

Adaptation of EQ-5D-Y-5L into Chichewa (Malawi)

## **Cross-cultural adaptation of the beta EQ-5D-Y-5L into Chichewa (Malawi)**

Ngwira, LG<sup>1,2</sup>, Jelsma, J<sup>3</sup>, Maheswaran, H<sup>4</sup>, Kapakasa, F<sup>2</sup>, Petrou, S<sup>5</sup>, Niessen, L<sup>6,7\*</sup>, Smith, S<sup>8\*</sup>

<sup>1</sup>Department of Clinical Sciences, Liverpool School of Tropical Medicine

<sup>2</sup>Clinical Research Programme, Malawi-Liverpool-Wellcome Trust

<sup>3</sup>Department of Physiotherapy, University of Cape Town

<sup>4</sup>Institute of Global Health Innovation, Imperial College

<sup>5</sup>Nuffield Department of Primary Care Health Sciences, University of Oxford

<sup>6</sup>Department of International Public Health, Liverpool School of Tropical Medicine

<sup>7</sup>Department of International Health, John Hopkins School of Public Health

<sup>8</sup>London School of Hygiene & Tropical Medicine,

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### **Abstract**

#### **Objectives**

The EuroQol Group is developing a new EQ-5D-Y-5L version with five severity levels for each of the five dimensions. The five severity levels describe different health severity and there is a potential for severity level inversion. This paper aims to report the process of cross-cultural adaptation of the beta EQ-5D-Y-5L into Chichewa (Malawi) using the card ranking exercise which has been added to the EQ-5D-Y-5L translation protocol.

#### **Methods**

## Adaptation of EQ-5D-Y-5L into Chichewa (Malawi)

To assess correct hierarchical ordering of severity levels, the adaptation followed the EQ-5D-Y-5L translation protocol. Cognitive interviews were undertaken to establish conceptual equivalence. Thereafter, four iterations of ranking exercises were conducted, leading to amendments of the translated Chichewa version to arrive at a final version.

### **Results**

The iterations were assessed by 18 participants aged 8-14 years. Health proved to be a difficult concept to translate as was ‘discomfort’. Cognitive interviews identified further conceptual issues, particularly with the ‘looking after myself’ dimension. Considerations about lack of soap or water indicated that some children did not fully comprehend this dimension as being about the *ability* to wash and dress themselves. The iterative card ranking exercise detected severity level inversion between ‘a little bit’ and ‘some’, and between ‘a lot’ and ‘extreme’ and alternative Chichewa words/phrases were then tested. Ultimately, intended hierarchical severity ranking was achieved and an acceptable Chichewa version produced.

### **Conclusions**

Conceptual and linguistic equivalence to the English EQ-5D-Y-5L was established for the Chichewa EQ-5D-Y-5L version. The card ranking exercise was instrumental in correcting severity level inversion and supporting the comprehensible translation.

Key words: EQ-5D-Y-5L, EQ-5D-Y, childhood, ‘health-related quality of life, HRQoL, translation, adaptation, ranking exercise, sub-Saharan Africa

**Highlights:**

- i. What is already known about the topic?

The EuroQol's Version Management Committee has a standard cross-cultural translation protocol for all of the EQ-5D versions (EQ-5D-Y, EQ-5D-3L, EQ-5D-5L). The protocol aims to establish both conceptual and linguistic equivalence of the EQ-5D versions cross-culturally. A ranking exercise has now been incorporated into the cognitive debriefing.

- ii. What does the paper add to existing knowledge?

There were items of the new beta EQ-5D-Y-5L for which linguistic and conceptual equivalent terms were difficult to identify in Chichewa. Additional descriptors needed to be tested to ensure all concepts were understood by children in Chichewa. Severity level inversion is a major challenge for a health-related quality of life questionnaire with five severity levels, particularly in children. This paper describes how the potential for level inversion can be decreased during the cross-cultural adaptation of the EQ-5D-Y-5L.

- iii. What insights does the paper provide for informing health care-related decision making?

Instruments developed in high income, mostly English-speaking contexts, need to be interrogated in depth for use in middle to low income countries. Care needs to be taken in health-related quality of life instruments with multiple severity levels, such as the beta EQ-5D-Y-5L, that no severity level inversion is present in the descriptors. This is particularly important if preference-based weights are to be developed for the use of the instrument in economic evaluation and health technology assessments. The resolution of severity level

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inversion as reported in this paper is a necessary first step towards attaining this during the translation phase.

## 1 INTRODUCTION

2 In 2010, the EuroQol Group developed a child-friendly EQ-5D-Y to measure health-related quality  
3 of life (HRQoL) in children and adolescents across five dimensions ('mobility', 'looking after  
4 myself', 'doing usual activities', 'having pain or discomfort', and 'feeling worried, sad or  
5 unhappy'), with three severity levels (e.g. no problems, some, a lot of problems) indicating the  
6 degree of problems experienced in each of the dimensions.(1) The EQ-5D-Y has, however, been  
7 criticised for only containing three severity levels, and for being insensitive to small changes in  
8 health status and exhibiting ceiling effects.(2)

9

10 In order to overcome this, the EuroQol Group developed simultaneously in four languages  
11 (German, Spanish, Swedish and English) a beta (trial) version, the EQ-5D-Y-5L.(3) The EQ-5D-  
12 Y-5L is an extension of the EQ-5D-Y with five severity levels (e.g. no problems (or not), a little,  
13 some (or quite), a lot (or really), and cannot do (or extreme or extremely)) in each dimension. An  
14 experimental EQ-5D-Y-5L version has also been evaluated in Chinese for Hong Kong using a  
15 standard EuroQol translation protocol.(4) The adult EQ-5D-3L has become one of the most widely  
16 used HRQoL measures.(5) The EQ-5D-Y was developed in 2010 and although it has not been used  
17 as widely in comparison to the adult EQ-5D-3L, it has the potential for increased usage.(6) The  
18 EQ-5D-Y-5L has been developed to have more response options so as to increase sensitivity and  
19 resolve ceiling effects observed with the EQ-5D-Y. (2, 3) An increased number of severity levels  
20 means the EQ-5D-Y-5L can more comprehensively describe HRQoL in children and adolescents.  
21 It is therefore imperative to establish whether the beta EQ-5D-Y-5L achieves conceptual  
22 equivalence in other settings and languages including those of Sub-Saharan Africa.

23

1 To ensure that the beta (UK English) EQ-5D-Y-5L is appropriate for use in other settings, the  
2 translated versions must be linguistically and conceptually equivalent,(7) and there should be no  
3 issues of severity level inversion.(8) Severity level inversion is where a worse severity level is  
4 ranked higher than a better severity level, e.g. ‘*a lot of problems*’ is preferred to ‘*having a little bit*  
5 *of problems*’. A key requirement for HRQoL measures is that the severity levels should be discrete,  
6 and participants should be able to rank them hierarchically in order of severity. (8) If this is not  
7 resolved, it could eventually lead to preference inversion in self-reported health and in a utility  
8 valuation exercise. (9)

9

10 Preference-based HRQoL measures play a vital role in economic evaluation and policy decision  
11 making. The Malawi health sector uses the National Health Policy (2018-2030) as a long-term  
12 strategic document and the Health Sector Strategic Plan II (2017-2022) as a medium-term  
13 strategy. The goal is to achieve universal health coverage (UHC) and health financing plays a  
14 critical role in the achievement of UHC goals and objectives. Economic evaluation will therefore  
15 become important in determining programs for health financing and application of the adult EQ-  
16 5D-3L (and EQ-5D-5L), EQ-5D-Y and EQ-5D-Y-5L could be key instruments for assessing  
17 whether these goals are achieved. Malawi’s population is increasing, about half being below the  
18 age 15 years, and at the current growth rate its project to double by 2038. (10) The focus on  
19 attaining SDG goal 3 means that health programmes will not only aim to reduce childhood  
20 mortality, but also children’s HRQoL and this requires robust instruments. (11) Currently, only  
21 the adult EQ-5D-3L is available in the Chichewa language for Malawi. Chichewa is the national  
22 language of Malawi (with a population of 18 million),(12) and is also spoken in the neighbouring  
23 countries of Mozambique and Zambia.(13)

1

2 The standard EQ-5D translation protocol includes translation (forward and backward), and  
3 cognitive interviews to establish linguistic and conceptual equivalence.(14) As the EQ-5D-Y has  
4 three severity levels, this protocol does not involve specific detailed assessment of severity level  
5 inversion. In view of this, the EuroQol's Version Management Committee (VMC), the body within  
6 EuroQol that is responsible for overseeing translations of all instruments developed by the  
7 EuroQol, has developed a card ranking exercise for the beta EQ-5D-Y-5L. Previously, a rating by  
8 children was found useful in the development of the beta EQ-5D-Y-5L severity level wording.(3)  
9 A card ranking exercise developed by the VMC, similar in principle to the rating tasks, has been  
10 added to the standard EQ-5D-Y cross-cultural translation protocol for the beta EQ-5D-Y-5L  
11 (hereby referred to as draft EQ-5D-Y-5L translation protocol).(15) The card ranking exercise has  
12 been developed to assess the suitability of the translated wording of the five severity levels for  
13 children. The ranking exercise allows assessment of severity level inversion during the translation  
14 process by asking children to rank EQ-5D-Y-5L severity levels from least to most severe problems.

15

## 16 **AIM**

17 This study aimed to cross-culturally adapt the EQ-5D-Y-5L for use in Malawi, using the draft EQ-  
18 5D-Y-5L translation protocol.

19

## 20 **METHODS**

### 21 **Participants and recruitment**

1 This study with healthy and sick children was undertaken in Blantyre, Malawi, between March  
2 2019 and December 2019. Blantyre is the commercial capital of Malawi and comprises an urban  
3 population. The healthy children consisted of a convenience sample of children attending primary  
4 schools within Blantyre. The sick children consisted of a convenience sample of children visiting  
5 the out-patient department at the Queen Elizabeth Central Hospital (QECH) in Blantyre. QECH is  
6 the largest referral and teaching hospital in Malawi. Written assent and consent were obtained  
7 from both children and parents/guardians, respectively, for each interview. For sick participants,  
8 the invitation came at the end of clinical care. For healthy participants, invitations were through  
9 the school via a teacher. For both sets of participants, once consent was obtained, the  
10 questionnaires were distributed by the research team at the end of clinical care or on arranged  
11 school day for interviews.

12

### 13 **Instruments**

14 The EQ-5D-Y-5L consists of a descriptive system with the same five dimensions as the EQ-5D-  
15 Y: ‘mobility’, ‘looking after myself’, ‘doing usual activities’, ‘having pain or discomfort’, and  
16 ‘feeling worried, sad or unhappy’ (and visual analogue scale (EQ VAS)), each with five severity  
17 levels: for example, 1) ‘no problems/not’, 2) ‘a little bit of a problem’, 3) ‘some problems/quite’,  
18 4) ‘a lot of problems/really’ and 5) ‘extreme problems/extremely/cannot’. Self-rated health is also  
19 assessed with an EQ VAS on a ‘thermometer-like’ vertical scale with scores ranging between 0  
20 (worst imaginable health) and 100 (best imaginable health). The adult EQ-5D-3L Chichewa  
21 version has been validated for orthopaedic patients in Malawi. (16) The adult EQ-5D-3L Chichewa  
22 version and the English-language UK EQ-5D-Y source version were provided by the EuroQol to  
23 be used in the translation. Apart from differences in age-appropriate language, the main difference



1 between all these instruments is that beta EQ-5D-Y-5L has five levels of severity while the others  
2 have only three. The translators strove for consistency between the EQ-5D-Y-5L and the other  
3 versions as far as this was appropriate.

4

## 5 **Procedure**

### 6 *Translation process*

7 We undertook the translation process of the EQ-5D-Y-5L into Chichewa using the draft EQ-5D-  
8 Y-5L translation protocol including the card ranking exercise (Figure 1). Forward translations from  
9 English to Chichewa were undertaken by experienced local translators, whilst translations from  
10 Chichewa back to English were undertaken by international volunteers (whose first language is  
11 English but also conversant with Chichewa). First, two sets of translators independently forward  
12 and backward translated the EQ-5D-Y from English to Chichewa and back to English. The forward  
13 and back translation of the EQ-5D-Y-5L included additional text in the EQ-5D-Y-5L. The EQ-  
14 5D-Y-5L severity level descriptions were discussed by translators and the lead researcher to reach  
15 consensus versions. The versions were forwarded and discussed in an iterative way with the VMC  
16 reviewer leading to ultimate approval. The approved translated questionnaire was then piloted  
17 through cognitive interviews.

18

### 19 *Cognitive interview process*

20 The cognitive interviews were conducted in order to establish conceptual equivalence of the  
21 concepts in the translated Chichewa and English languages. The cognitive interviews, which  
22 included the ranking exercise, were conducted in four rounds made up of different participants  
23 each time. The first round of the interviews was conducted with four healthy and three sick children

1 aged 8-15 years according to the VMC translation protocol. However, in order to resolve any  
2 apparent severity level inversion, a further three subsequent cognitive interviews were conducted  
3 with healthy children alone; it was not considered likely that severity inversion would relate to the  
4 health status of participants. The participants took part in the following three cognitive interview  
5 steps: i) *card ranking exercise (a new translation protocol feature) to evaluate comprehension of*  
6 *the EQ-5D-Y-5L questionnaire; ii) self-completion of the EQ-5D-Y-5L questionnaire, and iii) in-*  
7 *depth interviews.* The first ten participants took part in all the three steps of cognitive interviews.  
8 The rest (n=8) of the participants took part in the card ranking exercise only because it was seen  
9 that no new information was emerging from the last two completed cognitive interviews.

10

#### 11 *i) Card ranking exercise*

12 The card ranking exercise was specifically developed by the VMC to detect severity level inversion  
13 in the beta EQ-5D-Y-5L so that this could be investigated and corrected during the adaptation  
14 process. (15) The card ranking exercise involved children ranking sets of five cards describing the  
15 translated severity levels from least to most severe problems. The five ranked card sets consisted  
16 of an introductory (warm-up) set, and then four of the five EQ-5D-Y-5L dimensions. The EQ-5D-  
17 Y-5L translation protocol has by design four of the five dimensions. (15) This is because all the  
18 five severity levels have the same qualifiers for the ‘mobility’, ‘looking after myself’, and ‘doing  
19 usual activities’ dimensions. On the other hand, the ‘having pain or discomfort’ dimension has the  
20 same qualifiers as the first three dimensions except for the fifth severity level. The ‘feeling worried,  
21 sad or unhappy’ dimension also has unique qualifiers for the third to fifth severity levels. Due to  
22 similarity of qualifiers for all the severity levels for the first three dimensions (mobility, doing  
23 usual activities, and looking after myself), the VMC decided not to keep the ‘doing usual activities’

1 dimension as part of the card ranking exercise. (15) At the start of the interviews, participants first  
2 ranked the *introductory set* and any issues with understanding the card ranking process were  
3 clarified before moving on to the other four sets. Interviewers, with prior interview guide, were  
4 interested in observing whether or not the intended card order of the translated Chichewa cards  
5 were in the order anticipated (from no problems to extreme problems).

6

7 *ii) Self-completion of the EQ-5D-Y-5L questionnaire*

8 Following the card ranking exercise, the participants completed the Chichewa EQ-5D-Y-5L  
9 questionnaire. By design, the Chichewa EQ-5D-Y-5L was administered to the children *after* the  
10 card ranking exercise. This was done to avoid any possible biases that may have emerged from  
11 children seeing the intended ordering of the severity levels when self-completing the EQ-5D-Y-  
12 5L. If necessary, children who struggled to understand the instructions for self-completion of the  
13 questionnaire were given help to understand the task. However, the children were not given help  
14 to respond to the questionnaire. Any difficulties that the children experienced when self-  
15 completing the questionnaire were noted by the interviewer. Additionally, any assistance given to  
16 help them understand the instructions was also recorded on a separate sheet of paper.

17

18 *iii) In-depth interviews about the EQ-5D-Y-5L questionnaire*

19 Each child participating in the first two rounds of interviews then took part in a one-to-one  
20 interview about his/her understanding of the questionnaire. The interview questions were open  
21 ended and were adapted from the draft EQ-5D-Y-5L translation protocol. (14) Participants were  
22 first asked to comment on: a) the comprehensibility of the whole questionnaire, b) words they  
23 found difficult to understand (in the dimensions, severity levels and instructions), and c) what they

1 would change/add to make the instructions easy to understand. Additionally, the participants were  
2 asked to reflect on how they understood: i) each question and ii) severity levels and, subsequently,  
3 iii) provide real or hypothetical examples of people experiencing specific severity levels. Other  
4 than comprehension of instructions and wording of the questionnaire, participants were not asked  
5 regarding the survey in general.

6

7 At the end of the interviews the children were thanked for their participation and were compensated  
8 with an exercise book and a pen/pencil for their time.

9

## 10 **Data analysis**

11 For the card ranking exercise, individual severity level ordering by each child and any observed  
12 difficulties to do so were recorded on a data sheet by the interviewer, which was later summarized  
13 into a chart for all participants. The correct rank orderings were given an orange colour whereas a  
14 blue colour represented incorrect rankings. The blue squares gave an indication of where the  
15 problems were that needed addressing for the next iteration. For the self-completion exercise and  
16 in-depth interviews, the recorded text was similarly put in a table format with a comments section.  
17 The comments section provided guidance on the part of the text that needed changing for the next  
18 iteration.

19

20 Subsequently, the translated wordings were revised following each iteration of cognitive  
21 interviews until all inconsistencies were resolved. This version was then proofread for  
22 typographical and layout errors. The pre-final version was forwarded to the VMC and EuroQol  
23 Office for endorsement as the final translated Chichewa (Malawi) beta EQ-5D-Y-5L version.

1

2

### 3 **RESULTS**

#### 4 **Participants and recruitment**

5 The cognitive interviews were carried out in four separate rounds. The first round involved seven  
6 children (four healthy and three sick) as per the EQ-5D-Y-5L translation protocol. Each of the next  
7 three rounds comprised of four (all healthy) children. All participants were attending primary  
8 school, and none were already familiar with the EQ-5D-Y-5L. In total, 19 children (10 boys, nine  
9 girls) aged 8-14 years (mean 9.6 years), were interviewed over the four rounds (Table 1). After  
10 consultation with the VMC reviewer, data from first respondent was removed from the results due  
11 to some confusion the child had in understanding the task. This confusion could have arisen from  
12 either that this was the first interviewee and it is possible that the interviewer did not clearly  
13 articulate instructions, or the child may have been confused by the task, or a combination of both.  
14 Results from the remaining 18 children (3 sick -all acutely ill- and 15 healthy) are presented.

15

#### 16 **Translation**

17 There were a number of conceptual and linguistic problems identified from the translation process.  
18 Most of these were identified and resolved by translators during the first consensus process.  
19 However, translation issues, particularly pertaining to qualifiers for the severity levels, were  
20 resolved during the ranking exercise and cognitive interviews. The results of the cognitive  
21 interviews are discussed below. Regarding translation, the first amendment was from the  
22 Chichewa adult EQ-5D-3L version. The bracketed (Nyanja) was removed from the heading  
23 Chichewa (Nyanja) for Malawi' as Nyanja is longer spoken in Malawi but in some neighbouring

1 parts of Zambia and Mozambique. This may not have altered the concept but was done to be  
2 consistent with the language being translated into.

3

4 *Conceptual issues:*

5 *Health*

6 From the outset, it became apparent that translation of the term “health” was a problem. “Health”  
7 was translated differently by translators as ‘umoyo’ which is general health; ‘moyo’ which is life;  
8 and ‘thanzi’ which is about being healthy. This was discussed at length in the consensus discussion  
9 with the translators, and the agreement was that ‘moyo’ is about being alive and not necessarily  
10 about being healthy (good life) or health per se (umoyo). ‘Umoyo’ was agreed upon as the correct  
11 translation for the term “health” through group consensus among the translators.

12

13 *Pain or Discomfort*

14 The adult Chichewa EQ-5D-3L version had translated ‘pain’ as ‘*ululu*’. This word does mean pain  
15 but implies extreme pain and is not frequently used by children. Thus ‘pain’ was translated as  
16 ‘*kuphwanya m’thupi*’ (body pain) in the EQ-5D-Y-5L. The aspect of physical pain was added  
17 because pain can also be interpreted as mental anguish and the VMC’s definition of terms indicates  
18 that pain is intended to refer to physical pain. Additionally, the conjunction ‘*kapena*’ (“or”) seems  
19 not to have the same effect as in English where it separates ‘pain’ from ‘discomfort’. So “*m’thupi*”  
20 (body) was added to the descriptor even though it appears repetitively in the same sentence. This  
21 is not problematic as this is often the case in the Chichewa language.

22

1 'Discomfort' was translated '*kusamva bwino*' in contrast with '*kuphwanya m'thupi kosowetsa*  
2 *mtendere*' in the adult EQ-5D-3L version. We opted for the former because '*kuphwanya m'thupi*  
3 *kosowetsa mtendere*' conveys pain of greater intensity, which differs from the VMC's intended  
4 definition of discomfort as "uncomfortable physical sensation, of a *lower* grade of intensity than  
5 pain". (14)

6

7 *Semantic issues:*

8 Other deviations from the existing Chichewa adult EQ-5D-3L version included changing the  
9 expression 'I have (no problems) ...' that was translated '*Ndimakhala ndi...*' in the adult version to  
10 '*Ndili ndi...*'. This is because '*Ndimakhala ndi...*' carries past/present continuous action, i.e. how  
11 the person is (always has been) up to this very moment. To a child, this does not reflect how one  
12 feels on a particular day, 'today'. Other phrases explored and rejected included '*Ndili ndi vuto*',  
13 which does imply a problem with performing a particular task due to (in)ability to do so but could  
14 not because of one's attitude (child being disobedient for example) or other issues.  
15 '*Ndikuvutikirapo*' (I have a problem) was rejected as it refers to a struggle. '*Ndili ndi...*' was thus  
16 retained as the most accurate translation.

17

18 Additionally, the severity qualifier 'some problems' is translated '*mavuto ena*' in the adult EQ-  
19 5D-3L version. However, '*ena*' relates to 'other' and so '*mavuto ena*' could imply other problems  
20 on top of, or in addition to, the current problem relating to walking. '*Ena*' was therefore removed  
21 in the severity level.

22

1 We also included the qualifier for each of the discrete concepts in the ‘having pain or discomfort’,  
2 and ‘feeling worried, sad or unhappy’ dimensions. For example, the English version reads ‘I am a  
3 bit worried, sad or unhappy’ and this is understood to mean a bit relating to ‘feeling worried, sad  
4 or unhappy’. However, this could be quite confusing in the Chichewa version as it could be read  
5 that ‘a bit’ applies to ‘worry’ only. In order to overcome this potential problem, we included the  
6 qualifier for each of these concepts so that the reader is clear that this applies to ‘feeling worried,  
7 sad, or unhappy’.

8

### 9 **Cognitive interviews**

10 A summary of the cognitive interviews is provided in Table 2.

11

#### 12 *i) Card ranking exercise*

13 In the first round, each of the six participants ranked five severity levels for the four dimensions  
14 to give a total of 120 rankings (Table 3). Of these, 43% (52/120) across all dimensions were  
15 incorrect rankings (from the intended order). Of the incorrect rankings, 62% (32/52) were  
16 attributed to severity level inversion between the Chichewa wording for ‘*a little bit*’ and ‘*some*’.

17 It was evident that ‘*a little bit*’, initially translated ‘*pang’ono kwambiri*’, was the source of the  
18 confusion. The Chichewa words ‘*pang’ono*’ and ‘*kwambiri*’ mean ‘*less*’ and ‘*a lot*’, respectively.

19 While the combination of these two words was supposed to imply ‘*a lot less*’, it was interpreted  
20 as ‘*a lot more*’, and led participants to interpret severity level two as worse than that of level three.

21 A further 14% of incorrect rankings were due to severity level inversion between the Chichewa  
22 words for ‘*a lot*’ (6%) and ‘*extreme*’ (8%). The rest of the incorrect rankings were made up of a



1 mixture of incorrect ordering among all the severity levels. Since there were several cases of  
2 severity level inversion between ‘a little bit’ and ‘some’, this was revised and then re-tested.

3

4 The re-testing in round two indicated that the change in translation generally resolved the severity  
5 level inversion for levels two (*a little bit*) and three (*some*). The severity level inversion was only  
6 evident in one respondent for both ‘having pain or discomfort’ and ‘feeling worried, sad or  
7 unhappy’, and since this was equal to only two responses, it was judged that this change had  
8 satisfactorily resolved the problem. However, half of the incorrect rankings in round 2 were then  
9 due to severity level inversion between the qualifiers for levels four (*a lot*) and five (*extreme*),  
10 which re-emerged in all dimensions except for the ‘looking after myself’. It was discovered that  
11 the translated qualifier for severity level four (*kwambiri*) was generally understood to mean  
12 “*extreme*” by children because in their everyday usage *kwambiri* is understood to mean *extreme*.  
13 The severity level five qualifier was therefore changed to ‘*moonjeza kwambiri*’ to emphasize the  
14 intensity and this was then re-tested during the third round of iterative interviews.

15

16 In round three of testing, 12 of all 28 incorrect rankings were still due to translated severity level  
17 inversions between qualifiers for levels four (*a lot*) and five (*extreme*). The latter was therefore  
18 further changed to ‘*kwambiri zedi*’ for the ‘having pain or discomfort’ and ‘feeling worried, sad or  
19 unhappy’ dimensions and then re-tested. The qualifiers for the other three dimensions were not  
20 changed because they have a different qualifier for level five (*cannot*), which was not problematic  
21 for the translated version.

22

1 The final round of testing showed that the changes made to the qualifier for extreme severity level  
2 five had resolved the severity inversion for levels four and five. At this point, the EQ-5D-Y-5L  
3 translated version was deemed to have established appropriate hierarchical ordering. The  
4 translated questionnaire was then ready for proofreading ahead of self-completion and in-depth  
5 interviews.

6

7 *ii) Self completion of the questionnaire*

8 We observed that appropriate self-completion of the questionnaire without interviewer assistance  
9 was problematic among some children in this setting. Seven of ten children who were aged 8-10  
10 years tended to tick every box instead of choosing one option for each of the five dimensions,  
11 which could indicate a lack of understanding of the instructions. However, once the interviewer  
12 read and explained the instructions clearly to these children, they were able to appropriately choose  
13 one severity level per dimension. (Table 4)

14

15 Table 4 also shows that the children with health conditions reported health states that were sub-  
16 optimal, and reported lower scores on the EQ VAS scale, compared with healthy children. On the  
17 other hand, all healthy children reported perfect health on the descriptive system and  
18 corresponding high EQ VAS scores (where one child reported 95 and six children reported 100).  
19 One sick child, with a poor health state of 32132, had a high EQ VAS score of 95, whereas another  
20 sick child with a better health state of 11222 provided a lower (worse) EQ VAS score of 60.

21

22 *iii) In-depth interviews*

1 Similar to the translation work, it emerged during cognitive interviews that some children  
2 struggled to draw a distinction between health, (umoyo), healthy (thanzi) and life (moyo). The  
3 majority of the participants mentioned that ‘umoyo’ was about how one’s daily life was/how the  
4 body was feeling compared to ‘moyo’, which was the state of being alive, i.e. opposite of death.  
5 Some of the participants were not able to draw this distinction between these three terms, and a  
6 few others expressed no opinion regarding, this but agreed that this was about health. Therefore,  
7 the word ‘umoyo’ was kept as decided during the translation process.

8

9 Despite this, we observed that the majority of participants were able to give appropriate examples  
10 of the different severity levels. For example, when it came to examples to illustrate ‘a little bit’,  
11 ‘some’ and ‘a lot’ of problems in the ‘mobility’ dimension, the children described such examples  
12 as someone with a sprained knee, an injured leg and having mobility issues due to some health  
13 problems, respectively. For ‘a little bit’ in the ‘doing usual activities’ dimension, children gave  
14 examples of someone who was unwell but able to go to school; and similarly, appropriate examples  
15 were given for ‘a little bit’, ‘some’ and ‘a lot’ of problems in the ‘having pain or discomfort’  
16 dimension. Examples such as someone with an upset tummy or with tonsillitis indicated  
17 appropriate comprehension for ‘having pain or discomfort’. It was also very clear that the majority  
18 of children interviewed understood the ‘feeling worried, sad or unhappy’ concept as evidenced by  
19 examples given for this dimension. Participants cited that losing a friend or losing a loved one to  
20 death, lack of basic needs or money, lack of food at home, or home-based violence, or lack of  
21 school materials would result in different levels of worry, sadness or unhappiness.

22

1 There were also some inaccurate responses. In the ‘looking after myself’ dimension, two of the  
2 ten participants gave examples of severity levels relating to lack of provisions such as soap or  
3 water as examples of ‘some problems’. In the ‘having pain or discomfort’ dimension, two different  
4 participants gave examples that related to loss of a loved one in death (emotional pain) or a friend  
5 that is sick and could not attend school as things that would make someone ‘having pain or  
6 discomfort’. Another child gave an example for ‘a lot’ of ‘having pain or discomfort’ of an adult  
7 who is diagnosed with a certain disease (e.g. epilepsy) and therefore unable to do usual activities.  
8 From a child’s perspective, an epileptic person would be affected in physical functioning, but this  
9 example may pertain more to emotional problem as opposed to bodily pain.

10

11 At the end of the interviews, when asked to make suggestions to change the wording of dimensions  
12 or severity levels at no point during the in-depth interviews did the participants make additional  
13 meaningful suggestions to further improve the Chichewa wording of dimensions and severity  
14 levels.

15

16

## 17 **DISCUSSION**

18 Ultimately, a version of the beta EQ-5D-Y-5L was developed in the Chichewa language. The  
19 version established acceptable linguistic and conceptual equivalence with the original UK version.  
20 However, there were a few issues that needed to be resolved during the adaptation process.

21

22 The concept of health was difficult to translate as three terms are used interchangeably. However,  
23 this is problematic as these concepts are rather different. This confluence of health and life

1 concepts is also common to other Bantu languages possibly due to different views or models of  
2 health existing in these settings. (17) In Zulu, “health” and “life” are both translated with “Mpilo”  
3 and in Kinyarwanda “ubuzima” can be used for both. One study in Kenya, found that this was the  
4 case when they tried to disentangle health. (18) So, we conclude that while the children generally  
5 did seem to understand health, we recommend that the concepts of health and life in these Bantu  
6 cultures should be explored further perhaps through focus group discussions to elicit more views  
7 from the target population.

8

9 The validity of including composite dimensions in the EQ-5D instruments has been questioned.  
10 (19, 20) However, as the items are entrenched in the measure which has been universally applied  
11 (21), no changes were made to the constructs included in the ‘having pain or discomfort’ and  
12 ‘feeling worried, sad or unhappy’ dimensions. To highlight that all two or three components of  
13 these dimensions were highlighted and given equal prominence, we found it helpful to add the  
14 qualifier at each component to emphasize that it referred to every construct. For example, the  
15 severity level ‘I have a little bit of pain or discomfort’ could imply that ‘a little bit’ applies only to  
16 pain and not to both pain and discomfort. This was altered to read, “I have a little bit of pain or a  
17 little bit of discomfort”. This solution is not unique and has been incorporated into other  
18 translations, such as Krio self-complete EQ-5D-3L and the Arabic for Jordan EQ-5D-Y versions  
19 (Personal communication, VMC, 2021). We recommend that future cross-cultural adaptation in  
20 other contexts similarly explore the need to emphasize all components in composite dimensions to  
21 maintain the correct meaning.

22

1 The Chichewa EQ-5D-Y-5L was found to be generally difficult to self-complete. We found that  
2 younger children, in particular, needed some interviewer assistance to accurately complete the  
3 questionnaire. For example, younger children tended to tick every severity level response option  
4 instead of choosing one unless interviewer assisted. Consequently, expanding the instructions  
5 could solve this problem. Users of the Chichewa EQ-5D-Y-5L might also consider using the  
6 Interviewer Administered rather than the self-complete version, for children <12 years and  
7 particularly those younger than 10 years.

8  
9 In addition, although we were generally satisfied that this Chichewa version established both  
10 linguistic and conceptual equivalence with the English UK version, caution in administering this  
11 version is advised. While the majority of participants gave specific examples that fittingly  
12 explained their understanding of the severity levels and dimensions, there were helpful lessons  
13 learnt from in-depth interviews with a few participants who struggled to understand some  
14 dimensions. This also highlighted contextual differences in terms of how people understand  
15 translated dimensions of HRQoL instruments. For the EQ-5D-Y-5L, we particularly observed  
16 difficulties with regard to the ‘looking after myself’. In high income countries, washing is simply  
17 the action of washing the body. In low income countries, the availability of water and soap may  
18 be considered by the participants rather than simply the *ability* to wash and dress themselves. This  
19 was also highlighted during the exercise in Sierra Leone to translate the EQ-5D-Y into Krio.  
20 (Personal communication, VMC, 2021) The inclusion of needing to getting water, i.e. from a well  
21 or river in the activity of self-care was highlighted in that translated version. It was recommended  
22 that the EuroQol Group should provide further guidance on environmental factors in the translation  
23 protocol. We believe omission of such clarification as water availability and ‘mobility’ issues

1 might affect item equivalence particularly in some low income countries. (22) Our results endorse  
2 that recommendation.

3

4 ‘Having pain or discomfort’ has proven somewhat problematic in the past, firstly because these  
5 constructs, which are meant to refer to physical pain or discomfort are often interpreted as  
6 emotional or mental pain or discomfort. Our results similarly showed that some children made  
7 reference to emotional or mental pain instead of physical. This finding was curious because we  
8 had included ‘m’thupi’(body) in the descriptor to establish conceptual equivalence with the  
9 concept about bodily pain. It is possible that the words used for discomfort (kusamva bwino) could  
10 perhaps have led others to conclude that discomfort was about emotional pain as opposed to  
11 uncomfortable physical sensation, which is the concept here. The descriptor for discomfort in the  
12 adult Chichewa EQ-5D version is ‘kuphwanya m’thupi kosowetsa mtendere’ that would seem to  
13 indicate pain of greater intensity as opposed to pain of lower intensity, which is the concept for  
14 discomfort here. We therefore changed the descriptor for discomfort in the youth Chichewa  
15 version to ‘kusamva bwino’, which means to feel uncomfortable. The ‘having pain or discomfort’  
16 dimension has proved difficult to translate in the past. In the Shona translation of the adult EQ-  
17 5D-3L, it was reported that such expression as “I cannot even stay in one place” was considered  
18 for translation. In addition, discomfort was not regarded as a sensation separate from pain (23) and  
19 as such the phrase “kurwadziwa” for pain was used. We would therefore recommend that future  
20 users of the youth Chichewa EQ-5D-Y-5L version should explain to participants (through  
21 interviewer assistance) that the discomfort mentioned here refers to physical sensation. Another  
22 option would be to include ‘physical’ in the descriptor, so that the dimension reads ‘physical pain  
23 or physical discomfort’.

1

2 The ranking exercise was instrumental in identifying translation problems in understanding the  
3 qualifiers for the five different severity levels. We believe that had it not been for the card ranking  
4 exercise, coming up with accurate qualifiers to establish linguistic equivalence and hierarchical  
5 ranking would not have been adequately established. As noted previously, severity level inversion  
6 in the questionnaire is a threat to the validity of valuation sets. If the severity level is either not  
7 properly understood, or does not accurately distinguish between levels, it could lead to preference  
8 inversion in self-report health and utility valuation exercises. This has been previously reported as  
9 a problem. (9) We thus highly recommend the use of the ranking exercise when adapting the EQ-  
10 5D-Y-5L cross-culturally.

11

12 Finally, as regards possible differences between the EQ VAS score and that associated with the  
13 descriptive system health state, we would not want to over-interpret this. There were only two out  
14 of three participants who had EQ VAS scores that seemed inconsistent with their reported  
15 descriptive system health state. We would, however, recommend that future studies should explore  
16 which other aspects of ‘health’ may be important to children, beyond the five EQ-5D-Y-5L  
17 dimensions.

18

19 A limitation of our assessment of the Chichewa version of the EQ-5D-Y-5L was in the sample of  
20 participants. Collectively, there were more healthy than sick children involved in the other rounds  
21 of the cognitive interviews compared to the first one. (14) In a South African study it was found  
22 that the psychometric properties of the EQ-5D-Y were superior in children with health conditions  
23 than in healthy children. (24) Although following the EQ-5D-Y-5L translation protocol, and there



1 being no reason to suppose that hierarchical ordering of severity levels would differ between sick  
2 and healthy children, it is recommended that future validation studies include more children with  
3 health conditions.

4

5 The strengths of this study include, firstly, being the first to pilot cross-cultural adaptation of the  
6 beta EQ-5D-Y-5L using the card ranking exercise as part of the draft EQ-5D-Y-5L translation  
7 protocol. The importance of rigorous translation and cross-cultural adaptation of HRQoL  
8 instruments cannot be overemphasised.(25) The use of a poorly translated instrument could  
9 invalidate otherwise carefully planned research. The card ranking exercise was instrumental in  
10 identifying and resolving severity level inversion through a series of interviews. Secondly, it is  
11 expected that older children/adolescents will have less problems in understanding the  
12 questionnaire. For this reason, the age of the children we interviewed was deliberately skewed to  
13 younger children (8-10 years) in order to establish comprehensibility among this younger age  
14 group. The next steps in understanding the newly translated Chichewa EQ-5D-Y-5L version will  
15 be to test its psychometric properties in healthy, acutely ill and chronically ill children.

16

17

## 18 **CONCLUSION**

19 A final adapted version of the beta Chichewa EQ-5D-Y-5L was somehow comprehensible to  
20 children in Malawi in terms of instructions and concepts covered by the measure. However, we  
21 recommend that future users of the Chichewa EQ-5D-Y-5L should consider opting for the  
22 Interviewer Assisted version rather than the Self-Complete version in children aged 8-10 years.  
23 Regarding concepts, the dimensions of ‘mobility’, ‘doing usual activities’ and ‘feeling worried,

1 sad or unhappy’ clearly established conceptual equivalence and were understood by participants.  
2 However, there were mixed results with comprehension of the ‘looking after myself’ and ‘having  
3 pain or discomfort’ dimensions. The EuroQol Group could consider including specific examples,  
4 particularly for the ‘looking after myself’ dimension, in order to make this concept easier to  
5 understand by children in resource-limited countries or settings. Due to its usefulness in this study,  
6 we recommend the use of the ranking exercise when developing translated versions of the EQ-5D-  
7 Y-5L in different cultural settings.

8

9

## 10 **Declarations**

### 11 **Competing interests**

12 The authors declare that they have no competing interests. JJ and SD are members of the EuroQol  
13 Version Management Committee, and the Chichewa translation study received part funding from  
14 the EuroQol Research Foundation (Project 20190200). However, JJ, SD or the EuroQol Research  
15 Foundation had no influence on the findings reported in this paper.

16

### 17 **Copy right**

18 The EuroQol Research Foundation holds the copy right to the EQ-5D-Y-5L. Copies of the  
19 questionnaire can be obtained free of charge from EuroQol.org

20

### 21 **Authors’ contributions**

22 LGN, HM, SCS, SP and LN conceived the concept; LGN and FK oversaw the translation; JJ  
23 reviewed the translation; SD led the development of the English language version of the ranking

- 1 exercise; LGN, HM, SCS, SP and LN drafted the original manuscript; LGN, JJ, HM, SD, SP, LN
- 2 and SCS reviewed the manuscript. All authors read and approved the final manuscript.

## 1 6.0 REFERENCES

2

- 3 1. Wille N, Badia X, Bonsel G, Burstrom K, Cavrini G, Devlin N, et al. Development of the  
4 EQ-5D-Y: a child-friendly version of the EQ-5D. *Qual Life Res.* 2010;19(6):875-86.
- 5 2. Ravens-Sieberer U, Wille N, Badia X, Bonsel G, Burstrom K, Cavrini G, et al. Feasibility,  
6 reliability, and validity of the EQ-5D-Y: results from a multinational study. *Qual Life Res.*  
7 2010;19(6):887-97.
- 8 3. Kreimeier S, Astrom M, Burstrom K, Egmar AC, Gusi N, Herdman M, et al. EQ-5D-Y-5L:  
9 developing a revised EQ-5D-Y with increased response categories. *Qual Life Res.* 2019.
- 10 4. Wong CKH, Cheung PWH, Luo N, Cheung JPY. A head-to-head comparison of five-level  
11 (EQ-5D-5L-Y) and three-level EQ-5D-Y questionnaires in paediatric patients. *Eur J Health Econ.*  
12 2019.
- 13 5. Chen G, Ratcliffe J. A Review of the Development and Application of Generic Multi-  
14 Attribute Utility Instruments for Paediatric Populations. *Pharmacoeconomics.*  
15 2015;33(10):1013-28.
- 16 6. Kreimeier S, Greiner W. EQ-5D-Y as a Health-Related Quality of Life Instrument for  
17 Children and Adolescents: The Instrument's Characteristics, Development, Current Use, and  
18 Challenges of Developing Its Value Set. *Value Health.* 2019;22(1):31-7.
- 19 7. Epstein J, Santo RM, Guillemin F. A review of guidelines for cross-cultural adaptation of  
20 questionnaires could not bring out a consensus. *J Clin Epidemiol.* 2015;68(4):435-41.
- 21 8. Craig BM, Busschbach JJ, Salomon JA. Modeling ranking, time trade-off, and visual  
22 analog scale values for EQ-5D health states: a review and comparison of methods. *Med Care.*  
23 2009;47(6):634-41.
- 24 9. Craig BM, Monteiro AL, Herdman M, Santos M. Further evidence on EQ-5D-5L  
25 preference inversion: a Brazil/U.S. collaboration. *Qual Life Res.* 2017;26(9):2489-96.
- 26 10. World Bank U. <https://www.worldbank.org/en/country/malawi/overview> last accessed  
27 2021 [
- 28 11. WHO G, Switzerland. Sustainable development goals.  
29 <http://www.un.org/sustainabledevelopment/sustainable-development-goals/>.last assessed 15th  
30 September 2017.
- 31 12. Colbourn T, Masache G, Skordis-Worrall J. Development, reliability and validity of the  
32 Chichewa WHOQOL-BREF in adults in Lilongwe, Malawi. *BMC Res Notes.* 2012;5:346.
- 33 13. Kayambazinthu E. The Language Planning Situation in Malawi. *Journal of Multilingual  
34 and Multicultural Development.* 1998;19(5):369-439.
- 35 14. EuroQol Group. Full translation guidelines for the EuroQol EQ-5D-3L,5L and Y versions.  
36 Rotterdam, Netherlands: EuroQol Research Foundation; 2018.
- 37 15. Derrett S, Herdman M, Ngwira LG, Moore EY, Jelsma J. A New Approach to Assessing  
38 Children's Interpretation of Severity Qualifiers in a Multi-Attribute Utility Instrument–The EQ-  
39 5D-Y-5L: Development and Testing. *The Patient - Patient-Centered Outcomes Research.* 2021.
- 40 16. Chokotho L, Mkandawire N, Conway D, Wu H-H, Shearer DD, Hallan G, et al. Validation  
41 and reliability of the Chichewa translation of the EQ-5D quality of life questionnaire in adults  
42 with orthopaedic injuries in Malawi. *Malawi Medical Journal.* 2017;29(2):84.

- 1 17. Chavula C, Suleman H. Assessing the Impact of Vocabulary Similarity on Multilingual  
2 Information Retrieval for Bantu Languages. the 8th annual meeting of the Forum2016.
- 3 18. Fox-Rushby J. Operationalising conceptions of 'Health' Amongst the Wakamba and  
4 Maragoli of Kenya: the basis of the KENQOL instrument. Qual Life Res. 2000;9(3):316e.
- 5 19. Lee GL, Tan RL-Y, Herdman M, Luo N. Assessing the Content Validity of the EQ-5D  
6 Questionnaire Among Asians in Singapore: A Qualitative Study. Annals Academy of Medicine  
7 Singapore. 2020;49(5):294-305.
- 8 20. McDonald R, Mullett TL, Tsuchiya A. Understanding the composite dimensions of the  
9 EQ-5D: An experimental approach. Soc Sci Med. 2020;265:113323.
- 10 21. Devlin NJ, Brooks R. EQ-5D and the EuroQol Group: Past, Present and Future. Appl  
11 Health Econ Health Policy. 2017;15(2):127-37.
- 12 22. Youkee D. EQ-5D-3L equivalence in Sierra Leone. 1st EuroQol African Regional Meeting;  
13 Cape Town, South Africa13-14 February 2020.
- 14 23. Jelsma J, Chivaura V, de Weerd W, de Cock P. A bridge between cultures: A report on  
15 the process of translating the EQ-5D instrument into Shona. South African Journal of  
16 Physiotherapy. 2000;56(4):3-9.
- 17 24. Scott D, Ferguson GD, Jelsma J. The use of the EQ-5D-Y health related quality of life  
18 outcome measure in children in the Western Cape, South Africa: psychometric properties,  
19 feasibility and usefulness - a longitudinal, analytical study. Health Qual Life Outcomes.  
20 2017;15(1):12.
- 21 25. Mkoka S, Vaughan J, Wylie T, Yelland H, Jelsma J. The pitfalls of translation--a case study  
22 based on the translation of the EQ-5D into Xhosa. S Afr Med J. 2003;93(4):265-6.
- 23