CROSS-CULTURAL ADAPTATION AND VALIDATION TO SPANISH OF THE PANELVIEW INSTRUMENT TO EVALUATE THE HEALTH GUIDELINES DEVELOPMENT PROCESS

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ABSTRACT

Objective: The PANELVIEW questionnaire identifies the strengths and weaknesses of the process and methods used for developing health guidelines from the guideline development group's perspective. To expand its use, PANELVIEW ideally should be available in different languages. We aimed to cross-culturally adapt PANELVIEW into Spanish and assess its acceptability, validity, and reliability.

Study Design and Setting: To translate and culturally adapt PANELVIEW to Spanish, we followed ISPOR's Translation and Cultural Adaptation Good Practice Principles guidelines. The process consisted of 1) forward and back translation, 2) input from an expert panel, and 3) cognitive debriefing interviews. We assessed the content validity with experts in guideline development who rated instrument items for relevance to determine the item and scale content validity index (I-CVI; S-CVI). We tested the reliability with health guidelines panels from Spanish-speaking countries, and measured internal consistency (Cronbach's alpha). We examined acceptability through the number of missing responses for each item.

Results: The content comparison between the back-translation and the original version showed that most items (24/34) were conceptually equivalent but with grammatical differences. Through the cognitive interviews, we identified six items with wording issues, ten with clarity issues, and two with applicability issues. I-CVI ranged from 0.77 to 1.00, with two items needing revision. S-CVI was 0.92, showing excellent content validity. The Spanish version of PANELVIEW (PANELVIEWsp) demonstrated very good reliability (Cronbach's alpha coefficient of 0.96). Panel members responded to all items, showing good acceptability.

Conclusion: The PANELVIEWsp was conceptually equivalent to the original version and provided satisfactory evidence of acceptability, validity and reliability.

KEYWORDS: Practice guideline; Psychometric; Translations;

WHAT IS NEW?

Key findings

The PANELVIEWsp provided satisfactory evidence of acceptability, validity and reliability.

What this adds to what was known?

- This is the first study to adapt and validate the PANELVIEW instrument to be used by European and Latin American Spanish health guideline panel members. We used a rigorous cross-cultural adaptation process to ensure the understanding of the items included in PANELVIEWsp in all Spanish-speaking countries.

What is the implication, and what should change now?

The PANELVIEWsp tool can help Spanish-speaking organizations responsible for health guideline development identify potential issues during the development process. Future research should assess the reproducibility of the PANELVIEWsp.

INTRODUCTION

Health guidelines (e.g., clinical practice guidelines, public health guidelines, health policy guidelines) are the cornerstone of giving evidence-informed advice in response to clinical, public health and health policy questions(1). Health guidelines have become essential for healthcare decisions: healthcare professionals use them to inform clinical decisions, decision-makers rely on them to decide on coverage for specific interventions, and patients may use them to request treatments(2).

The most trustworthy guidelines are those that are based on the best available scientific evidence and use a transparent methodology to formulate recommendations(3, 4). The systematic and explicit development of recommendations can prevent errors, facilitate the critical appraisal of the evidence, and facilitate knowledge translation (5). Although there are several methodological manuals on how to develop trustworthy guidelines (2, 6), guideline recommendations may be affected by process failures, improper selection of the guideline panel members, conflicts of interest, and other factors(3, 4, 7).

The PANELVIEW instrument(8) allows guideline developers to assess processes, methods, and outcomes from the perspective of the different groups of members involved in health guideline development or adaptation. The information collected through PANELVIEW can help identify aspects to improve, adjust methods and procedures when necessary, and improve the quality of future guidelines.

For PANELVIEW to be used by guideline developers worldwide, it needs to be available in different languages. To our knowledge, the instrument is only available in English(8) and German(9). This study aimed to develop and validate the Spanish version of PANELVIEW to evaluate the process of developing and updating health guidelines in Spanish-speaking countries.

METHODS

Study design

This study had three phases: In the first phase, using qualitative research methods we translated PANELVIEW and culturally adapted it to Spanish-speaking countries. In the second phase, experts in guideline development assessed the instrument's content validity. Finally, using a quantitative cross-sectional design, we tested reliability and acceptability among Spanish-speaking countries' guideline panel members (GPM) (Fig. 1). The Reloncaví Health Service Ethics Committe, Chile, approved the study protocol (resolution n° 019/2022).

PANELVIEW instrument

The PANELVIEW instrument was designed to identify strengths and weaknesses of a guideline-development group's process and methods in a structured manner and highlight specific areas for improvement as identified by the participants. The tool enables the evaluation of guideline development by participating group members in its entirety or in specific phases. PANELVIEW is a self-administered instrument composed of 34 items covering 15 domains: administration, training, panel chair, conflict of interest, scoping the guideline, methodology and process, considering the evidence and contributing through expertise, formulating the recommendations, group composition, group role, group interaction, implementation and dissemination planning, writing guideline, incentive, overall satisfaction. Each question is rated on a seven-point Likert scale where 1 means 'totally disagree,' and 7 means 'totally agree.'(8).

Phase 1: Translation and Cultural Adaptation

The translation and cultural adaptation of the PANELVIEW instrument into Spanish followed the guidelines proposed by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (10). There are two variants of Spanish (European Spanish and Latin American Spanish). To increase applicability, we conducted a unique translation for both groups. To ensure clarity and understanding by native speakers of both variants, we validated the translation with panel members who were native speakers of European and Latin American Spanish.

Three independent translators conducted a forward translation of the PANELVIEW from the original language (English) to the target language (Spanish). The translators were native Spanish speakers fluent in

English and had knowledge and experience in guideline development. They were asked to maintain the conceptual equivalence of the original version rather than literal equivalence. Then, an expert panel that included translators, the project manager, and guideline development experts conducted the reconciliation process (comparing and merging more than one forward translation into a single forward translation). The group discussed discrepancies until obtaining a first version through consensus.

Two native English speakers fluent in Spanish independently translated this first Spanish version of PANELVIEW back into English. After reconciling the two versions, the expert panel evaluated the equivalence between the original version and back-translation to rate the items as A: conceptually and linguistically equivalent to the original item; B: conceptually equivalent, but with grammatical differences; or C: conceptual equivalence is not obvious. Subsequently, the expert panel met to discuss the discrepancies in equivalence (categories B and C) and find an equivalent version in Spanish. The lead researcher of the original scale evaluated the report on the equivalence between the original and back-translated versions.

Finally, to assess difficulties in understanding the first Spanish version, we conducted cognitive interviews with seven GPMs using the verbal probing technique (10). We included GPM who had participated in guidelines development recently (less than 1 year), regardless of their profession, academic degree, or role on the panel (clinical expert, methodologist, patient representative, etc.). To ensure including people from countries with local variations of the Spanish language, we used a purposive sample. We asked GPMs to complete the questionnaire independently before the interview, and then we conducted interviews via Zoom™ using an interview script. (Supplement 1).

We conducted content analysis through triangulation among interviewers and the principal investigator. We used the constant comparison method, coding each unit of analysis to classify the codes into the following categories: 1) no problems with the item; 2) wording issues: the text is confusing or redundant; 3) clarity issues: lack of understanding regarding what aspect of the guideline is being measured or the perspective from which the item should be answered; and 4) applicability issues: situations for which the item would not be appropriate. Items with wording or clarity issues were reworded, while items with applicability issues were divided or deleted.

Phase 2: Validity assessment

We assessed the content validity through the content validity index (CVI) (11). We asked 13 experts in health guideline development from Spanish-speaking countries who had training in clinical epidemiology to rate instrument items regarding their relevance. The experts rated each item of PANELVIEW using a 4-point scale wherein: 1=not relevant, 2=somewhat relevant, 3=quite relevant, and 4=highly relevant. They also provided reasons for rating an item as not relevant or somewhat relevant. We calculated the item content validity index (I-CVI) by the proportion of experts rating each item as 3 or 4. We considered I-CVI > 0.79 as relevant; if the I-CVI was between 0.70 and 0.79, we reworded the item, and if the value was below 0.70, we eliminated (12). The scale-level-CVI (S-CVI) for the entire tool was also computed by averaging I-CVIs across items. We considered 0.9 as the lowest acceptable S-CVI (13).

In addition, the experts used a 3-point Likert scale to evaluate each item for clarity (wording) where 1= not clear, 2 = item needs some revision, and 3 = very clear. We also calculated the I-CVI for clarity using the proportion of experts rating each item as 2 or 3.

Experts provided feedback on the relevance and clarity of the instructions and items and were contacted when some clarification was required. Experts' feedback was coded into the same categories as cognitive interviews: 1) no problem with the item, 2) wording issues, 3) clarity issues, and 4) applicability issues. We used the QuestionPro platform (www.questionpro.com) for validity assessment.

Phase 3: Reliability and Acceptability Assessment

We tested the translated PANELVIEW on ten clinical practice guidelines panels from Spanish-speaking countries. We included GPMs who had participated in health guideline development less than 1 year ago. GPM anonymously completed the PANELVIEW questionnaire through the QuestionPro platform (www.questionpro.com).

We performed a descriptive analysis to examine the distribution of the translated PANELVIEW scores. We calculated mean, standard deviations, score range, floor and ceiling effects (percentage of GPM with minimum and maximum theoretical scores, respectively). We also registered information about the characteristics of the GPM and the time required to answer the questionnaire.

We assessed reliability through internal consistency using McDonald's omega coefficient. McDonald's omega coefficient >0.70 is considered acceptable, 0.71-0.80 respectable, and >0.80 very good (14).

We examined the acceptability of the translated PANELVIEW by calculating the percentage of GPM who did not respond to some items (15). We analyze the data using Stata 18 [Stata Corp, College Station, TX, USA].

RESULTS

Translation and Cultural Adaptation

Forward translation

During the reconciliation of the three forward translations, the main issue was clarifying the meaning of some words. For example, we replaced the term "guideline group members" (*miembros del grupo de la guía*) with "guideline development group members"(*miembros del grupo elaborador de la guía)*, and "final panel meeting"(*reunión final del panel*) with "meetings to formulate recommendations"(*reuniones de formulación de las recomendaciones).* In addition, the items in the English version used the words "appropriate"(*apropiado*) and "adequate"(*adecuado*) interchangeably, but to be consistent throughout the questionnaire, we only used the translation of the word "adequate" in the Spanish version. We validated these modifications with the lead researcher of the original version of PANELVIEW to ensure that the meaning of the items did not change.

Back translation

In the content comparison between the back-translation and the original version, the expert panel did not rate any item as C (equivalence is not obvious), and rated 24 of 34 items as B (conceptually equivalent, but with grammatical differences). The items rated as B included the modifications made in the forward translation. When reviewing the back-translation report, the lead researcher of the original PANELVIEW instrument did not identify any lack of equivalence between the original and the back-translated versions (Supplement 2).

Cognitive interviews

We conducted cognitive interviews in a convenience sample with seven GPM from Argentina, Bolivia, Cuba, Chile, Panama, Peru, and Spain. Supplement 3 shows the characteristics of the sample.

Regarding the global evaluation, the GPM thought the instrument collected the intended information. However, they highlighted that the instructions were insufficient for adequately understanding the questionnaire's aim and answering it appropriately. As a result, we modified the instructions, provided details on how to answer them, and added meaning to some concepts used. In addition, they reported that some items were written in first person and others in third person, which was confusing. Thus, we reworded items 32 and

33 to be in the third person. Furthermore, the GPM did not make observations about response options. In addition, the GPM did not report understanding issues related to different variants of Spanish.

Regarding the domains, GPM identified only two clarity issues that were corrected. For domain 3, the concept of "*panel chair"(presidente del panel)* was not understood; they suggested changing it to "*guideline coordinato*r"(*coordinador de la guía*), which has a leadership rather than an administrative connotation among guideline developers in Spanish-speaking countries. To be consistent with the order in which they happen, GPMs also suggested modifying the order of the terms in domain 12, "Implementation and dissemination planning", and having "dissemination" appear first.

Regarding the items, GPMs identified wording issues in six items, clarity issues in ten items and applicability issues in two items. The main issues with the clarity were that GPM did not understand what some terms were referring to. As a result, we modified the wording of the items to improve the understanding.

The main applicability issue was that it was unclear what an appropriate panel size refers to since what is relevant is its representativeness; therefore, we clarified the concept of appropriate panel size. When considering item 30 "*Appropriate consideration was given for the planning of dissemination and implementation of the guideline*," interviewees highlighted that dissemination and implementation are two different processes and should be considered separately. This was taken into consideration for the content validity stage.

Most wording issues in the items were caused by words that are not commonly used in the formal Spanish language. Supplement 4 provides details about the issues identified with each item.

Finally, there were no reported issues related to the understanding of different variants of Spanish.

Content Validity

We included 13 experts in developing health guidelines from Argentina (n=3), Chile (n=4), Spain (n=5), and the United States (n=1). Ten had an MSc or Ph.D. degree, and all worked as methodologists (61.5%) or academics (38.5%). Ten had participated in at least five guidelines (Supplement 5).

Table 1 shows I-CVIs for relevance and clarity of each item. Most items were considered relevant, except *"The contributions of the guideline group members were valued, and appropriate credit was given"* and

"Appropriate consideration was given for the planning of dissemination and implementation of the guideline," which needed revision and were reworded. The S-CVI was 0.92 showing excellent content validity.

The experts identified three items with minor wording issues, five with clarity issues, and one with applicability issues. The clarity issues were related to the meaning of some words or clarification of the stage of the process that is being evaluated. In addition, following the suggestion of the expert, we changed the name of the domain "incentive" to "motivation" due to the economic connotation for the Spanish language that the former has.

Concerning applicability, the experts considered that because dissemination and implementation must be evaluated separately, item 30, "*Appropriate consideration was given for the planning of dissemination and implementation of the guideline,"* should be converted into two items. Therefore, the final Spanish version of PANELVIEW (PANELVIEWsp) included 35 items (Supplement 6.)

Reliability and Acceptability

We administered PANELVIEWsp in ten guidelines panels, which had a total of 120 GPM. The response rate was 41.7%, with a final sample of 50 GPM. Supplement 7 shows the characteristics of the participants.

Table 2 shows distribution statistics and Cronbach's alpha coefficient of PANELVIEW. GPMs completed all items of PANELVIEWsp, showing good acceptability. PANELVIEWsp mean score was 6.29 (SD 0.59) (range 1-7, higher scores, better perception of the guideline process), with a mean score across guidelines panels ranging from 5.8 to 6.5 (p=0.477) (Table 3). The average completion time was 10.7 (SD 5.3) minutes. No floor effect was observed, but a ceiling effect was observed (4.0%).

The Omega coefficient was 0.97, showing a very good correlation across items. Omega coefficient ranged from 0.91 to 0.99 across the different guidelines' panels (Table 3). The inter-item average for the scale was 0.41, which means there are no redundant items.

DISCUSSION

To develop the PANELVIEWsp, we used a standard cross-cultural adaptation process that included forward and back translation, input from an expert panel, and cognitive debriefing interviews.

Although some items were reworded or separated, the results are consistent with those obtained for the original version and suggest that the Spanish version is conceptually and metrically equivalent since it demonstrated good acceptability, high reliability, and good content validity.

Clarifying the meaning of some words was the main challenge during translation and cultural adaptation. The expert panel committee reviewed the consolidated version and proposed synonyms to ensure a conceptually equivalent translation. For this reason, as international cross-cultural adaptation guidelines recommend, we carefully selected Spanish-speaker experts with extensive experience in guideline development (10, 16). Goossen et al. reported the same difficulty during the translation process of the German version of PANELVIEW(9).

S-CVI was over the lower acceptable of 0.9, which means that PANELVIEWsp measures all factors related to the assessed construct. Experts confirmed this since all items presented an I-CVI over 0.7, which proves that all items are relevant and necessary to assess the construct(13).

No data were missing in the PANELVIEWsp, suggesting that the items making up the scale were well understood and acceptable for the GPM. This means assistance is unnecessary to self-complete the questionnaire, and the instructions and items are clear(17).

Although the PANELVIEWsp has one more item, the instrument's burden is similar to the original version (11 vs 12 min). This point is relevant since a low respondent burden facilitates its applicability and compliance(18).

PANELVIEWsp did not show a floor effect but a slightly higher ceiling effect (4.0%). However, both values were less than 15%, reflecting good content coverage(19). Conversely, most domains showed a higher ceiling effect, indicating limited content validity and reliability. That higher ceiling effect is likely due to a lack of items in some domains (19), as we can observe in one-item domains such as training and group interaction domains (ceiling effect 66% and 84%, respectively).

The reliability of the PANELVIEWsp, assessed by Omega coefficient was very good, as was the reliability reported for the original tool(8).

The instrument could not discriminate between health guidelines, probably because the different guidelines used similar methods in their development. Our results agree with the original version, which reported a low overall reliability coefficient of 0.35 to discriminate between groups. They also attributed it to the guidelines surveyed, used similar methods and involved experienced group chairs(8).

Strength and Limitations

Among our main strengths is that we rigorously followed a structured approach to validate and culturally adapt PANELVIEW, and we tested it in diverse Spanish-speaking cultures. In addition, we tested content validity with recognized experts in health guideline development from diverse Spanish-speaking countries, which provided relevant insight for improving the tool.

A potential limitation was the small sample size used to evaluate the reliability. However, the Omega coefficient showed an excellent internal consistency despite this small sample size.

Another potential limitation was the homogeneity of the sample studied to assess reliability. All guidelines included were developed by government agencies with a large amount of resources and vast experience in guideline development together with consolidated method groups. In addition, all guidelines used similar methods in the development process and used the GRADE approach for assessing the quality of evidence and the strength of recommendations. This could explain the high mean score across guidelines.

Implications for Practice and Research

The PANELVIEWsp tool can help Spanish-speaking organizations responsible for guideline development identify potential issues during the development process. This allows adjustment procedures and improves the quality of future guidelines. For this reason, we recommend using the PANELVIEWsp in guideline development.

Future research should assess the reproducibility of the PANELVIEWsp. In addition, it should be tested in guidelines that use other methodologies, technical skills, and experience levels.

CONCLUSIONS

We conclude that PANELVIEWsp is conceptually equivalent to the original version and provides satisfactory evidence of content validity, reliability, and acceptability to be used by Spanish-speaker organizations responsible for guideline development. The PANELVIEW can be found at https://macgrade.mcmaster.ca/resources/panelview/.

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AUTHOR'S CONTRIBUTION

Conceptualization: CZ, RBP; Methodology: CZ, RBP, DLS; Formal analysis: CZ, GB; Investigation: CZ, GBS, MJO, PB, WW, IEI, GB, TS, IN, HS; Writing - original draft preparation: CZ, RBP; Writing - review and editing: GBS, MJO, PB, WW, IEI, GB, TS, IN, HJS, DLS; Supervision: RBP.

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ETHICAL APPROVAL

The study protocol was approved by the Reloncaví Health Service Ethics Committee, Chile, with resolution number 019/2022.

INFORMED CONSENT

Informed consent from all participants was obtained to consider their participation in the study.

DATA AVAILABILITY

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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FIGURE LEGEND

Fig. 1: Flow diagram of cross-cultural adaptation and validation process

TABLES

Table 1: Content validity index results

Item	I-CVI (Relevancy)	Interpretation	I-CVI (Clarity)	Interpretation
Q1	1.00	Relevant	0.92	Clear
Q2	0.85	Relevant	1.00	Clear
Q3	1.00	Relevant	1.00	Clear
Q4	1.00	Relevant	0.92	Clear
Q5	1.00	Relevant	1.00	Clear
Q6	1.00	Relevant	0.92	Clear
Q7	1.00	Relevant	1.00	Clear
Q8	1.00	Relevant	1.00	Clear
Q9	1.00	Relevant	0.92	Clear
Q10	1.00	Relevant	1.00	Clear
Q11	1.00	Relevant	1.00	Clear
Q12	1.00	Relevant	0.84	Clear
Q13	1.00	Relevant	1.00	Clear
Q14	1.00	Relevant	1.00	Clear
Q15	1.00	Relevant	1.00	Clear
Q16	1.00	Relevant	0.77	Need revision
Q17	1.00	Relevant	1.00	Clear
Q18	1.00	Relevant	1.00	Clear
Q18	1.00	Relevant	1.00	Clear
Q20	1.00	Relevant	1.00	Clear
Q21	1.00	Relevant	1.00	Clear
Q22	0.92	Relevant	0.92	Clear
Q23	0.85	Relevant	1.00	Clear
Q24	1.00	Relevant	1.00	Clear
Q25	1.00	Relevant	1.00	Clear
Q26	1.00	Relevant	1.00	Clear
Q27	0.77	Need revision	1.00	Clear
Q28	1.00	Relevant	1.00	Clear
Q29	0.92	Relevant	1.00	Clear
Q30	1.00	Relevant	0.92	Clear
Q31	0.92	Relevant	1.00	Clear
Q32	0.77	Need revision	0.77	Need revision
Q33	1.00	Relevant	1.00	Clear
Q34	1.00	Relevant	0.84	Clear

Table 2: Distribution and reliability of the PANELVIEW score and its domains

Scale	Number of items	Observed range	Median [IQR]	Mean [SD]	Percent floor [%]	Percent ceiling [%]	Interitem correlation
PANELVIEW total score	35	4.2 – 7	6.4 [0.8]	6.3 [0.6]	0.0	4.0	0.41
Administration	5	4 -7	6.7 [0.8]	6.4 [0.7]	0.0	30.0	0.52
Training	1	5 -7	7 [1]	6.6 [0.7]	0.0	66.0	NA
Panel chair	2	4 - 7	7 [0.5]	6.6 [0.6]	0.0	62.0	0.71
Conflict of interest	2	3.5 - 7	6.5 [1]	6.3 [0.8]	0.0	42.0	0.68
Scoping the guideline	2	3 – 7	6.5 [1]	6.3 [0.8]	0.0	42.0	0.57
Methodology and process	2	4 -7	6.5 [0.7]	6.4 [0.7]	0.0	44.0	0.59
Considering the evidence and contributing through expertise	4	3.75 – 7	6 [1.25]	5.9 [0.9]	0.0	12.0	0.37
Formulating the recommendations	5	3.8 – 7	6.6 [1]	6.4 [0.6]	0.0	28.0	0.59
Group composition	2	4 -7	6.5 [1.5]	6.3 [0.8]	0.0	42.0	0.21
Group roles	2	4.5 – 7	6.3 [1]	6.3 [0.7]	0.0	38.0	0.60
Group interaction	1	6 -7	7 [0]	6.8 [0.4]	0.0	84.0	NA
Implementation and dissemination planning	3	1.7 – 7	6 [2]	5.6 [1.4]	0.0	16.0	0.74
Writing guideline	1	4 -7	7 [1]	6.3 [0.9]	0.0	53.1	NA
Incentive	1	3 -7	6 [1]	6.1 [1.0]	0.0	38.0	NA
Overall satisfaction	2	5 - 7	7 [0.5]	6.6 [0.5]	0.0	52.0	0.41

Table 3: Distribution and reliability of the PANELVIEW across guideline panels

Guideline	Observed range	Median [IQR]	Mean [SD]	Interitem correlation	Omega coefficient
1	5.86 – 6.91	6.49 [0.60]	6.41 [0.43]	0.23	0.94
2	5.57 – 6.40	6.37 [0.66]	6.09 [0.41]	0.26	0.95
3	5.74 – 6.94	6.71 [0.69]	6.50 [0.51]	0.35	0.94
4	6.03 – 6.74	6.74 [0.71]	6.51 [0.41]	0.42	0.96
5	5.11 – 6.69	5.84 [1.26]	5.87 [0.75]	0.69	0.94
6	5.46 – 6.94	6.44 [1.23]	6.29 [0.69]	0.46	0.96
7	5.63 – 6.41	5.8 [0.63]	6.00 [0.37]	0.17	0.91
8	6.29 – 6.76	6.38 [0.48]	6.48 [0.25]	0.24	0.96
9	5.58 – 7.00	6.66 [0.77]	6.51 [0.49]	0.23	0.96
10	4.20 – 6.86	6.47 [2.66]	5.84 [1.44]	0.88	0.99