites are accessible anymore, probably because these were removed.

Please could you also clarify who you obtained permission from to access and use the claims records from Achmea and the clinical records from dental practices and clearly state this in the Ethics approval and consent to participate section. If permission was not obtained please state this with a justification.

Prior to project initiation permission from the Achmea Committee on Health Research Data was obtained to access and use the claims records. Permission from the dental practices was part of a contract between the dental practices and Achmea concerning participation in this project. We added to the ‘Ethics approval and consent to participate’ section (page 22, line 12) that claims records and clinical records were used with permission from Achmea and the dental practices.

3. We note that experts and GDPs took part in your study as well as patients. Please confirm whether informed consent, written or verbal, was obtained from them in the Ethics approval and consent to participate section. If verbal, please state the reason and whether the ethics committee approved this procedure. If the need for consent was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation.

The experts are co-authors (JB, WvdS, GvdH) and consented; Melanie Nieuweboer consented as well (see also point 10). Consent of the participating dentists was part of the contract between the dental practices and Achmea. The need for informed consent from patients was not necessary according to national regulations as described in point 1. The GDPs asked permission from patients with clinical assessed measures during consultation. The data for the clinical assessed measures were collected and anonymized before being analyzed by Achmea. So re-identification was precluded and written permission not required.

4. We note that you state in the Ethics approval and consent to participate section that consent was obtained from patients during consultation. Please could you clarify whether written or
verbal informed consent was obtained from them. If verbal, please state the reason and whether the ethics committee approved this procedure. We also note that some of the participants in your study were minors, please could you clarify whether consent was obtained from their parents or legal guardian on their behalf.

Verbal consent was asked. In case of minors, verbal permission was asked from their parents or legal guardian. See also point 3.

5. We note that you have not included a ‘Consent for publication’ section in the Declarations. Consent for publication refers to consent for the publication of identifying images or other personal or clinical details of participants that compromise anonymity. Seeing as this is not applicable to your manuscript please state “Not Applicable” in this section.

Consent for publication is not applicable, the manuscript does not contain any images or details that compromise anonymity. We added the heading ‘Consent for publication: Not applicable’ in the ‘Declarations’ section (page 22, line 14).

6. Thank you for providing an Availability of data and materials section in the Declarations. We understand that the data cannot be made publically available. We would however, like to confirm whether the data can be made available on reasonable request. If so please state this in this section including who should be contacted if someone wants to request the data.

The data cannot be made available, Achmea contractually agreed with the participating dentists that data shall not be shared with other parties in any form.

7. Please note that, as a standard, we require that all commercial sources of funding are mentioned in the Competing Interests section. You may choose to duplicate the funding statement in the Competing Interests section.
We duplicated the funding statement under the ‘Competing Interests’ heading in the ‘Declarations’ section (page 22, line 23).

We also note that some of the authors are employees of Achmea, as per our editorial policies this should be declared in the Competing interests section. Please see our editorial policies for more information [http://www.biomedcentral.com/getpublished/editorial-policies#competing+interests](http://www.biomedcentral.com/getpublished/editorial-policies#competing+interests)

We added to the ‘Competing Interests’ heading in the ‘Declarations’ section that two of the authors are employees of Achmea (page 22, line 23): ‘This study was funded by Achmea. The authors RH and OvdG are employees of Achmea. All authors declare no competing interest.’

8. In the Funding section please provide a statement clarifying whether the funding body played a role in the design of the study and/or collection, analysis, and interpretation of data and/or in writing the manuscript.

We added a statement clarifying that the funding by Achmea did not play any role in the design of the study and/or collection, analysis, and interpretation of data and/or in writing the manuscript (page 22, line 18).

9. Please provide the full names of all authors in the format first name, last name on the title page.

We note that author Hummel GI is listed as Riët (G.I.) Hummel in the system and has the initials GH in the Authors’ contributions section. Please ensure that the names of all authors are the same in the manuscript and the system and that the initials used in the Authors’ contributions section are consistent with this.
The names of the authors on the title page have been changed into the format first name, last name. The initials used in the ‘Authors’ contributions’ have been made consistent with this.

The names in the system are adjusted as well.

10. We note that you have included Melanie Nieuweboer in the Acknowledgements section who was part of the expert group. Please could you clarify whether you obtained permission from Melanie Nieuweboer and all others mentioned by name in this section to acknowledge them.

Before this resubmission we reconfirmed permission from all persons mentioned by name in the ‘Acknowledgements’ section.

11. Please provide a list of all the abbreviations used in the manuscript. This list should be placed just before the Declarations section. All abbreviations should still be defined in the text at first use.

A list with all the abbreviations is added and placed just before the ‘Declarations’ section (page 21, line 13).

12. Unfortunately BMC does not accept boxes for publication. Please remove Box 1 and include the information in a different format.

Box 1 is changed into a figure (figure 1) and the original figure 1 is changed into figure 2.
13. Please provide a ‘Figure legends’ section after the References where you include the legend for Figure 1.

We have added a ‘Figure legends’ section after the ‘References’ with the legend for figures 1 and 2 (page 27).

14. I'm afraid the quality of the English used throughout your manuscript does not currently meet our requirements and requires a minor copy-edit. For example “testedmeasures” in the Table 5 title should be corrected to “tested measures.” We recommend that you thoroughly check your entire manuscript for language errors and ask a native English speaking colleague to help you copyedit the paper.

We thoroughly checked the entire manuscript for language errors with the help of a native English speaker. Now if unintended typo’s are remaining we humbly will accept your help in the preparation for the galley proofs of our manuscript and will critically review these with your queries.

15. Please change the heading ‘Aim’ to ‘Background’ in the Abstract. Please also provide some information on the context of your study in this section.

The heading ‘Aim’ is changed into ‘Background’ and we added information on the context:

‘Background It is well known that treatment variation exists in oral healthcare, but the consequences for oral health are unknown as the development of outcome measures is still in its infancy. The aim of this study was to identify and develop outcome measures for oral health and explore their performance using health insurance claims records and clinical data from general dental practices.’ (Abstract, page 2, line 2)
16. We require a ‘Conclusions’ heading before your article can be handed to our Productions department. Please include a Conclusions section in your article after the Discussion section and before the Abbreviations.

We added a ‘Conclusions’ heading after the ‘Discussion’ section (page 21, line 5):

Conclusions. The evaluated measures ‘time to first restoration’, ‘distribution of risk categories for dental caries’, ‘filled-and-missing score’ and ‘retreatment after restoration’, were considered valid and relevant measures and a proxy for oral health status. As such, they improve the transparency of oral health services delivery that can be related to oral health outcomes, and may serve to improve these oral health outcomes after further development. As yet, these measures may inform discussions on quality of oral healthcare.

17. Please upload your revised manuscript as a clean copy and remove the manuscript with tracked changes from the additional files as it is no longer required at this stage of the editorial process.

We have uploaded a revised manuscript, one new figure and one revised figure. The manuscript with tracked changes is removed.