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Personalized Medicine

Creating accessible Spanish language materials for Clinical Sequencing Evidence-Generating Research consortium genomic projects: challenges and lessons learned

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Aim: To increase Spanish speakers' representation in genomics research, accessible study materials on genetic topics must be made available in Spanish. **Materials & methods:** The Clinical Sequencing Evidence-Generating Research consortium is evaluating genome sequencing for underserved populations. All sites needed Spanish translation of recruitment materials, surveys and return of results. **Results:** We describe our process for translating site-specific materials, as well as shared measures across sites, to inform future efforts to engage Spanish speakers in research. **Conclusion:** In translating and adapting study materials for roughly 1000 Spanish speakers across the USA, and harmonizing translated measures across diverse sites, we overcame numerous challenges. Translation should be performed by professionals. Studies must allocate sufficient time, effort and budget to translate and adapt participant materials.

Lay abstract: To encourage Spanish speakers to join research studies, researchers need to give them written study materials they can easily read and understand. Our study of genome sequencing adapted and translated study materials for use by Spanish speakers across the USA. We describe our process and share our lessons to help others engage Spanish speakers in research. Studies that want to reach Spanish speakers must plan to spend time, effort and money to produce consistent, accurate Spanish-language study materials.

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Keywords: cultural adaptation • genomics research • health disparities • participant materials • translation • underrepresentation

The need to enhance diversity in genomic research is widely recognized. In many cases, diagnosis of an actionable genetic condition can improve clinical outcomes [1]. However, historically underserved populations, including Hispanic individuals, receive less frequent clinical genetic counseling and testing [2–5]. Because this disparity also exists in research settings, knowledge about genetic variants is overwhelmingly based on individuals of European ancestry [6,7]. Over 80% of participants in genomic databases are of European ancestry, with only 0.5% of Hispanic ancestry [6,8]. The European bias in genomic studies is likely the result of methodological, systemic, historical and sociocultural factors [7,9]. To reduce disparities, we must find new strategies to include individuals from historically

underrepresented groups in genomic research [7,10]. Consortia-based team science is important to leverage the populations needed to accomplish this work.

The Office of Management and Budget (OMB) and the US Census Bureau define Hispanic or Latino as "*a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture regardless of race.*" [11] The terms Hispanic and Latino have different meanings in the USA and abroad. Place of residence, ancestry group or immigration generation may influence individuals' preference for the term Hispanic, Latino, both or neither [12]. Is this paper, the term Hispanic refers to persons of Spanish or Latin American descent who live in the USA; that is, those who self-identify or trace their roots to Spain or countries in the Americas where Spanish is the predominant language.

The US Census Bureau estimates that there are 58.8 million Hispanics living in the USA – nearly one-fifth (18.1%) of the US population [13]. The Hispanic category encompasses highly diverse populations with different socioeconomic profiles, migration histories and linguistic characteristics [12]. At 63%, people of Mexican origin comprise the largest Hispanic subpopulation, followed by mainland Puerto Ricans and Central Americans (each at 9.5%) [14]. Despite efforts to eliminate disparities [15], Hispanics lag behind other racial and ethnic groups in access to healthcare and remain overrepresented in the prevalence of diabetes, hypertension, [16,17] advanced-stage cancer [18] and inadequate cancer screening [19–22].

Language is a well-recognized barrier to accessing health-related services and participation in research [23]. Spanish is the most common non-English language spoken in the USA. Among the 41.4 million Spanish speakers in the USA, nearly 40% (or 16.2 million) are of limited English proficiency [24]. With more than 13% of USA residents speaking Spanish at home [25], language constitutes a major barrier to Spanish speakers' access to genomic research. To increase Spanish speakers' representation in this research area, accessible, socioculturally coherent study materials on complex genetic topics must be made available in Spanish. A historical mistrust of scientific research can also prevent Hispanics from participating in and receiving the benefits of genetic research [26–31]. To be fully transparent and address historical mistrust, materials must be written in plain language, clearly stating the process, costs, duration and potential benefits and risks of research participation.

The CSER consortium

The Clinical Sequencing Evidence-Generating Research (CSER) consortium seeks to address the underrepresentation of minority populations in genomics research. This national multi-site research program funded by the National Human Genome Research Institute, the National Cancer Institute and the National Institute on Minority Health and Health Disparities is evaluating the integration of genome sequencing into the clinical care of diverse and medically underserved populations [32]. Goals include measuring the clinical and personal utility of sequencing and analyzing patient and familial responses to genomic testing in different clinical settings. The consortium model was chosen to meet the need for very large sample sizes to investigate questions of clinical utility, and explore ethical, legal and social implications of genomic sequencing in diverse populations.

The six CSER sites host six separate studies targeting different populations (some adult and some pediatric) and addressing different research questions, but with the common goal of returning genetic findings that may inform treatment decisions and impact clinical care. Each site under the consortium umbrella designed its own set of survey questions and participant-facing materials, although some survey measures ('harmonized' measures, Table 1) were used by most if not all sites, in order to look at research questions about genetics studies across different subgroups. A detailed description of the CSER sites has been published elsewhere [32]. All sites set recruitment goals of at least 60% participants from underserved populations, of which a significant portion would be Spanish speakers. Toward this goal [33], the CSER consortium planned to include Spanish versions of all participant-facing documents for each site, including individual sites' Spanish versions of recruitment materials, surveys and return of results materials, as well as 'harmonized' measures that would be used by most CSER sites. Table 2 presents a list of the documents and measures translated by individual sites, along with translation strategies, cost and time spent on translation by each site, and barriers encountered by each site during their translation work.

Previous genetic and genomic multisite, multilingual consortia have used various approaches in the production of shared foreign language materials across sites [48–50], with some consortia having sites translate shared measures independently and some using different surveys already in existence in the foreign language. This approach requires using statistical methods to account for the resulting shared variance across sites. The CSER consortium decided to have each site undertake the Spanish translation of its site-specific measures, and to have a single independent translation of all harmonized measures that would be shared across sites. This paper describes the process followed

Table 1. Clinical Sequencing Evidence-Generating Research harmonized measures translated into Spanish†.

Harmonized measure	Harmonized translation	Novel measure	Ref.
Demographics	X	X	
Reasons for decline	X	X	
Sex	X	X	
Age	X	X	
Language	X	X	
Income	X	X	
Education level	X	X	
Insurance status	X	X	
Country of origin	X	X	
Access to care	X	X	
Subjective numeracy scale (Fagerlin, 2007 #629)	X		[34]
Single item race measure with Hispanic ethnicity	X	X	
Distrust (Shea, 2008 #1416)	X		[35]
Zip code	X	X	
Quality of Life Ascertainment – VAS (Huskisson, 1974 #1427)	X		[36]
Quality of Life Ascertainment – PedsQL (Varni, 1999 #1417)	X		[37]
Quality of Life Ascertainment – SF12 (Ware, 1996 #1276)	X		[38]
Feelings About Genomic Testing Results (Li, 2019 #1418)	X		[39]
Patient Reported Utility (Kohler, 2017 #1419)	X		[40]
Understanding	X	X	
Information seeking V1	X	X	
Overall satisfaction with results	X	X	
Satisfaction with mode of communication of results	X	X	
Perceptions of Uncertainties in Genomic Sequencing (Biesecker, 2017 #1420)	X		[41]
Understanding	X	X	
Family communication	X	X	
Information seeking V1 and V2	X	X	
Follow through on medical actions attributable to genomic testing	X	X	
Patient-initiated actions attributable to genomic testing	X	X	

†The Spanish-language harmonized measures are available at: https://cser-consortium.org/cser-research-materials.

by four CSER sites for translating their site-specific materials, as well as the process followed in the translation of the harmonized measures that were used across sites. We hope sharing our experience may support future efforts to conduct complex translation work for research consortiums, with a goal of increasing the participation of individuals of limited English proficient (LEP) in genomics research.

Cancer Health Assessments Reaching Many

Cancer Health Assessments Reaching Many (CHARM) is recruiting racially, ethnically and socioeconomically diverse adult primary care patients for risk assessment and genetic testing for hereditary cancer syndromes. CHARM will compare how exome sequencing impacts care utilization and health outcomes for 880 patients versus patients receiving usual care. All study materials are available in print or electronic format in both English and Spanish and bilingual recruitment staff are available. Data collection surveys and telephone interviews are conducted in Spanish or English.

Interested patients complete two validated risk assessment tools for hereditary cancer syndromes (B-RST™ 3.0 and PREMM$_5$™, respectively) [51,52] and/or an assessment for limited family structure or family knowledge [53,54]. Patients receive a plain-language summary of their risk results; at risk patients are offered clinical exome sequencing. Using an illustrated, plain-language web tool, patients receive pretest genetic education, consent to genetic testing and research use of information and select categories for secondary findings they want to receive.

Result disclosure is conducted by genetic counselors in English or via a professional Spanish-language interpreter. All participants who receive genetic testing complete surveys administered electronically containing unique-to-

Table 2. Measures translated into Spanish by individual studies participating in the Clinical Sequencing Evidence-Generating Research consortium (funds and time spent on translations; translation strategies, barriers and solutions).

Site	Documents translated	Estimated amount and time spent by study staff on document translation		Strategies used for Spanish translation at site	Barriers encountered in translation and implemented solutions	
		Amount spent ($USD)	Time spent (h)		Barriers	Solutions
CHARM	• Study recruitment materials (email, postcards, text messages) • Reasons for participating • Concerns about participation • Barriers to genetic testing • Risk assessment consent • Understanding of consent • Interactive risk assessment (patient-facing literacy adapted versions of PREMM5TM, B-RSTTM 3.0 and a novel limited family history algorithm) • Web-based genetic testing education, enrollment consent and Privacy Rule Authorization • Category selection for secondary findings • Instructions for saliva collection • Site-specific survey measures • Survey emails and survey reminders • Interview recruitment materials • Letters for patients with negative results • Return of genetic test results cover letter • Family recruitment letter for eligible family members • Family consent form • Satisfaction with Interpretation • Cultural concordance • Values self-assessment • Call Test Results • Decision Aid Knowledge Questions • Understanding Utility of Results • Religiosity	3040	400	• All materials were translated by a professional certified translator with knowledge of the subject matter and extensive expertise in development bilingual materials for individuals of limited literacy • Selected portions of documents were presented to a group of native Spanish-speaking CHARM medical staff of various nationalities to ensure clarity • Selected portions of documents were presented to monolingual Spanish speakers not participating in the study to assess clarity and appropriateness of reading level, cultural coherence, clarity and comprehension of text	• Greatest barrier was insufficient funding for translation • Repeated changes to English documents by Institutional Review Board required multiple edits to Spanish documents • Limited time for getting feedback from Spanish individuals providing feedback and incorporating suggestions into materials bound for Institutional Review Board • Limited time to incorporating changes to Spanish translations to programmed web applications and programmed surveys	• An imperfect solution was to delegate proof-reading of Spanish materials to Spanish-speaking staff who had adequate, although not sufficient, Spanish literacy
KidsCanSeq	• Consent documents and forms • Patient education and communication materials • Genetic results summary letters • Educational video scripts	3720	725	• Sent to professional translation company for initial Spanish translation • Spanish-speaking staff checked translations for accuracy, made additional changes to simplify language • Sent to professional translation company for initial Spanish translation. Spanish-speaking staff reviewed translations for accuracy and edited for clarity feedback	• Some professional translations were found to be inaccurate or written at a reading level above the literacy level of the participants • Professional translations were incorrect • Professional translations were often written as a higher reading level than participants	• Spanish-speaking study staff evaluated, edited and approved all translations • Pilot tested surveys with nonstudy Spanish speakers and incorporated their feedback to improve survey wording • Spanish-speaking staff reviewed documents for accuracy Spanish-speaking staff edited translations to make sure language was understandable to participants

CHARM: Cancer Health Assessments Reaching Many; CSER: Clinical Sequencing Evidence-Generating Research; P3EGS: Program in Prenatal & Pediatric Genomic Sequencing; ROR: Return of Results; UCSF: University of California, San Francisco.

Table 2. Measures translated into Spanish by individual studies participating in the Clinical Sequencing Evidence-Generating Research consortium (funds and time spent on translations; translation strategies, barriers and solutions) (cont.).

Site	Documents translated	Estimated amount and time spent by study staff on document translation		Strategies used for Spanish translation at site	Barriers encountered in translation and implemented solutions	
		Amount spent ($USD)	Time spent (h)		Barriers	Solutions
NYCKidSeq	• Study recruitment (i.e. brochure, website, phone script) and retention (visit reminder, hard to reach and no show letters) materials • Site-specific survey measures • Consent documents • Patient education/ROR materials (GUIA tool) • History of genetic testing {Horowitz, 2016 #1421} • Expectations of genetic testing • Healthcare utilization {Hebert, 2008 #1422} • Valuation of Informal Care {Hoefman RJ, 2011 #1423} • Child's Insurance Status (2 items) {CDC, 2004 #1424} • Objective understanding of genomic testing results • Perceived understanding of genomic testing results (2 questions in addition to the one that was CSER harmonized) • Experience with GUÍA (novel ROR tool) {Lobb, 2006 #1425;Sanderson, 2016 #1426} • Use of communication tool post-ROR	None	Unknown	• All NYCKidSeq translations were done by study staff. We did not track hours spent on this task overall or per person and therefore are unable to provide any reasonable time or cost figure	• Repeated changes to English documents by Institutional Review Board	
P3EGS	• Consent documents • Study recruitment materials including brochures • Participant qualitative interview materials including study information sheets • Sample collection instructions • Participant survey email communication • New study materials including consents and Bill of Rights forms for other UCSF enrollment sites.	5,000	120		• Due to budget constraints, only pediatric consent documents were professionally translated. • Revisions made to consent forms during course of study needed to be translated to which additional funding was not available	• A bilingual research assistant (not a professional translator) translated consent forms and other study documents, including Institutional Review Board modifications to consent forms

CHARM: Cancer Health Assessments Reaching Many; CSER: Clinical Sequencing Evidence-Generating Research; P3EGS: Program in Prenatal & Pediatric Genomic Sequencing; ROR: Return of Results; UCSF: University of California, San Francisco.

CHARM and harmonized measures. Some patients are selected for qualitative interviews (conducted in English or Spanish). Eligible participants who decline genetic testing are offered a survey containing harmonized measures.

CHARM is recruiting participants at Kaiser Permanente Northwest (KPNW) and Denver Health (DH). KPNW is an integrated healthcare system serving over 600,000 members in Northwest Oregon and Southwest Washington. Members are demographically representative of the coverage area. Approximately 30% are non-White, 9% self-identify as Hispanic and nearly 10% are Medicaid recipients. DH is an integrated healthcare system that includes a network of federally qualified health centers. DH serves approximately 150,000 patients. More than 75% of DH patients are racial/ethnic minorities (56% Hispanic, 16% African American), 98% live at or below 200% of the

federal poverty level, 15% are uninsured and approximately 70% receive Medicaid or Medicare [55]. Less than 1% of KPNW patients and 21% of the DH primary care population have a documented need for Spanish interpretation. Targeted recruitment at both sites is used to enrich Spanish-speakers in the study population.

CHARM: site-specific translations

Although the CHARM study planned to enroll Spanish-speaking participants, no specific plans were developed or and the budget allocated for the translation process was limited (US$3040). One of the study co-investigators with expertise in adapting materials for populations of limited literacy (Dr Lindberg) is also a certified and experienced translator; she conducted the translation work. Prior to the Spanish translation, she led a literacy adaptation workgroup that evaluated and edited all CHARM materials for readability in English.

Budget constraints made it impossible to conduct a series of forward and back translations, so CHARM opted for a functionalist-collaborative approach. English to Spanish translations typically raise the literacy level of the text, making it more difficult to read. Our goal was to create a translation that was accurate, as easy to read or more readable than the original and culturally coherent. We created an interdisciplinary translation review team composed of three native Spanish-speaking healthcare providers and ten Spanish-speaking individuals with demographic characteristics mirroring those of anticipated study participants. This team was tasked with examining text that was more difficult or that included English colloquialisms or phrases – like 'flipping a coin' – that might involve Spanish regionalisms. Disagreements were resolved by consensus. We sought to produce a translation at a fifth grade-level, verified by the Inflesz program [56]. Because US Spanish speakers frequently use Anglicized terms (Spanglish), if Anglicisms were used in the translations, alternate Spanish terms were also included. To ensure consistency across CHARM surveys and documents, Dr Lindberg developed a lexicon on Spanish terms used in the Spanish translation of the study documents, as well as the terms used in the response options.

CHARM materials translated in this way (Table 2) included recruitment materials (e.g., postcards, brochures, emails), consent for hereditary cancer risk assessment, a hereditary cancer risk assessment tool, risk assessment results, information about genetic testing for eligible patients, consent for genetic testing and research use of information, genetic testing results letters, letters informing family members about positive genetic findings, participant survey questions unique to CHARM and qualitative interview guides.

Texas KidsCanSeq Study

The Texas KidsCanSeq Study seeks to integrate genomic sequence information into the care of childhood cancer patients with high-risk solid tumors and brain tumors. It aims to enroll pediatric cancer patients and their parents, as well as oncologists from six sites across Texas. In conjunction with Texas Children's Cancer Center and BCM's Genome Laboratory, KidsCanSeq assesses the utility of exome sequence testing compared with more targeted methods in pediatric cancer patients.

Approximately half of the population served by this study's sites is Hispanic, with the majority (80%) of patients being of Mexican origin. Approximately one third of the parents enrolled in the study are Spanish speakers, and most prefer to speak Spanish with their child's doctor. Nearly half of study families live at or below 200% of the federal poverty level. About one third of the parents in the study are uninsured. Nearly half (45%) of the study's pediatric patients are insured through Medicaid and 10% are insured by the Children's Health Insurance Plan.

Spanish-speaking participants are recruited by bilingual study staff. During enrollment, participants choose their preferred language for receiving study communications. Parents watch videos that explain the informed consent process and all aspects of the study. Parents complete surveys at three time points: at enrollment, immediately after results disclosure and 6 months after results disclosure.

Texas KidsCanSeq: site-specific translations

The Texas KidsCanSeq Study has a research assistant (AG) of Nicaraguan and Honduran descent who is bilingual in English and Spanish. She is not a trained, professional, or certified translator but has over 7 years of experience working with Spanish-speaking communities. She manages quality control for all Spanish-language surveys. Recruitment documents, consent forms and site-specific survey measures were translated by a professional company. Enrollment videos scripts were translated into Spanish by a video development team. Table 2 shows documents translated for KidsCanSeq.

Translation strategy: Following completion of translation by professional translation companies, the individual designated as site translator (AG) reviewed translated survey measures for accuracy and further simplified complex

language by consulting other Spanish-speaking study staff, and using online Spanish translation resources such as WordReference or Linguee as needed. After participants at one clinical site notified study staff that completion of surveys took up to 2 h, rather than the estimated 30 min, because of language complexity and unclear skip logic on paper surveys, the team decided to informally pilot-test the survey measures with a nonstudy Spanish-speaking population and, following review by bilingual study staff members, feedback on survey wording was incorporated to improve participant experience. Most problems were due to direct translation that did not include adaptations to increase readability.

NYCKidSeq

NYCKidSeq is a New York City-based study recruiting from two large health systems, Mount Sinai Health System and Montefiore Medical Center. The study has four broad goals: to evaluate the clinical utility and diagnostic yield of genomic testing in a diverse population; to improve the delivery of genomic information through a novel communication tool; to engage stakeholders to facilitate implementation of genomic medicine; and to utilize novel electronic health record-based resources to enhance comprehension of genomic results. NYCKidSeq will compare the diagnostic yield of whole genome sequencing with targeted gene panels for 1130 children and young adults with neurologic disorders, primary immunodeficiencies and cardiovascular disorders with suspected genetic etiologies.

NYCKidSeq focuses on pediatric patients (up to 21 years) from predominantly low-income and minority communities in Harlem and the Bronx. Household poverty in the target recruitment areas of East and Central Harlem and the Bronx, ranged from 23.5 to 28% in 2017, significantly higher than the NYC average of 17.9% [57]. Parents complete questionnaires, in English or Spanish, about themselves and their child. The study estimated that approximately two thirds of participants would be of Black/African or Hispanic ancestry, with some being Spanish-speakers who would require study materials in Spanish and Spanish-speaking staff.

NYCKidSeq: site-specific translations

Translation strategy: For NYCKidSeq materials that were translated (Table 2), six US-born bilingual staff of Latin American descent translated recruitment and retention materials (website information, brochures, hard to reach letters), informed consent forms and survey items specific to NYCKidSeq. None were professional or certified translators. All grew up in exclusively or mostly Spanish-speaking homes, completed Spanish coursework in high school or college and have worked on research projects that recruited Spanish-speaking participants of a variety of ages, countries of origin and literacy levels. All had assisted with translation and administration of study materials for prior projects. To translate patient-facing site materials, one research coordinator would translate a document, another would back-translate it and then the Program Manager (MAR), a native Spanish speaker with a degree in Spanish literature, would review it for accuracy and handle any discrepancies or questions by consulting several online Spanish translation resources such as WordReference or Linguee.

The translated site-specific survey measures and result disclosure communication tool were piloted with a group of NYCKidSeq parents to obtain their feedback, including understandability of the translated survey items and information for Spanish speakers. Their feedback was recorded and provided to MAR who discussed it with the translation team, revised survey items and communicated modifications. If relevant to the harmonized measures, changes were communicated to the harmonized measures translation group for consideration and consortium-wide adoption.

Program in Prenatal & Pediatric Genomic Sequencing

The Program in Prenatal & Pediatric Genomic Sequencing (P3EGS) study is based at the University of California, San Francisco and aims to enroll 200 prenatal and 700 pediatric families to undergo exome sequencing as duos and trios. The prenatal arm is recruiting pregnant women with fetal anomalies detected by ultrasound. The pediatric arm is enrolling patients up to age 25 who present with intellectual disability, metabolic disease, epilepsy, or multiple congenital anomalies. P3EGS is focused on evaluating the clinical utility of exome sequencings as well as addressing the ethical, social and economic issues surrounding genomic testing through consented observations and in-depth interviews. Families who decline exome sequencing are also asked to complete a brief demographic survey as well as an optional interview. Interviews are conducted in-person or over the phone in both English and Spanish.

The study is recruiting from four sites around the San Francisco Bay Area and one site in Fresno. 38% of P3EGS families live below 200% of the federal poverty level, compared with an estimated 25.5% of the Bay Area population overall [58]. 88% of pediatric participants and 9% of prenatal families are uninsured or enrolled in Medi-

Cal/Medicaid. Based on parental self-report 42.1% of P3EGS families identify as Hispanic. Approximately 24% of families utilized a Spanish-speaking medical interpreter and 28% of those asked reported Spanish as the primary language they spoke most often at home [59]. This reflects the statistics indicating that 28.9% of Californians speak Spanish at home [60] and demonstrating a clear need to provide Spanish-language study materials for the P3EGS project.

P3EGS: site-specific translations

The P3EGS study has one bilingual research assistant (BA) who is a fluent Spanish speaker of Mexican descent. She is not a certified translator but has over 5 years of experience working with Spanish-speaking communities and has completed 40 h of healthcare interpreter training. She serves as the lead team member in data collection of Spanish surveys, translating research materials and integrating the CSER harmonized survey measures into P3EGS workflows. Translation strategy: Table 2 shows materials translated for P3EGS. The designated site translator (BA) translated the P3EGS interview guides, informational sheets, brochures and integrated the CSER harmonized measures. For all materials, BA completed an initial translation, using the online translation resource SpanishDict as a reference, then a Spanish-proficient study co-investigator reviewed the materials for quality control and consolidation of differences in meaning and word choices, and BA then finalized the materials. The study consent forms were translated into Spanish by a professional company. The prenatal recruitment brochure was reviewed for quality control by additional native Spanish speakers, including a clinician and a clinical research coordinator. The pediatric recruitment brochure was tested with study participants in the pediatric clinic. BA also pretested site-specific survey measures with patients by administering the surveys and assessing their readability based on participant feedback.

Overall translation & adaptation of harmonized consortium measures

Further information about the selection process for measures harmonized across CSER sites can be found in the CSER website [61]. Preference was given to well established and psychometrically validated measures. In cases where no surveys were available, Consortium investigators (including geneticists, health economists, health service researchers and genetic counselors) developed survey measures which were then translated into Spanish.

Because the CSER consortium focused on medically underserved populations, it was important for patient-facing surveys to be accessible and consistent. While the CSER consortium intended to recruit a significant number of Spanish speakers across sites, there were no specific plans for translating the harmonized measures and no budget was allocated a priori for this work. Given her credentials, translation expertise and experience adapting materials for readability and translating materials for the CHARM study, Dr Lindberg was also tasked with the translation and adaptation of the harmonized measures (Table 1). To facilitate communication between the lead translator and the CSER steering committee as well as the various site translators, a translation coordinator (FA) was appointed. Despite the expectation that harmonized measures would be translated, the CSER Coordinating Center did not provide any specific funding for the translation work.

The linguistic adaptation of the surveys began with assessing readability, using the Flesch-Kincaid grade level formula [62] to establish a Reading Ease Score. Dr Lindberg then examined the text, modifying it as needed using plain language, familiar terms [63], concrete terms, avoiding superfluous words and using transition words [64] (e.g., providing examples, restating, contrasting, or sequencing ideas). A review of the translation work that was completed has yielded a total of approximately 180 pages of English text (~37,000 words) which would have required approximately 90–180 h of work and cost between US$8000–12,000 if done by a professional translator, excluding updates to modified text, or adaptation of text or format for individuals of limited literacy.

Considerations for the harmonized measures

Hispanic individuals of various national origins are united by a common language and by some shared cultural traditions and values. Yet, there are important regional and national linguistic differences across Spanish speakers. We aimed to produce a translation that used a neutral Spanish, without regional characteristics specific to any country. This was of paramount importance because CSER harmonized measures would be administered to Spanish speakers of diverse national origins across the country, from highly acculturated Spanish-speaking US-born Hispanic individuals, to recent immigrants from Mexico, Central and South America and Spain.

To ensure comprehension across different national origins, for Spanish terms that do not have a 'universal' equivalent, we provided several terms. To ensure the surveys were culturally accessible, texts were also modified for

sociocultural congruency. For example, if a survey of physical activity offered an example involving "*playing golf or skiing*," we substituted more culturally congruent activities, such as "*bailar o jugar fútbol*" ("*dancing or playing soccer*").

In Spanish, the second person singular formal voice ("*usted*") creates potential confusion regarding the target of the question (*you* vs *he/she*). This was of concern, particularly because some surveys were to be completed by a parent of a child participating in the study. Adding clarifying words would greatly increase survey length and participant burden. Thus, the informal voice ("*tú*") was used throughout the harmonized measures. To ensure consistency across the translation of harmonized measures, Dr Lindberg developed a lexicon on Spanish terms used in the translated documents, as well as the wording and formats used in the response options of the harmonized measures. Translated harmonized measures from the CSER Consortium are available for public use from: https://cser-consortium.org/cser-research-materials

Review & feedback by site translators

Budget and time constraints prevented multiple translations and back translations. Instead, we followed a similar approach to that used for the CHARM site. After Dr Lindberg translated the harmonized survey measures, each survey was reviewed by three native Spanish speakers (AMG, BA and MAR). Each was experienced with Spanish-speaking patients and had collaborated in the Spanish translation work of their respective CSER sites. The reviewers proofread the translation, provided feedback on wording (both in terms of readability and regional use) and helped ensure consistent terminology across surveys. Proposed edits were discussed in bi-weekly web meetings between the translator (Dr Lindberg), the three reviewers AMG, BA, MAR and the CSER translation coordinator (FA). Changes were made by consensus.

Post-translation adaptation of Spanish text

Following consensus, surveys were again reviewed by the translator and the translation coordinator to improve accessibility. There is a cultural bias associated with the use of Likert-style scales among Hispanics [65], particularly those with limited formal education, who often have difficulties understanding the graded response format [66,67]. To improve the quality of the resulting data, we modified the wording of some choices to increase clarity. For example, providing statements for each point of the Likert-style scale rather than providing statements for only the extreme anchor points. Similarly, we modified the wording of some response choices where the resulting Spanish terms presented some ambiguity. For instance, for the term "*uncertain*," one Spanish term ("*inseguro*") may denote feeling unsafe, while another ("*indeciso*") suggests capriciousness. In those cases, we opted for a more familiar term ("*I am not sure*" – "*no estoy seguro*"). Additional modifications included limiting sentence length, providing clear and concise instructions and using socioculturally appropriate examples.

Survey version control posed a repeated challenge. Multiple updates to the original English-language surveys necessitated corresponding changes to the translated versions, and many versions of the translated surveys were generated prior to reaching final consensus. Then, even after consensus was reached, additional translation work was required as minor changes to the harmonized measures were agreed upon by the wider consortium. The largest change resulted from the decision not to implement a translated survey in any site. While this may represent lost or unnecessary work, harmonizing survey data among several large research projects is a fluid process that requires iteration. Ongoing translation work is to be expected until all measures are complete.

The final harmonized Spanish language measures were posted to the CSER website for the individual consortia sites to download. In some cases, minor modifications were implemented by individual sites where staff did not feel comfortable with some wording, such as the use of the informal '*tú*' that was used in the official translation, and instead used the formal voice.

Discussion & recommendations

In translating and adapting a large volume of complex, genetic-themed material for roughly 1000 Spanish-speaking study participants across the USA, and harmonizing translated measures across diverse study sites, we encountered numerous challenges. Along with the list of documents translated by each CSER site, Table 2 presents available data from the CSER Consortium and four participating sites on budget allocated for the translation work, estimated hours spent on the translation, barriers encountered during this translation process and some solutions that were implemented to address them. In light of our experience, we recommend the following for studies with participants of limited English proficiency:

Translation work must be acknowledged, planned for & prioritized

- Translation may be the most important factor impacting recruitment and data quality. Translation work, like other core elements of a research study, should be performed only by qualified and experienced professionals;
- Studies must include in the original grant specific plans for translation of patient-facing materials, and allocate sufficient time, staff and funding to translate, pilot test and administer materials;
- Because English-language surveys on genetics tend to be written at a high reading level, and translation into Spanish generally increases reading level, we recommend that materials first be adapted for readability [68] in English, then translated, and then reviewed by experienced bilingual/bicultural study staff, experts in culturally appropriate language, and members of the target population, who then provide feedback to the translator;
- Studies, especially across consortia, must implement training and practice for the standardized administration of surveys. This will allow translators to explain to those administering the surveys the reasoning behind specific wording and format choices and allow survey administrators to provide feedback on the translations.

Carefully select the materials to be translated

- The confusing and imprecise language and inappropriate literacy level of some survey measures were major challenges. Responses can be influenced by the wording, order of items and response options. A feedback loop between scientist, survey developer, translator and cultural expert would improve data quality;
- Given the complexity of genomic information and jargon, it was difficult to balance making a translation accessible for a population of limited literacy and avoiding over-simplification of complex terms. A close partnership between translator, genetic specialists and readability experts could improve this process;
- Many Spanish-language surveys used in the United States have been validated with samples (e.g., Spanish college students) whose country of origin and literacy level differ significantly from those of most Spanish-speaking target populations in the United States. Ideally, projects should use, if available, translated measures that have been validated with populations of similar sociocultural background to the target population. Otherwise, pilot-testing validated measures with members of the target population would improve data quality.

If current trends continue, the Hispanic population in the USA is projected to grow to over 21% of the population, and the number of Spanish speakers is projected to increase to well over 50 million. This suggests that providing services in Spanish to this population will become more critical in the next decade. Particularly in healthcare, accurate and culturally sensitive translation and adaptation of communications will likely become a cornerstone of culturally competent care. This will be especially important as genomic services move into day-to-day clinical care. We hope that the next decade will bring the establishment of guidelines for accurate Spanish translations that faithfully reflect the content and tone of original materials. Standards, increased professionalism and guidelines for translations may improve understanding of health-related information and reduce disparities in the healthcare and health of Hispanic populations.

Summary points

- To reduce disparities in genomics research, we need to include historically underrepresented groups, such as Hispanic Americans.
- Six Clinical Sequencing Evidence-Generating Research (CSER) consortium sites across the USA are enrolling adults and children in genomic research focused on returning findings that may inform clinical care.
- We adapted and translated English-language study materials for Spanish-speaking study participants with low literacy. In translating and adapting materials for roughly 1000 Spanish-speakers across the USA, and harmonizing translated measures across sites, we encountered numerous challenges.
- We provide a detailed account of how we overcame challenges at each study site. We describe our process for translating site-specific materials, as well as for translating shared measures across sites.
- Our experience and the processes we used can inform future efforts to engage Spanish speakers in research.
- Recommendations:
  - Translation may be the most important factor impacting recruitment and data quality. Translation work, like other core elements of a research study, should be performed by qualified and experienced professionals;
  - Studies must include in the original grant specific plans for translation of patient-facing materials, and allocate sufficient time, staff and funding to translate, pilot test and administer materials;
  - English-language genetics surveys tend to be written at a high reading level, and translation into Spanish generally increases reading level. We recommend that materials first be adapted for readability in English,

then translated, and then reviewed by experienced bilingual study staff, experts in culturally appropriate language, and members of the target population, who provide feedback to the translator;
- Studies must standardize survey administration. This will allow translators to explain to survey administrators the reasoning behind wording and format choices and allow survey administrators to provide feedback on the translations;
- The confusing language and inappropriate literacy level of some survey measures were major challenges. A feedback loop between scientist, survey developer, translator and cultural expert would improve data quality;
- It was difficult to balance making a translation accessible for limited literacy and avoiding over-simplifying complex terms. A close partnership between translator, genetic specialists and readability experts could improve this process;
- Many Spanish-language surveys have been validated with samples that differ significantly from those of target populations. Ideally, projects should use translated measures validated with populations of similar background to the target population. Otherwise, pilot-test validated measures with the target population to improve data quality.

Author contributions

AM Guttierrez, KF Mittendorf, MA Ramos, B Anguiano and F Angelo contributed to the conceptualization of the manuscript. Conducted the translation and/or adaptation work as described in the manuscript. Individually drafted the presented work and revised it critically for content and style, and contributed to the integration of all portions of the manuscript. Provided final approval to all portions of the manuscript to be published. Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. G Joseph, contributed to the conceptualization of the manuscript. Edited the presented work and revised it critically for content and style, and contributed to the integration of all portions of the manuscript. Provided final approval to all portions of the manuscript to be published. Agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Ethical conduct of research

The translation and adaptation work described in this paper preceded subject recruitment and did not involve human subjects. However, the CSER consortium, including the Coordinating Center and all participating sites, obtained IRB approval for all aspects of the research, including final versions of produced materials.

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