Linguistic Validation of Indonesian Version of the Audit of Diabetes-Dependent Quality of Life Questionnaire

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Abstract

Background: *One of the impacts experienced by diabetes mellitus patients is a decrease in their quality of life. The Audit of Diabetes-Dependent Quality of Life (ADDQoL) is a widely used individualized diabetes-specific quality of life measure. However, there was no version available in the Indonesian language.* ***Objective:*** *This study is aimed to undertake linguistic validation, including a cultural adaptation of the ADDQoL questionnaire into the Indonesian language.* ***Method:*** *The original developer granted permission to use and modify the questionnaire. The international linguistic validation procedure developed by the Mapi Research Institute was used. There were six steps involved: forward translation, reconciliation, back translation, expert panel review by a psychologist and clinician, cognitive debriefing with diabetes patients, and proofreading.* ***Result:*** *Problems that arose during the linguistic validation process were resolved by finding conceptually equivalent alternatives and changing sentence structures to achieve equivalence in language, concept, and culture with the original version of the ADDQoL. The developer's team reviewed and discussed all actions taken. Cognitive debriefing interviews with five respondents showed that the ADDQoL questionnaire was simple to understand.* ***Conclusion****: The Indonesian version of the ADDQoL is linguistically and culturally validated. Further studies are needed to confirm the structure and reliability of the Indonesian ADDQoL.*

Keywords*: ADDQoL, diabetes mellitus, cultural adaptation, quality of life, linguistic validation*

Abstrak

Pendahuluan: Salah satu dampak yang dialami oleh pasien diabetes melitus adalah penurunan kualitas hidup. *Audit of Diabetes-Dependent Quality of Life* (ADDQoL) adalah alat ukur kualitas hidup individual spesifik diabetes yang telah banyak digunakan. Namun, tidak ada versi yang tersedia dalam bahasa Indonesia. **Tujuan**: Penelitian ini bertujuan untuk melakukan validasi linguistik, termasuk adaptasi kultural kuesioner ADDQoL ke dalam bahasa Indonesia. **Metode**: Pengembang orisinal telah memberikan izin untuk menggunakan dan memodifikasi kuesioner. Prosedur validasi linguistik internasional yang dikembangkan oleh *Mapi Research Institute* digunakan dalam penelitian ini. Terdapat enam langkah yaitu: terjemahan maju, rekonsiliasi, terjemahan kembali, tinjauan panel ahli oleh psikolog dan dokter, pembekalan kognitif dengan pasien diabetes, dan koreksi. **Hasil**: Permasalahan yang muncul selama proses validasi linguistik diselesaikan dengan menemukan alternatif kata yang setara secara konseptual dan mengubah struktur kalimat untuk mencapai kesetaraan dalam bahasa, konsep, dan budaya dengan versi asli ADDQoL. Tim pengembang meninjau dan mendiskusikan semua tindakan yang diambil. Wawancara pembekalan kognitif dengan lima responden menunjukkan bahwa kuesioner ADDQoL mudah dipahami. **Kesimpulan**: ADDQoL versi bahasa Indonesia telah tervalidasi secara linguistik dan budaya. Studi lebih lanjut diperlukan untuk mengonfirmasi struktur dan keandalan kuesioner ADDQoL Indonesia.

Kata kunci: ADDQoL, diabetes, kualitas hidup, validasi, linguistik

INTRODUCTION

Diabetes mellitus (DM) is a serious long-term condition characterized by an increase in blood sugar level because the body cannot produce enough insulin or effectively use its insulin (International Diabetes Federation, 2019). The prevalence of people with diabetes increases each year. Based on the IDF report in 2019, the number of adults with DM aged 20 - 79 globally was 463 million people, and it is estimated that this number will increase by 51% to 700 million people in 2045. Indonesia is in the 7th position of the top 10 countries with the most DM, with 10.7 million people with diabetes (International Diabetes Federation, 2019). A comparison of the number of people with diabetes in Indonesia based on location shows that the prevalence is higher in urban areas than in rural areas, with 1.89% and 1.01%, respectively. In addition, DM affects women (1.78%) more than men (1.21%) (Riskesdas, 2018).

Diabetes is a chronic disease requiring long-term treatment. DM can affect various aspects of a person's life. The progression of the disease causes complex and potentially life-threatening complications, but the demands of the treatment regimen also have an impact on patients. Many studies have shown that people with diabetes have a lower quality of life than the general population (Jing *et al.*, 2018)

Good quality instruments that can measure the QoL well are needed to support assessing the quality of life (QoL) of people with diabetes. Two types of instruments can be used: general instruments such as WHOQOL and SF-36 (Kiadaliri *et al.*, 2013), and diabetes-specific instruments like The Audit of Diabetes-Dependent Quality of Life (ADDQoL) (Bradley *et al.*, 1999). One of the advantages of using diabetes-specific instruments over general instruments is that they can cover important aspects of life-related to people who have diabetes (Ostini *et al.*, 2011). There are essential domains such as diet, food and drink, the impact of disease complications, the type of diabetes treatment used (Rubin & Peyrot, 1999), and the impact of diabetes on sexual life (Kizilay *et al.*, 2016). The ADDQoL questionnaire itself has advantages over other questionnaires. For example, it enables patients to respond only to aspects of life that are relevant to them, assess whether the impact of diabetes on these aspects of life is positive or, to varying degrees, negative, and assess the perceived importance of each aspect of life for their quality of life (Singh & Bradley, 2006).

The ADDQoL has been used widely in various countries and has been translated and adapted culturally into multiple languages, including Slovenian (Turk *et al.*, 2014), Japanese (Hirose *et al.*, 2016), Malaysian (Musa *et al.*, 2007), Bulgarian (Levterova *et al.*, 2017), and Chinese (Kong *et al.*, 2011). Studies on the use of ADDQoL in multi-ethnic Asian patients have also shown promising results regarding validity, reliability, and cultural adaptation (Wee *et al.*, 2006). However, according to internationally standardized guidelines, an Indonesian version of the ADDQoL questionnaire that has gone through a linguistic validation process was not available. Because of cultural differences between the original country of the ADDQoL questionnaire and the country where the questionnaire will be used, a simple translation would be insufficient. Therefore, this study aimed to undertake linguistic validation, including the cultural adaptation of the ADDQoL questionnaire into the Indonesian language.

MATERIALS AND METHODS

The Audit of Diabetes Dependent Quality of Life audit (ADDQoL) measures the quality of life specific to diabetes in the form of a questionnaire developed by Bradley *et al.* (1999) in UK English. This questionnaire has undergone three revisions, namely ADDQoL-13, ADDQoL-18, and the last one was ADDQoL-19 (Bradley & Gilbride, 2008). The ADDQoL-19 questionnaire assesses the impact of diabetes on 19 life domains of both type 1 and type 2 diabetes patients. The questionnaire has two preliminary items for audit purposes: an item to determine the current quality of life in general and an item to assess the specific impact of diabetes on quality of life. Then, it is followed by 19 domains related to the impact of diabetes on every particular aspect of life (Wee *et al.*, 2006).

On the items assessing the quality of life-related to diabetes, the impact of diabetes on the life domain is evaluated on a scale of -3 (maximum negative impact) to +1 (maximum positive impact) and for how important the life domain is rated on a scale of 0 (not at all important) to + 3 (very important). The weighted score from each domain is calculated by multiplying the diabetes impact score by the importance value. Then, to get the average weighted score (Average Weighted Impact/AWI) or the ADDQoL score, it is calculated by adding up all the weighted scores from each completed domain divided by the number of completed domains. The AWI score ranges from -9 (maximum negative impact of diabetes on quality of life) to +3 (maximum positive impact of diabetes on quality of life) (Bradley *et al.*, 2018).

The questionnaire was linguistically validated using international guidelines developed by Mapi Research

Institute (Acquadro *et al*., 2008). The procedure was divided into three main phases. The first phase was the forward translation, reconciliation, and back translation steps; the second phase included piloting, a review by doctor and psychologist and cognitive debriefing with people who have diabetes; and the third phase was the finalization step, which included formatting and proofreading as shown in Figure 1. The original developer granted permission for the linguistic validation of the ADDQoL questionnaire. The results of each stage were reported and discussed with the linguistic validation team at Health Psychology Research (HPR) Ltd (the company that licenses Clare Bradley's questionnaires).
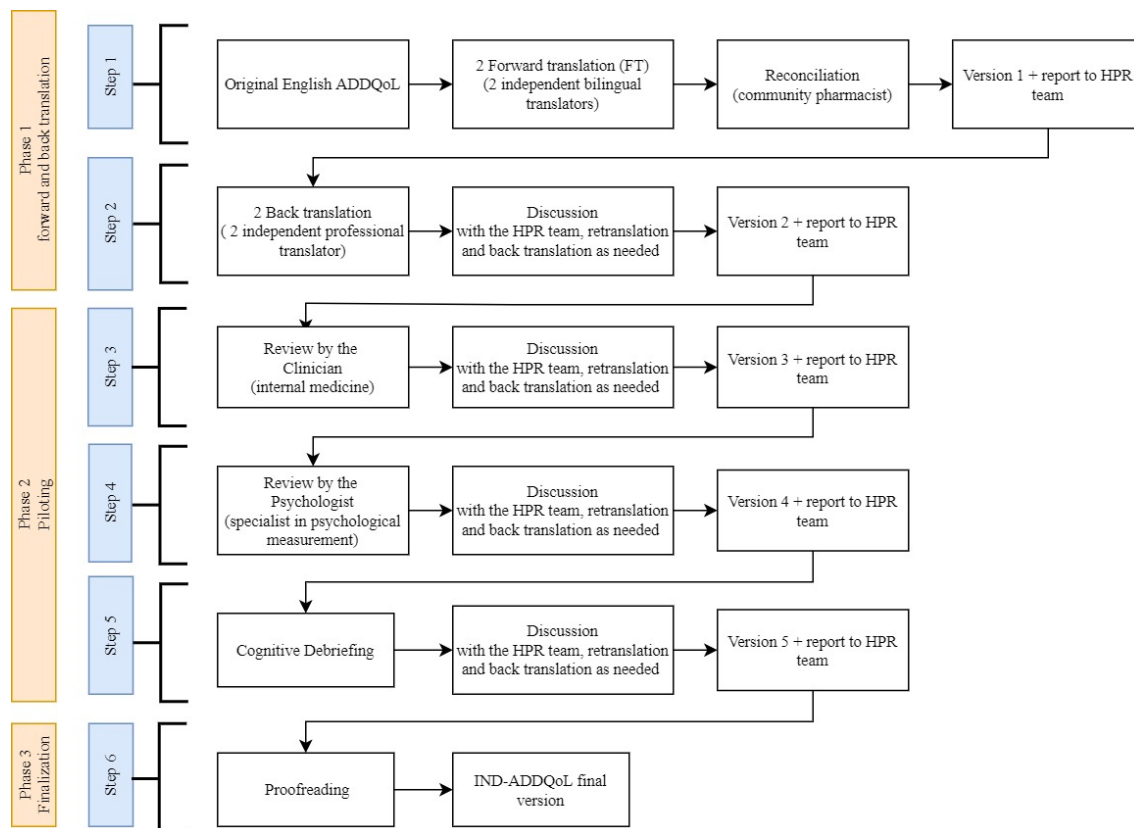

Figure 1. The stages of translation and cultural adaptation of the Indonesian version of the ADDQoL questionnaire using the linguistic validation method

Step 1 - forward translation

The UK English version of the ADDQoL-19 questionnaire was translated into Indonesian by two professional translators. They were both translators at the Language Center of Universitas Airlangga, native Indonesian speakers, who were fluent in English, and lived in Indonesia. Each translator worked independently in producing one of the two versions of the forward translation (FT1 and FT2).

Step 2 - reconciliation

A reconciler combined the two Indonesian translations (FT1 and FT2) to produce the first Indonesian version. The reconciler was a community pharmacist who spoke native Indonesian and English fluently. This stage involved comparing, combining, and resolving the differences between the two translations.

Step 3 - back translation

The first reconciled Indonesian version of the ADDQoL-19 questionnaire was then translated back into English by two translators. One translator was a native Indonesian speaker fluent in English, a professional translator from the Faculty of Humanities - English Department of Universitas Airlangga, and had experience with forward-backwards translation. The other translator (commissioned by HPR Ltd) was a native UK English speaker, a professional translator who also spoke Indonesian fluently. The original English questionnaire was not provided to the two back-translators. To achieve conceptual equivalence, a review by the HPR team identified any discrepancies in meaning between the back translations and the original English ADDQoL. The reconciled FT was checked and edited as needed and back-translated again. This was repeated until the back translation reflected the English

source accurately. An interim version of the ADDQoL-19 in Indonesian was prepared for review by a clinician and psychologist.

Step 4 - committee review/expert panel

Two expert panels then reviewed the interim Indonesian ADDQoL questionnaire from the back translation step. The ADDQoL questionnaire is related to diabetes and quality of life, so the criteria for the expert panel conducting the reviews were an Internal Medicine Specialist, an Endocrine, Metabolic, and Diabetes Consultant, and a psychologist who had experience in designing a questionnaire. At this stage, the clinician review took place before the psychologist review. All suggestions and improvements from the two expert reviewers were documented and discussed with the HPR team.

Step 5 - cognitive debriefing

The expert reviewers' approved wording for the Indonesian ADDQoL questionnaire was tested on five respondents selected to represent the target population. People with diabetes mellitus, including those with type 1 and type 2 diabetes on various treatment regimens with varied sexes, ages, occupations, and levels of education were involved in this process. During the interview, this process can be carried out by having the respondent complete the questionnaire from start to finish on their own. The interviewer checks the questionnaire with the respondent to assess understanding of the instructions, meaning of items, response options, and ease of reading all the sentences in the questionnaire. The respondents are asked to provide their comments as they complete the questionnaire to check for comprehension problems. All suggestions and improvements from the respondents were documented and reviewed by the Indonesian linguistic validation coordinator and HPR team.

Step 6 - formatting and proofreading

The formatting step was carried out to ensure that the format and form of the ADDQoL questionnaire, which had been culturally adapted to the target language, remained consistent with the original version,

including letter type and size. Format changes and adjustments were made if a font other than the original version was used, such as Japanese, Korean, Chinese, and others. On the other hand, the proofreading step was carried out by a native speaker of the target language (Indonesian) to ensure that there were no errors in writing, grammar, spelling, or punctuation.

Ethics committee approval

This study was approved by the Health Research Ethics Committee, Faculty of Pharmacy, Universitas Airlangga (No.14/LE/2020).

RESULTS AND DISCUSSION

The translation and adaptation of the Indonesian version of the ADDQoL questionnaire in this study followed the linguistic validation procedure developed by Mapi Research Institute (Acquadro *et al.*, 2004). Several other studies on the adaptation of an English version of various instruments for Indonesia used different methods such as the Premature Infant Pain Profile-Revised (PIPP-R) using the Brislin method (Fitri *et al.*, 2019), the Diabetes Distress Scale using the guidelines from the European Organization for Research and Treatment of Cancer (EORTC) (Arifin *et al.*, 2017). The Pain Detect Questionnaire (PDQ) using the guidelines from the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (Margareta *et al.*, 2017). So far, there has been no empirical study or gold standard for the guidelines of the instrument adaptation process. Each method has requirements, qualifications, or characteristics of the people involved in the process. However, the evidence has shown a meticulous multistep approach with a centralized review procedure allows for better translations (Acquadro *et al.*, 2008). The adaptation method in this study or in previous studies are commonly used methods. The selection is based on the provisions or recommendations by each of the original questionnaire developers.

Table 1. Problems and solutions in the process of translation and cultural adaptation of the ADDQoL questionnaire

Item	Original version	Problems	Actions
Instruction	Now we would like to know how your quality of life is affected by your diabetes, its management and any complications you may have.	If translated literally without any additional explanation, the word ""management*""* would be difficult to understand and might cause a difference in meaning from the original version.	As an alternative, the word ""management"" was translated into Indonesian as ""*penanganannya*"" or ""treatment"" in English and included an additional explanation in brackets after the word. ***(including medication, visit to the doctor, and diet)

Instruction	This questionnaire asks about your quality of life – in other words how good or bad you feel your life to be.	When re-translated, the sentence ""how good or bad you feel your life to be"" transformed into ""how good or bad the life that you experience"". This sentence had a different meaning from the original version because the quality of life referred to in the ADDQoL questionnaire was how a person described feelings about his or her life, not how good or bad his or her life was.	Re-translation was done by revising the Indonesian translation to ""*Seberapa baik atau buruk Anda merasakan hidup Anda*"" (""how good or bad you feel your life"")
Overview item 2	Are you currently working, looking for work, or would you like to work?	During the pre-test interview, many respondents said this question was quite difficult to understand and confusing because there were three questions in one sentence to determine a yes/no answer. Some suggested changing the format and separating each question.	Format changes were not permitted for reasons of maintaining consistency in all language versions of the ADDQoL questionnaire. Finally, it was decided to add the word "" atau""(""or"") to emphasize and differentiate the three questions into ""*Apakah saat ini Anda sedang bekerja atau sedang mencari kerja atau apakah Anda ingin bekerja?*"" (Are you currently working or looking for work or would you like to work? "".
Response 1b	very important – important – somewhat important – not at all important	""Important"" was translated as "" *penting*"" and ""somewhat important"" was translated as ""*cukup penting*"" in Indonesian. At the back-translation stage the phrase ""*cukup penting*"" was back-translated as ""somewhat important"" and ""quite important"" by the two back-translators. This led to discussions whether ""*penting*"" is stronger than ""*cukup penting*"" in Indonesian.	It was confirmed at the back-translation stage, as well as in cognitive debriefing interviews with patients, that in Indonesian ""*penting*"" ("" important"") is stronger than "" *cukup penting*"" (""somewhat important""/""quite important""). No changes were made.
2b	For me, having a working life is	Inaccuracy in the translation of the sentences ""having a working life"" into Indonesian, which was ""*memiliki pekerjaan*"" (""having a work/job"").	Revision to the Indonesian translation had been made to match what was meant by the original version to ""*memiliki kehidupan bekerja*"" (""having a working life"")
5b	For me, how much I can do physically is	Inaccuracy in the translation of the word ""do physically"" to ""*kegiatan fisik*"" (""do physical activity"").	Re-translation was done by revising the Indonesian translation into ""*secara fisik*"" (""physically"").
17a	If I did not have diabetes, I would have to depend on others when I do not want to	If translated literally, many of the respondents said that the statement sentence was too complicated and not easy to understand. They had to read repeatedly and were slow to respond to this item.	Revision was made by changing the sentence structure to ""*ketergantungan saya terhadap orang lain walaupun saya tidak menginginkannya akan* "" (""my dependence on others

			even though I don't want it would be"")
19a	If I did not have diabetes, my freedom to drink as I wish (e.g. fruit juice, alcohol, sweetened hot and cold drinks) would be	Translation of the word ""sweetened"" to ""*pemanis*"" in Indonesian differs from the concept referred to in the original version. Culturally, most Indonesians considered ""*pemanis*"" to be chemical substances added to food or beverages as a substitute for real sugars such as saccharin or aspartame.	The sentence ""sweetened hot and cold drinks"" was changed into ""hot and cold drinks with sugar"".

The title of the questionnaire was not translated and was retained in the abbreviated ADDQoL form. Some of the problems and actions that were taken during the process are described in Table 1. Next, on the cognitive debriefing stage, the respondents' characteristics are presented in Table 2.

Table 2. Characteristics of respondents on the cognitive debriefing

Respondents	Ages (years)	Sexes	Types of DM	Backgrounds of education	Occupations	Treatment	Duration of DM (months/years)
R1	58	F	Type 2	Elementary School	Housewife	Insulin+ OAD	9 years
R2	63	M	Type 2	Elementary School	Trader	OAD	5 years
R3	53	M	Type 2	Higher Education	Civil Servant	Insulin	10 years
R4	29	F	Type 2	Higher Education	Laboratory Assistant	Insulin	8 months
R5	40	F	Type 1	Higher Education	Nurse	Insulin	5 years

Note: F = Female; M = Male; DM = Diabetes Mellitus; OAD = Oral Anti Diabetes

In this study, one of the issues that arose during the back-translation stage was to ensure the correct order of response options on the scale. "Somewhat important" was translated in Indonesian as "cukup penting". This was then back-translated by the two back translators as "somewhat important" and "quite important". In UK English "important" is stronger than "quite important", however, it is the opposite in US English (Bradley *et al*., 1999). So, we needed to ensure that in Indonesian "penting" ("important") is perceived as stronger than "cukup penting" ("somewhat important" or "quite important"). This was confirmed at the back-translation stage and cognitive debriefing interviews with patients, and no changes were necessary. The results of the Indonesian translations were appropriate to describe the level of response of the original version.

Another problem was the word "sweetened" which was translated as "*pemanis*" in Indonesian. In Indonesian culture, "*pemanis*" is often considered to be an artificial sweetener. Therefore, this word did not fit the concept of the original version of a drink with added or containing sugar. This result will certainly provide a

different understanding for the target population where the questionnaire will be used. For this reason, the word change in Indonesian was made to achieve conceptual equivalence with the original version to "with sugar".

In this study, problems with grammar, sentence or item complexity, or which word equivalents were more appropriate were resolved by rewriting with additions, subtractions, other word choices, and repeated translation until equivalence with the original English was achieved. This was also observed in the study of the translation and cultural adaptation of the ADDQoL questionnaire into Norwegian, where the words "statement," "not applicable," and "the effect of your diabetes" were changed (Thulin *et al*., 2008).

At this stage of cognitive debriefing, five participants were used. The cultural adaptation method used determines the cognitive debriefing criteria and the number of samples required. The linguistic validation method, for example, requires 5 - 10 samples, whereas other methods, such as EORTC, needs 10 - 15 samples, and ISPRO requires 5-8 samples (Acquadro *et al*., 2008; Wild *et al*., 2005). The challenge was to find

respondents who met the criteria for type 2 diabetes patients on a diet alone during the recruitment process. The vast majority of diabetic patients are on either oral or insulin therapy. The current numbers and criteria, on the other hand, are fairly representative of the existing target population.

The cognitive debriefing step has the advantage of allowing respondents to analyze difficulties in reading and filling out the questionnaire and to provide suggestions for alternative sentence wording that would be simpler and easier to understand. For example, the sentence in item 17a was difficult to understand for some respondents because the original Indonesian sentence was too complex; thus, rewriting was done based on the respondents' suggestions without changing the meaning or concept of the original version.

The study's limitation is that the linguistically validated Indonesian version of the ADDQoL requires additional research. The current study is only the first step in the process of instrument adaptation and should be followed by psychometric analysis. Psychometric analysis, including validity and reliability testing, is now underway to ensure the quality of the findings when using this Indonesian version of the ADDQoL in studies among the Indonesian-speaking population.

CONCLUSION

The ADDQoL questionnaire in Indonesian has been linguistically and culturally validated using international standard methods and the participation of experts in their fields using predetermined criteria. A large data collection study is currently underway to allow the psychometric properties of the Indonesian ADDQoL to be determined.

Access to the ADDQoL: please visit www.healthpsychologyresearch.com for the Indonesian and other language versions of the ADDQoL and other questionnaires developed by Bradley and colleagues.

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