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Patient-Reported Outcomes

Barriers to Diabetes Adherence: Translation and Cultural Adaptation of the Instrument Into Arabic Context



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ABSTRACT

Objectives: Barriers to Diabetes Adherence (BDA) instrument is a measure developed in English to assess barriers to adherence in adolescents with type 1 diabetes (T1DM). The main objectives of the present study were to translate and culturally adapt the BDA tool into Arabic for the assessment of barriers to adherence in adolescents with T1DM in Arabic-speaking populations.

Methods: The International Society for Pharmacoeconomics and Outcomes Research guidelines for the translation and cultural adaptation of patient-reported outcome measures were used for the process. Permission to use the instrument was obtained from the developers. This was followed by 2 forward translations of the tool into Arabic. The 2 Arabic versions were combined into a reconciled Arabic version that was then back-translated into English. This was then tested against the original tool. The resultant Arabic version underwent a cognitive debriefing process to assess its comprehension and appropriateness among potential users, and this resulted in further refinements, leading to the final Arabic version of the tool.

Results: The translation and cognitive debriefing processes revealed issues related to the cultural or conceptual equivalence of the tool that were addressed and resolved by rewording, restructuring, or addition or elimination of words or phrases that in certain circumstances necessitated communications with the developers for further clarifications of the intended meaning of relevant items. This process generated an easy, comprehensive, clear, and culturally acceptable tool as proven by the cognitive debriefing and clinical review processes.

Conclusion: A culturally acceptable Arabic translation of the BDA tool was developed to be used in adolescent Arabic population with T1DM.

Keywords: adaptation, adherence, Arabic, adolescents, diabetes, translation.

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Introduction

Type 1 diabetes mellitus (T1DM) is an autoimmune disease characterized by absolute insulin deficiency. It is usually diagnosed at an early age and is classified as juvenile-onset diabetes.^{1,2} T1DM is a chronic and complex disease that has multiple facets for successful management.³ It is the most common metabolic non-communicable chronic disease in children, accounting for approximately 5% to 10% of all diabetes cases, and the annual increase in its incidence is approaching 3%.^{2,4} This incidence is highly variable among different populations.^{4,5} The variability in the incidence of T1DM is partly explained by diverse ethnicities, climate, geographic regions, and socioeconomic backgrounds.⁶ In the Middle East and North African region, studies have reported large variations in T1DM incidence, ranging from 2.54 per 100,000 population in Oman up to 29 per 100,000 population in Saudi

Arabia.⁴ In Qatar the incidence of T1DM is considered relatively higher than most countries in the region.^{7,8} The latest reported incidence in 2011 was 23.64 cases per 100,000 children population.⁸

Achieving and maintaining glycemic control is critical in managing diabetes because it reduces the incidence of future diabetes-related complications.⁹ Lower hemoglobin A1c (HbA1c) levels are associated with reduced risks for microvascular and macrovascular complications.¹⁰ However, only 21% of adolescents diagnosed with T1DM achieve the target HbA1c levels set by the American Diabetes Association.¹¹ Adolescence is a transition period from childhood to adulthood, when multiple changes occur, including hormonal, cognitive, and psychosocial changes associated with puberty.^{11,12} These changes could be related to the poor glycemic control that occurs during adolescence.¹² Hormonal changes and worsening insulin resistance

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could lead to increased levels of glucose in blood, which affects diabetes control.^{12,13} Incomplete development in cognitive and executive functioning could also result in poor glycemic control.¹³ In addition, psychosocial factors are the most substantial, where adolescents start exhibiting more autonomy and independence for decision making in their lives. They spend more time away from home, and their peers start to become more influential on their lives, with their parents' authority diminishing.^{12,13} The responsibility of managing diabetes shifts from parents to the youths themselves, which can lead to family conflicts related to self-management tasks.¹³ Collectively, glycemic control is usually at its worst and the rates of acute complications are the highest during adolescence.¹⁴

Many targeted efforts have attempted to address the issue of poor glycemic control in adolescents; yet, understanding the reasons behind the poor control is a crucial step toward optimal interventions and control.¹¹ One of the reported suggested reasons for uncontrolled T1DM is the declines in adherence to medications, lifestyle, and self-care that occur when children with diabetes enter puberty.⁹ Adherence is defined as the extent to which patients comply to medical advice.¹⁴ In T1DM, such advice includes monitoring blood glucose frequently, adjusting insulin doses according to glucose readings, administering insulin, attending regular clinics, counting carbohydrates, modifying lifestyle, and maintaining medical supplies.^{14,15} These multiple self-care tasks are highly demanding in nature and variable in their frequency, which largely explains the suboptimal adherence, especially during adolescence period.¹⁶ The extent of non-adherence among adolescents with T1DM can reach up to 93%, resulting in complications and hospitalizations with economic consequences.^{17,18} An estimated annual cost of nonadherence in the United States is reported to be as high as \$300 billion per year.¹⁸

To improve glycemic control through optimizing adherence, an initial step should be to identify barriers to adherence and strengths and facilitators of adherence. This step helps in developing holistic interventions that aim to improve adherence, improve glycemic control, and consequently minimize diabetes-related complications.¹⁸ Previous studies have investigated the factors and barriers contributing to nonadherence in adolescents with T1DM; these include psychosocial factors such as family functioning, parental monitoring, peer support, mood disorders, and eating disorders. Other barriers include communication with providers, cost, and regimen-related barriers.^{11,14} These factors are highly variable among cultures, especially when it comes to parenting styles and family functioning, which in this case play a major role on adherence. Therefore, it is essential to investigate barriers specific to Qatar or the Middle Eastern region.

The Barriers to Diabetes Adherence (BDA) measure is an instrument that assesses barriers to adherence in adolescents with T1DM. It is a 21-item self-reported measure that addresses 5 main domains: stress and burnout, time pressure and planning, social support, autonomy support, and stigma. It contains statements about things that can get in the way of taking care of diabetes, which respondents have to rate as true or untrue using a 5-point scale from 1 (not at all true) to 5 (completely true).¹⁶ This tool is not available in Arabic; because the national language in Qatar and other Middle East and North African countries is Arabic, this study aimed to translate and culturally adapt the BDA tool in Arabic for the assessment of barriers to adherence among adolescents with T1DM in Arabic-speaking populations.

Methods

The Translation and Cultural Adaptation Process

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines for adaptation, validation, and translation of questionnaires related to the measurement of patient reported outcomes (PROs) were followed in this study¹⁹ (Fig. 1).

Preparation

The permission to use the BDA was initially obtained from the original developers of the questionnaire. A protocol was then developed that included comprehensive details about the objectives, methodology, and timeline of the translation and cultural adaptation process. This protocol was shared with the research team and other stakeholders throughout the process.

Forward translation

Two independent translators who were native Arabic speakers and fluent in English conducted the translation of the BDA tool from English to Arabic. The translators had previous experience in translating PRO measures, and they were provided with the study protocol before the translation process.

Reconciliation

The translation panel comprising the research team in addition to the 2 forward translators arranged a meeting for developing 1 reconciled Arabic version of the BDA. This step was essential to resolve any discrepancies between both translations and to reach consensus on a linguistically equivalent, Arabic version of the BDA tool.

Back translation and review

Two bilingual, independent translators conducted a back translation of the reconciled Arabic version of the tool into English. Those 2 translators were not familiar with the original English instrument. The 2 back translations were compared with the original BDA tool item by item by the research team to ensure that the Arabic translation maintained the intended meaning. This review resulted in some minor refinements in the Arabic version of the questionnaire, which led to a second reconciled Arabic version.

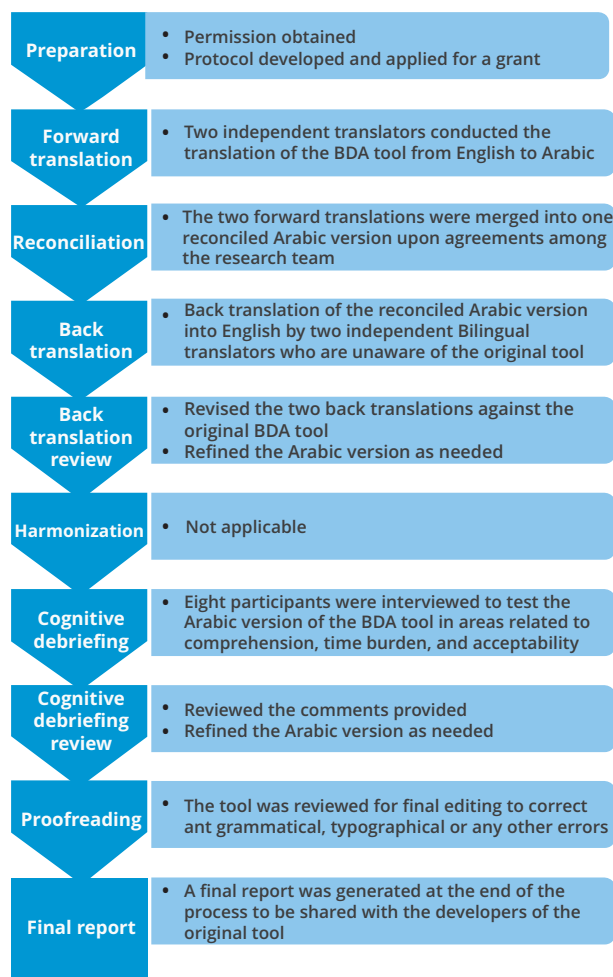
Cognitive debriefing and review

Eight native Arabs were interviewed during the cognitive debriefing step. The participants were selected to represent different ages, genders, nationalities, and occupations. The purpose of this step was to assess the comprehension, time burden, and acceptability of the Arabic version of the questionnaire. Participants selected were healthy adolescents, adolescents with T1DM diabetes aged from 13 to 17 years, and healthcare providers who cared for adolescents with T1DM. Participants were selected based on purposive sampling to ensure diverse characteristics among the selected participants. The review of the cognitive debriefing resulted in further refinements of the Arabic version of the questionnaire.

Proofreading and final report

The Arabic version of the questionnaire was proofread by an expert in the Arabic language, and it was revised by the research team to generate the final version of the Arabic-translated BDA tool. A final report was generated that included a detailed

Figure 1. Flow diagram of the steps followed for translation and cultural adaptation of the BDA tool based on ISPOR guidelines.



BDA indicated Barriers to Diabetes Adherence; ISPOR, International Society for Pharmacoeconomics and Outcomes Research.

description of the methodology and the outcomes of each step, which was shared with the original developers of the BDA tool.

Results

Translation and Cultural Adaptation

The translation and cultural adaptation process of the BDA tool included forward and backward translations to ensure the conceptual equivalence of the English and Arabic versions. When needed, some items were refined to adapt to the Arabic culture and language rules. Here we present a summary of the linguistic and cultural issues that were encountered during the processes and the actions taken to resolve those problems. Grammatical and spelling errors corrected are not presented in this article.

Overall

The word *diabetes* was translated as “diabetes disease” to make it meaningful in Arabic throughout the questionnaire because the

word *diabetes* by itself is not usually used to describe this disease in Arabic.

Title of the instrument “Barriers to Diabetes Adherence”

The term *adherence* in the title was translated to a phrase that means “adherence to treatment” to give the complete meaning because there is no literal translation to the term *adherence* in Arabic. The word *diabetes* was also translated to a phrase that means “patients with diabetes” because Arabic the disease cannot be described to have barriers. The final title in Arabic then translates to “Barriers to Adherence to Treatment Among Patients With Diabetes.”

Instructions

In the instructions statement, “These are some statements about things that can get in the way of taking care of diabetes. Rate HOW TRUE these statements are for you,” the word *please* was added before the sentence “Rate HOW TRUE these statements are for you” because this is more culturally acceptable in our setting. Without the word *please*, the instruction seems to be a command or an order, which is not culturally preferable.

Response options

For the response options “not at all true, a little, somewhat, mostly, completely true,” the word *true* was added to all the response options to make them more linguistically valid because “a little, somewhat, and mostly” does not provide the intended meaning according to the rules of the Arabic language. Moreover, to differentiate between “a little” and “somewhat,” the word *very* was added to “a little” because the literal translation would not convey the meaning of the scale in Arabic (they are both translated to the same word in Arabic). The final scale became “not at all true, very little true, somewhat true, mostly true, and completely true.”

Item 1: “I feel burned out with diabetes”

Item 1 was translated to “I feel burned out because of diabetes” to convey the intended meaning because literal translation would not be meaningful in Arabic.

Cognitive Debriefing and Review

Eight native Arabic speakers were interviewed during the cognitive debriefing. The participants were selected to represent different ages, genders, nationalities, and occupations. Selected participants were healthy (n = 4) and diabetic (n = 1) adolescents aged 13 to 17 years, in addition to healthcare providers (n = 3) who provide care for adolescents with T1DM. Healthy adolescents were included because of the difficulty in identifying adolescents with diabetes. Healthcare providers were mainly included to provide more comments about the appropriateness and the cultural acceptability of the items. The demographic characteristics of the participants interviewed in the cognitive debriefing process are presented in Table 1. The review of the cognitive debriefing resulted in further refinements of the Arabic version of the tool. Here we present a summary of the issues and actions of the cognitive debriefing process.

Overall

All healthcare providers interviewed suggested using the term *diabetes* instead of the phrase that is commonly used, *disease diabetes*, because there is a local initiative to avoid calling it a disease to minimize stigmatization of this population as

Table 1. Demographic characteristics of participants involved in cognitive debriefing process.

Participant	Gender	Nationality	Age (y)	Occupation	Duration of interview
1	Female	Sudanese	46	Physician	30 minutes
2	Female	Palestinian	29	Diabetes educator	30 minutes
3	Female	Lebanese	35	Dietitian	1 hour
4	Male	Egyptian	15	Student (healthy)	30 minutes
5	Female	Djiboutian	16	Student (healthy)	20 minutes
6	Male	Syrian	17	Student (healthy)	20 minutes
7	Female	Egyptian	13	Student (healthy)	30 minutes
8	Female	Egyptian	16	Student (diabetic)	40 minutes

diseased; instead, the word *diabetes* was used throughout the questionnaire.

Item 7: "I forget to carry diabetes supplies"

Some participants interpreted the translation of "diabetes supplies" as medicines only so the word *care* was added to the statement to convey the intended meaning. The final statement became "I forget to carry diabetes care supplies."

Item 8: "I get hungry and do not take care of diabetes"

Most participants had issues with the interpretation of this item. Some participants understood it in the context that when they get hungry, they eat unhealthy food, so they are not taking care of their diabetes. However, others interpreted it that they feel hungry, yet they do not eat anything (and thus they become at risk of hypoglycemia), so they are not taking care of their diabetes. To resolve this, the developers of the tool were contacted to clarify the intended meaning and the word *and* was replaced by the word *so* to clarify the statement. The final statement became "I feel hungry, so I do not take care of diabetes."

Item 10: "I feel like I do not have anyone to talk to about diabetes problems"

Some participants were confused whether the intended meaning was "general diabetes problems" or "my diabetes problems." Again, the developers were contacted and agreed on adding the word *my* to the statement. The resultant statement became "I feel like I do not have anyone to talk to about my diabetes problems."

Discussion

Identifying barriers to adherence among adolescents with T1DM in Arabic-speaking population is essential because it helps in identifying the reasons behind poor adherence to therapy that commonly occur during this period. Consequently, the barriers identified can be used to inform the development of intervention strategies addressing them. The BDA tool is a 21-item self-reported questionnaire that assesses psychosocial barriers to adherence in adolescents with T1DM.¹⁶ This tool was not available in Arabic. Therefore, we followed best practices for the translation and cultural adaptation of the tool into Arabic to be used in Arabic-speaking populations. Guidelines exist for the translation and cultural adaptation of already existing tools to be adapted and used in different populations.¹⁹⁻²² Those guidelines mainly differ in their technical translation, yet they all have a common objective of achieving functional equivalence, which can be defined as "the extent to which an instrument does what it is supposed to do equally well in two or more cultures."²³ The diversities in the

approaches can be dependent on the various languages, settings, cultures and the type of tool to be adapted.²⁴ In this study we followed the ISPOR guidelines for adaptation, validation, and translation of questionnaires related to the measurement of PROs.

Although the adaptation of the questionnaire was considered holistically, a literal translation was possible in some items and inappropriate in others. For instance, the word *adherence* in the title was translated to a phrase that means "adherence to treatment" to give the complete meaning because there is no literal translation of the word *adherence* in Arabic. Moreover, to differentiate between "a little" and "somewhat" in the response options, the word *very* was added to "a little" because the literal translation would not convey the scale (ie, they both translate to the same word). Regarding the back translation, the ISPOR guidelines advise that the back translation be done by a single translator who is a native speaker of the original language of the tool but fluent in the target language—in this case, a native of English fluent in Arabic.¹⁹ A person meeting these criteria was identified but had no medical background; therefore, a second back translator was added who is bilingual and has a medical background to ensure the appropriate translation of the medical terms. Both back translations were considered during the back-translation review. In fact, in other guidelines it is essential that this step be done by a minimum of 2 independent translators.^{20,21}

During the cognitive debriefing process, interviews were conducted to assess the comprehension, acceptability, cognitive equivalence, and time burden of the questionnaire. According to the ISPOR guidelines,¹⁹ those interviews should be conducted with native speakers of the target language who adequately represent the target population in as many criteria as possible, including age, gender, education, and diagnosis. However, the guidelines also state the possibility of including healthy respondents in certain circumstances. In the present study we included healthy adolescents and adolescents with diabetes, in addition to healthcare professionals who provide care to adolescents with T1DM. Healthy adolescents were included because of the difficulty in recruiting sufficient number of adolescents with T1DM; because the main aim was to assess the comprehension and cognitive equivalence of the tool, it was assumed that the comprehension level would be similar among diabetic and healthy adolescents. Healthcare providers were mainly included to provide more comments about the appropriateness and the cultural acceptability of the items. The involvement of clinicians is also recommended by other guidelines, which would add value to the outcomes of the cognitive debriefing step of the study.²⁰⁻²²

Because the target language was Arabic, which has a single written language but multiple dialects that vary significantly among different nationalities, the interviews were purposively done with participants from different regions with various dialects to ensure that the translated tool was interpreted similarly across

different Arabic dialects.²⁵ This is particularly important in a country like Qatar with its diverse, multicultural populations who could be potential users of the tool.

Overall, the translated Arabic version of the BDA demonstrated good comprehension. This can be partly explained by the rigorous development process of the tool, which incorporated adolescents from the initial phase of the tool development and took into consideration their feedback during the piloting process.¹⁶ A few items necessitated the feedback of the original developers of the tool for further clarifications, which led to minor refinements in the Arabic version of the tool. For example, most participants had problems with the interpretation of item 7, “I get hungry and do not take care of diabetes.” Therefore the original developers were contacted to clarify the intended meaning, and the word *and* was replaced with the word *so* to clarify the statement. One of the major outcomes of the cognitive debriefing process was the comment provided by all healthcare providers about the phrase “diabetes disease” and the consensus to replace it with the word *diabetes* to make it more culturally acceptable and to avoid the stigma associated with the word *disease*.

One of the limitations of the study was the difficulty in recruiting adolescents with T1DM for the cognitive debriefing step. However, as previously stated, the approach of including healthy adolescents is acceptable. Another limitation was that all participants were educated, which is justified by the fact that the vast majority of adolescents in Qatar are educated. Finally, the psychometric properties of the translated tool were not reassessed in the new target population (Arabs). Further research is needed to assess the psychometric properties of the Arabic version of the tool before its use among Arabic-speaking populations.

Conclusion

We successfully developed a culturally acceptable Arabic translation of the BDA tool to be used in adolescents with T1DM in Arabic-speaking countries. Further steps will be to determine the psychometric properties of the Arabic-translated tool in adolescents with T1DM.

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