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Face Validation of a Spanish Non-Invasive Prenatal Screening Knowledge Scale

Kenya Michelle De Leon

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FACE VALIDATION OF A SPANISH NON-INVASIVE PRENATAL SCREENING KNOWLEDGE
SCALE

by

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DEDICATION

I would like to dedicate this project to my parents who have always believed in me. Thank you for being the greatest support system.

ACKNOWLEDGEMENTS

First, I want to thank my family for their continuous love and support. Also, I want to thank Oscar for his constant support throughout my time working on this project; he made everything the past two years much easier to accomplish. I would also like to thank my wonderful friends and classmates. You all have made graduate school the best time, and I am thankful for the lasting friendships we have built.

I would like to thank NSGC's Research, Quality and Outcomes Committee for recognizing the need and providing funding for the project. I would also like to thank Priscila Hodges for her time dedication to this project. Priscila has been very supportive throughout the entirety of this project. Also, thank you to Valentina Caceres who contributed her time and expertise when revising items on the knowledge scale. I would also like to thank Jessica Fairey and Jill Slamon for their support for this project. Thank you Amy Wardyn for introducing me to the RQO committee and for your encouragement and continued support throughout this project. Finally, thank you Janice Edwards for all of your support throughout graduate school.

ABSTRACT

Non-invasive prenatal screening (NIPS) provides risk assessment for chromosome aneuploidy in pregnancy. Previous studies in the United Kingdom and United States have attempted to measure patient knowledge, decisional conflict, and informed choice in cohorts of English-speaking pregnant patients who elected NIPS (Griffin et al., 2023; Lewis et al., 2016). However, knowledge scales utilized in these studies have not been validated. The current study was conducted in order to assess face validity of a Spanish NIPS knowledge scale that was originally written in English. This scale was developed as part of a larger project to ultimately provide more validated research measures for future genetic counseling research.

Prenatal genetic counselors at Prisma Health Midlands identified qualifying participants who were Spanish-speaking, seen for prenatal genetic counseling and offered NIPS from May 2022 to January 2023. Participants were reached via phone, verbal consent to participate was obtained, and interviews were scheduled. Interviews were conducted via phone. Interview transcripts were analyzed using a “traffic light system” coding method described by Connell et al. (2018). All communication between the primary author and participants was conducted in Spanish.

Thirteen participants were interviewed for this study. All participants identified as Hispanic/Latina women with the majority reporting being born outside of the United States. After seven interviews were conducted, transcribed and coded, three items required revision. All items reached face validity with the completion of six additional

interviews. This is the first study to assess face validation of a Spanish NIPS knowledge scale. After achieving concept validity, this Spanish scale could be implemented into the multi-dimensional measure of informed choice (MMIC), which argues that a choice is considered informed when patients have adequate knowledge and their attitude about the choice aligns with their decision (Marteau et al., 2001). Having a validated NIPS MMIC scale in Spanish would allow for more diverse and inclusive research regarding NIPS decision-making.

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CHAPTER 1: BACKGROUND

1.1 Informed Consent

Informed consent involves a healthcare professional disclosing an appropriate amount of information to a patient who is allowed to make a voluntary choice on whether or not they want to undergo testing (Richardson, 2013). There are three fundamental criteria that are needed for someone to give their informed consent: 1) the patient must be competent, 2) must have received an appropriate amount of information, and 3) must not have been coerced (Varkey, 2021). These criteria ensure that patients understand the information given to them and thus understand the potential consequences of their decision (Cocanour, 2017).

Informed consent is a concept that falls under the broader discipline of ethics. Ethics involves four fundamental principles: beneficence, nonmaleficence, autonomy, and justice. More specifically, informed consent falls under the autonomy principle of ethics. Based on the autonomy principle, everyone should have the power to make logical and moral decisions in order to reach their full personal capacity. Healthcare providers should respect every patient's autonomy by providing all the necessary information while supporting informed consent (Varkey, 2021). Every patient should not only be appropriately informed but must also understand the information provided to them in order to give their true informed consent (Richardson, 2013; Varkey, 2021). It is unethical for patients to not be well-informed when consenting for medical interventions,

including genetic testing. Healthcare providers should understand that even in situations where patients receive enough information about medical interventions, patients will not always have an adequate understanding.

Informed consent occurs when patients comprehend the relevant information regarding the medical intervention including any risks and benefits. Obtaining patient informed consent assists with setting expectations leading to increased patient satisfaction. Several factors that contribute to patient comprehension include education level, language barriers, age, and culture (Varkey, 2021). Another factor that can contribute to patient comprehension is health literacy. According to a study performed by Becerra et al. (2017), low health literacy is associated with limited English language proficiency, which describes individuals who do not speak English as their primary language and who have a limited ability to communicate or understand English (Federal Coordination and Compliance Section, 2011). This particular study noted significant differences for several sociodemographic characteristics, such as living in poverty and lacking health insurance, between immigrant Hispanic/Latine adults with low health literacy versus those with adequate health literacy (Becerra et al., 2017). There is evidence that there is a connection between low health literacy and health disparities. According to Soto Mas and Jacobson (2019), research has shown that most Hispanic/Latine immigrants are at a greater risk of having limited health literacy because they must also face the barriers that are present due to a primarily English-language health care system. Therefore, it is important for healthcare providers to be aware of these factors to better tailor the amount and level of information needed for patient comprehension and understanding.

1.2 Multi-dimensional Model of Informed Choice (MMIC)

In order to measure patient comprehension, Marteau et al. (2001) developed a measure of informed choice. The definition of informed choice used for this measure is “one that is based on relevant knowledge, consistent with the decision-maker’s values and behaviorally implemented.” The measure consists of a knowledge scale that includes eight items and an attitude scale that includes four items. The attitude scale investigates a patient's attitude toward the uptake of a particular test. Many studies do not take the multidimensional aspect of informed choice into account. An example of this includes measures of knowledge; although they measure knowledge, they do not assess values, making them single dimension measures (Marteau et al., 2001). Given that Marteau et al.’s study measures each of these aspects, it does take the multidimensional aspect of informed choice into account.

Regarding screening tests, an informed choice to undergo a particular test is made when a patient has a positive attitude related to the test and an appropriate level of knowledge leading to an election of pursuing that test. On the other hand, an informed choice to decline a particular test is made when a patient has a negative attitude related to the test with an appropriate level of knowledge and thus declines to proceed. In both cases of informed choice, a patient must have appropriate knowledge about the particular test they are electing or declining. Marteau et al.’s (2001) model of informed choice can be applied to patients who are offered any screening test. Using this model, such patients can be classified into one of eight different categories based on the amount of knowledge they have about the test, their attitude towards the test, and whether they decide to undergo the test. Two categories are representative of informed choices, while six

categories are representative of choices that are not well-informed. An example of an informed choice is when an individual has a positive attitude about the test and chooses to undergo it, while an example of an uninformed choice is when an individual has a positive attitude about the test but declines it (Marteau et al., 2001).

Marteau et al. (2001) developed a measure to assess informed choice to undergo prenatal screening for Down syndrome. They developed a knowledge scale based on the pertinent information found in medical professional guidelines. The construct validity of the knowledge scale was then tested by comparing participant's level of knowledge to their open-ended response regarding their understanding of the test. In order to assess the attitudes of the participants, four scaled items were developed. Again, the participant's responses on the attitude scale were compared to their open-ended responses regarding their attitudes towards the test. After the construct validities were determined, the participants' choices were classified as either informed or uninformed. Eighteen of 42 choices were determined to be informed. Although this was a preliminary study, it provided the evidence necessary to measure informed choices to undergo screening tests using a measure that assesses knowledge, attitude, and behavior altogether. If there is variation between any of these dimensions, then the choice is not informed (Marteau et al., 2001).

In 2002, Michie et al. worked to validate the MMIC developed by Marteau et al. (2001). This MMIC assessed informed consent through three categories: knowledge, attitudes towards undergoing the test, and uptake. The knowledge section consisted of eight items and the attitude section consisted of four items. Screening uptake was measured using laboratory records. Decision outcome and anxiety were assessed using

the Ottawa Decisional Conflict Scale and the Spielberger State Trait Anxiety Inventory, respectively. This study showed that the MMIC is psychometrically robust in pregnant women who have the choice to undergo prenatal screening for Down syndrome and who received a low-risk score. Additionally, attitudes towards undergoing the test, but not knowledge, predicted decision outcome. When the attitude and knowledge components of informed choice were examined separately, knowledge alone was not associated with any decision outcome variables such as feeling uninformed, feeling unsupported, and poor quality decision. In contrast, positive attitudes towards undergoing testing were associated with feeling that the decision had been informed. This shows the importance of including a measure of attitude into the measure of informed choice, as knowledge alone is not a good predictor of decision outcome. Michie et al. (2002) suggested that this study be replicated in other groups with other outcomes.

1.3 Knowledge Scale Validation

Validation of knowledge scales is an important aspect of informed consent, as a valid questionnaire is reliable. A validated scale is one that measures what it is intended to measure. In the case of the MMIC, there are three phases of validity testing: face validity, concept validity, and content validity. Face validity is the degree to which a scale evaluates what it is meant to evaluate. Face validity is conducted to determine if individuals believe the items on a knowledge scale are accurately stating the intended meaning. Concept validity is the extent to which a scale includes the necessary aspects related to the concept it is evaluating. Concept validity is done to ensure that the items on a knowledge scale are meaningful in making an informed choice. Finally, content validity is the degree to which the items of the scale measure what is intended (Boparai et al.,

2018). Once fully validated, knowledge scales can be implemented as part of an MMIC. Previous studies in the UK and US have attempted to measure patient knowledge, decisional conflict, and informed choice in cohorts of English-speaking pregnant patients who elected NIPS (Griffin et al., 2023; Lewis et al., 2016). However, the knowledge scale utilized in these studies has not been validated. A patient knowledge scale in any language has not been assessed for any type of validity to date. In 2016, Lewis et al. validated a modified MMIC for NIPS in any public health service; however, this study was not validated specifically for genetic counseling patients. Lewis et al. (2016) found that ethnicity was a major predictor of informed choice. Specifically, White participants were more likely to make an informed choice than people of other ethnicities, who were likely to consent to testing despite their personal beliefs. Based on this study alone, White individuals are three times more likely to make an informed choice when compared to individuals of other ethnicities. The study also found that ethnicity significantly affected knowledge scores (Lewis et al., 2016). These findings demonstrate that non-White patients are not educated in the same way as White patients, and are thus less likely to be knowledgeable and less likely to make an informed choice. Lewis et al.'s study aims at bridging the gap between White individuals and individuals of Hispanic/Latine ethnicity in regards to informed choice.

1.4 Non-invasive Prenatal Screening (NIPS)

This study focuses on completing face validation for a knowledge scale about NIPS in the Spanish language. NIPS is also known as non-invasive prenatal testing (NIPT) and cell-free DNA (cfDNA) testing. NIPS screens for trisomies 13, 18, and 21 and sex chromosome aneuploidies through a maternal blood sample (Carbone et al.,

2020). Cell-free DNA in the sample is largely from maternal DNA while a proportion is from placental trophoblasts, which typically reflect fetal DNA. The percentage of cfDNA that comes from the trophoblast is known as the fetal fraction (Harraway, 2017). cfDNA is extracted from maternal blood, the DNA is sequenced, and then the sequenced regions are analyzed to determine the risk for chromosomal abnormalities. The higher the fetal fraction, the easier it is to identify fetal cfDNA, making the results more reliable. If the fetal fraction is below 4% (low fetal fraction), then the results become much more unreliable, leading to a failed test. The possibility of a low fetal fraction is a known limitation of NIPS (Carbone et al., 2020). Based on this technology, NIPS has a higher sensitivity and specificity than traditional screening tests.

NIPS is a screening tool used to identify women at a higher risk for common trisomies in their pregnancy. Women who are found to be at a higher risk are offered prenatal diagnostic testing, such as a chorionic villus sampling (CVS) or an amniocentesis, to confirm their screening results. The American College of Medical Genetics and Genomics (ACMG) recommends NIPS for all pregnant women, regardless of whether it is a singleton or twin pregnancy (Dungan et al., 2023). Similarly, the American College of Obstetricians and Gynecologists (ACOG) recommends NIPS for all pregnant women regardless of maternal age or baseline risk (The American College of Obstetricians and Gynecologists, 2020). Given these practice guidelines, NIPS is routinely being offered, creating a greater need for a validated Spanish NIPS knowledge scale.

1.5 Views of Hispanic/Latina Women on NIPS and Termination

As previously mentioned, a few factors that can affect patient comprehension are low educational level, language barriers, age, and culture (Richardson, 2013). For this reason, it is important that the comprehension of Spanish-speaking patients be assessed carefully. A study by Farrell et al. (2015) was one of the first to look at the views of Hispanic/Latina women on NIPS. For this study, researchers used a knowledge scale containing six knowledge questions. Eleven percent of participants correctly answered all six items, 44% correctly answered three items or less, and 19% correctly answered two items or less. The study found that the most significant factors associated with a higher NIPS knowledge score were being born in the United States, having education beyond high school, and type of employment. The study also showed that the most significant factors that affected the participants' choice to undergo NIPS were a higher educational level, language, and a high NIPS knowledge score. Participants that reported lower educational levels were more likely to have lower knowledge scores and decline NIPS; based on these findings it is possible to suggest that some Spanish-speaking women with lower educational levels may be declining NIPS due to a lack of understanding. It is important to note that despite obtaining a low knowledge score, some of the women in the study knew that test results would not affect their decision to continue their pregnancy. Therefore, it is possible that they declined NIPS for that reason (Farrell et al., 2015). The most common misconception that Spanish-speaking women had towards NIPS, as determined from the knowledge scale, involved the limitations of the screen, including that it is not a screen for all chromosome abnormalities. This is an area where

there is a clear gap in NIPS knowledge amongst Spanish-speaking women (Farrell et al., 2015).

In 1999, Cunningham and Tompkinson found that Spanish-speaking women were less likely than women of other ethnicities to consider prenatal diagnostic tests. However, this reluctance demonstrated by Spanish-speaking women does not signify a lack of interest in prenatal information (Cunningham & Tompkinson, 1999). Although this study investigated Spanish-speaking women's views on prenatal testing, their views on NIPS were not understood at the time. In 2016, Floyd et al. conducted a study to address this lack of knowledge about the views of diverse women on NIPS. The study found that Spanish- and English-speaking women had similar views on the ways to assess the risks and benefits of the screening tool; however, there were several differences in various areas: informational needs, ethical concerns, and perceptions of their relationships with their prenatal providers. In terms of informational needs, English-speaking women asked for a wider range of information beyond just a simple description of the screen. This included the ethical implications of NIPS and the implications or follow-up steps in the case of a positive result. Alternatively, Spanish-speakers needed more descriptive information about the screens, including what they are and what they do. Also under the informational needs category is access to information. It was noted that English-speaking women were likely to assume that they could look for additional information online, while Spanish-speaking women more often requested printed materials. For the Spanish-speaking women in this study, their requests were due to several reasons: a lack of internet access, not knowing how to search for the information, and wanting the information in print to be able to process it at their own pace.

Floyd et al. (2016) also found that there are clear differences between the ethical and moral concerns between English- and Spanish-speakers. English-speakers in the study were more concerned about people having the ability to electively terminate pregnancies affected with Down syndrome as a form of eugenics. Although they expressed this concern, they generally described termination using neutral terms. Spanish-speakers believed it was more ethical to redirect research efforts towards treatments for conditions like Down syndrome rather than focusing research efforts on NIPS. Most Spanish-speaking women in this study disclosed that they would continue their pregnancy regardless of their screening or testing results. They also described termination using more negative terms like “harm”, “take the life of a human being”, or “destroy”, but still acknowledged that every woman has the right to choose for themselves (Floyd et al., 2016). Shellenberg et al. (2011) examined stigma surrounding termination within five different countries, including Mexico and Peru. They found that in countries like Mexico and Peru, where termination is highly stigmatized, phrases like “murderer”, “evil” and “not normal” were used to describe women who went through pregnancy termination. One of the study’s participants, a woman from Mexico, explained that “what [they] learn of abortion is that it is bad, and then [they] talk of those having abortion as murderers.” The study also describes social consequences of undergoing a termination in some countries. Another participant from Mexico disclosed that “in the community in general, when people find out that a woman had an abortion, they get horrified, they say she is a bad woman and they treat her badly.” A participant from Peru explained that “when [women] have an abortion, God punishes them, [...] when they go to have their first child they are no longer going to be able to have it.” The word “sin”

was also used often. Some women in this study feared that God would judge them upon their own death if they elected to have a termination of pregnancy (Shellenberg et al., 2011).

An earlier study carried out by Hunt and de Voogd (2005) examined clinicians' views of Hispanic/Latine culture and then compared them to actual views of Hispanic/Latina women. Clinicians (i.e., physicians, nurses, genetic counselors, etc.) were interviewed on their perceptions of issues they face when providing care to Hispanic/Latina patients. Over 50% of clinicians said Hispanic/Latina women were most likely to decline prenatal testing. Many clinicians described that Hispanics/Latinas are most likely to decline testing because they are Catholics who would not ever consider abortion or because they believe that God's will means they should accept whatever God sends to them. Other clinicians explained that they often hear Hispanic/Latina patients say "si Dios quiere" ("God willing") when declining testing. One of the clinicians explained that "most of [her Hispanic/Latina] patients say, 'I'm going to leave it to God's hands. It's God's will. God sent me this baby, and it's for a reason.'" When interviewing Hispanic/Latina patients themselves, most did bring up God and prayer. They made comments including "if God sends us a child like that, we have to accept it", "it will be whatever God wants", and "I decided to put it all in God's hands" (Hunt and de Voogd, 2005). These articles display the values that Hispanic/Latina women hold, which can be tied back into Floyd et al.'s (2016) finding that most Spanish-speaking women in their study disclosed that they would continue their pregnancy regardless of the screening or testing results. Another common religious value in Hispanic/Latine culture is the idea of *Marianismo*. According to Lara-Cinisomo et al. (2018), *Marianismo* describes the

traditional role of females in Hispanic/Latine culture. This traditional role includes the ideas of virtue, passivity, priority of others over oneself, and self-sacrifice. These gender roles are based on and refer to Virgin Mary (Nuñez et al., 2016). This value of *Marianismo* could be related to the Hispanic/Latine belief in God's will and sacrificing oneself for a child that was "sent by God". Evidently, religion plays a significant role in the health practices of the Hispanic/Latine community (Ransford et al., 2010).

1.6 Views of Hispanic/Latina Women on the Patient-Provider Relationship

Finally, in terms of the perceptions of their relationships with their prenatal providers, in Floyd et al.'s (2016) study, English-speaking women were more likely to critique their doctors' advice and the current prenatal screening processes. Alternatively, Spanish-speaking women tended to report relying on and trusting their doctors' advice on prenatal screening and testing. A Hispanic/Latina woman in this study noted that "if [the providers] offered something, it is so that you would be less concerned, more assured, more prepared." The first attempt to describe or conceptualize this language and communication barrier that exists between healthcare providers and Hispanic/Latine patients was done by Quesada (1976). Quesada explains that Hispanic/Latine patients often expect that the healthcare provider will be authoritative in the way that they provide their treatment. Because of this, Hispanic/Latine patients may go into appointments expecting to receive more answers, rather than questions, from their healthcare provider. When providers ask patients more questions, the satisfaction with an appointment is lower, and the patient leaves more disappointed (Quesada, 1976). According to Poma (1983), this may be due to the emphasis on respect for authority, or "*respeto*", that exists within Hispanic/Latine culture. He describes that when a patient does not understand

what a provider is telling them, it is easy for them to agree to do whatever they are told or recommended to do. Poma explains that nodding or affirmation by Hispanic/Latine patients does not always mean they are agreeing to or accepting something. He also describes an authoritarian-paternalistic patient-physician relationship among Hispanic/Latine patients. This means that when providers present several treatment options to patients, Hispanic/Latine patients may consider this as a sign of weakness or a lack of knowledge of the provider (Poma, 1983). Floyd et al. (2016) found that, despite this clear difference in the patient-clinician relationship between English- and Spanish-speaking women, most women, regardless of ethnicity, ended up accepting the tests recommended by their doctors. A conclusion obtained from this study was that prenatal practices should be making constant efforts to lessen language barriers (Floyd et al., 2016).

1.7 Rationale and Purpose

These studies all investigate the views of Spanish-speaking women on NIPS. Farrell et al. (2015) found several factors that affect Hispanic/Latine patients' choice to undergo NIPS. These studies also identified misconceptions about NIPS within Hispanic/Latina women. Floyd et al. (2016) compared the views on NIPS of English- and Spanish-speaking women and found significant differences between these two groups. Both studies emphasize the need for a validated Spanish NIPS knowledge scale. Such a scale would reduce language and cultural barriers that may otherwise be present in the field of prenatal genetic counseling, allowing Hispanic/Latine patients to give their true informed consent. In validating a Spanish knowledge scale, it is important to consider the views and differences in understanding of Hispanic/Latina women.

CHAPTER 2: FACE VALIDATION OF A SPANISH NON-INVASIVE PRENATAL
SCREENING KNOWLEDGE SCALE¹

¹De Leon, K., Fairey, J., Hodges, P., Slamon, J., Caceres, V. To be submitted to *Journal of Genetic Counseling*.

2.1 Abstract

Non-invasive prenatal screening (NIPS) provides risk assessment for chromosome aneuploidy in pregnancy. Previous studies in the United Kingdom and United States have attempted to measure patient knowledge, decisional conflict, and informed choice in cohorts of English-speaking pregnant patients who elected NIPS (Griffin et al., 2023; Lewis et al., 2016). However, knowledge scales utilized in these studies have not been validated. The current study was conducted in order to assess face validity of a Spanish NIPS knowledge scale that was originally written in English. This scale was developed as part of a larger project to ultimately provide more validated research measures for future genetic counseling research.

Prenatal genetic counselors at Prisma Health Midlands identified qualifying participants who were Spanish-speaking, seen for prenatal genetic counseling and offered NIPS from May 2022 to January 2023. Participants were reached via phone, verbal consent to participate was obtained, and interviews were scheduled. Interviews were conducted via phone. Interview transcripts were analyzed using a “traffic light system” coding method described by Connell et al. (2018). All communication between the primary author and participants was conducted in Spanish.

Thirteen participants were interviewed for this study. All participants identified as Hispanic/Latina women with the majority reporting being born outside of the United States. After seven interviews were conducted, transcribed and coded, three items required revision. All items reached face validity with the completion of six additional interviews. This is the first study to assess face validation of a Spanish NIPS knowledge scale. After achieving concept validity, this Spanish scale could be implemented into the

multi-dimensional measure of informed choice (MMIC), which argues that a choice is considered informed when patients have adequate knowledge and their attitude about the choice aligns with their decision (Marteau et al., 2001). Having a validated NIPS MMIC scale in Spanish would allow for more diverse and inclusive research regarding NIPS decision-making.

2.2 Introduction

There are several factors that can contribute to a patient's comprehension of their medical care: education level, language barriers, age, and culture (Varkey, 2021).

Another factor that can contribute to patient comprehension is health literacy. According to a study performed by Becerra et al. (2017), low health literacy is associated with limited English language proficiency, which describes individuals who do not speak English as their primary language and who have a limited ability to communicate or understand English (Federal Coordination and Compliance Section, 2011). This study noted significant differences for several sociodemographic characteristics, such as living in poverty and lacking health insurance, between immigrant Hispanic/Latine adults with low health literacy versus those with adequate health literacy (Becerra et al., 2017).

According to Soto Mas and Jacobson (2019), research has shown that most Hispanic/Latine immigrants are at a greater risk of having limited health literacy because they must also face the barriers that are present due to a primarily English-language health care system. Therefore, it is important for healthcare providers to be aware of these factors to better tailor the amount and level of information needed for adequate patient comprehension and understanding.

There is evidence that there is a connection between low health literacy and health disparities. A study by Farrell et al. (2015) was one of the first to look at the views of Hispanic/Latina women on NIPS. For this study, researchers used a knowledge scale containing six knowledge questions. Eleven percent of participants correctly answered all six items, 44% correctly answered three items or less, and 19% correctly answered two items or less. The study found that the most significant factors associated with a higher NIPS knowledge score were being born in the United States, having education beyond high school, and type of employment. The study also showed that the most significant factors that affected the participants' choice to undergo NIPS were a higher education level, native language, and a high NIPS knowledge score. Participants that reported lower education levels were more likely to have lower knowledge scores and decline NIPS; based on these findings, it is possible to suggest that some Spanish-speaking women with a lower educational level may be declining NIPS due to a lack of understanding. It is important to note that despite obtaining a low knowledge score, some of the women in the study knew that test results would not affect their decision to continue their pregnancy; therefore, it is possible that they declined NIPS for that reason (Farrell et al., 2015).

Floyd et al. (2016) also found that there are clear differences between the ethical and moral concerns between English- and Spanish-speakers. In their study, English-speakers were more concerned about people having the ability to electively terminate pregnancies affected with Down syndrome as a form of eugenics. Although they expressed this concern, they generally described termination using neutral terms. Spanish-speakers believed it was more ethical to redirect research efforts towards

treatments for conditions like Down syndrome rather than focusing research efforts on NIPS. Most Spanish-speaking women in this study disclosed that they would continue their pregnancy regardless of their screening or testing results. They also described termination using more negative terms like “harm”, “take the life of a human being”, or “destroy”, but still acknowledged that every woman has the right to choose for themselves (Floyd et al., 2016).

Shellenberg et al. (2011) examined the stigma surrounding termination within five different countries, including Mexico and Peru. They found that in countries like Mexico and Peru, where termination is highly stigmatized, phrases like “murderer”, “evil” and “not normal” were used to describe women who went through with pregnancy termination. One of the study’s participants, a woman from Mexico, explained that “what [they] learn of abortion is that it is bad, and then [they] talk of those having abortion as murderers.” Another participant from Mexico disclosed that “in the community in general, when people find out that a woman had an abortion, they get horrified, they say she is a bad woman and they treat her badly.” A participant from Peru explained that “when [women] have an abortion, God punishes them, [...] when they go to have their first child they are no longer going to be able to have it.” Some women in this study feared that God would judge them upon their own death if they elected to have a termination of pregnancy (Shellenberg et al., 2011). An earlier study carried out by Hunt and de Voogd (2005) examined clinicians’ views of Hispanic/Latino culture and then compared them to actual views of Hispanic/Latina women. Clinicians (e.g., physicians, nurses, genetic counselors, etc.) were interviewed on their perceptions of issues they face when providing care to Hispanic/Latina patients. Some clinicians explained that they

often hear Hispanic/Latina patients say “si Dios quiere” (“God willing”) when declining testing. One of the clinicians explained that “most of [her Hispanic/Latina] patients say, ‘I’m going to leave it to God’s hands. It’s God’s will. God sent me this baby, and it’s for a reason.’” When interviewing Hispanic/Latina patients themselves, most brought up God and prayer. They made comments including “if God sends us a child like that, we have to accept it”, “it will be whatever God wants”, and “I decided to put it all in God’s hands” (Hunt and de Voogd, 2005).

Previous studies in the UK and US have attempted to measure patient knowledge, decisional conflict, and informed choice in cohorts of English-speaking pregnant patients who elected NIPS (Griffin et al., 2023; Lewis et al., 2016). However, the knowledge scale utilized in these studies has not been validated. A patient knowledge scale in any language has not been assessed for any type of validity to date.

The current study was conducted in order to assess face validity of a Spanish NIPS knowledge scale that was originally written in English. It was predicted that Spanish-speaking patients would need a different NIPS knowledge scale from the English scale in order to mitigate any language barriers. The items on the original English NIPS knowledge scale were developed by the National Society of Genetic Counselors’ (NSGC) Research, Quality and Outcomes (RQO) Committee. Each item was developed based on a concept that was determined to be important in making an informed choice when deciding whether to undergo NIPS. The original Spanish version of the scale was obtained through a direct translation of the English scale. Because of this, it was hypothesized that the current version of the scale would require several revisions. The objectives of the study were as follows:

1. To ensure the Spanish NIPS knowledge scale is culturally tailored so that it makes sense to Spanish-speaking patients and
2. To accomplish face validity of a Spanish NIPS knowledge scale.

2.3 Materials and Methods

This study was conducted at Prisma Health Midlands in Columbia, South Carolina. It was reviewed by the Prisma Health IRB and was determined to not be research that required IRB approval. The population of interest included Hispanic/Latina women who 1) used an interpreter during their genetic counseling session OR whose preferred language is Spanish regardless of use of an interpreter, and 2) were offered NIPS during their genetic counseling session at Prisma Health Midlands Maternal Fetal Medicine clinic regardless of whether they decided to undergo the screen. Exclusion criteria included women below the age of 18 years, males, women whose primary or preferred language is English, and women who were not offered NIPS during their genetic counseling session.

This study attempted to achieve face validity of the Spanish NIPS knowledge scale by conducting telephone interviews with Spanish-speaking participants. Prenatal genetic counselors at Prisma Health Midlands provided qualifying participants a study recruitment packet which included an invitation to participate, a letter with the consent to participate in the research study, and the corresponding Spanish knowledge scale (Appendices A, B, and C). The documents included in this packet were all in Spanish. Participants' information (name, phone number, and date NIPS was offered) was entered into Prisma Health REDCap, a secure database, by the genetic counselor. The next phase was completed by conducting phone interviews with patients who volunteered to

participate in the study. Participants were reached via phone to obtain verbal consent and interviews were scheduled. After interviews were scheduled, participants were reached via email (Appendix D) with the date and time of their interview and an electronic copy of the study recruitment packet. Patients were then reached via phone during their scheduled interview time, and the interview was conducted in Spanish by the primary author (KDL).

The original Spanish knowledge scale consisted of eight true/false items related to NIPS, which were obtained through a direct translation of an English NIPS knowledge scale developed by the NSGC's RQO Committee. At the time of direct translation to Spanish, the English scale had not yet been validated. During the interviews (Appendix E), which were all conducted in Spanish, each participant was asked to explain what they believed each of the eight items on the scale meant. This was done by asking participants to read each item on the scale and then asking them to explain what they understood each item to mean. It was made clear that this was not done to test their understanding and correctly answering the item was not necessary. After going through all eight items on the knowledge scale, each participant was asked to answer six demographic questions, and their responses were recorded. Each interview was recorded, transcribed, and then translated to English. Transcription and translation was done by the Audio Transcription Center. Participants received a \$10 Amazon gift card via email (Appendix F) as compensation.

For the first version of the knowledge scale, seven interviews were conducted. Although English translations were obtained in order to capture participant quotes, the Spanish transcripts were used for analysis. Interview transcripts were analyzed using a

“traffic light system” coding method. A response that aligned with the intended meaning of an item received a “green” label, a response that was not aligned with the intended meaning of an item received a “red” label, and a response where there was confusion was given a “yellow” label. This method of analysis is described in a study by Connell et al. (2018). The interviews were coded separately by two native Spanish-speakers, authors KDL and PDH. Once consensus was reached on a label for each item of the interview, counts for each red, yellow, and green label were obtained. Items that were labeled as majority (>70%) red across all interviews were revised based on feedback from the interviewees. Revisions were made by three individuals: KDL, PDH, and VCC, who is also a native Spanish-speaker. Items that were majority green were left as is. Once revisions were made to the original knowledge scale, six more interviews were conducted using the revised knowledge scale. The same methodology was used to transcribe, translate, and analyze the second set of interviews. Concept and content validity were not assessed during this study.

2.4 Results

2.4.1 Demographic Information

A total of 13 participants were interviewed for this study. Demographic information for participants is detailed in Table 2.1. All participants identified as Hispanic/Latina women, and most (92.3%) reported being born outside of the United States. The majority of the participants (53.8%) reported that their highest level of education was high school.

Table 2.1 Participant Demographics

Item	n	% of Total (N=13)
Age		
18-25	5	38.5%
26-33	5	38.5%
34-41	1	7.8%
42+	2	15.40%
Highest level of education completed		
No level of education	1	7.8%
Grade school/junior high	2	15.4%
Some high school	1	7.8%
High school graduate	7	53.8%
Trade/technical/vocational school	0	0%
Some college	1	7.8%
College graduate	1	7.8%
Post-graduate work or graduate degree	0	0%
Prefer not to answer	0	0%
Race/Ethnicity		
Black or African American	0	0%
Hispanic or Latina	13	100%
White	0	0%
Asian	0	0%
Native American or Alaskan Native	0	0%
Native Hawaiian or other Pacific Islander	0	0%
Born in the United States		
Yes	1	7.8%
No	12	92.3%
Gender Identity		
Woman	13	100%
Man	0	0%
Non-binary	0	0%
Transgender	0	0%
Prefer not to answer	0	0%

2.4.2 First Set of Interviews

The results of the first set of coded interviews are detailed in Table 2.2. After the first set of interviews, three items required revision (items 3, 6, and 7). The original wording for item number three was “Prenatal screening results are less accurate if you are a younger woman.” Participants interpreted this item by saying that “Women are always more likely to have a baby with Down’s syndrome after the age of 30. Based on what they explained to [her]” and “[...] People’s age determines the baby’s condition, [their] genetics.” The original wording for item number 6 was “If the prenatal screening test fails to give a result, it means that my fetus has Down syndrome.” After reading this item, most participants asked “What does ‘If the prenatal screening test fails to give a result’ mean?” The original wording for item number 7 was “If my fetus has a condition, my only options are to continue the pregnancy or end the pregnancy.” After reading this item, participants expressed that they would “Not terminate [their pregnancy]. [...] There’s no other option” and that “[They would] go on with [their] pregnancy if [their] fetus [was] coming badly.”

Item 2 underwent a slight revision for grammar purposes, as a verb in the original knowledge scale was not conjugated properly. A single word for item number 4 was changed to match a revision of item number 7. Revisions to each item are detailed in Table 2.3.

Table 2.2 Interview Counts (Set 1)

Item Number	Counts (N=7)		
	Aligned with intended meaning (n)	Confusing	Did not align with intended meaning (n)
1	5 (71.4%)	0	2 (28.6%)
2	7 (100%)	0	0
3	2 (28.6%)	0	5 (71.4%)
4	6 (85.7%)	0	1 (14.3%)
5	7 (100%)	0	0
6	3 (42.9%)	0	4 (57.1%)
7	3 (42.9%)	0	4 (57.1%)
8	7 (100%)	0	0

Table 2.3 First Revisions to Knowledge Scale

Item Number	Original	Revised (bolded font)
1	Las pruebas prenatales pueden indicarme si mi feto tiene una alta probabilidad de tener síndrome de Down u otra afección médica poco común.	Las pruebas prenatales pueden indicarme si mi feto tiene una alta probabilidad de tener síndrome de Down u otro problema médico poco común.
2	Este examen analiza las condiciones que se puede curar.	Este examen analiza las condiciones que se pueden curar.
3	Los resultados de las pruebas prenatales son menos precisos si es una mujer más joven .	Las pruebas prenatales son mejores para detectar problemas genéticos si una mujer es mayor de edad .
4	Si los resultados de mi prueba prenatal son negativos (normales), significa que mi feto no tiene ninguna afección médica .	Si los resultados de mi prueba prenatal son negativos (normales), significa que mi feto no tiene ningún problema médico .
5	Se necesitarán más exámenes si los resultados de mi prueba prenatal son positivos (anormales).	No revisions needed
6	Si la prueba de detección prenatal no me da un resultado, eso significa que mi feto tiene síndrome de Down.	Cuando la prueba genética de sangre no me da un resultado (es decir que no es ni negativa ni positiva) , eso quiere decir que mi feto tiene síndrome de Down.
7	Si mi feto tiene una afección, mis únicas opciones son continuar con el embarazo o interrumpirlo.	Si una persona tiene un feto con un problema médico, las opciones que esa persona puede tomar son continuar con el embarazo o interrumpirlo.
8	Un examen de ultrasonido puede indicarme si mi feto tiene síndrome de Down.	No revisions needed

2.4.3 Second Set of Interviews

The results of the second set of coded interviews are detailed in Table 2.4. Following revisions, all items achieved face validity. During the second set of interviews, participants had the following thoughts on item number 3: “[...] from what I’ve heard, once women are over a certain age, they can have complications with the pregnancy [...]” and “[...] when your body is very young, like it’s not totally prepared or totally developed, I don’t know, maybe, perhaps, it can’t be examined completely.” When asked about the meaning of “fails to give a result” in item number 6, participants explained that it meant that “you don’t really know what [the fetus] has” and “[...] [the test] doesn’t tell you anything, if [the fetus] has [a genetic condition] or it doesn’t.” Another participant expressed the following:

[...] there could have been a mistake, maybe the blood was contaminated or maybe something went wrong so that [the test] didn’t come back negative or positive. But for me, it would be better to do another test to make sure and to get a result.

For item number 7, one participant expressed that in regards to pregnancy management options, “[...] [providers] give [her] the option if [she] wants to terminate the pregnancy or continue with the pregnancy, it’s your decision.” Another participant expressed that

[...] the mom or the parents, well, they can decide if the baby be born or not.

If a person has a fetus with a medical problem, the options that that person can choose are to continue with the pregnancy or to terminate it. [...] If the fetus has genetic problems [...] if the parents decide not to continue with the pregnancy, they can terminate it.

After the second set of interviews, all items were majority (>70%) green and participant interpretation aligned with the intended meaning of each item. The items on the knowledge scale did not require further revisions.

Table 2.4 Interview Counts (Set 2)

Item Number	Counts (N=6)		
	Aligned with intended meaning (n)	Confusing	Did not align with intended meaning (n)
1	6 (100%)	0	0
2	5 (83.3%)	0	1 (16.7%)
3	5 (83.3%)	0	1 (16.7%)
4	6 (100%)	0	0
5	6 (100%)	0	0
6	6 (100%)	0	0
7	6 (100%)	0	0
8	6 (100%)	0	0

2.5 Discussion

To our knowledge, this is the first study to assess face validation of a Spanish NIPS knowledge scale. This is the first step towards a complete validation of this scale. A validated NIPS knowledge scale in Spanish will work to lessen language and cultural barriers that may otherwise be present in the field of prenatal genetic counseling, allowing Hispanic/Latine patients to make more informed choices. This study

demonstrates the importance of considering the views and perceptions of Hispanic/Latine individuals while validating this Spanish knowledge scale. A validated Spanish scale can be implemented into a full MMIC, which not only measures patients' knowledge, but their attitudes as well. Utilizing a MMIC will allow genetic counselors to better assess the knowledge and attitudes that Hispanic/Latine patients have about NIPS before they give their consent to pursue screening.

For item number 3, the majority of participants believed that the item was asking about the increased risk for older women to have a pregnancy affected by a genetic condition versus about the preciseness or accuracy of NIPS. For this reason, the wording for this item was changed from "Prenatal screening results are less accurate if you are a younger woman." to "Prenatal screening is better at detecting genetic problems if a woman is older." A few participants expressed that they had not previously heard of this concept during their genetic counseling session. Personal communication with several genetic counselors included that this concept is not often discussed in genetic counseling sessions unless there is a high-risk NIPS result. Therefore, it was understandable that participants may not understand the meaning of the item. After the second set of interviews, most participants continued to state that item number 3 was asking about the increased risk for older women to have a pregnancy affected by a genetic condition versus about the preciseness or accuracy of NIPS. After further discussion with NSGC's RQO Committee, these statements related to increased risk in older women were accepted as concordant. The team agreed that by understanding this concept, participants understood the underlying meaning of the item. This question also reached face validity for the English scale, but it has not yet gone through concept validity, which determines

if the item is meaningful for making an informed choice. The current part of this analysis is only assessing face validity, so this item may not reach concept validity in the future since several participants noted not discussing this information during their genetic counseling session. Therefore, this item may not be important to include for patients to make an informed choice.

For item number 6, participants understood what was meant by the item only after the meaning of “fails to give a result” was explained. Therefore, this statement was defined by following it with “(i.e., it is neither negative nor positive)”. A similar style was used for items number 4 and 5: “negative” was followed with “(normal)” and “positive” was followed with “(abnormal)”. This proved to be helpful as participants no longer required clarification on the meaning of “fails to give a result”.

For item number 7, participants believed that if their fetus was affected with a condition, they only had one option. Most participants expressed that their only option was to continue the pregnancy. A couple of participants expressed that their only option was to terminate the pregnancy if their fetus was affected with any condition. This made it evident that participants felt that there was only one management option if their fetus was affected. In a study by Floyd et al. (2016), most Spanish-speaking women disclosed that they would continue their pregnancy regardless of screening or testing results. Additionally, Spanish-speaking women in that study used more negative terms to describe termination, but acknowledged that every woman has the right to choose for themselves (Floyd et al., 2016). Because of this, the item was changed to include less personal language. The item was changed to include wording like “If a person has a fetus with a medical problem...” and “...the choices that person can make...” versus “If my

fetus...” and “...my only options...”. After revisions to the original knowledge scale were made, all six participants’ responses to item number 7 aligned with the intended meaning of the item. Rather than expressing that their only option was to continue the pregnancy, all participants expressed that everyone has the option to continue or terminate their pregnancy and that each woman or couple can make their own decision. Using less personal language for this item was a very important revision that allowed participants to understand what the item was asking.

2.5.1 Practice Implications

A validated Spanish NIPS knowledge scale is important to lessen some of the language and cultural barriers that may otherwise be present in prenatal genetic counseling. A validated Spanish scale can be implemented into a full MMIC, which not only measures patients’ knowledge, but their attitudes as well. This will allow genetic counselors to better assess the knowledge that Hispanic/Latine patients have about NIPS. Also, having a validated NIPS MMIC scale in Spanish would allow for more diverse and inclusive research regarding NIPS decision-making.

2.5.2 Study Limitations

This study only included the face validity phase for the NIPS knowledge scale for Spanish-speaking women. Although assessing face validity does not require a large number of participants, all participants were from Prisma Health Midlands and most were at least high school graduates. More diversity amongst the participants may have led to more revisions to the scale being required. Additionally, although the process was explained to participants, some found it difficult to explain what each item meant to them rather than just providing a true/false answer to each item. When participants answered

with their true/false response, they were asked to explain why they believed that was the answer to the item. However, some did not know how to explain further.

2.5.3 Future Research

This study only assessed face validity of this Spanish NIPS knowledge scale. There are two other validity testing phases required in order to fully validate the knowledge scale: concept validity and content validity. Concept validity assesses whether each item on the scale is meaningful to making an informed choice. Concept validity can be assessed by administering the knowledge scale to between five and fifteen interviewees and asking them to voice their mental processing and the answer they selected for each item. The participants will review each item and determine how relevant it is for their decision making. Those interviews should also be recorded and transcribed. The findings should then be analyzed in Spanish, and the scale should be adjusted as needed. If adjustments are made at any point, at least five more interviews should be conducted to test the revisions. Content validity assesses whether each item measures what is intended. In order to assess content validity, the Spanish scale should be administered to prenatal genetic counseling patients who made a decision whether to undergo testing during their session. At least 150 participants, who ideally were counseled by different genetic counselors, will be required for this phase. Upon completion of data collection, data should be analyzed in order to assess full validity of the NIPS knowledge scale.

Future research can also include validation of knowledge scales for different genetic screens and tests in English, Spanish, and other languages. Other knowledge scales currently being assessed for validation include the English NIPS knowledge scale,

an English cancer genetic testing knowledge scale, a Spanish cancer genetic testing knowledge scale, and an English cardiogenetics knowledge scale. Patient knowledge scales for genetic testing in other specialties, like neurology genetic counseling or testing, may also be beneficial. Any validated knowledge scale can then be implemented as part of a full MMIC model to further assess informed choice. Utilizing validated scales as part of an MMIC leads to impactful quality research and clinical outcome studies to better benefit patient care in the future.

CHAPTER 3: CONCLUSION

Face validity was reached for all items on the Spanish non-invasive prenatal screening (NIPS) knowledge scale. During the first interview set, participants believed that item number 3 was asking about the increased risk for older women to have a pregnancy affected by a genetic condition versus about the preciseness or accuracy of NIPS. The item was revised to account for this. Initially, the item did not achieve face validation after the second set of interviews. However, after further discussion with National Society of Genetic Counselors' (NSGC) Research, Quality and Outcomes (RQO) Committee, these statements related to increased risk in older women were accepted as concordant. The team agreed that by understanding this concept, participants understood the underlying meaning of the item. Item number 6 did not reach face validity after the first set of interviews. Participants understood what was meant by the item only after the meaning of "fails to give a result" was explained. After this item was revised to include a definition of this statement, all participants understood the meaning of the item. Item number 7 was the last item that did not reach face validity after the first set of interviews. Participants believed that if their fetus was affected with a condition, they only had one option. Most participants expressed that their only option was to continue the pregnancy, while a couple of participants expressed that their only option was to terminate the pregnancy if their fetus was affected with any condition. The item was revised to include less personal language. After this change was made, all participants understood what the item meant. This is the first study to assess face validation of a

Spanish NIPS knowledge scale. This is the first step towards a complete validation of this scale. A validated NIPS knowledge scale in Spanish will work to lessen some of the language and cultural barriers that may otherwise be present in prenatal genetic counseling. Also, having a validated NIPS MMIC scale in Spanish would allow for more diverse and inclusive research regarding NIPS decision-making.

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APPENDIX A: INVITATION TO PARTICIPATE

Below is the invitation to participate in Spanish, followed by the invitation to participate in English:



Escuela de Medicina de la Universidad de Carolina del Sur
Programa de asesoramiento genético

INVITACIÓN DE PARTICIPACIÓN

Estimada participante potencial:

Está usted invitada para participar en un estudio de investigación de posgrado sobre las pruebas prenatales no invasivas (NIPS). Yo soy una estudiante de posgrado en el programa de asesoramiento genético en la Escuela de Medicina de la Universidad de Carolina del Sur. El propósito de mi estudio es validar una escala de conocimiento sobre NIPS en español. Esto es importante para asegurar que los pacientes que hablan español estén dando su consentimiento informado para NIPS.

La escala de conocimiento intenta interpretar su conocimiento sobre NIPS, pero mi estudio intenta entender su interpretación de las preguntas. Esto se hará por una entrevista de teléfono. Es importante reconocer que este estudio no está evaluando su conocimiento, y no importa que decisión haya tomado con respecto a hacer NIPS.

Todas las respuestas de la entrevista son anónimas y confidencial. Su nombre y número de teléfono solo se registrarán si está interesada en recibir una tarjeta de regalo valorada en 10 dólares, pero su información se mantendrá separada de las respuestas de su entrevista.

Su participación en este estudio es completamente voluntaria. Al participar en la entrevista, usted está dando su consentimiento de que leyó y entendió esta información. En cualquier momento, usted puede retirarse de la entrevista.

Muchas gracias por su tiempo y consideración a participar en este estudio. Sus respuestas pueden ayudar a asesores genéticos asegurar que los pacientes que hablan español entiendan lo que es NIPS y den su consentimiento informado. Esto es un paso adelante para la comunidad Hispana/Latina en el logro de un cuidado de salud equitativo. Si tiene

preguntas sobre este estudio, me puede contactar a mi o a mi asesora de tesis, Jessica Fairey, quien es una asesora de genética certificada, usando la información de contacto disponible abajo.

Información de contacto:

Kenya De Leon
Estudiante de asesoramiento genético

864-992-9705

Jessica Fairey
Asesora de genética
certificada
803-545-5746



**University of South Carolina School of Medicine
Genetic Counseling Program**

INVITATION TO PARTICIPATE

Dear Potential Participant:

You are invited to participate in a graduate research study focusing on non-invasive prenatal screening (NIPS). I am a graduate student in the genetic counseling program at the University of South Carolina School of Medicine. The purpose of my study is to validate a knowledge scale about NIPS in Spanish. This is important in order to ensure that Spanish-speaking patients are giving their informed consent when undergoing NIPS.

The knowledge scale attempts to interpret your knowledge about NIPS, but my study attempts to understand your interpretation of the items being asked. This will be done through a phone interview. It is important to recognize that this study is not evaluating your knowledge, and it does not matter what decision you made in regards to undergoing NIPS.

All of the answers from the interview will remain anonymous and confidential. Your name and phone number will only be recorded if you are interested in receiving a gift card valued at \$10, but your information will be kept separate from your interview responses.

Your participation in this study is completely voluntary. By participating in this interview, you are consenting that you read and understand this information. At any time, you may withdraw from the interview.

Thank you so much for your time and consideration to participate in this study. Your responses may help genetic counselors ensure that Spanish-speaking patients understand what NIPS is and give their informed consent. This is a step forward for the Hispanic/Latinx community in achieving equitable healthcare. If you have any questions

regarding this study, you can contact me or my advisor, Jessica Fairey, MS, CGC, using the contact information below.

Contact information:

Kenya De Leon
Genetic Counseling Student

864-992-9705

Jessica Fairey
Certified Genetic
Counselor
803-545-5746

APPENDIX B: CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Below is the consent to participate in a research study in Spanish, followed by the consent to participate in a research study in English:

CONSENTIMIENTO PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

VALIDACIÓN DE UNA ESCALA DE CONOCIMIENTOS DE PRUEBAS PRENATALES NO INVASIVAS (NIPS) EN ESPAÑOL

Estudio a realizar en: Prisma Health Midlands
2 Medical Park Road
Columbia, SC 29203

Nombre del Patrocinador: Comité de Investigación, Calidad y Resultados de la Sociedad Nacional de Asesores Genéticos

Investigadores Principales: Kenya De Leon (864-992-9705) y Jessica Fairey, MS, CGC (803-545-5746)

INFORMACIÓN CLAVE

Se le está pidiendo que participe en un estudio de investigación. La participación en un estudio de investigación es voluntaria. La información en este formulario de consentimiento está destinada a informarlo mejor para que pueda decidir si participar o no en este estudio de investigación. Pida al personal del estudio que le explique cualquier cosa que no entienda.

El propósito de este estudio es validar una escala de conocimiento de las pruebas prenatales no invasivas (NIPS) en español para su uso en la subespecialidad prenatal de asesoramiento genético. Esto es importante para garantizar que los pacientes hispanos den su consentimiento informado al someterse a NIPS. La escala de conocimiento intenta interpretar su conocimiento sobre NIPS, pero mi estudio intenta entender la interpretación de los elementos que se le preguntan. Esto se hará por una entrevista de teléfono. Es importante reconocer que este estudio no está evaluando su conocimiento, y no importa que decisión haya tomado con respecto a hacer NIPS. Todas las respuestas de la entrevista son anónimas y confidenciales. Su nombre y número de teléfono solo se registrarán si está interesada en recibir una tarjeta de regalo valorada en 10 dólares, pero su información se mantendrá separada de las respuestas de su entrevista. Su participación en este estudio es completamente voluntaria. Al participar en la entrevista, usted está dando su

consentimiento de que leyó y entendió esta información. En cualquier momento, usted puede retirarse de la entrevista. Sus respuestas pueden ayudar a asesores genéticos asegurar que los pacientes que hablan español entiendan lo que es NIPS y den su consentimiento informado. Esto es un paso adelante para la comunidad Hispana//Latina en el logro de un cuidado de salud equitativo.

El Comité Institucional de Revisión de Prisma Health ha revisado este estudio para la protección de los derechos de los participantes humanos en estudios de investigación, de acuerdo con los reglamentos federales y estatales.

PROPÓSITO

Se le pide que participe en este estudio porque es una mujer embarazada que habla español.

- *El propósito de este estudio es validar una escala de conocimiento las de pruebas prenatales no invasivas (NIPS) en español para su uso en la subespecialidad prenatal de asesoramiento genético.*
- *Se han desarrollado escalas que incluyen NIPS, pero no se ha evaluado su validez. Dado que NIPS es una prueba que se ofrece a todas las pacientes embarazadas, sería beneficioso disponer de una medida de consentimiento informado válida en español.*
- *Una vez que se valide la escala en español, trabajará para disminuir las barreras culturales y de idioma que de otro modo podrían estar presentes, permitiendo que los pacientes hispanos den su verdadero consentimiento informado.*
- *Aproximadamente 50 participantes estarán involucrados en este estudio.*

Este estudio de investigación se realiza debido a que actualmente no existe una escala de conocimiento de pruebas prenatales no invasivas en español.

Su participación durará hasta el final de su entrevista.

Este estudio se lleva a cabo como parte de los requisitos de tesis del Programa de Asesoramiento Genético de la Universidad de Carolina del Sur.

CÓMO FUNCIONA EL ESTUDIO

- *Los asesores genéticos prenatales de Prisma Health Midlands darán una carta de “invitación de participación” a los pacientes que cumplan los requisitos para participar en el estudio.*
- *Se realizarán entrevistas telefónicas con los pacientes que se ofrezcan como voluntarios para participar en este estudio. Durante las entrevistas, se le pedirá a cada participante que explique qué significa para ella cada uno de las ocho preguntas de la escala. Después de revisar todos los elementos de la escala, se la harán preguntas demográficas al participante y se registrarán sus respuestas. Cada entrevista será grabada y transcrita. Las transcripciones en español serán luego traducidas al inglés.*
- *Las entrevistas se realizaran en grupos de 10 hasta que el análisis de las entrevistas den resultados similares entre participantes. Cada participante solo participará en una entrevista.*

- *Si se realizan suficientes entrevistas y el tiempo lo permite, la escala de conocimiento se administrará a 5-15 participantes mientras “piensan en voz alta” sobre su proceso de pensamiento. Esto permitirá que los investigadores ajusten aún más la escala de conocimiento.*
- *Asesores genéticos de la Universidad de Indiana y del Centro Médico de la Universidad de Vanderbilt, junto con un profesor de español de la Universidad de Clemson, recibirán transcripciones y traducciones de entrevistas para ayudar con el análisis, pero no recibirán su información personal.*

POSIBLES RIESGOS

No existen riesgos médicos conocidos relacionados con la participación en este estudio. El mayor riesgo es la posible liberación de su información médica personal. Los registros de su estudio se consideran confidenciales, pero no se puede garantizar la confidencialidad absoluta. Este estudio puede resultar en presentaciones y publicaciones, pero se tomarán medidas para asegurarse de que su nombre no sea identificado.

Algunas preguntas de la entrevista son personales y pueden molestar a algunos participantes. El personal del estudio estará disponible para discutir estas preguntas si tiene alguna inquietud o problema. No tiene que responder ninguna pregunta que no desee.

POSIBLES BENEFICIOS

No es posible saber si usted puede o no beneficiarse de participar en este estudio. La información obtenida de este estudio puede ser útil y puede ayudar a otros.

- *Los participantes recibirán (si desean) una tarjeta de regalo valorada en 10 dólares.*

NUEVA INFORMACIÓN

Su asesor genético le informará sobre nueva información que pueda afectar su deseo a participar en este estudio de investigación.

No hay planes de compartir los resultados individuales de la investigación con usted.

PAGO POR PARTICIPACIÓN

Para usted:

Se la pagará con una tarjeta de regalo valorada en 10 dólares.

PARTICIPACIÓN VOLUNTARIA

La participación en este estudio de investigación es voluntaria. Puede negarse a participar o retirarse del estudio en cualquier momento. Si se niega a participar o se retira del estudio, no será penalizado ni perderá ningún beneficio y su decisión no afectará su relación con su médico u hospital.

CONFIDENCIALIDAD

Los registros de su estudio se consideran confidenciales (privados), pero no se puede garantizar la confidencialidad absoluta. La información puede mantenerse en una computadora. Todos los registros pueden ser examinados y copiados por la Comité Institucional de Revisión de Prisma

Health y otras agencias reguladoras. Este estudio puede resultar en presentaciones y publicaciones, pero se tomarán medidas para asegurarse de que su nombre no sea identificado.

CONTACTO PARA PREGUNTAS

Para más información sobre este estudio y los riesgos o lesiones relacionados con la investigación, o para dar comentarios o expresar inquietudes o quejas, puede comunicarse con el investigador principal. Su información se incluye abajo.

También puede comunicarse con un representante de la Oficina de Protección de Investigaciones Humanas de Prisma Health para obtener información sobre sus derechos como participante en un estudio de investigación o para hacer comentarios o expresar inquietudes, quejas u ofrecer aportes. Puede obtener el nombre y número de esta persona llamando al (864) 455-8997.

Nombre del investigador principal: Kenya De Leon

Número de teléfono: 864-992-9705

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

VALIDATION OF A SPANISH NON-INVASIVE PRENATAL SCREENING (NIPS) KNOWLEDGE SCALE

Study to be Conducted at: *Prisma Health Midlands
2 Medical Park Road
Columbia, SC 29203*

Sponsor Name: *National Society of Genetic Counselors Research, Quality and Outcomes Committee*

Principal Investigator: *Kenya De Leon (864-992-9705) and Jessica Fairey, MS, CGC (803-545-5746)*

KEY INFORMATION

You are being asked to participate in a research study. Participation in a research study is voluntary. The information in this consent form is meant to better inform you so you may decide whether or not to participate in this research study. Please ask the study staff to explain anything you do not understand.

The purpose of my study is to validate a Spanish non-invasive prenatal screening (NIPS) knowledge scale for use in the prenatal genetic counseling subspecialty. This is important in order to ensure

that Spanish-speaking patients are giving their informed consent when undergoing NIPS. The knowledge scale attempts to interpret your knowledge about NIPS, but my study attempts to understand your interpretation of the items being asked. This will be done through a phone interview. It is important to recognize that this study is not evaluating your knowledge, and it does not matter what decision you made in regards to undergoing NIPS. All of the answers from the interview will remain anonymous and confidential. Your name and phone number will only be recorded if you are interested in receiving a gift card valued at \$10, but your information will be kept separate from your interview responses. Your participation in this study is completely voluntary. By participating in this interview, you are consenting that you read and understand this information. At any time, you may withdraw from the interview. Your responses may help genetic counselors ensure that Spanish-speaking patients understand what NIPS is and give their informed consent. This is a step forward for the Hispanic/Latinx community in achieving equitable healthcare.

The Institutional Review Board of the Prisma Health has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations.

PURPOSE

You are being asked to participate in this study because you are a Spanish-speaking pregnant woman.

- *The purpose of this study is to validate a Spanish non-invasive prenatal screening (NIPS) knowledge scale for use in the prenatal genetic counseling subspecialty.*
- *Scales that include NIPS have been developed, but they have not been assessed for validity. Since NIPS is a test offered to all pregnant patients, it would be beneficial to have a Spanish validated measure of informed consent.*
- *Once the Spanish scale is validated, it would work to lessen the language and cultural barriers that may otherwise be present, allowing Hispanic patients to give their true informed consent.*
- *Approximately 50 participants will be involved in this study.*

This research study is being done because there is currently not an available non-invasive prenatal screening knowledge scale in the Spanish language.

Your participation will last through the end of your interview.

The study is being conducted as part of the thesis requirements of the University of South Carolina Genetic Counseling Program.

HOW THE STUDY WORKS

- *Prenatal genetic counselors at Prisma Health Midlands will provide qualifying patients the "Invitation to Participate" letter.*
- *Phone interviews will be conducted with patients who volunteer to participate in this study. During the interviews, each participant will be asked to explain what each of the eight items on the scale means to them. After going through all of the items on the scale, the participant will be asked demographic questions, and their responses will be recorded. Each interview*

will be recorded and transcribed. The Spanish transcriptions will then be translated into English.

- *Interviews will be conducted in sets of 10 until analysis of the interviews gives similar results between individuals. Each participant will only be expected to participate in 1 interview.*
- *If enough interviews are conducted and time permits, the knowledge scale will be administered to 5-15 participants while they “think aloud” through their thought process. This will allow investigators to further adjust the knowledge scale.*
- *Genetic counselors from Indiana University and Vanderbilt University Medical Center as well as a Spanish professor from Clemson University will receive interview transcriptions and translations in order to help with the analysis, but they will not receive any of your personal information.*

POSSIBLE RISKS

There are no known medical risks related to participation in this study. The greatest risk is the possible release of your personal health information. Your study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

Some of the questions in the interview are personal and may be upsetting to some participants. The study staff will be available to discuss these questions should you have a concern or problem. You do not have to answer any questions that you do not want to answer.

POSSIBLE BENEFITS

It is not possible to know whether or not you may benefit from participating in this study. The information gained from this study may be useful and may help others.

- *Participants will receive (if desired) and gift card valued at \$10.*

NEW INFORMATION

Your genetic counselor will tell you about new information that may affect your willingness to participate in this research study.

There are no plans to share individual research results with you.

PAYMENT FOR PARTICIPATION

To You:

You will be paid with gift card valued at \$10.

VOLUNTARY PARTICIPATION

Participation in this research study is voluntary. You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

CONFIDENTIALITY

Your study records are considered confidential (private), but absolute confidentiality cannot be guaranteed. Information may be kept on a computer. All records may be examined and copied by

the Institutional Review Board of Prisma Health, and other regulatory agencies. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, whose information is included below.

You may also contact a representative of the Office of Human Research Protection of Prisma Health for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

Principal Investigator Name: Kenya De Leon

Telephone Number: 864-992-9705

APPENDIX C: NIPS KNOWLEDGE SCALES

Below is the original Spanish NIPS knowledge scale, followed by the original

English NIPS knowledge scale:

Medida multidimensional de elección informada (MMIC) de pruebas prenatales

Las pruebas prenatales no invasivas también se denominan NIPS (non-invasive prenatal screening), NIPT (non-invasive prenatal test) y ADN libre de células. Todas son la misma prueba.

Indique si cada una de estas afirmaciones sobre las pruebas prenatales es verdadera o falsa.

1. Las pruebas prenatales pueden indicarme si mi feto tiene una alta probabilidad de tener síndrome de Down u otra afección médica poco común. Verdadero o Falso
2. Este examen analiza las condiciones que se puede curar. Verdadero o Falso
3. Los resultados de las pruebas prenatales son menos precisos si es una mujer más joven. Verdadero o Falso
4. Si los resultados de mi prueba prenatal son negativos (normales), significa que mi feto no tiene ninguna afección médica. Verdadero o Falso
5. Se necesitaran más exámenes si los resultados de mi prueba prenatal son positivos (anormales). Verdadero o Falso
6. Si la prueba de detección prenatal no me da un resultado, eso significa que mi feto tiene síndrome de Down. Verdadero o Falso
7. Si mi feto tiene una afección, mis únicas opciones son continuar con el embarazo o interrumpirlo. Verdadero o Falso
8. Un examen de ultrasonido puede indicarme si mi feto tiene síndrome de Down. Verdadero o Falso

Prenatal screening scale for the MMIC

Rate the degree to which you agree or disagree with each of the following statements about prenatal screening. Prenatal screening is also called NIPS (non-invasive prenatal screening), NIPT (non-invasive prenatal testing) and Cell-free DNA. They are all the same test.

Indicate whether each of these statements about prenatal screening is true or false.

1. Prenatal screening can tell me if my fetus has a higher chance of having Down syndrome or another rare condition. True or False
2. This test screens for conditions that can be cured. True or False
3. Prenatal screening results are less accurate if you are a younger woman. True or False
4. If my prenatal screening results are negative (normal), it means that my fetus does not have a condition. True or False
5. Further testing will be needed if my prenatal screening results are positive (abnormal). True or False
6. If the prenatal screening test fails to give a result, it means that my fetus has Down syndrome. True or False
7. If my fetus has a condition, my only options are to continue the pregnancy or end the pregnancy. True or False
8. An ultrasound exam can tell me if my fetus has Down syndrome. True or False

Below is the revised Spanish NIPS knowledge scale, followed by the revised NIPS knowledge scale in English:

Medida multidimensional de elección informada (MMIC) de pruebas prenatales

Las pruebas prenatales no invasivas también se denominan NIPS (non-invasive prenatal screening), NIPT (non-invasive prenatal test) y ADN libre de células. Todas son la misma prueba.

Indique si cada una de estas afirmaciones sobre las pruebas prenatales es verdadera o falsa.

1. Las pruebas prenatales pueden indicarme si mi feto tiene una alta probabilidad de tener síndrome de Down u otra afección médica poco común. Verdadero o Falso
2. Este examen analiza las condiciones que se puede curar. Verdadero o Falso
3. Los resultados de las pruebas prenatales son menos precisos si es una mujer más joven. Verdadero o Falso
4. Si los resultados de mi prueba prenatal son negativos (normales), significa que mi feto no tiene ninguna afección médica. Verdadero o Falso
5. Se necesitaran más exámenes si los resultados de mi prueba prenatal son positivos (anormales). Verdadero o Falso
6. Si la prueba de detección prenatal no me da un resultado, eso significa que mi feto tiene síndrome de Down. Verdadero o Falso
7. Si mi feto tiene una afección, mis únicas opciones son continuar con el embarazo o interrumpirlo. Verdadero o Falso
8. Un examen de ultrasonido puede indicarme si mi feto tiene síndrome de Down. Verdadero o Falso

Prenatal screening scale for the MMIC

Rate the degree to which you agree or disagree with each of the following statements about prenatal screening. Prenatal screening is also called NIPS (non-invasive prenatal screening), NIPT (non-invasive prenatal testing) and Cell-free DNA. They are all the same test.

Indicate whether each of these statements about prenatal screening is true or false.

1. Prenatal screening can tell me if my fetus has a high chance of having Down syndrome or another rare medical problem. True or False
2. This test screens for conditions that can be cured. True or False
3. Prenatal testing is best for detecting genetic problems if a woman is older. True or False
4. If my prenatal test results are negative (normal), it means that my fetus does not have any medical problems. True or False
5. Further testing will be needed if my prenatal screening results are positive (abnormal). True or False

6. When the genetic blood test does not give me a result (i.e., it is neither negative nor positive), that means my fetus has Down syndrome. True or False
7. If a person has a fetus with a medical problem, the choices that person can make are to continue the pregnancy or terminate it. True or False
8. An ultrasound test can tell me if my fetus has Down syndrome. True or False

APPENDIX D: INTERVIEW CONFIRMATION EMAIL

Below is the Spanish interview confirmation email sent to participants who provided verbal consent and scheduled an interview, followed by the English translation of the email:

Buenos días,

Aquí le mando la información que le prometí sobre mi estudio.

La primera página es una letra de parte mía que describe el estudio. Las próximas tres páginas describen todo sobre el estudio con más detalle. La última página es la escala de conocimientos que usaremos durante la entrevista el [fecha] a la(s) [hora]. Por favor tenga la última página disponible durante la entrevista.

Si tiene alguna pregunta, por favor no dude en enviarme un correo electrónico o en llamarme.

Muchísimas gracias,

Kenya De Leon

Estudiante de asesoramiento genético

tel.: 864-992-9705

Good morning,

Here is the information I promised you about my study.

The first page is a letter from me that describes the study. The next three pages describe everything about the study in more detail. The last page is the knowledge scale that we will use during the interview on [date] at [time]. Please have the last page available during the interview.

If you have any questions, please feel free to email or call me.

Thank you very much,

Kenya De Leon

Genetic Counseling Student

tel.: 864-992-9705

APPENDIX E: INTERVIEW SCRIPT

Below is the script used during the interviews with participants, followed by the

English translation of the script:

Buenas tardes, habla Kenya, la estudiante de asesoramiento genético. Pudiera hablar con [Nombre]? Como esta hoy?

Esta lista para la entrevista para el estudio?

Recibió los documentos que le mande por correo electrónico? La última página de ese documento la vamos a usar ahora. La tiene disponible?

Vamos a hablar sobre cada pregunta de esa escala. Es importante notar que no estamos probando su comprensión, sino estamos interesados en aprender sobre lo que piense que significa cada punto de la escala.

Esta lista para empezar?

Puede usted por favor leer en voz alta el primer punto de la escala y luego me puede decir qué significa para usted? ¿Qué piensa usted que le estamos preguntando en el punto número uno?

Muchas gracias.

[Repetir con el resto de los puntos de la escala]

Muchísimas gracias por hacer eso. Ahora le voy a hacer unas preguntas demográficas. Le recuerdo que las respuestas no tendrán su nombre y serán anónimas.

- 1. ¿Qué edad tiene?*
- 2. ¿Cuál es el nivel más alto de estudios que ha completado o el título más alto que ha recibido? (if needed for clarification, the following options were offered: Ningún nivel de educación, Escuela primaria/secundaria, Algo de secundaria, Graduado de la escuela secundaria, Escuela comercial/técnica/vocacional, Un poco de universidad, Graduado universitario, Trabajo de posgrado o título de grado, Prefiero no contestar)*
- 3. ¿Cuál es su raza/etnicidad? (if needed for clarification, the following options were offered: Negra o afroamericana, Hispana o Latina, Blanca, Asiática, Nativa americana o nativa de Alaska, Nativa de Hawái u otras islas del Pacífico, Otro)*
- 4. ¿Nació en los Estados Unidos?*
- 5. ¿Cuál es su género? (if needed for clarification, the following options were offered: Mujer, Hombre, No binario, Prefiere autodescribirse, Prefiero no contestar)*
- 6. ¿Es usted transgénero?*

Muchísimas gracias. En unos momentos le enviaré un correo electrónico con la tarjeta de regalo. Que tenga buen día

*Good afternoon, this is Kenya, the genetic counseling student. May I speak with [Name]?
How are you today?*

Are you ready for the study interview?

Did you receive the documents I emailed you? The last page of that document we are going to use now. Do you have it available?

Let's talk about each question on that scale. It is important to note that we are not testing your understanding, but we are interested in learning what you think each item on the scale means.

Are you ready to begin?

Can you please read aloud the first item on the scale and then tell me what it means to you? What do you think we are asking you in item number one?

Thank you very much.

[Repeat with the rest of the items on the scale]

Thank you very much for doing that. Now I'm going to ask you some demographic questions. I'll remind you that the answers will not have your name on them and will be anonymous.

- 1. How old are you?*
- 2. What is the highest level of education you have completed or the highest degree you have received? (if needed for clarification, the following options were offered: No level of education, Grade school/junior high, Some high school, High school graduate, Trade/technical/vocational school, Some college, College graduate, Post graduate work or graduate degree, Prefer not to answer)*
- 3. What is your race/ethnicity?(if needed for clarification, the following options were offered: Black or African American, Hispanic or Latina, White, Asian, Native American or Alaskan Native, Native Hawaiian or other Pacific Islander, Other)*
- 4. Were you born in the United States?*
- 5. What is your gender? (if needed for clarification, the following options were offered: Woman, Man, Non-binary, Prefer to self-describe, Prefer not to answer)*
- 6. Are you transgender?*

Thank you very much. I will send you an email with the gift card in a few moments. Have a nice day.

APPENDIX F: COMPENSATION EMAIL

Below is the Spanish email including compensation sent to participants following the interviews, followed by the English translation of the email:

Buenas tardes,

Muchísimas gracias por participar en mi estudio de tesis. Aquí le mando la información para la tarjeta de regalo que le prometí.

Sitio: <https://www.amazon.com>

Cantidad: \$10.00

Código de tarjeta de regalo: [código]

Por favor déjeme saber si tiene alguna duda.

Gracias,

Kenya De Leon

Good afternoon,

Thank you very much for participating in my thesis study. Here is the information for the gift card I promised you.

Site: <https://www.amazon.com>

Amount: \$10.00

Gift card code: [code]

Please let me know if you have any questions.

Thank you,

Kenya De Leon