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Validation of the Spanish version of the 9-item Shared Decision-Making Questionnaire

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Abstract

Objective To translate and assess the psychometric properties of the 9-item Shared Decision-Making Questionnaire (SDM-Q-9) for measuring patients' perceptions of how clinicians' performance fits the SDM process.

Design Cross-sectional study.

Setting and Participants Data were collected in primary care health centres. Patients suffering from chronic diseases and facing a medical decision were included in the study.

Measurements The original German SDM-Q-9 was translated to Spanish using the process of cross-cultural adaptation of self-reported measures as the methodological model for Spanish translation. Reliability (internal consistency) and construct validity [exploratory (EFA) and confirmatory factor analysis (CFA)] were assessed.

Results The final Spanish version of the SDM-Q-9 was tested in a primary care sample of 540 patients. The SDM-Q-9 presented adequate reliability and acceptable validity. Internal consistency yielded a Cronbach's alpha of 0.885 for the whole scale. EFA showed a two-factorial solution, and for the CFA, the best solution was obtained with a one-dimensional factor with the item 1 excluded, which produced the best indexes of fit.

Discussion and Conclusions The Spanish version of the SDM-Q-9 showed adequate reliability and acceptable validity parameters among primary care patients. The SDM-Q-9 is suitable for use in Spain and other Spanish-speaking countries with similarly organized health-care systems. The use of the SDM-Q-9 may contribute to the evaluation of SDM process from the patient's perspective.

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Introduction

Over the last few decades, there has been an increasing emphasis on patient participation in clinical decision making, with the new role of the patient as an active agent, manager and producer of his or her own health, and the paradigm of patient-centred care. The involvement of patients is a new way of understanding the relationship between patients, health professionals and health-care systems, and one way to address this is by involving patients in a shared decision-making (SDM) process[1].

Shared decision making is an interactive process of clinical decision making that ensures that both patient and physician are equally and actively involved and share information to reach an agreement, for which they are jointly responsible[2]. The last years have seen a clear move towards SDM and increased patient involvement in many countries. At present time, the Spanish National Health System recognizes the importance of considering patients' values and preferences in clinical decisions with patient participation in SDM gaining importance as a suitable approach to patient–health professional communication and decision making in Spain[3]. However, not all patients are prepared or want to participate to the same degree in the process of making decisions about the treatment of their disease. Achieving SDM in clinical practice depends on the willingness of both patients and health-care professionals to engage in it, the skills to do it, decision aids or reliable information to facilitate the process and wider support from the health-care organization[4].

We have observed a positive attitude towards SDM both in professionals and among patients[5–7], but further studies were needed to address the extent to which this apparently accepted model is reflected in the daily practice of health professionals.

Appraisal of efficacy of SDM closely depends on the quality of measurement methods. According to recent reviews of the literature[8–11], different instruments are available to assess different aspects of SDM, but only few have been evaluated formally for reliability, validity and responsiveness. Even though a great number of translations have been made into several languages, no Spanish short scale for assessing the patient's perception of clinician facilitation of the SDM process is available.

In Spain, the importance of patient participation in health-care decisions has achieved growing recognition in the National Health System. In particular, some health technology assessment units in Spain have been reviewing the methods to develop patient decision aids (PtDAs) and producing some PtDAs themselves[7]. As these intervention strategies need adequate measures to evaluate their effectiveness and for the purpose of fully capturing process and effects of SDM, both the views of physicians and patients robust measures are needed to enable comparisons and conclusions[8–11].

The 9-item Shared Decision-Making Questionnaire (SDM-Q-9)[12] is a brief and easy-to-administer patient-report instrument for measuring SDM process in clinical encounters and a theory-driven instrument for assessing the process of SDM from the patient's perspective[11], which considers the Elwyn's model of competences for involving patients[13], theories from general psychology[14] and decision analysis, which can also be found in the Ottawa Decision Support Framework[15]. The psychometric properties of the scale have been examined both in primary and in secondary outpatient care samples. The SDM-Q-9 has shown good acceptability, reliability and validity as indicated by good response rates (≥80%), high internal consistency (Cronbach's alpha > 0.9) and high item discriminations, as well as high face and factorial validity. Factor analyses have revealed that the scale has a one-dimensional structure. The SDM-Q-9 can be used in studies assessing the effectiveness of interventions aimed at the implementation of SDM and as a quality indicator in health services assessments[12,16–18].

The aim of the present study was to assess the psychometric properties of a Spanish version of the SDM-Q-9 and to test the reliability and factorial validity of this brief instrument to measure the process of SDM in clinical encounters from the patient's perspective.

Methods

Instrument

The nine-item Shared Decision-Making Questionnaire is a brief tool that assesses the patient's view of the decision-making process in a consultation (Table 1) [12]. The questionnaire consists of nine items each describing one step of the SDM process[19]. The questionnaire was developed to show the extent to which patients feel they were involved in the process through nine items scoring from 0 to 5 on a 6-point Likert scale.

Questionnaire translation

We used the guidelines described for Beaton *et al.*[20] for the process of cross-cultural adaptation of self-reported measures as the methodological model for Spanish translation. In this model, five distinct steps were followed by the researchers. In the first step, translation, two independent bilingual translators, competent in both German and Spanish, translated the original questionnaire from German into Spanish. In the second step, translators reached consensus on the translation of words, phrases and items based on the synthesis of the translations, working from the original questionnaire as well as the first translator's and the second translator's versions.

The third step was cultural appropriateness and content validity testing, which was performed by five independent primary care physicians, psychiatrists and psychologists. They rated degree that each item of the instrument covers the content that it is supposed to measure as an index for representativeness and content validity. They also rated understandability and translation equivalence (semantic and content equivalence) between German and Spanish version.

In the fourth step, the revised Spanish version was back-translated by another two bilingual translators who were blind to the original German version. This step assured that the meaning of Spanish version was reflected in the back-translation version.

The final step was equivalence testing. In this step, the original authors (IS, MH) were asked to review and compare the original version in German and the back-translated version in German of the SDM-Q-9. Following this step, the back-translation was compared with original questionnaire by the study directors from Spain (DC, LP, AR), and after some minor revisions, the Spanish version was ready to use (Table 2). After this translation process, the final version was pre-tested with the first twelve adult patients attended at the two primary care health centres who were invited to participate in this study. Their responses were analysed to identify necessary modifications; however, it was not necessary to make any modification after this pre-test.

Study sample and procedure

Along August 2012, 795 consecutive adult patients (older than 18 years of age) attended at two primary care health centres (one urban and one suburban) in Tenerife (Canary Islands, Spain) were invited to participate in the study. Each participant received a written full explanation of the study, after which they signed an informed consent document approved by the local ethics committee. Each patient completed immediately after her/his clinical consultation with their general practitioner, and not in the presence of the treating health professional, an anonymous questionnaire that included the patient's socio-demographic variables (sex, age and educational level), clinical variables (appointment type, self-reported diagnosis and treatment decision), health professional variables (doctor, sex and age) and the '9-Item Shared Decision-Making Questionnaire'

Table 1 Items and contents of the SDM-Q-9, response distribution, means, standard deviations and corrected item-total correlations (n = 540)

Items and contents of the SDM-Q-9[12,14]	Completely disagree (%)	Strongly disagree (%)	Somewhat disagree (%)	Somewhat agree (%)	Strongly agree (%)	Completely agree (%)	Mean (SD)	Corrected item-total correlation
1. My doctor made clear that a decision needs to be made (*recognizing that a decision needs to be made*)	3	5.9	9.4	19.1	28.7	33.9	3.66 (1.34)	0.272**
2. My doctor wanted to know exactly how I want to be involved in making the decision (*asking for preferred involvement in decision making*)	9.8	8.1	13.5	22.6	25.7	20.2	3.07 (1.55)	0.594**
3. My doctor told me that there are different options for treating my medical condition (*informing that different options are available*)	5.4	5.9	9.4	18.9	27.6	32.8	3.56 (1.45)	0.682**
4. My doctor precisely explained the advantages and disadvantages of the treatment options (*explaining on the options' advantages and disadvantages*)	5.4	5	9.4	18.5	28.1	33.5	3.60 (1.43)	0.634**
5. My doctor helped me understand the information (*helping to understand the information*)	1.9	2.2	4.6	10.4	22.8	58.1	4.24 (1.14)	0.516**
6. My doctor asked me which treatment option I prefer (*asking for preferred option*)	10.7	9.3	14.8	16.9	23.7	24.6	3.07 (1.65)	0.754**

Table 1. Continued

Items and contents of the SDM-Q-9[12,14]	Completely disagree (%)	Strongly disagree (%)	Somewhat disagree (%)	Somewhat agree (%)	Strongly agree (%)	Completely agree (%)	Mean (SD)	Corrected item-total correlation
7. My doctor and I thoroughly weighed the different treatment options (*weighing the options*)	8.5	9.1	14.6	21.5	24.8	21.5	3.09 (1.54)	0.820**
8. My doctor and I selected a treatment option together (*selecting an option*)	19.6	9.8	12	17.2	20.7	20.6	2.71 (1.80)	0.744**
9. My doctor and I reached an agreement on how to proceed (*agreeing on how to proceed*)	11.3	6.1	9.4	14.3	25.6	33.3	3.37 (1.68)	0.685**

**$P < 0.001$.

(SDM-Q-9). To rate the SDM-Q-9, participants were instructed to think about their last consultation and to use this consultation as a reference for the rating. Questionnaires were self-administered in all cases. Patients did not receive any financial compensation for participating.

We considered two appointment types as follows: *Follow-up scheduled appointments* that correspond to patients who have any medical condition that should be scheduled for planned follow-up visits at periodic interval to assess their condition control and modify treatment if needed and included prescription refills; and *non-scheduled consultations* that involve patients seeking non-scheduled medical care in situations they perceive as a medical emergency, but many times may not be a true emergency.

Treatment decisions options were categorized as follows: prescription of a *new treatment*, *maintenance* of the previous treatment and *modification* of the previous treatment by increasing or decreasing dosages of the drug treatment.

The study was carried out in accordance with the Code of Ethics of the Declaration of Helsinki, and all procedures and consent forms were reviewed and approved by the Ethics Committee of the University Hospital Nuestra Señora de la Candelaria (Spain).

Data analysis

Demographic information for non-participants was collected. Age means and sex distributions were compared between participants and non-participants using t-test and χ^2 test, respectively. Item analysis included the observation of the ceiling effect obtained (percentage of patients scoring on the category '*completely agree*' for each item), the corrected item-total correlations, and item means and standard deviations. Internal consistency of the scale was assessed with Cronbach's alpha. These analyses were performed for the whole sample and also by demographic (gender, age and education), appointment type (follow-up scheduled appointments and non-scheduled consultation) and treatment (new

Table 2 The Spanish version of the 9-item Shared Decision-Making Questionnaire (SDM-Q-9)

¿Por qué motivo acudió a su médico (*p. ej. con qué síntomas, diagnóstico, problema de salud*)?						
¿Qué decisión se tomó (*p. ej. iniciar un tratamiento nuevo, seguir con el tratamiento previo, cambiar a otro tratamiento, finalizar el tratamiento*)						
Las siguientes afirmaciones están relacionadas con la experiencia que ha tenido en la consulta con su médico. Por favor, marque con una cruz su nivel de acuerdo o desacuerdo con estas afirmaciones						
	Totalmente en desacuerdo	Muy en desacuerdo	Algo en desacuerdo	Algo de acuerdo	Muy de acuerdo	Totalmente de acuerdo
1. Mi médico me dijo expresamente que debía tomarse una decisión						
2. Mi médico quería saber exactamente cómo me gustaría participar en la toma de decisiones						
3. Mi médico me informó de que existen distintas opciones de tratamiento para mi problema de salud						
4. Mi médico me explicó con exactitud las ventajas y desventajas de las distintas opciones de tratamiento						
5. Mi médico me ayudó a entender toda la información						
6. Mi médico me preguntó qué opción de tratamiento prefiero						
7. Mi médico y yo valoramos con detenimiento las distintas opciones de tratamiento						
8. Mi médico y yo elegimos juntos una opción de tratamiento						
9. Mi médico y yo llegamos a un acuerdo sobre el modo de proceder						

prescription, maintenance of previous treatment and modification of previous treatment) subgroups.

Factor analysis is a statistical method used to describe variability among observed and correlated variables in terms of a potentially lower number of unobserved variables called factors. The theoretical framework from which the SDM-Q-9 has been developed conceptualizes the perception of SDM as a latent construct (a psychological experience of involvement) that can be measured by some indicators (i.e. the items of the scale). Therefore, factor analysis techniques were used to assess the scale's dimensionality. First, the sample was randomly split into two groups. A principal components analysis (PCA) with oblimin rotation was performed in the first split-half sample, extracting components with eigenvalues >1. Adjustment of the structure obtained was then tested with a confirmatory factor analysis (CFA). Maximum likelihood with robust correction was used to avoid distributional problems in the data set. A range of global goodness of fit indices was used to assess the degree to which observed data were accounted for by the proposed models: comparative fit indexes (CFI), goodness of fit index (GFI), root mean square error of approximation (RMSEA) and standardized root mean square residual (SRMR). According to Hu and Bentler[21], the following criteria were used to indicate the fit of the CFA models to the data:

CFI and GFI > 0.90, and RMSEA and SRMR < 0.08. These fit statistics and the chi-square were selected because of previous research that demonstrated their performance and stability[21,22]. CFA was performed with EQS software for Windows version 6.1[23], whereas for the remaining analyses, SPSS version 12 was used.

Finally, *t*-test and Pearson correlations were used to assess the relationship between total scores in the scale and patients and physicians' gender and age, respectively. A one-way analysis of variance (ANOVA) was performed to assess differences between the types of treatment decisions on the SDM-Q-9.

Results

Sample characteristics

Seven hundred and ninety-five patients were invited to participate and 540 (67.9%) accepted. Non-participants were significantly older than participants (47.6 ± 15.8 vs. 44.7 ± 16.4, respectively; $t = 2.32$, $P = 0.02$) and included more men (40% vs. 29.8%; $\chi^2 = 7.66$, $P = 0.006$). Among participants, age ranged between 18 and 87, 11.9% had no formal education, 40.9% had completed primary education, 33.7% had completed secondary education, and 13.5% had a university degree.

Descriptive analyses of the SDM-Q-9 items and reliability analysis

Table 1 shows responses distribution, means, standard deviations and the corrected item-total correlation for each item. Item 5 shows a ceiling effect (58.1%), with a percentage range of 20.2–33.9 for the other eight items. Items means ranged from 2.71 (item 8) to 4.24 (item 5), although the majority of them obtained scores between 3 and 3.6 (between '*somewhat agree*' and '*strongly agree*'). Item 1 obtained a low corrected item-total correlation ($r = 0.27$), and the remaining showed values that ranged between 0.52 and 0.82. Cronbach's alpha for the whole scale was 0.885.

Table 3 shows these psychometric properties by demographic and treatment subgroups. Results in subgroups are comparable to results in the total sample, with item 5 showing a ceiling effect and item 1 obtaining the lowest item-total correlations. However, a slightly different pattern can be observed for younger participants and those with a higher educational level, who show lower mean item scores.

Factor structure

To assess the factor structure of the scale, sample was randomly split into two groups. PCA was performed on the first split-half sample. The Kaiser–Meyer–Olkin value was 0.821, and the Barlett sphericity test was statistically significant ($\chi^2 = 1289.7$, df = 36, <0.001) indicating that a factor analysis of the data was appropriate. PCA yielded two components with eigenvalues >1. Table 4 shows this two-factorial solution. Before oblimin rotation, the two components explain 51.1% and 12.5% of the variance, respectively. Items 3–9 loaded above 0.5 on the first component, whereas items 1 and 2 showed their highest loadings on the second component. Item 1 obtained a factor loading of 0.92, so this component was almost exclusively represented by this item.

A CFA was performed in the second split-half sample (Table 5). Considering that the original scale showed a unidimensional structure[12] and the results obtained in the PCA, three different models were tested: the original one-factor model, representing the nine items (Model 1); the structure obtained with PCA in the current sample, composed by two factors (Model 2); and a monofactorial structure but excluding item 1 (Model 3). The best solution was obtained with the one-factor structure with the item 1 excluded (Model 3), and it produced the best indexes of fit (CFI and GFI).

Association with patient and practitioner characteristics

Scores on the total scale were not related to patient gender, but they were significantly asso-

Table 3 Ceiling effect, means, standard deviations and corrected item-total correlations, by socio-demographic and treatment subgroups (n = 540)

	n	Ceiling effect (% completely agree) range	Corrected item-total correlation range	Mean range	Internal consistency (Cronbach's alpha)
Gender					
Female	379	20.1–57.5	0.314–0.841	2.74–4.24	0.89
Male	161	19.3–59.6	0.175–0.779	2.65–4.25	0.872
Age					
18–40	225	16.0–52.0	0.353–0.795	2.45–4.07	0.89
41–60	213	22.5–60.6	0.180–0.805	3.08–4.35	0.876
>60	102	20.6–66.7	0.176–0.887	2.54–4.41	0.87
Education					
No formal education	64	17.2–64.1	0.177–0.867	2.30–4.39	0.862
Primary studies	221	22.2–62.0	0.270–0.839	3.07–4.35	0.891
Secondary studies	182	15.9–56.0	0.303–0.785	2.62–4.20	0.873
University degree	73	13.7–46.6	0.311–0.801	2.25–3.90	0.902
Follow-up scheduled appointment	269	20.1–58.4	0.308–0.835	2.88–4.26	0.886
Non-scheduled consultation	271	19.2–57.9	0.244–0.803	2.55–4.23	0.822
New prescription	319	17.6–55.2	0.281–0.798	2.64–4.18	0.882
Maintenance previous	187	17.6–61.5	0.250–0.847	2.78–4.32	0.888
Modification previous	34	26.5–67.6	0.140–0.855	3.06–4.41	0.869

Table 4 PCA solution (oblimin rotation). Factor loadings higher than 0.50 are in bold

Item no	Component 1	Component 2	h^2
1.	−0.11	**0.92**	0.794
2.	0.29	**0.66**	0.648
3.	**0.81**	−0.04	0.631
4.	**0.76**	−0.06	0.544
5.	**0.57**	0.27	0.334
6.	**0.77**	0.15	0.683
7.	**0.88**	0.04	0.791
8.	**0.76**	0.14	0.673
9.	**0.83**	−0.14	0.628

ciated with the gender of the physician, with males obtaining better scores than women (t = 2.44; P = 0.015). Both patients and physicians' age was statistically significantly but weakly related to total scale scores (r = 0.13, P = 0.02 and r = 0.19, P < 0.001, respectively).

Patients with follow-up scheduled appointments scored statistically significantly higher than those with non-scheduled consultations (t = 2.289, P = 0.022). Finally, an ANOVA with the type of treatment decision as independent variable was statistically significant (F = 3.791, P = 0.023): patients whose treatments were

Table 5 Results of the confirmatory factor analysis (CFA)

Model	χ^2	CFI	GFI	SRMR	RMSEA (Confidence interval)
Model 1	134.80*	0.903	0.840	0.077	0.122 (0.101–0.142)
Model 2	127.26*	0.909	0.840	0.077	0.120 (0.100–0.141)
Model 3	105.03*	0.921	0.856	0.072	0.126 (0.102–0.149)

CFI, comparative fit index; GFI, goodness of fit index; SRMR, standardized root mean square residual; RMSEA, root mean square error of approximation recommended values: CFI and GFI > 0.90; SRMR and RMSEA < 0.08.
*P < 0.001.

modified scored higher than those that received a new prescription ($P = 0.044$), while those that remained on their treatments did not differ significantly from the other two groups.

Discussion

This study reports the psychometric characteristics of the Spanish version of the SDM-Q-9 in a sample of primary care patients. The translation and validation of the SDM-Q-9 in Spain have followed international multiphase translation guidelines to assure accurate content and semantic equivalence as well as construct validity[20]. Although the SDM-Q-9 and other instruments are available to evaluate the various aspects of SDM[8–11], the newly translated Spanish version of the SDM-Q-9 is the first psychometrically tested instrument to assess the process of SDM from the patient's perspective in Spanish.

The Spanish version of the SDM-Q-9 has demonstrated good reliability and factorial validity. Internal consistency, as determined by the Cronbach's alpha coefficient for the whole scale, was considered to be adequate in this study (Cronbach's alpha = 0.89) and the corrected item-total correlations ranging from 0.52 to 0.82 (except for item 1, which had the lower value, $r = 0.27$). The results were similar to those of Kriston *et al.*[12] and Scholl *et al.* [16], in which the Cronbach's alpha values were 0.94 and 0.92, respectively, and the corrected item-total correlations ranged from 0.69 to 0.85[12] and from 0.52 to 0.85[16].

In the PCA, we found a two-factorial solution. All nine items had an adequate factor loading. In factor 1, items 3–9 had factor loadings >0.5, and items 1 and 2 had factor loadings >0.5 in factor 2 (mostly represented by item 1). Nevertheless, given that the factorial validation of the original version showed a clear one-dimensional structure[12], we decided to test this hypothesis and we found in the CFA that the structure of the hypothesized one-factor model was consistent with the data and that the model provided acceptable fit with the observed variables. The correlation between items verified in this study was in the same direction as previous studies, although correlations are somewhat lower than those obtained by Kriston *et al.*[18] The main problem is with item 1 ('*My doctor made clear that a decision needs to be made*'), which correlates little with others. Similar results were reported in previous studies, where Kriston *et al.*[18] also found that item one is a bit separate from the others, and Scholl *et al.*,[17] on the physician version (SDM-Q-Doc) also found that item 1 had the lowest factor loadings.

Some limitations of the present study should be considered. The present study included a convenience sample of patients with different backgrounds which could have biased our results. Also, the non-participants were significantly older than participants and included more men. In this sense, this sample may not be representative of the entire population attending primary health-care settings. However, considering that the educational characteristics of the patients in this study are correspondent to those of the Spanish population, we may have mitigated the aforementioned limitation.

Another limitation to our results refers to the wide range of medical topics that are considered within the decision-making consultations in primary care. The Spanish version of the SDM-Q-9 presented adequate reliability and acceptable validity parameters among primary care patients, which indicates that the scale appears to yield accurate measurement, but only the repeated use of the questionnaire by testing the scale in clinically more heterogeneous samples (mental health problems, cancer…) and in situations where the complexity of decision making is greater will determine the validity of the inferential process, which will indicate that the questionnaire repeatedly generates reliable and valid data.

An additional issue to consider when we use a self-reported measure is that measures such as this may not accurately reflect respondents' experiences, expectations and behaviour. Social desirability and inaccurate recall must be taken into account when interpreting our results[16].

Conclusion

Our findings suggest that the Spanish translation of the SDM-Q-9 is suitable for use in Spain and other countries with similarly organized health-care systems. Considering some cultural similarities between Spain and developing countries, the Spanish version of the SDM-Q-9 could also be useful in other countries where Spanish is spoken.

The current results contribute to research on SDM process in clinical practice and may have important clinical implications. The Spanish version of the SDM-Q-9 may be used to evaluate the effectiveness of SDM implementation strategies and as a quality indicator in health-care programmes and health services research. The questionnaire may facilitate measurement of patients' perceived level of involvement in decision making about their own treatment and care, which, in turn, could provide rapid feedback to health professionals, enabling them to monitor their own practice and address any associated training/practical issues. Furthermore, the use of the SDM-Q-9 may be a valuable reminder to health professionals to think about SDM in their consultations.

Use of the SDM-Q-9 allows further expansion of this field of study in Spanish context, resulting in better insight into the nature, predictors, effects and implications for implementation of SDM in clinical practice. Confidence in the cross-cultural validity of the SDM-Q-9 enables its use in different countries, allowing direct comparisons between patients' views on the SDM process internationally. Ultimately, this could improve patient care.

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Conflict of interest

The authors have declared no conflict of interest.

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