Translation, Cross-Cultural Adaptation and Validation of the Gestational Diabetes Mellitus Knowledge Questionnaire in the Western Cape, South Africa

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Abstract

Background.

Gestational diabetes mellitus (GDM) is a major public health concern. The International Diabetes Federation estimated that the global prevalence of hyperglycemia in pregnancy is 16.2%. In South Africa, the most recent prevalence of GDM ranges between 9.1-25.8%. Serious adverse events associated with GDM can be mitigated by lifestyle modifications and education. Good comprehension of GDM, and improved understanding has been shown to translate into better glycemic control and reduces peri-natal complications. Assessing the knowledge base of mothers with GDM, whether in a country like South Africa, or any other similar country, is therefore imperative in bridging the gap and improving their understanding and control of their condition.

Objective.

To ascertain the validity and reliability of translated, cross-culturally adapted South African English, Afrikaans and isiXhosa versions of the Malaysian GDM Knowledge Questionnaire (M-GDMKQ).

Methods.

This mixed-method study was conducted prospectively within a high-risk antenatal clinic setting. The study consisted of three phases. Women ≥18-years, with GDM who were able to read basic level English, Afrikaans or isiXhosa; and attended the high-risk antenatal clinic throughout the index pregnancy were consecutively sampled and stratified into three language groups across phases.

Results.

The cross-culturally adapted English, Afrikaans and isiXhosa South African GDMKQ demonstrated reasonable face and content validity. Kappa values ranged between Kappa (SE), -0.03 (0.18) to 0.89 (0.13) for the English version, Kappa (SE), -0.07 (0.18) to 0.53 (0.13) for the Afrikaans version and Kappa (SE), 0.28 (0.18) to 0.87 (0.17) for the isiXhosa version respectively. Cronbach alpha for the individual questions ranged from 0.31 to 0.90, while correlation between overall scores was rho=0.79 (p<0.001).

Conclusion.

While the translated and cross-culturally adaptation South African English, Afrikaans and isiXhosa versions of the GDMKQ were found to be feasible, acceptable and easy to comprehend, more research is required to confirm validity and reliability.
1. Introduction

Gestational diabetes mellitus (GDM) is a major public health concern with adverse perinatal and long-term effects that surpass generations. The diagnosis of GDM is confirmed clinically with a 75-gram oral glucose tolerance test (OGTT). Diagnostic GDM values on OGTT include fasting plasma glucose (FPG) between 5.1–6.9 mmol/L, and/or the 1-hour plasma glucose >10.0 mmol/L and/or the 2-hour plasma glucose 8.5–11.0 mmol/L \[1\]. When OGTT glucose values at 24 to 28-week gestation exceed the FPG (7mmol/L) and two-hour plasma glucose (11.1mmol/L) cut-offs for diabetes, the International Association for Diabetes in Pregnancy Study Group (IADPSG) criteria categorizes women with hyperglycemia first detected in pregnancy (HFDP) as having overt diabetes \[1\]. Reported GDM prevalence data differs across geographical settings, a result of variation in screening methods, non-uniform diagnostic criteria and heterogeneity of populations \[2,3\].

In 2017, the International Diabetes Federation estimated that the global prevalence of hyperglycemia in pregnancy is 21.3 million (16.2%). Of these, the majority of cases (86.4%) is attributed to GDM \[4\]. In South Africa, the most recent prevalence of GDM ranges between 9.1-25.8% in the Gauteng province only\[2,5\]. Considering the prevalence and high rate of Type 2 Diabetes Mellitus (T2DM) after GDM, coupled with limited resources in South Africa and other low- and middle-income countries, the projected escalation in the burden of disease is concern \[6,7\]. Any degree of HFDP, including GDM is associated with a myriad of complications during and after pregnancy \[8,9\]. Over and above the well documented antenatal and perinatal complications, epidemiological surveillance indicates that GDM mothers and their offspring develop more readily develop chronic non-communicable diseases (NCD’s) \[9\]. These NCD’s emerge as early as adolescence, and mostly occurs in developing countries \[10,11,12\].

The management of any hyperglycemic pregnancy, including GDM requires lifestyle modification and education. This is achieved by identifying and addressing modifiable factors that contribute to hyperglycemia. It is noteworthy that many of the serious adverse events associated with GDM and T2DM can be mitigated by timely glucose control during pregnancy \[13\] which is achieved through educating individuals about their understanding of their conditions and their lifestyle choices.. Lifestyle modification requires good comprehension of GDM, and improved understanding has been shown to translate into better glycemic control and reduces peri-natal complications \[14\]. Educational strategies aimed at improving comprehension in women with GDM should however be evidence based and take cultural factors, beliefs local norms and practices into account \[15\].

In order to address knowledge gaps in GDM women, an assessment aimed at determining their current understanding is warranted. This assessment may identify important deficits and shed light on the GDM women’s ability to attain the knowledge that would empower her to address the lifestyle factors that contribute to hyperglycemia in pregnancy. In healthcare in general, knowledge is assessed by means of a questionnaire. To the best of our knowledge, there is no validated questionnaire fit for purpose in South Africa. In fact, there is a paucity of questionnaires that assesses knowledge in the GDM context globally.
Limitations of existing questionnaires are the applicability to South Africa, and the fact that no provision is made for differences between people of different socio-economic status and between cultural practices. A Malaysian validated, Gestational Diabetes Knowledge Questionnaire (M-GDMKQ), consisting of 15 questions that addresses risk factors, diet and food management, treatment and management, complications and outcomes were deemed most suitable for a South African context[14]. South Africa consist of a population where diversity regarding language, ethnicity, socio-economic status, cultural and religious aspects is vast. The three official languages in the Western-Cape (WC) Province of South Africa are Afrikaans, English and isiXhosa[16]. The following study therefore aimed to ascertain the validity and reliability of the translated and cross-culturally adapted South African English, Afrikaans and isiXhosa versions of the Malaysian GDM Knowledge Questionnaire (M-GDMKQ) among pregnant females with GDM visiting a local hospital in South Africa. It is envisaged that the methods and limitations faced in this study can be extrapolated to other similar resource settings.

2. Materials And Methods

2.1 Study design, setting and sample size calculation

A mixed-method study was prospectively conducted during the period of 5 February 2019 to 6 September 2019, at the high-risk antenatal clinic at Tygerberg Hospital (TH). TH is situated in the northern suburbs of the Cape Metropole area of the Western Cape province, South Africa. This study had a qualitative (phase 1) and cross-sectional component (phase 2 and 3). TH is the largest tertiary hospital in the WC and has the largest catchment area including Northern Metro sub-districts, Khayelitsha, Eastern Tygerberg, West Coast, Cape Winelands and Overberg rural districts. Ethical approval was obtained from the Health Research Ethics Committee, Stellenbosch University (Ethics number: 518/10/268. Written informed consent was obtained from all participants. In other countries, a cross-cultural adaptation, translated and validation of an outcome measure is usually conducted for one ethnic or language group. Due to the heterogeneity of the local population, the validation and implementation of only the English version of the GDMKQ was therefore not regarded appropriate in our context. The aim of this study was to translate and cross-culturally adapt the Malaysian GDM Knowledge Questionnaire (M-GDMKQ) for South African English, Afrikaans and isiXhosa population in the WC and then validate the tool.

There are no clear guidelines on the adequate sample size for cross-cultural adaptation and validation studies. We deemed a sub-group of n=10, for each language group, sufficient and acceptable for phase 1 and 2 of this study. The sample size required for phase 3 of this study was based on the intraclass correlation coefficient (ICC)[17]. The total sample size n=89 (at least n=30 per group), was calculated within an MS Excel sheet assuming a significance level of 0.05 and power of 70%[17]. The acceptable reliability was set at 0.70 and the expected reliability was estimated at 0.80 based on previous studies.

2.2 Participants
A total of 124 participants were consecutively sampled. The participants were identified and sourced from the high-risk antenatal clinic at TH and stratified into three language groups (phase 1 to 3). In phase 1 and 2, the sub-groups were randomly. The inclusion criteria included participants: clinically diagnosed with GDM according to the National Institute for Health and Care Excellence criteria (fasting glucose above 5.5 mmol/L and OGTT 2-hour glucose over 7.8 mmol/L); who were able to read at a basic level in either English, Afrikaans or isiXhosa; who were >18 years; whom attended the high-risk antenatal clinic at TBH throughout the index pregnancy between 31 January to 1 October 2019. This clinic only attends to women with high risk pregnancies. Women are eligible to attend this clinic on a referral basis from lower care levels. Women unable to comprehend the project and what was expected of them were excluded from the study. Informed consent was obtained for all participants.

2.3 Phase 1: Translation and Cross-Cultural Adaption Process

Professional and independent freelance Afrikaans and isiXhosa translators forward and back translated the English GDMKQ. Forward- and back-translation was done by two different translators. These translators were not informed about the project details. During back translation, they did not receive the English version of the GDMKQ as reference. An expert panel was identified and invited to participate in the study. This panel included, endocrinologists (n=2), obstetrician and gynecologists (n=2), dietitians (n=3), biostatistician (n=1) and a diabetes educator (n=1) working in the public health sector in Cape Town. Three sub-groups of participants (n=10), one in each language, were randomly selected per stratum to evaluate semantic and conceptual equivalence in relation to the original items of the English version of the M-GDMKQ. To improve applicability, the expert panel and participants were asked to review the M-GDMKQ in order to identify factors that was not appropriate to the context and suggest changes towards cross-cultural applicability. Guiding questions were emailed to the expert panel and they were requested to complete the questionnaire at the high-risk antenatal clinic. The principle investigator and isiXhosa translator were available to clarify any uncertainties. The principle investigator coded data obtained during the cross-cultural adaptation process in common themes and analyzed by identifying key themes. The principal investigator collated all the changes and sent it to the expert panel until consensus was reached and no more changes were recommended.

2.4 Phase 2: Validation Process

The expert panel determined the content validity of the translated and cross-culturally adapted GDMKQ. Three sub-groups (n=10) for each language group, were randomly selected to determine the face validity of the cross-culturally adapted and translated GDMKQ, for each version of the South African GDMKQ. Firstly, the sub-groups completed the cross-culturally adapted and translated South African GDMKQ and the PI and isiXhosa translator kept time with a calibrated stopwatch and recorded the data. The sub-groups then completed a questionnaire relating to the acceptability and comprehensibility of the cross-culturally adapted and translated GDMKQ. The PI and isiXhosa translator were available to clarify any uncertainty.
2.5 Phase 3: Reliability Process

A total of n=93 participants were consecutively sampled to determine the reliability of the translated, cross-culturally adapted and validated versions of the South African GDMKQ. The participants were asked to complete the GDMKQ, in their home language, two weeks apart. The participants completed the GDMKQ at the high-risk antenatal clinic at TBH, in an isolated room, at both time points.

2.6 Instruments

The GDMKQ is a questionnaire consisting of 15 multiple-choice questions developed in Malaysia from the Diabetes Knowledge Questionnaire, appendix 6 [14]. This questionnaire focusses on basic GDM knowledge (question 1-3), risk factors (question 4-6), diet and food management (question 7-9), treatment and management (question 10-12) and complications and outcomes (question 13-15). For each correct answer 1 mark is allocated and for an incorrect answer and 'I do not know' option a score of 0 is allocated. Therefore, the higher the score, the better the knowledge about GDM [14]. The M-GDMKQ was previously validated and translated to Bahasa Melayu, a Malaysian native language, with good internal consistency, Cronbach's alpha 0.77 [14].

The study phases and study flow described above are depicted in figure 1.

2.7 Statistical Analysis

All analyses were performed using Stata/IC 15.1 for Windows. The mean and standard deviation (SD) were reported for all normally distributed variables and median and IQR for variables that were not normally distributed. Categorical variables were reported by frequency and proportion. To compare variables between participants in each language group, One-way ANOVA hypothesis test was conducted for data that is normally distributed and a Kruskal-Wallis test for data that is not normally distributed. Chi-Squared test or Fishers exact test was used for categorical data. For the other quantitative data from the questionnaire (yes/no responses), frequencies and percentages were presented.

Psychometric testing included face and content validity, internal consistency (Cronbach's alpha-α) and test-retest validity (Spearman's Correlation and Cohens Kappa). A Cronbach's α of 0.7 was considered acceptable and a value of 0.8 reflects excellent internal consistency. Test-retest reliability measures reproducibility[18] and was quantified by Spearman's rho correlations coefficient (total score) and Cohens Kappa (per question). A Spearman's rho of > 0.6 was deemed reliable. Cohens Kappa is commonly used to determine the coefficient of agreement for categorical variables and ranges between −1 to 1 [19]. A score of 1 indicates perfect agreement and a score of 0 indicates agreement no better than that expected by chance [20]. A negative kappa would indicate agreement worse than that expected by chance [21]. A Cohens Kappa score of 0.6 was considered as acceptable and a value of 0.8 reflect strong level of agreement [19]. Incomplete GDMKQ forms were considered and analysed accordingly.

3. Results
3.1 Baseline Characteristics

A total of 30 participants were enrolled to participate in phase 1 and 2 of the study. The mean age of the participants was 32.93 (SD 0.85) years in phase 1 and 31.83 (SD 5.54) years in phase 2, respectively. For phase 1 and 2, majority of the participants resided in the Cape Flats (43.33-50%) and Northern-Suburbs (33.33%) and (36.67% and 60%) had an educational level lower than Grade 12, respectively. During phase 1 and 2, the median gestational age of the participants was 26 (IQR 9) weeks in phase 1 and 28.5 (IQR 5), phase 2. The median multigravida was 3 (IQR 1) pregnancies in all three phases of this study. In the final phase of the study, 93 participants with a mean age of 32.35 (SD 4.96) years were enrolled. Most of the participants resided in the Cape Flats (41.93%) and Northern-Suburbs (36.56%). Half of the participants in phase 3 were educated till a Grade 12 level (50.54%). The participants in the three language groups did not differ significantly across the phases, except for the area of residence in phase 1 (p=0.021) and marginally in phase 3 (p=0.049) (Table 1).
## Table 1
Baseline Characteristics of participants per language group and phase of the study

| Variable                      | Phase 1                        | Phase 2                        |
|-------------------------------|--------------------------------|--------------------------------|
|                               | Overall (N=30)                 | English (N=10)                 |
|                               | English (N=10)                 | Afrikaans (N=10)               |
|                               | isiXhosa (N=10)                |                               |
|                               | p-value                        | p-value                        |
| Age, years                    | Mean (SD)                      | Mean (SD)                      |
|                               | 32.93 (0.85)                   | 31.83 (5.54)                   |
|                               | 34.10 (1.64)                   | 33 (4.88)                      |
|                               | 32.33 (1.89)                   | 34 (5.72)                      |
|                               | 32.30 (0.87)                   | 28.50 (4.84)                   |
|                               | 0.626                          | 0.055                          |
| Area:                         | Frequency (%)                  | Frequency (%)                  |
| Cape Flats                    | 15 (50)                        | 15 (50)                        |
|                               | 4 (40)                         | 6 (60.00)                      |
|                               | 2 (20)                         | 8 (80.00)                      |
|                               | 9 (90)                         | 3 (30.00)                      |
|                               | 0.021                          | 0.122                          |
| Cape Winelands                | 2 (6.67)                       | 15 (50)                        |
|                               | 0 (0)                          | 6 (60.00)                      |
|                               | 2 (20)                         | 2 (20)                         |
|                               | 0 (0)                          | 7 (70.00)                      |
| Helderberg                    | 3 (10)                         | 15 (50)                        |
|                               | 1 (10)                         | 8 (60.00)                      |
|                               | 2 (20)                         | 2 (20.00)                      |
|                               | 0 (0)                          | 3 (30.00)                      |
| Northern-Suburbs              | 10 (33.33)                     | 15 (50)                        |
|                               | 5 (50)                         | 6 (60.00)                      |
|                               | 4 (40)                         | 8 (80.00)                      |
|                               | 1 (10)                         | 3 (30.00)                      |
|                               | 0.221                          | 0.122                          |
| Gestational Age, weeks        | Median (IQR)                   | Median (IQR)                   |
|                               | 26 (9)                         | 31.83 (5.54)                   |
|                               | 28.5 (4)                       | 33 (4.88)                      |
|                               | 22 (10)                        | 34 (5.72)                      |
|                               | 24 (9)                         | 28.50 (4.84)                   |
|                               | 0.053                          | 0.055                          |
| Highest Educational Level:    | Frequency (%)                  | Frequency (%)                  |
| Grade 7-11                    | 18 (60)                        | 15 (50)                        |
|                               | 3 (30.00)                      | 4 (40.00)                      |
|                               | 6 (60.00)                      | 8 (80.00)                      |
|                               | 9 (90.00)                      | 3 (30.00)                      |
|                               | 0.251                          | 0.122                          |
| Grade 12                      | 8 (26.67)                      | 15 (50)                        |
|                               | 5 (50.00)                      | 6 (60.00)                      |
|                               | 2 (20.00)                      | 2 (20.00)                      |
|                               | 1 (10.00)                      | 7 (70.00)                      |
| Tertiary Qualification        | 4 (13.33)                      | 15 (50)                        |
|                               | 2 (20.00)                      | 6 (60.00)                      |
|                               | 2 (20.00)                      | 2 (20.00)                      |
|                               | 0 (0)                          | 3 (30.00)                      |
| Employment Status:            | Frequency (%)                  | Frequency (%)                  |
| Employed                      | 15 (50)                        | 15 (50)                        |
|                               | 4 (40.00)                      | 6 (60.00)                      |
|                               | 8 (80.00)                      | 2 (20.00)                      |
|                               | 3 (30.00)                      | 7 (70.00)                      |
| Unemployed                    | 15 (50)                        | 15 (50)                        |
|                               | 6 (60.00)                      | 6 (60.00)                      |
|                               | 2 (20.00)                      | 2 (20.00)                      |
|                               | 7 (70.00)                      | 3 (30.00)                      |
| Gravida                       | Median (IQR)                   | Median (IQR)                   |
|                               | 3 (1)                          | 31.83 (5.54)                   |
|                               | 3 (3)                          | 33 (4.88)                      |
|                               | 2.5 (2)                        | 34 (5.72)                      |
|                               | 2.5 (1)                        | 28.50 (4.84)                   |
|                               | 0.549                          | 0.055                          |
| **Age, years**                | **Mean (SD)**                  | **Phase 2**                    |
|                               |                               | Overall (N=30)                 |
|                               |                               | English (N=10)                 |
|                               |                               | Afrikaans (N=10)               |
|                               |                               | isiXhosa (N=10)                |
|                               | **p-value**                    | **p-value**                    |
|                               | **31.83 (5.54)**               | **33 (4.88)**                  |
|                               | **34 (5.72)**                  | **28.50 (4.84)**               |
|                               | **0.055**                      | **0.055**                      |
| Variable                      | Phase 1                                                                 |
|-------------------------------|--------------------------------------------------------------------------|
|                               | Overall (N=30)   | English (N=10) | Afrikaans (N=10) | isiXhosa (N=10) | p-value |
|                               |                  |                |                 |                 |         |
| - Cape Flats                  | 13 (43.33)       | 2 (20)         | 4 (40)           | 7 (70)          | 0.201   |
|                               |                  |                |                 |                 |         |
| - Cape Winelands              | 4 (13.33)        | 3 (30)         | 1 (10)           | 0 (0)           |         |
|                               |                  |                |                 |                 |         |
| - Helderberg                  | 3 (10)           | 2 (20)         | 1 (10)           | 0 (0)           |         |
| - Northern-Suburbs            | 10 (33.33)       | 3 (30)         | 4 (40)           | 3 (30)          |         |
| Gestational Age, weeks        | Median (IQR)     | 28.5 (5)       | 29 (3)           | 28.5 (6)        | 27 (6)  | 0.975   |
| Highest Educational Level:    | Frequency (%)     | 11 (36.67)     | 2 (20)           | 6 (60)          | 3 (30)  | 0.170   |
| - Grade 7-11                  | 15 (50)          | 7 (70)         | 3 (30)           | 5 (50)          |         |
| - Grade 12                    | 4 (13.33)        | 1 (10)         | 1 (10)           | 2 (20)          |         |
| Employment Status:            | Frequency (%)     | 18 (60)        | 7 (70)           | 6 (60)          | 5 (50)  | 0.439   |
| - Employed                    | 12 (40)          | 3 (30)         | 4 (40)           | 5 (50)          |         |
| Gravida                       | Median (IQR)     | 3 (1)          | 2.5 (1)          | 3 (1)           | 3 (1)   | 0.580   |

| Variable                      | Phase 3                                                                 |
|-------------------------------|--------------------------------------------------------------------------|
|                               | Overall (N=93)   | English (N=30) | Afrikaans (N=31) | isiXhosa (N=32) | p-value |
|                               |                  |                |                 |                 |         |
| Age, years                    | Mean (SD)        | 32.35 (4.96)   | 33.1 (4.83)      | 32.32 (4.89)    | 31.69 (5.30) | 0.539   |
| Area:                         | Frequency (%)     | 39 (41.93)     | 7 (23.33)        | 12 (38.71)      | 20 (62.50)  | 0.049   |
| - Cape Flats                  | 7 (7.53)         | 3 (10)         | 4 (12.90)        | 0 (0)           |         |
| - Cape Winelands              | 13 (13.98)       | 5 (16.67)      | 5 (16.13)        | 3 (9.38)        |         |
| Variable                        | Phase 1                                                                 |
|--------------------------------|-------------------------------------------------------------------------|
|                                | Overall (N=30) | English (N=10) | Afrikaans (N=10) | isiXhosa (N=10) | p-value |
| - Northern-Suburbs             | 34 (36.56)     | 15 (50)        | 10 (32.26)       | 9 (28.12)       |
| Gestational Age, weeks         | Median (IQR)   | 28 (5)         | 29 (6)           | 28 (6)          | 28 (5.5) | 0.799 |
| Highest Educational Level:     | Frequency (%)  |                |                  |                |          |
| - Grade 7-11                   | 33 (35.48)     | 9 (30)         | 11 (35.48)       | 13 (40.62)      | 0.575   |
| - Grade 12                     | 47 (50.54)     | 14 (46.67)     | 16 (51.61)       | 17 (53.13)      |
| - Tertiary Qualification       | 13 (13.98)     | 7 (23.33)      | 4 (12.9)         | 2 (6.25)        |
| Employment Status:             | Frequency (%)  |                |                  |                |          |
| - Employed                     | 58 (62.37)     | 17 (56.67)     | 21 (67.74)       | 20 (62.5)       | 0.202   |
| - Unemployed                   | 35 (37.63)     | 13 (43.33)     | 10 (32.26)       | 12 (37.5)       |
| Gravida                        | Median (IQR)   | 3 (1)          | 3 (2)            | 3 (1)           | 2 (1)   | 0.422 |

Abbreviations: SD, standard deviation; IQR, interquartile range.

### 3.2 Phase 1

The GDMKQ underwent four rounds of revision until consensus was reached. The main themes identified were: (1) Simplified language (2) Inaccurate content (3) Proper linguistic and (4) Cultural adaptation. The expert panel simplified language usage across the three translated versions of the SA-GDMKQ. To reduce guessing, the panellists also included “Please do not guess” in the instruction. Furthermore, all complexities from the original GDMKQ were removed to make it more comprehensible. GDM can present without any signs and symptoms. The original GDMKQ asked participants ‘The most common sign of hyperglycaemia (high blood sugar) is’ and listed three options ‘Sweating’, ‘Hunger’ and ‘Increased thirst’. The expert panel deemed this question as inappropriate and felt that there was no correct answer as recent knowledge suggest. To ensure cross-cultural acceptability, all linguistic changes as recommended by the panellists were implemented. Linguistic changes included, grammar and spelling errors and semantic changes. The panellists also suggested changes to the options listed for the questions.
focussing on diet. The food choices in the original questionnaire was not culturally appropriate in the WC, South Africa and the most culturally appropriate food choices were included in the new versions.

3.3 Phase 2

The expert panel deemed all items of the South African GDMKQ (SA-GDMKQ) relevant and acceptable. All the participants who participated in the face validity phase felt that the questions were clear and easy to understand. Most of the participants ‘agreed’ (20%) and ‘strongly agreed’ (80%) that the SA-GDMKQ was easy to complete. All the participants in the English and Afrikaans group deemed all the items important. However, one participant in the isiXhosa group felt that questions 11 and 12 were not important, ‘no one explained to me what normal sugar level is, they should tell me if it is high or not. I should not know this’. Furthermore, all of the participants agreed that the SA-GDMKQ was well designed and structured in a way that makes it easy to read. The mean time taken to complete the SA-GDMKQ was 7.53 (SD 1.36) minutes.

3.4 Phase 3

A sample of n=93 participants agreed to complete the SA-GDMKQ, two weeks apart. One participant did not complete the second questionnaire, due to inability to attend the follow-up visit. Therefore, the final sample for reliability assessment consisted of English (n=30), Afrikaans (n=31) and isiXhosa (n=32) participants. Figure 2 presents the Cronbach’s alpha (σ) for each question of the SA-GDMKQ. Questions 1 and 2 reflected excellent internal consistency of σ=0.89 and σ=0.90 respectively. Questions 4 (σ=0.72), 6 (σ=0.73) and 8 (σ=0.71) demonstrated acceptable internal consistency. Only 2 questions (10 and 11) had poor Cronbach alpha, below 0.5.

Kappa values ranged between Kappa (SE), -0.03 (0.18) to 0.89 (0.13) for the English version, Kappa (SE), -0.07 (0.18) to 0.53 (0.13) for the Afrikaans version and Kappa (SE), 0.28 (0.18) to 0.87 (0.17) for the isiXhosa version, respectively, see table 2. Question 1 pertaining to basic knowledge, overall, had the best agreement ranging between Kappa (SE), 0.89 (0.13) to 0.53 (0.13) across the three versions of the South African GDMKQ. Only one question, question 7, for food and diet values of the isiXhosa version, demonstrated strong agreement, Kappa (SE), 0.81 (0.13). Question 6 in both the English and Afrikaans versions had Kappa value of 0.

The overall test-retest Spearman’s rank correlation coefficient of the total scores, was 0.79 (p<0.001). All three versions of the South African GDMKQ had a statistically significant (p<0.001) positive linear correlation between the total scores obtained in the first attempt, compared to the total scores obtained in the second attempt. The highest correlation was IsiXhosa (rho = 0.77, p <0.001), followed by the Afrikaans (rho = 0.73, p< 0.001) and lastly English (rho = 0.67, p <0.001).

Table 2. Kappa for test-retest reliability per item of English, Afrikaans and isiXhosa versions of SA-GDMKQ
| Topic           | Question | English Kappa (SE) | Afrikaans Kappa (SE) | isiXhosa Kappa (SE) |
|-----------------|----------|-------------------|----------------------|--------------------|
| Basic Knowledge | 1        | 0.89 (0.13)       | 0.53 (0.13)          | 0.87 (0.17)        |
|                 | 2        | 0.66 (0.13)       | -                    | 0.57 (0.15)        |
|                 | 3        | 0.60 (0.12)       | 0.33 (0.13)          | 0.42 (0.10)        |
| Risk Factors    | 4        | -0.03 (0.18)      | -0.07 (0.18)         | 0.56 (0.11)        |
|                 | 5        | 0.52 (0.13)       | 0.16 (0.18)          | 0.54 (0.12)        |
|                 | 6        | 0.00 (0.00)       | 0.00 (0.00)          | 0.49 (0.11)        |
| Food and Diet Values | 7    | 0.28 (0.12)       | 0.46 (0.12)          | 0.81 (0.13)        |
|                 | 8        | 0.54 (0.13)       | 0.37 (0.12)          | 0.55 (0.12)        |
|                 | 9        | 0.46 (0.16)       | 0.52 (0.14)          | 0.54 (0.17)        |
| Management      | 10       | 0.32 (0.11)       | 0.33 (0.11)          | 0.33 (0.12)        |
|                 | 11       | 0.50 (0.14)       | 0.41 (0.13)          | 0.43 (0.12)        |
|                 | 12       | 0.51 (0.13)       | 0.43 (0.12)          | 0.59 (0.12)        |
| Complication    | 13       | 0.19 (0.18)       | 0.31 (0.17)          | 0.64 (0.13)        |
|                 | 14       | 0.00 (0.00)       | -0.05 (0.16)         | 0.51 (0.17)        |
|                 | 15       | 0.28 (0.15)       | 0.37 (0.14)          | 0.28 (0.18)        |

Abbreviations: SA-GDMKQ, South African Gestational Diabetes Knowledge Questionnaire; SE, Standard Error.

4. Discussion

In this research, we cross-culturally adapted and translated the Malaysian GDMKQ into English, Afrikaans and isiXhosa versions and assessed the psychometric properties of the new South African GDMKQ. This is one of the first attempts in South Africa to develop a GDM knowledge questionnaire for pregnant women that may be used across cultures and three language groups. The South African GDMKQ demonstrated reasonable face and content validity. All the participants felt that the South African GDMKQ was clear and easy to understand. Internal consistency for the individual questions ranged between $\sigma=0.90$ to $\sigma=0.31$. Although the total scores between the first and second attempt demonstrated good test-retest reliability $\rho=0.79$, agreement of the individual questions fluctuated between different items and different versions of the South African GDMKQ and were not consistent over time.
In recent years, translation and cross-cultural adaptation of outcome measures in healthcare has increased, to ensure idiomatic, experiential and conceptual equivalence of outcome measures across cultures[22]. This process was therefore complex, due to the linguistic and cultural diversity in South Africa. Cross-cultural adaptation produced major changes to the original Malaysian GDMKQ. The South African GDMKQ underwent four rounds of revision before it was deemed acceptable for use in the WC, South Africa. Even though the South African GDMKQ underwent subsequent rounds of expert review, the current options listed for question 11, 'The normal value of fasting blood sugar is', the range of the blood glucose levels (mmol/L) listed in the options ‘1.5 – 3 mmol/l’ ‘3.6 – 6.1 mmol/l’ ‘7.5 – 9.5 mmol/l’, is not applicable to our setting. Question 11 also demonstrated poor internal consistency (σ=0.39), and low Kappa scores ranging between Kappa (SE) 0.41 (0.13) - 0.50 (0.14). These results indicate that the participants most likely guessed the answers, and we decided to remove the question from the South African GDMKQ.

The face and content validity of the three versions of the South African GDMKQ were deemed applicable and easy to understand. Additionally, the South African GDMKQ is structured and designed in a way that makes it easy to complete. However, face and content validity are the weakest form of validation[23]. A great limitation of this study is that the South African GDKMQ were not validated against the gold-standard, as no such measure exist. A good outcome measure should not only be acceptable but feasible as well. The final version of the South African GDMKQ was not time consuming and took a mean (SD), 7.53 (1.36) minutes to complete. If the healthcare worker needs to assess a patient’s knowledge of GDM, they would be able to do it without taking too much time off their other tasks. This tool is practical, especially in South Africa where there is limited resources and staff[24].

A study conducted in 2011 found that in Africa there is less than one health care worker per 1000 population[25]. In South Africa this is however further exacerbated by unequal distribution of health professionals between the private and public sectors and the distribution of public sector health professionals among the provinces[24,26]. Therefore, the South African GMKQ is an applicable, easy to complete, easy to understand and feasible tool to use in the clinical and research setting. Further validation of the psychometric properties of the English, Afrikaans and isiXhosa South African GDMKQ among larger sample groups as well as participants attending private health care facilities, is however warranted.

The final versions of the South African GDMKQ demonstrated unsatisfactory internal consistency. Only five questions demonstrated good internal consistency. Two of the questions (question 1 and 2) focused on basic knowledge, two questions (question 4 and 6) on risk factors and one question (question 8) focused on diet and food values. The internal consistency was the lowest in the GDM management category (question 10 to 12), with the Cronbach’s alpha ranging between 0.31 to 0.68. The internal consistency of the original GDMKQ, reported Cronbach’s alpha as 0.77, which is higher than most of the items[27]. However, it is not clear how the measure was derived and what the sample size was. The
reason for the low internal consistency values could be because we determined it per question and not per construct \[28\].

Due to time constraints and funding, we only assessed reliability in n=93 participants, with one participant who did not attend follow-up. All three versions of the South African GDMKQ demonstrated a statistically significant positive linear correlation between the total scores obtained in the first attempt, compared to the total scores obtained in the second attempt (\(p<0.0001\)). The correlation of the English version was \((\rho = 0.67, \ p < 0.001)\), Afrikaans \((\rho = 0.73, \ p < 0.001)\) and isiXhosa \((\rho = 0.77, \ p < 0.001)\). The Spearman's Correlation Coefficient value however does not provide any insight to systematic errors that may be inherent in the measurement obtained during the completion of the South African GDMKQ \[29\].

Despite good test-retest reliability between the total scores, the South African GDMKQ is not a reliable tool when inspecting individual questions. A fluctuation of Kappa scores of the South African GDMKQ were seen between the different versions as well as between questions. Only 2 of the 15 questions in the English version, 1 of the 15 questions in Afrikaans version and 3 questions of the isiXhosa versions of the South African GDMKQ were deemed acceptable. At least 2 questions in the English and 1 item in the Afrikaans version of the South African GDMKQ had a Kappa score of 0. Question 6 in both the English and Afrikaans versions of the South African GDMKQ demonstrated agreement no better than that expected by chance. This implies that the participants guessed the answers, even though the instructions instruct patients not to guess and choose the “I don't know option”. Furthermore, there were also Kappa values less than 0. This raises concern as it means that there is no agreement between the first and second attempt, indicating poor test-retest reliability. The Kappa statistic considers the possibility of guessing, but the assumptions it makes about independence of the different attempts and other factors are not well supported, which may lower the estimate of agreement excessively \[20\].

To minimise detection bias, the translators were blinded to the study aim and objectives. Furthermore, there were also two independent translators who participated in phase 1 of the study. This study had several limitations. The participants included in this study are from a single centre. Although the drainage service area encompasses a wide spectrum of English, Afrikaans and isiXhosa participants, it will not include all. The results of this study may therefore be difficult to use in settings with different languages and cultures. During the translation process, the second translators were health professionals and not professional translators. This could be the reason for the discrepancy of the translated versions in the isiXhosa versions. The sample size was also smaller than anticipated, decreasing the power of the study. Therefore, despite the reasonable face and content validity, the South African GDMKQ is not ready for use in clinical settings.

**Conclusion**

Although the South African GDMKQ has reasonable face and content validity and is deemed feasible to assess the knowledge of women with GDM, it has poor internal consistency and test-retest reliability.
Further expert review and subsequent rounds of psychometric evaluation is still needed before it can be used in the clinical and research setting.

Declarations

This study was submitted as a research project of LCM’s MSc. Clinical Epidemiology degree. LM was the main supervisor, and TC was the co-supervisor.

Ethics approval and consent to participate. Ethical approval was obtained from the Health Research Ethics Committee, Stellenbosch University (Ethics number: 518/10/268. Written informed consent was obtained from all participants. All methods in this study were performed in accordance with the World Medical Association’s Declaration of Helsinki of 1964.

Consent for publication. Not applicable.

Availability of data and materials. All datasets related to this research study can be obtained by contacting the lead authors.

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Figures
Figure 1

Illustration of study phases and study flow

- Malaysian GDMKQ
  - Forward translation from English to Afrikaans and isiXhosa
    - Translator 1
    - Translator 2
  - Synthesis of translated versions
    - Back Translation
  - Cross-Cultural Adaptation
    - Assessment by Expert Panel and subgroups and cultural adaption of items
      - Four subsequent rounds of expert panel review
    - Synthesis of potential new GDMKQ
  - Evaluation of Psychometric Properties
    - Pre-Testing:
      - Face and Content Validity
    - Final GDMKQ
    - Reliability: Test retest
      - Loss to follow-up:
        - (n=1) Afrikaans
Figure 2

South African GDMKQ Cronbach alpha results per question