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TRANSLATION AND DETERMINATION OF THE COMPREHENSIBILITY OF A LUGANDA VERSION OF ORAL MUCOSITIS DAILY QUESTIONNAIRE
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TRANSLATION AND DETERMINATION OF THE COMPREHENSIBILITY OF A LUGANDA VERSION OF ORAL MUCOSITIS DAILY QUESTIONNAIRE

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ABSTRACT

***Objective*: This study aimed to translate, determine the comprehensibility and examine the linguistic equivalence of a Luganda Oral Mucositis Daily Questionnaire (OMDQ MTS) among patients undergoing chemotherapy.**

***Design*: This was a validation study design in which bilingual patients who were receiving chemotherapy at Uganda cancer institute and had experienced some sort of oral discomfort after the start of their treatment were asked to complete OMDQ MTS Luganda followed by the English version on the same visit. The tools were administered at least two hours apart and had different item order.**

***Results and Conclusions*: Fifty participants accepted to take part by completing both versions of OMDQ MTS data. All item mean score differences between the two versions were less than ±0.25. The Cronbach's α for the Luganda and English versions were 0.78 and 0.86 based on standardized items while Guttman's lambada 2 and 3 were 0.89 and 0.79 respectively. A translated Luganda version of OMDQ MTS is reliable and easy to understand. Thus, it has the potential in being used to monitor mucositis among patients undergoing chemotherapy.**

INTRODUCTION

Patients undergoing treatment for cancer experience disease and or therapeutic-related symptoms. These symptoms may affect their daily function (1). As a way of ensuring adequate control of symptoms, we need to have ongoing symptom monitoring and assessment throughout the course of the disease and treatment. Capturing patient experiences through patient-reported outcome instruments have gained popularity and it is equally effective. Unlike the traditional health personnel ratings which may not accurately capture the patient true functionality, patient-reported symptom assessment scores are increasingly being relied on for both care and clinical research (2). It has been reported that acute and long-term toxicity plus the functional impact of key mucositis-associated symptoms correlate strongly with observer-rated mucositis severity(3). Besides the use of patient reports that offer frequent symptoms assessment gives a better continuum of the progression than scheduled clinician interfaces. These self-administered tools reduce patient inconveniences and may boost willingness to participate in research compared to frequent clinic visits(4).

The OMDQ MTS was initially constructed as part of the clinical development program for palifermin, to capture patient-reported outcomes of OM daily without requiring clinic visits. It was developed through a series of focus groups and one-on-one interviews with cancer patients and was later refined after preliminary versions were used in phase 1 and 2 trials of palifermin. The Mouth and Throat Soreness-Related questions of the oral mucositis daily questionnaire OMDQ MTS is a brief, reliable, and validated self-administered mucositis assessment tool that quantifies the grade of mucositis. It contains 8 "core items" representing important symptoms common to all patients that get mucositis. Three items on overall health, overall mouth and throat soreness, and overall diarrhea are numbered scales capturing the effect of mucositis on daily functioning(5). The tool specifically addresses challenges of eating, swallowing, drinking, talking, and sleeping with each item on the OMDQ MTS scored on a scale of 0 to 4 (5). A couple of non-English versions of the OMDQ MTS-C have been previously psychometrically validated in terms of content, construct, reliability validity (6)(7). Thus using the OMDQ MTS has previously shown that the oral mucositis patient symptom profile both before and during chemotherapy can be accurately profiled and the severity of the symptom experience established(5)(6)(7). The OMDQ MTS patient reported mucositis outcome tool is currently being used in different clinical settings as part of routine patient evaluation processes during cancer management and research(8)(9).

More studies assessing the use of the OMDQ MTS among non-English speaking populations and the psychometric evaluation of this tool is likely to help enhance standardized research on mucositis in different parts of the world. It will also encourage the adoption of mucositis assessment into daily clinical care leading to more generalizable evidence-based practices all over the globe. Luganda is one of the Bantu languages therefore it will form a basis for translation into many more Bantu languages that will cover a big part of the Southern hemisphere on the African continent. Thus, the objectives of the study were to translate the OMDQ MTS into Luganda (OMDQ MTS- L) for an adult population receiving chemotherapy at the Uganda Cancer Institute

and to evaluate the psychometric properties of this version.

We hope this will allow integration of the Mouth and Throat Soreness-Related questions of the oral mucositis daily questionnaire (Luganda OMDQ MTS-) as a clinical assessment tool in Luganda speaking are Uganda. Hopefully it acts as a springboard to linguistically validate the (OMDQ MTS) into other African languages.

MATERIALS AND METHODS

Using a validation study design, we started by forward translation of the questions, response options, and instructions was conducted by two independent translators both graduates of BA arts Luganda majors. These two had not been briefed on the purpose of the tool and one of them was experienced in translating medical questionnaires into Luganda. After that, the two versions were looked at by three of the investigators who are fluent in both Luganda and English and some words or phrases were modified to ensure contextual relevance and cultural applicability. In some instances, we chose one translation over the other if the three of us felt it best captured the aim of the tool. This was in line with the recommendation by Sousa and Rojjanasrirat(10).

The preliminary Luganda version was then validated by 2 other language experts. This time around the experts were informed of the purpose of the translation and were given both the reconciled Luganda version and the original English versions to allow them carry out the verification of the forward translation process.

The experts were requested to evaluate the accuracy and semantics of the translated questions, ensuring that the meaning of the Luganda OMDQ MTS captured that of the original English version. These experts conducted their tasks separately but upon completion, their comments and recommendations were summarized and discussed by the researchers in close coordination with the language experts.

Back-translation. The reconciled Luganda OMDQ MTS was then back-translated to English, by another two independent research tool translation experienced translators who didn't know about the previous process. This step was to ensure that the original meaning of the OMDQ MTS was captured by the translated tool (semantic equivalence)(11).

Panel reconciliation involved the forward and back translators plus selected cancer treatment providers. These resolved the discrepancies emanating from the forward-back translation processes. Consensus was reached on outstanding issues before the final Luganda OMDQ MTS was ready for pretesting.

Pretesting involved 10 respondents with aphthous ulcers each starting with the Luganda version followed by the original English questionnaire. After answering both the versions of OMDQ MTS, respondents underwent a cognitive interview using targeted verbal probes to identify any parts of the tool that were unclear or needed refinement (12).

Field testing of the final Luganda OMDQ MTS was done to ensure that the translated tool meets the quality standards for the original purpose of the tool and also evaluate the equivalence of the translated and original tool. We purposively chose cancer patients undergoing chemotherapy who were fluent and conversant in both Luganda and English.

During the field testing, both the Luganda and English versions, with different item order, were administered to the respondents. In all cases, participants first filled the luganda version.

Patient and Setting: The protocol was approved by an institutional review board (UCI REC REF: 13-2016) under a bigger study on mucositis for patients undergoing chemotherapeutic treatment for solid tumors. Fifty adult bilingual i.e. Luganda and English-speaking patients with cancer undergoing treatment at the UCI, able to read, understand and write in both languages, were purposively recruited from the outpatients department. The participants were identified by their routine monitoring team. After enrolment, informed written consent was obtained from each participant.

The OMDQ MTS was self-administered by the participating patients. Although the purpose of this study was only linguistic and cultural validation, we still captured patient demographics, tumor, and treatment details.

Sample size: A sample size of 50 participants was used since it has been reported that fifty participants and a prevalence of any problem at 0.03 and above, the sample size will give a power of 87% upwards to detect that problem(13)

Data Analysis: Statistical analysis was performed using SPSS Statistical Software, version 20 (IBM Corp LP, College Station, Texas). A P value of 0.05 was considered significant. Descriptive statistics included mean, standard deviation (SD), frequency, percentage depending on the nature of data measurement. Basic item analysis using Spearman's rank-order correlation was performed to evaluate inter-item correlations. This study evaluated the equivalence between the English and the Luganda versions of OMDQ MTS through running reliability coefficients using Cronbach's alpha with the cutoff set at 0.70 (14). Bland-Altman plots were used to assess the degree of agreement of the composite score that captures the effect on swallowing, drinking, eating, talking, and sleeping.

RESULTS

Demographic and Clinical Profiles of the Respondents

Results indicated that respondents were nearly equally distributed with females being 51.3%, 50.1% were of tertiary-level education while the rest were all secondary education. Most of the respondents were in formal employment (58.31%). The average age of the participants was 40.3±10.6 years.

Linguistic Equivalence

Table 1 shows the mean (SD) and the mean difference (SD) scores (Luganda minus English) for each item. Moreover, all mean score differences were less than +0.25. Further analyses showed that all items were not statistically different between the Luganda and the English versions.

Table 1

The mean (SD) and the mean difference (SD) scores (Luganda minus English) for each item

Item	Mean score (SD) Luganda version	Mean score (SD) English version	Mean difference (SD) of scores	95% confidence interval of the mean difference
Rating overall health in last 24 hours	5.24 (2.70)	5.20 (2.62)	-0.04 (0.53)	-0.19 - 0.11
Mouth and throat soreness	0.86 (1.17)	0.84 (1.16)	-0.02 (0.14)	-0.06 - 0.02
Mouth and throat soreness limit swallowing	0.41 (0.90)	0.49 (0.97)	0.08 (0.34)	-0.02 - 0.17
Mouth and throat soreness limit drinking	0.33 (0.74)	0.39 (0.75)	0.06 (0.24)	-0.01 - 0 .13
Mouth and throat soreness limit eating	0.63 (0.96)	0.63 (0.94)	0.00 (0.20)	-0.06 - 0.06
Mouth and throat soreness limit talking	0.26 (0.74)	0.26 (0.74)	0.00 (0.20)	-0.06 - 0.06
Mouth and throat soreness limit sleeping	0.20 (0.66)	0.23 (0.67)	0.02 (0.14)	-0.02 - 0.06
Overall mouth and throat soreness	1.94 (2.45)	1.94 (2.55)	0.00 (0.60)	-0.17 - 0.17
Past 24 hours how much diarrhoea	0.59 (1.04)	0.53 (0.99)	-0.06 (0.42)	-0.18 - 0.06
Rate your overall diarrhoea in past 24 hours	2.22 (3.15)	2.18 (3.20)	0.04 (0.45)	-0.09 - 0.16

The Bland-Altman plots for the English and Luganda OMDQ MTS for the composite question on how mucositis affected swallowing eating drinking talking and sleeping are presented in Figure 1. The Bland-Altman plots illustrated the difference in mean scores against the average scores of each item measure for both versions.

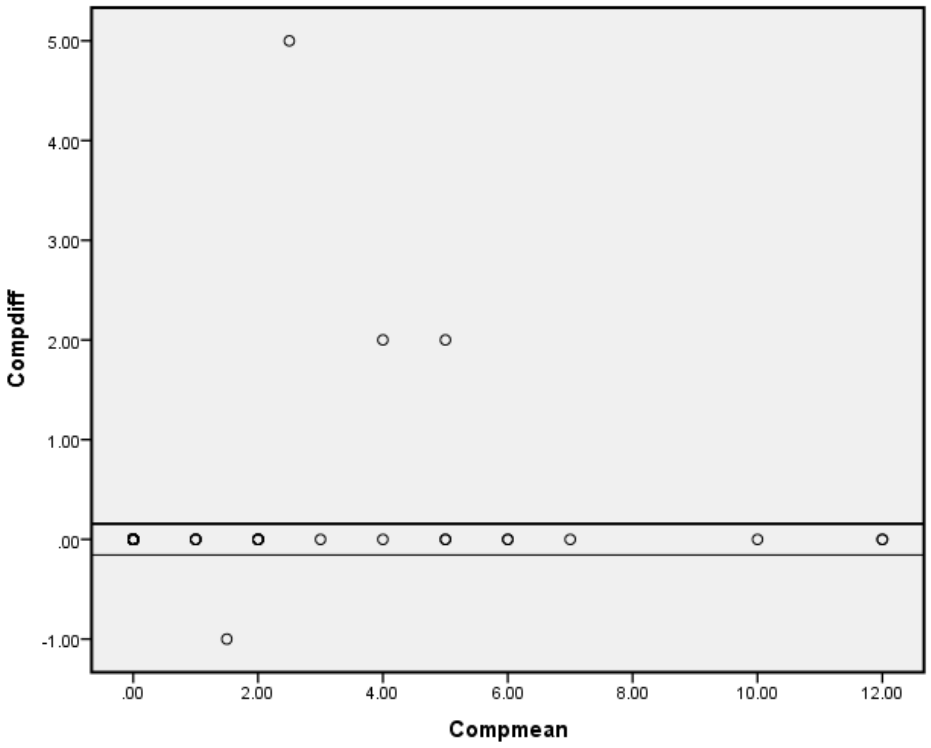

Figure 1: The Bland-Altman plots for the English and Luganda OMDQ MTS for the composite question on how mucoistis affected swallowing eating drinking talking and sleeping

Internal Consistency

The Cronbach's α for the Luganda and English versions was 0.78 and 0.86 based on standardized items while the Guttman's lambada 2 and 3 were 0.89 and 0.79 respectively. Comparative analyses indicated that these values were not statistically different, suggesting good internal consistency for both versions of the instrument. Additionally, the correlation between the scores for each item was very good as shown in table 2.

Table 2

The OMDQ MTS-L compared to English version Spearman's correlation and Guttman coefficients

Item	Guttman λ 2	Spearman's correlation
Rating overall health in last 24 hours	0.99	0.98
Mouth and throat soreness	0.99	0.99
Mouth and throat soreness limit swallowing	0.97	0.94
Mouth and throat soreness limit drinking	0.97	0.95
Mouth and throat soreness limit eating	0.99	0.96
Mouth and throat soreness limit talking	0.98	0.96
Mouth and throat soreness limit sleeping	0.99	0.98
Overall mouth and throat soreness	0.99	0.97
Past 24 hours how much diarrhoea	0.96	0.92
Rate your overall diarrhoea in past 24 hours	0.99	0.99

DISCUSSION

The OMDQ MTS was developed as a patient outcomes measure for self-evaluation of oral mucositis and its effect on daily function. A panel discussion on oral mucositis in Uganda established a need for a mucositis instrument that is easily understandable, convenient to fill, easy to use by most patients but also eliminates the need for frequent clinic visits. In this research, a standardized forward-backward translation was done in developing the Luganda version of the OMDQ MTS, taking into account the cognitive and linguistic levels of participants.

No participant in this study reported any items of the OMDQ MTS-L as difficult to understand or tough to answer. The OMDQ MTS-L questions had a very good degree of internal consistency (all Spearman's correlation coefficients and Guttman λ 2 >0.9 as shown in table 2), thus supporting its reliability,

The composite questions on MTS and the resultant limitations on swallowing, drinking, eating, talking, and sleeping as a measure of the same construct, the Luganda version did well as shown in figure 1.

In comparison with the original validation with the adult population, both the corrected item-total correlation coefficients (0.92–0.99) and the alpha coefficients if item deleted (0.973–0.981) for the OMDQ MTS-L were equal to those reported by a Korean version of the same tool(7). The closeness in correlation coefficients for reliability analysis between this study and the Korean(7) one may signal how reliable the initial tool is but also how adaptable it is in different settings. The modified version for children likewise did well in English and even better in Chinese an indication of the versatility of the OMDQ MTS(6)(15).

We Translated the OMDQ, a patient-reported out-come measure for mucositis, for a Luganda speaking population receiving chemotherapy at the Uganda Cancer Institute. Testing an acceptable number of participants, we found that the translated OMDQ was

understandable and performed well compared to the English version. Additionally, input from these participants helped us make the required changes to come up with a version that should enable its routine use. Even though only minor alterations were made before pretesting it, we believe these alterations increased the comprehensibility and overall applicability of the Luganda version of the OMDQ MTS. Our study is in line with others who have reported that pretesting of translated tools is a vital formative phase that ensures that participants will understand and use the tool appropriately.

CONCLUSION

We did not find a translated patient-reported outcome measures within Sub Saharan Africa for use in mucositis research. Therefore, will have set the pace in showing that tools developed elsewhere can be translated and used in Africa to enhance research on mucositis. This Luganda version of the OMDQ seems to be adequate in our setting. We are going to use the tool to examine its performance against other established mucositis scales such as the WHO one. We will also see how convenient it will be for patients to fill it at home.

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