Translation and cross-cultural validation of the non-invasive prenatal testing questionnaire in Arabic

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ABSTRACT

Objectives: To translate and cross-culturally adapt a Swedish questionnaire to Arabic to assess the awareness of pregnant women in Saudi Arabia regarding the availability of an accurate and safe prenatal screening procedure.

Methods: The study was conducted at the Obstetrics and Gynecology Clinic, King Abdulaziz Medical City, Riyadh, Saudi Arabia between December 2018 to April 2019. The non-invasive prenatal testing (NIPT) questionnaire, translated and validated in Arabic. Cronbach’s alpha reliability testing was carried out to validate the Arabic version of the questionnaire. The sample size was 100 pregnant women, at any gestational period, from 20 to 44 years old. This is a prospective cross-sectional.

Results: An Arabic translated, and culturally validated questionnaire related to the attitudes, knowledge, and self-perceived probability of delivering a child with chromosomal abnormality.

Conclusion: We translated and validated the NIPT questionnaire to assess the attitude and awareness of pregnant women regarding the availability of the NIPT.

Keywords: aneuploidy, NIPT, awareness, Arabic translation, pregnancy, Arabic questionnaire

Aneuploidies are numerical chromosomal anomalies considered as the most frequent causes of loss of pregnancy and developmental defects.1 Chromosomal abnormalities occur in approximately one in 150 live births.2 As the frequency of aneuploidy increases with maternal age,3 accurate and reliable screening during pregnancy for developmental defects is necessary to detect and diagnose such adverse events. Prenatal testing is a screening procedure, performed during pregnancy, to diagnose and detect pregnant women at high risk of having a fetus with chromosomal anomalies or developmental defects.4 Screening is usually offered in the first and second trimester of the pregnancy.5 Some examples of such tests are the first trimester screen (FTC), amniocentesis, chorionic villus sampling (CVS) and the non-invasive prenatal testing (NIPT).6 Non-invasive prenatal testing is a cell-free DNA test...
involve the isolation of fetal DNA from a maternal plasma sample. The cell-free DNA is from a placental origin, released in the maternal circulation from the fetal apoptotic trophoblasts. The release of fetal DNA fragments in maternal circulation increases with gestational age and the reliability of testing is more than 10% as early as 10 weeks gestation. The technology was introduced in 2011 and is based on the detection of cell-free fetal DNA, using next-generation sequencing (NGS) platforms, mainly for the detection of frequent aneuploidies such as trisomy 13, 18, and 21.

The advantage of NIPT, compared with other prenatal screening procedures, is that it does not require the invasion of the placenta for the collection of chorionic villus or amniotic fluid. The screening test provides the highest detection rate of screening tests for aneuploidies that included trisomy 13, 18 and 21. There is no literature available regarding the awareness of pregnant women in Saudi Arabia of this highly reliable and safer prenatal screening test. The aim of this study was to answer this question by providing a translated and culturally adapted NIPT questionnaire in Arabic. The questionnaire contains demographic information, including age, mother tongue, educational level, gestational week, number of children and previous miscarriages as well as multiple choice and Likert scale items exploring the attitudes, knowledge, preference for miscarriages as well as multiple choice and Likert scale questions related to their attitudes, and previous miscarriages as well as multiple choice and Likert scale questions related to their attitudes, knowledge, choice of information related to risk and decision-making of prenatal testing including NIPT. Items related to the attitude of delivering a child with a chromosomal defect, and the self-estimated probability of such event, are included. The questionnaire was translated by 2 groups of translators: content/language experts and language experts only. Each group consisted of 2 translators. The questionnaire was then validated and cross-culturally adapted by a human/medical geneticist and an epidemiologist. Given the increased frequency of chromosomal anomalies in the Saudi Arabian population and the need to assess the awareness of pregnant women of this safer and accurate screening test, we translated and adapted the original questionnaire for implementation in a Saudi Arabian cohort.

**Methods.** This prospective cross-sectional study was conducted at the Obstetrics and Gynecology (OB/GYN) clinic of King Abdulaziz Medical City (KAMC), Riyadh, Saudi Arabia between December 2018 to April 2019.

The participants were pregnant women, regardless of gestational period, from 20 to 44 years old. Investigators explained the purpose of the study to the target group and if they agreed, they signed an informed consent form. The translation team included a human/medical geneticist, biomedical scientists and an epidemiologist. Permission was obtained to translate and cross-culturally validate the original questionnaire into the Arabic language.

Inclusion criteria were all pregnant women at any week of gestation from (OB/GYN) clinic in KAMC, Riyadh and none from the exclusion criteria.

We utilized PubMed/MEDLINE, Cochrane and Google scholar databases to search for previously published studies on NIPT in Saudi Arabia. Additionally, these databases were used to find available questionnaires that assess the awareness of pregnant women on NIPT. The instrument we used was designed and validated by a Swedish research group, consisting of 2 senior experts in clinical genetics, biomedical scientists and a midwife, in questionnaire development. The questionnaire contains demographic information related to age, native language, educational level, gestational week, parity and previous miscarriages as well as multiple choice and Likert scale questions related to their attitudes, knowledge, choice of information related to risk and decision-making of prenatal testing including the NIPT. The attitudes regarding delivering a baby with a chromosomal defect, and the self-estimated probability of the event, was included in the assessment items.

**Translation and cross-cultural adaption.** To translate the questionnaire, we used 2 content and language experts and 2 additional language experts, total was 4 translators. The questionnaire was translated from English to Arabic and back to English, according to the internationally accepted World Health Organization (WHO) guidelines. As this process involves a totally different language from the original, instructions were given to the translators to not only focus on the literal translation but to consider the conceptual meaning of the items. The reason was that the proposed sample may include persons with no educational background. For the forward translation, 2 translators (T1 and T2) independently translated the questionnaire from English to Arabic. Subsequently, the 2 translators discussed any discrepancies in the translation and produced one version. T1 and T2 met the research committee, consisting of a human/medical geneticist (PhD holder) and an epidemiologist with a PhD, experienced in instrument translation and validation.

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The forward translators and the research team discussed the questionnaire, reached consensus and produced a final version of the forward translation (Figure 1). The resulting Arabic version was sent to 2 independent translators (T3 and T4), who had no access to the original English questionnaire, who translated the Arabic version to English. The research team gave the translators the same instructions that were given to the T1 and T2. After completing the independent translations, they discussed any differences, reached consensus and produced a final version of the back translation. The research committee met with all 4 translators to review the back-translated version and compare it with the original English questionnaire and produced the final Arabic version.

Validation of the questionnaire in the Saudi Arabian cohort. A pilot study was performed with 100 participants from the OB/GYN clinic at KAMC. Participants were fully informed about the purpose of the validation process and the study objectives. The questionnaire was distributed to the participants who were waiting at the clinics. This study included only consenting pregnant women at any gestational week. The face and content validity were ensured during the translation process. Any items that were not clear after the translation were modified before and after the pilot study.

The questionnaire was approved by the Institutional Review Board (IRB), King Abdullah International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia. The IRB at KAIMRC follows principles of Helsinki Declaration. The consent form was provided by the IRB Office at KAIMRC.

Statistical analysis. The Statistical Package for Social Sciences (SPSS) version 25 (IBM Corp., Armonk, NY,

Figure 1 - Schematic diagram of the translation and cross-cultural validation of the non-invasive prenatal testing questionnaire.
USA) was used to enter and clean the data. Level of education, Mother tongue and number of miscarriages were presented as percentages. The age and number of children was presented as mean ± standard deviation. The reliability of the items in the questionnaire was evaluated using the Cronbach’s alpha to measure internal consistency, values below 0.5 are classified as unacceptable, values between 0.5-0.7 were classified as acceptable. Values above 0.7 were classified as perfect.

**Results.** The translation process consisted of forward and back translations until consensus was achieved (Table 1). Since the criteria of the Likert scales were different, the coding of items 2a, 3, 5 and 7b were reversed to 1, the lowest score, and 5 the highest score. In item 2, for example, we changed “I think that examinations aiming to detect fetal abnormalities are” to “I believe that tests aiming to detect fetal abnormalities are”. Similarly, to make the scaling criteria clearer for item 3, between very positive and very negative, we inserted “positive”, “neutral” and “negative” to complete the options. Also for item 4, the original English had one neutral option and 2 negative options and for ease of understanding, we changed the options to positive, neutral and negative. The human/medical geneticist explained that the meaning of item 3, sub-category 4 which asked about their attitude related to the blood sample taken from the mother, to accurately determine if the fetus has a chromosomal abnormality, was called a non-invasive prenatal test (NIPT). Similar to item 2, in item 6 sub-category “a” and “b”, we changed the word “think” to “believe” as it is more culturally accepted. In item 7, we changed the wording of some of the questions from a passive to an active form. All these modifications were necessary to achieve idiomatic equivalence. The team also changed the currency in item 7d from euro (€) into Saudi Riyals (SAR). After all the amendments were completed, the research committee reviewed the instrument and a consensus was reached about the Arabic version (Table 1).

A pilot study was conducted with 100 participants, chosen using convenient sampling method from the

| Item | Original | Final consensus on the Arabic version |
|------|----------|--------------------------------------|
| 1    | Amniocentesis |
| 2    | I think that examinations aiming to detect fetal abnormalities are |
| 2.1  | Good |
| 2.1  | First trimester combined test |
| 3.1  | Not familiar with the method |
| 4    | How would you react upon having a child with a chromosomal aberration (such as down syndrome) |
| 4    | It would not matter |
| 6.a  | What do you think is a high probability of having a child with a chromosomal aberration |
| 6.b  | What do you think is your probability of having a child with a chromosomal aberration |
| 7.a  | Have you heard that it is possible to take a blood sample in early pregnancy that with high accuracy can tell if the fetus has a chromosomal aberration |
| 7.c  | Would you need information to help your decision if to perform such a test |
| 7.d  | If this blood test would not be covered by national health insurance, would you be willing to pay by yourself |
| 7.d  | If yes how much are you willing to pay? (Currency is in euros) |
| 9.b  | My partner |
pregnant women attending the OB/GYN clinic at KAMC. The age of the participants ranged from 20-44 years, with an average age of 31 ± 6 (Table 2). The majority of participants (61%) had university degree. More than half of the sample (55.6%) had no history of miscarriage (Table 2).

To assess the validity of the translation of the original English questionnaire, we performed reliability testing using the Cronbach alpha. The Cronbach alpha value ranged from 0.6 to 0.67. We did not achieve the desired 0.7 value, mainly because the questions in the questionnaire were not in the same category.

**Discussion.** The availability of the NIPT provides accurate and safe tool for prenatal screening. Previous report proved the accuracy of NIPT in prenatal diagnosis in more than 8594 pregnancies. In this study, we describe the translation and cultural adaptation of the NIPT questionnaire to Arabic. We adapted a questionnaire developed by Sahlin et al focusing on the awareness and attitudes related to the NIPT. After search of available databases that include PubMed, Chocrane and Google scholar, we decided to use the Swedish questionnaire (Appendix 1) as it was tested in a large cohort of more than 1000 participants and contained necessary items we believe are essential to assess the awareness of pregnant women. During the translation process, we modified some of the questions to ensure an acceptable fit with the Arabic culture until consensus was reached. The majority of the modifications were carried out during the translation process. Minor modifications were made after the pilot study. For example, after interacting with the patients, all from an Islamic background, we realized that most patients commented on item 4. In their opinion, “It will not affect me” was culturally inappropriate and that, due to their religious beliefs, they have to accept the outcome. We found that converting the options in item 4 to positive, negative and very negative more appropriate to the Arabic cohort than the original questionnaire. Despite these modifications on the questionnaire, the internal consistency (Cronbach alpha) was not altered significantly as we achieved. Values for the items that ranged between 0.6-0.67, which falls within the acceptable values used in questionnaire validation and adaptation. The reason for achieving less than the desired 0.7 score of Cronbach’s alpha is probably due to the fact that the original questionnaire contained mixed categories. The strength of our study is that it did not focus on the literal translation of the original questionnaire but rather focused on the conceptual meaning. Additionally, our pilot study included pregnant women with multiple educational background and age groups. Thus, this increased the strength of the validation. Since that the Cronbach alpha values were within the acceptable range we did not have to eliminate any of the items in the original questionnaire.

The limitation of this study is that it included only pregnant women visiting the OB/GYN clinic at KAMC, Riyadh, Saudi Arabia. Overall, we believe that the translation of the questionnaire was successful and acceptable and complies with international standards of research tools. Our translated questionnaire is ready for use of future studies to assess the awareness of pregnant women regarding the availability of NIPT in Arabic community.

In conclusion, we translated and culturally adapted the NIPT research tool that can be used to assess the attitude and awareness of pregnant women related to the availability of this safe and accurate prenatal examination procedure (Appendix 2).

**Table 2** - Participants’ demographic information and history of miscarriages.

| Variables                  | %    |
|----------------------------|------|
| Education                  |      |
| Elementary                 | 10.0 |
| High School                | 29.0 |
| University                 | 61.0 |
| Mother tongue              |      |
| Arabic                     | 99.0 |
| English                    | 1.0  |
| Number of miscarriages     |      |
| 0                          | 55.6 |
| 1                          | 15.6 |
| 2                          | 14.4 |
| 3                          | 7.8  |
| 4                          | 6.6  |
| Number of children (mean±SD)| 2 ± 2 |
| Age (years) (mean±SD)      | 31± 6 |

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### Questionnaire about Prenatal Examinations

**Age:**  
**Gestational week:**  
**Number of children:**  
**Previous miscarriages:**  
**Mother tongue:**  

**Education:**  
- Elementary school or similar  
- High school or similar  
- University, two years or more  
- Other:  

1. Have any examinations been performed on your fetus?  
   - Yes  
   - No  

If yes, which?  
- First trimester combined test (FCT)  
- Amniocentesis  
- Chorionic villus sampling  
- Ultrasound examination, week:  
- Other:  

2. I think that examinations aiming to detect fetal abnormalities are...  
   (Score one alternative per row.)  
   a) Good  
   b) Frightening  
   c) Not calming  
   d) Not self-evident  
   - Bad  
   - Not frightening  
   - Calming  
   - Self-evident  

3. What is your attitude towards:  
   - First trimester combined test (FCT)  
   - Amniocentesis/chorionic villus sampling  
   - Ultrasound  
   - Blood sample from the mother which with high accuracy can tell if the fetus has a chromosomal aberration  
   - So-called non-invasive prenatal testing (NIPT)  
   - Very positive  
   - Very negative  
   - Not familiar with the method  

4. How would you react upon having a child with a chromosomal aberration (such as Down syndrome)?  
   - It would not matter  
   - Negatively  
   - Very negatively  

5. How likely do you think it is that your expected child has a chromosomal aberration?  
   - Very likely  
   - Not likely at all  

6a. What do you think is a high probability of having a child with a chromosomal aberration?  
   - 1:20000  
   - 1:10000  
   - 1:2000  
   - 1:1000  
   - 1:200  
   - 1:100  
   - 1:20  
   - 1:10  
   - 1:2  
   - 1:1  
   - I don’t know  

6b. What do you think is your probability of having a child with a chromosomal aberration?  
   - 1:20000  
   - 1:10000  
   - 1:2000  
   - 1:1000  
   - 1:200  
   - 1:100  
   - 1:20  
   - 1:10  
   - 1:2  
   - 1:1  
   - I don’t know
### Appendix 1 - Original non-invasive prenatal testing questionnaire (continued).

7a. Have you heard that it is possible to take a blood sample in early pregnancy that with high accuracy can tell if the fetus has a chromosomal aberration?
- [ ] Yes
- [ ] No

7b. Would you like to have such a test if it was available?
- Yes, I am completely sure
- [ ] No, absolutely not

7c. Would you need information to help your decision if to perform such a test?  
- [ ] Yes
- [ ] No

If yes, how would you like to receive the information? **You may select several answers.**
- [ ] Oral information by the midwife at the maternity clinic
- [ ] A separate visit to a doctor/midwife
- [ ] Written information
- [ ] Information on the internet
- [ ] Other: ...........................................................

7d. If this blood sample would not be covered by the national health insurance, would you be willing to pay by yourself?  
- [ ] Yes
- [ ] No

If yes, how much would you be willing to pay?
- [ ] €50
- [ ] €100
- [ ] €200
- [ ] €500
- [ ] €1000
- [ ] €5000

8. What information would you like to get after undergoing NIPT?  
- [ ] Yes
- [ ] No

The fetal sex
- [ ]
- [ ]

If the fetus has Down syndrome
- [ ]
- [ ]

If the fetus has another, more severe chromosomal abnormality
- [ ]
- [ ]

All chromosomal abnormalities that are detectable
- [ ]
- [ ]

9a. What affects your decision to undergo chromosomal examinations on your fetus? **You may select several answers.**
- [ ] Expectations from others
- [ ] Worry about the baby’s health
- [ ] The values of the society
- [ ] I do not see any reason to decline
- [ ] It is important to know the fetal sex
- [ ] Everyone else is having such tests
- [ ] I want to know as much as possible
- [ ] Own experience by person with a chromosomal abnormality or other severe congenital disease
- [ ] Other: ...........................................................

9b. Who affects your decision to undergo chromosomal examinations on your fetus? **You may select several answers.**
- [ ] Myself
- [ ] My partner
- [ ] Family and friends
- [ ] The midwife at the maternity clinic
- [ ] The doctor at the maternity clinic
- [ ] Other: ...........................................................

**Thank you for your participation!**
Appendix 2 - Final Arabic version of the non-invasive prenatal questionnaire.

العمر ...........................................
 أسبوع الحمل ....................................
 عدد الأطفال ....................................
 عدد الإجهاضات السابقة ..........................
 اللغة الأم .......................................  
 مستوى التعليم
 □ ابتدائي أو ما شابهه
 □ ثانوي أو ما شابهه
 □ جامعي، ستيني أو أكثر
 □ أخرى ...........................................

هل عملت أي فحوصات ما قبل الولادة لجنينك؟

□ نعم
□ لا

إذا كانت الإجابة نعم، أيا من هذه الفحوصات؟

□ (First Trimester Combined Test-FCT)
□ فحص السائل الأمامي (Amniocentesis)
□ فحص الزغابات المشيمة (Chorionic Villus Sampling)
□ (Ultrasound) فحص الأشعة فوق الصوتية. في أي أسبوع تم عمل الأشعة.......
□ فحص آخر للجنين (إذكاري من فضلك).................................
Appendix 2 - Final Arabic version of the non-invasive prenatal questionnaire (continued).

| |  |  |  |  |  |  |
|---|---|---|---|---|---|---|
| 1/ | أعتقد أن المحاولات التي تهدف للكشف عن التشوهات الجنينية هي (المقياس من 1 إلى 5) | جيدة (5) | غير مخفية (5) | مخفية (1) | غير مريحة (1) | غير واضحة بذاتها (1) |
|  | سنية (1) |  |  |  |  |  |

ما هو انطباعك تجاه فحوصات ما قبل الولادة التالية؟

- **First Trimester Combined Test-FCT**
  - إيجابي جدًا
  - محدود
  - سليم
  - بالنسبة لأم الفحوص غير مألوف

- **Amniocentesis**
  - إيجابي جدًا
  - محدود
  - سليم
  - بالنسبة لأم الفحوص غير مألوف

- **Ultrasound**
  - إيجابي جدًا
  - محدود
  - سليم
  - بالنسبة لأم الفحوص غير مألوف

- **Non-Invasive Prenatal Testing (NIPT)**
  - إيجابي جدًا
  - محدود
  - سليم
  - بالنسبة لأم الفحوص غير مألوف

عينة دم من الأم الحامل لإخبارنا بدقة عالية إذا كان الجنين يحمل خلل كروموسومي.

4/ كيف ستتفاعل مع مولودك بعد معرفتك بأن مولودك مصاب بخلل كروموسومي (مثلًا: متلازمة داون)?

- إيجابي

- سوف آتي إلى الأمك مع الموضوع بشكل سليم

- سوف آتي إلى الأمك مع الموضوع بشكل سليم جداً
Appendix 2 - Final Arabic version of the non-invasive prenatal questionnaire (continued).

٧ ج / هل تحتاجين إلى أية معلومات تساعدك في أخذ القرار لعمل الفحص الدقيق؟

نعم □ لا □

إذا كانت الإجابة نعم، كيف تودين الحصول على هذه المعلومات؟ ( يمكنك اختيار أكثر من إجابة)

شرح لطبي من قبل القابلة في عيادة الأمومة □
زيارة متصلة للطبيب أو القابلة □
معلومات مكتوبة □
معلومات عن طريق شبكة الإنترنت □
طريق أخرى □

٧ د / إذا كان هذا الفحص لا يتم تغطيته من قبل شركة التأمين أو المستشفى الحكومي هل أنت مستعدة لدفع قيمة الفحص؟

نعم □ لا □

إذا كانت الإجابة نعم، كم تستطيعين أن تدفعين؟

٣٢٦ ريال سعودي □
٣٢٦ ريال سعودي □
٢١٧ ريال سعودي □
٢١٧ ريال سعودي □
٦٠ ريال سعودي □
٦٠ ريال سعودي □

٨ ما هي المعلومات التي ترغبين الحصول عليها بعد عمالك لفحص الحمل النووي قبل الولادة؟

لا □ نعم □

• جنس الجنين
• إذا كان الجنين مصاب بمتلازمة داون
• إذا كان الجنين مصاب بخلقي كروموسومي أكثر صرامة
• جميع الاضطرابات الكروموسومية الممكن فحصها
Appendix 2 - Final Arabic version of the non-invasive prenatal questionnaire (continued).

9 (أ) ما الذي قد يؤثر على اتخاذ قرارك في عمل الفحوصات الكروموسومية على جنينك؟ (يمكنك اختيار أكثر من إجابة)

- توقعات الآخرين
- قلقتي على صحة الجنين
- القيم الاجتماعية في المجتمع
- لا أجد أي سبب للرفض
- من المهم أن أعرف جنس الجنين
- الجميع يعمل مثل هذه الفحوصات
- أود أن أعرف كل ما أمكن عن جنيني
- خبرتي الشخصية مع مريض مصاب بخلل كروموسومي أو أمراض خلقيبة أخرى
- أخري

9 (ب) من قد يؤثر على اتخاذ قرارك في عمل الفحوصات الكروموسومية لجنينك؟

- نفسي
- زوجي
- الأهل والأصدقاء
- القابلة في عيادة الأمومة
- طبيب النساء والولادة في عيادة الأمومة
- أشخاص آخرين