Author’s response to reviews

Title: Adaptation and validation of the PEDSQLTM Oral Health Scale for toddlers in Chilean population

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Author’s response to reviews:

RE: Manuscript OHEA-D-19-00429; "ADAPTATION AND VALIDATION OF THE PEDSQLTM ORAL HEALTH SCALE, SPANISH LANGUAGE VERSION”

Prof. Anne Menard
Editor-in-Chief
BMC Oral Health

Thank you for the invitation to resubmit our manuscript “Adaptation and validation of the PEDSQLTM Oral Health Scale, Spanish language version” (now entitled “Adaptation and validation of the PEDSQLTM Oral Health Scale for toddlers in Chilean population”, following Reviewer 2’s kind suggestion).
Below is an itemized summary of the editors’ and reviewers’ comments, followed by our responses and additions or modifications in the manuscript. These modifications in response to comments are highlighted in blue throughout the paper to facilitate your review.

Thank you for giving us the opportunity to revise our paper. We believe that the comments and suggestions by the editors and reviewers have improved it.

RESPONSE TO REVIEWER #1

General Comment

This manuscript reports the work of validating a Chilean Spanish version of the PEDSQTLm Oral Health Scale. The work is clearly reported, well justified and methodologically sound, although there are a few details that the authors should add to clarify the methods:

Our response: We very much appreciate the positive comments by reviewer #1, and will introduce the suggested modifications (kindly see responses to specific comments).

Specific comment #1

Methods. The authors recruited parents of children at 11 preschools in a region of Chile. They need to justify their approach. It appears that they recruited a convenience sample rather than a purposeful sample, which would have permitted them to test the capacity of the instrument to discriminate between groups with different problems.

Our response: We appreciate the reviewer’s remark, which is right: it is a convenience sample that includes all the public preschools of the selected district. This has been discussed further in the new version of the manuscript.
DISCUSSION, Line 319-329: “The PedsQLTM Oral Health Scale was not able to measure the impact of malocclusion problems or traumatic dental injuries in our sample. A recent systematic review concluded that malocclusions in this age group are not perceived by the parents as a problem with impact on the child's quality of life. Furthermore, a meta-analysis showed that only very severe malocclusion could affect the overall OHRQoL. The type of traumatic dental injuries detected most frequently in our study was enamel fracture, which does not have a significant impact on the quality of life of pre-school children. It is important to consider that the prevalence of TDI was low (14.5%) in our sample and only 2 preschoolers suffered complicated TDI (avulsion). On the other hand, although differences per malocclusion or TDI were not statistically significant due to its small magnitude, in both cases the patients without these problems showed a better OHRQoL than those with them. Studies based on schools have the advantage of including children with a wide range of good and poor oral health, and the disadvantage of including less severe oral problems than in clinical settings.”

Specific comment #2

Furthermore, while the instrument is validated to measure OHRQoL among a wide age group range, the authors only validated it in a young age group - why?

Our response: One of the priority groups of Chilean oral health policies is preschoolers, and several public health programs have been implemented in this age group. The knowledge of their OHRQoL might help to improve the development of effective oral health programs and their evaluation. The following text has been added to the new version of the manuscript:

INTRODUCTION, Line 83-87: “Although the PedsQLTM Oral Health Scale was developed to measure OHRQoL among children aged 2 to 18 years (with parent-reported form for 2-4 years, and with parent- and self-report forms for 5-7 years, 8-12 years, and 13-18 years), we only adapted the version for toddlers because they were the priority group of Chilean oral health policies and several public health programs have been implemented in this age group.”

Specific comment #3

The authors did not provide an ad hoc sample size estimate. They presumably had one or somehow decided to recruit the number of parent/child dyads they did - this needs to be explained. The sample size seems sufficient, but the approach needs clarification.

Our response: We appreciate the reviewer’s remark, and the following information has been added into the Statistical Analysis subsection of the new version of the manuscript:
MATERIAL AND METHODS, Line 162-164: “The sample size was estimated following the recommended standard of 2 to 20 participants per item with a minimum of 100 to 250 subjects. Considering this last number of participants recommended, and assuming a 20% of potential missing answers, the sample size required was of 300 children.”

RESPONSE TO REVIEWER #2

General Comment

The reported aim of this study was to cross-culturally adapt the PedsQL Oral Health Scale into Chilean Spanish and assess its reliability and validity. It is a well written manuscript and seems to be well designed. However, I have a concern about what age group's form was adapted and validated, because there is no form that includes children from 2 to 5 years old. There is a form to 2-4 and another to 5-7 years old. The authors must carry out some major revisions in order to improve the manuscript.

Our response: We thank reviewer #2 for their feedback, and will introduce the suggested modifications (kindly see responses to specific comments).

Specific comment #1

The PedsQL Oral Health Scale is an instrument from 2 to 18 years-old, and this study validated only the instrument for toddlers (2-4 years-old). Thus, the title is not adequate since it does not inform that study only makes available toddler’s Spanish version of the PedsQL OH. The same information should be also clear in the aim of the study. Still in title, it is important to inform that the instrument was adapted for Spanish from Chile.

Our response: We appreciate the reviewer’s remark, and the title and objective have been modified accordingly.

TITLE: “ADAPTATION AND VALIDATION OF THE PEDSQLTM ORAL HEALTH SCALE FOR TODDLERS IN CHILEAN POPULATION”

OBJECTIVE, Line 81-83: “The aim of this study was to cross-culturally adapt the original parent-reported version for toddlers of the PedsQLTM Oral Health Scale into Chilean Spanish and to assess the acceptability, reliability and validity of this version in Chilean preschool population”.

Specific comment #2

Introduction. In the 4th paragraph, the authors have made a little confusion about the generic PedsQL instrument and those condition-specifics. The authors imply that specific modules for various chronic diseases and clinical situations are part of the generic instrument, what is not true. They are different instruments that could be used along with the PedsQL Generic Core Scale.

Our response: We appreciate the reviewer’s remark. The wording of this part in the manuscript has been modified.

INTRODUCTION, Line 70-73: “It also has specific modules for various chronic diseases and clinical situations such as asthma, arthritis, diabetes or pain, which could be used along with the PedsQLTM 4.0 Generic Core Scale. It is directed at both children suffering chronic or acute diseases and healthy ones.”

Specific comment #3

Materials and Methods. The study affirms that the pre-school version of the PedsQL Oral Health is completed by parents or guardians. It also affirms that pre-school children aged 2 to 5 years were included. However, there is not a form for this specific age group. Parent report forms are available for children ages 2 to 18 years that consist of a toddler form (2-4 years), a young child form (5-7 years), a child form (8-12 years), and an adolescent form (13-18 years). Child and adolescent self-report forms are available for respondents ages 5 to 7 years, 8 to 12 years, and 13 to 18 years. Thus, the authors should inform which forms were cross-culturally adapt and validated for Chile.

Our response: We thank the reviewer for highlighting this, and we have clarified that we validated only PedsQLTM Oral Health Scale for toddlers. The difference between the ranges of age for which it was designed and where it was applied has been added as a limitation in the new version of the manuscript.

INTRODUCTION, Line 83-87: “Although the PedsQLTM Oral Health Scale was developed to measure OHRQoL among children aged 2 to 18 years (with parent-reported form for 2-4 years, and with parent- and self- report forms for 5-7 years, 8-12 years, and 13-18 years), we only adapted the version for toddlers because they were the priority group of Chilean oral health policies and several public health programs have been implemented in this age group.”
DISCUSSION, Limitations, Line 342-345: “Although the PedsQL form for toddlers was developed for the age of 2-4 years, we decided to include children until five years because we needed a tool that can be used in preschoolers (2-5 years old). On the other hand, it is relevant to highlight that the parent-reported forms are the same for each specific age group.”

Specific comment #4

Was intra-examiner agreement performed?

Our response: We appreciate this question, as it was indeed performed, so we have added the global intra-examiner agreement.

MATERIAL AND METHODS, Line 155-156: “The global intra-examiner agreement was kappa=0.81”

Specific comment #5

In 3rd paragraph of the Statistical Analysis, I suggest informing the parameters values for Cronbach's alpha and ICC, in the same way that the authors did for convergent validity. The same suggestion for floor and ceiling effects. To provide these values is useful for readers interpret results.

Our response: Following the reviewer’s suggestions, we have added the parameters and values requested.

MATERIAL AND METHODS, Statistical Analysis, Line 171-172: “… floor and ceiling effects (percentage of patients with minimum and maximum theoretical scores, respectively). Small floor or ceiling effects (&lt;15%) are considered acceptable”.

Line: 175-177 “[…]Cronbach’s alpha coefficient ranges from 0 to 1 with values &gt;0.70 being considered acceptable. An ICC of &lt;0.40 indicates poor to fair agreement, 0.41–0.60 moderate agreement, 0.61–0.80 good agreement and &gt;0.80 excellent agreement.”

Specific comment #6

Results. Line 236 - What does mean ”The item most frequently reported as being affected”? Does it refer to frequency of "if it is almost always a problem" response?
Our response: We appreciate the reviewer’s remark. The wording of this part in the manuscript has been modified to clarify this issue.

RESULTS, Line 236-239: “The most reported problem was “having some dark-colored teeth” (32.6% almost never, sometimes, often or almost always) in the PedsQLTM Oral Health Scale; and for the PedsQLTM 4.0 Generic Core Scale, “[...] has feeling angry been a problem for your child” (80.9% almost never, sometimes, often or almost always).”

Specific comment #7
Line 265 - It were expected that Spearman correlation coefficient between PedsQL and ECOHIS would be negative, since higher scores indicate better OHRQoL for PedsQL and worse OHRQoL for ECOHIS.

Our response: We thank the reviewer for noticing this, and we have corrected it in the manuscript.

RESULTS, (Line 260-261): “An inverse moderate-to-strong (r= -0.64) correlation between the PedsQLTM Oral Health Scale and ECOHIS was found, while the correlation with the generic core scale was moderate (r= 0.25).”

Specific comment #8
Discussion. Line 320 - It is not clear how did the authors measured the improvement of performances of PedsQL Generic Core with the inclusion of the PedsQL Oral Health Scale. I did not understand the p-values presented at the end of this sentence.

Our response: We thank the reviewer for this remark, and the following sentence has been modified in order to clarify the message:

DISCUSSION, Line 314-318: “It is important to highlight that the PedsQLTM Oral Health Scale complemented the PedsQLTM 4.0 Generic Core Scale, adding relevant information on OHRQoL. Thus, the PedsQLTM total score (which combines the generic and the oral scales) allows discriminating between children with different severities of caries (p=0.014), while the PedsQLTM 4.0 Generic Core score does not (p=0.454).”
Specific comment # 9

Tables and Figure. Table 2 - Title could be more informative about the analyses presented in this table.

Our response: We appreciate the reviewer’s remark. The title has been changed in this table.

TABLE 2: “Distribution and reliability of the PedsQLTM 4.0 Generic Core Scale and Oral Health Scale scores.”

Specific comment # 10

Tables and Figure. In tables, I suggest including footnotes explaining the abbreviations used in each table, as well as the statistical tests performed.

Our response: We appreciate the reviewer’s remark. Footnotes have been included in each table.

Specific comment # 11

Tables and Figure. Figure 1 - What do mean the values inside rectangles (items)?

Our response: We thank the reviewer for noticing this. This number represents the constant or intercept. The constant is the predicted value when all variables are 0. Stata provides it by default and it is not relevant for the interpretation of the model. To avoid confusion, it has been eliminated.

Specific comment # 12

Line 98- The PedsQLTM Oral Health Scale has not 4.0

Our response: We appreciate the reviewer’s remark. The number 4.0 in the text has been deleted in the new version of the manuscript.

Specific comment # 13

Line 227 - Check the percent values with the Table #1.

Our response: We appreciate the reviewer’s remark. This has been amended.
Specific comment # 14

Line 229 - "The prevalence of caries in the population examined was 53.8%. It refers to dental caries experience (dmft ≥1). "Prevalence of caries" could mean caries cavities (decayed teeth ≥1).

Our response: We appreciate the reviewer’s remark. The following text has been added to the new version of the manuscript:

RESULTS, Line 231: “The prevalence of caries experienced (dmft≥1) in the population examined was 53.8%, with a mean dmft of 2.52 (SD 3.71);…”

Specific comment # 15

Line 446 - Update the reference #17.

Our response: Following the reviewer’s remark, we have updated the reference.