

Romanian version of SDM-Q-9 validation in Internal Medicine and Cardiology setting: a multicentric cross-sectional study

CRISTIAN BAICUS^{1,2}, PAUL BALANESCU*^{1,2}, ADRIANA GURGHEAN^{1,3}, CAMELIA GEORGETA BADEA^{1,2}, VLAD PADUREANU⁴, CIPRIAN REZUS^{5,6}, FLORIN MITU^{5,7}, RUXANDRA JURCUT^{1,8}, ANDRA RODICA BALANESCU^{1,9}, IOANA DAHA^{1,2}, EUGENIA BALANESCU², MIHAI BOJINCA^{1,10}, LARISA PINTE², ALEXANDRU MARIAN CONSTANTIN², NICOLETA DIMA^{5,6}, MARIANA FLORIA^{5,6}, MARIA MAGDALENA LEON-CONSTANTIN^{5,7}, MIHAI ROCA⁵, MAGDA MITU⁷, SILVIA CHIRIAC⁷, CODRUTA MINERVA BADESCU^{5,6}, SIMONA DANIELA IONESCU⁶, ELENA MITREA⁶, GABRIEL ROSU⁶, GEORGETA DANIELA IONESCU¹, ANA MARIA VISINESCU¹, GABRIELA MIHAILESCU^{1,2}, ROZALINA LAPADATU¹¹, EMILIA OPRISAN¹², STEFAN ZEH¹³, ISABELLE SCHOLL¹³, MARTIN HÄRTER¹³

¹“Carol Davila” University of Medicine and Pharmacy, Bucharest, Romania

²“Colentina” Hospital, Internal Medicine, Bucharest, Romania

³“Coltea” Hospital, Internal medicine, Bucharest, Romania

⁴University of Medicine Craiova, Internal Medicine, Craiova, Romania

⁵“Gr. T. Popa” University of Medicine and Pharmacy Iasi, Iasi, Romania

⁶“Sf. Spiridon” Emergency County Hospital Iasi, Internal Medicine, Iasi, Romania

⁷Rehabilitation Hospital Iasi, Cardiovascular Rehabilitation, Iasi, Romania

⁸“C.C. Iliescu” Emergency Institute for Cardiovascular Diseases, Bucharest, Romania

⁹“Sf. Maria” Hospital, Rheumatology, Bucharest, Romania

¹⁰“Cantacuzino” Hospital, Rheumatology, Bucharest, Romania

¹¹The Association of Patients with Autoimmune Diseases, Bucharest, Romania

¹²Faculty of Psychology and Educational Sciences, University of Bucharest, Bucharest, Romania

¹³University Medical Center Hamburg-Eppendorf, Department of Medical Psychology, Hamburg, Germany

Background. Shared decision making (SDM) is becoming more and more important for the patient-physician interaction. There has not been a study in Romania evaluating patients’ point of view in the SDM process yet. Therefore, the present study aims to evaluate the psychometric parameters of the translated Romanian version of SDM-Q-9.

Material and methods. A multicentric cross-sectional study was performed comprising eight recruitment centers. The sample consisted of in- and outpatients who referred to Hospital Units for treatment for atrial fibrillation or collagen diseases. Furthermore, patients who were members of Autoimmune Disease Patient Society were able to participate via an online survey. All participants completed the Romanian translated SDM-Q-9.

Results. Altogether, 665 questionnaires were filled in within the hospital setting (n = 324; 48.7%) and online (n = 341; 51.3%). The Romanian version had good internal consistency (Cronbach α coefficient of 0.96.) Corrected item correlations were good ranging from 0.64 to 0.89 with low corrected item correlations for item 1 and item 7. PCA found a one-factorial solution (similar with previous reports) but the first item had the lowest loading.

Conclusion. SDM-Q-9 is a useful tool for evaluation and improvement in health care that was validated in Romania and can be used in clinical setting in this country.

Key words: validation, SDM-Q-9, Romania, shared decision making.

INTRODUCTION

Shared decision making (SDM) is becoming more and more important for the patient-physician interaction. Evaluation of SDM is usually performed using questionnaires but in the literature, there have been described numerous methods to assess this complex [1]. A recent systematic review aimed to sum up all measures evaluating SDM. They are

divided into four main categories: patient questionnaires (evaluating SDM from the patients’ point of view), provider questionnaires (evaluating SDM from the physician point of view, for example SDM-Q-DOC), observer-based coding schemes and mixed instruments that measure different perspectives [1]. The authors reviewed and evaluated the quality of reporting for all available instruments applying COSMIN (CONsensus based Standards

for the selection of health status Measurement Instruments) guidelines [2–4] concluding that, in order to evaluate SDM instruments used, there is a great need for more rigorous studies.

One patient-oriented instrument is the SDM-Q-9 (Nine-item Shared Decision Making Questionnaire). It was first developed as 24 item score in German [5] but then reduced to a more easy form to administer, comprising 9-items [6, 7]. SDM-Q-9 was further translated and validated in various languages (English [8], Spanish [9], Dutch [10] or Hebrew-version of SDM-9 adapted for psychiatric disorders [11]).

In Romania, there has been little research addressing this issue. One interventional study (randomized controlled study) evaluated the influence of risk diagrams from decision aids on oral anticoagulant prescribing among physicians [12]. To the best of our knowledge, there has not yet been a study in Romania evaluating patients' point of view in the SDM process. Therefore, the present study aims to evaluate the psychometric parameters of the translated Romanian version of SDM-Q-9 and to test the reliability of this instrument to measure shared decision making process in Romania.

MATERIAL AND METHODS

Study participants

A multicentric cross-sectional study was performed comprising eight recruitment centers ("Colentina" Clinical Hospital, "Cantacuzino" Clinical Hospital, "Coltea" Clinical Hospital, Fundeni Institute, Craiova Clinical Hospital, "Saint Spiridon" Clinical Hospital, Iasi Rehabilitation Clinical Hospital, "Saint Mary" Clinical Hospital). The sample for the study were patients that referred to Hospital Units for treatment of atrial fibrillation or collagen-vascular diseases and they were recruited from Cardiology, Rheumatology or Internal medicine Units of the above-mentioned Centers. Patients were both inpatients and out-patients, and they were recruited between March 2017 – October 2018 and their data were processed after having signed the informed consent. The patients in the sample voluntarily participated in the survey. The study was approved by the Local Ethics Committee. Data collected was similar for each recruitment center, the medical personnel had the same

questionnaire (translated Romanian SDM-Q-9) and the same data form to be filled in. Participation of all patients did not affect their subsequent treatment. The questionnaires were filled by the participants without time limit. Data about patients were recorded by the physicians into the questionnaire. All questionnaires were centralised and the database was filled in by a single person (PB). Data privacy and confidentiality was assured. A total number of 324 questionnaires (48.7%) were filled in using this method.

Patients who were members of the autoimmune patient society were also able to participate in an anonymous survey by filling in the questionnaire on a platform (Google Survey). A total number of 341 questionnaires (51.3%) were filled in using this method.

Instrument used

We used the SDM-Q-9 questionnaire that measures patients' point of view of the decision making process after being consulted by the physician in a clinical setting. There are nine items included in the questionnaire [7]. Each item is scored on a six-point Likert scale that has ranges from ("completely disagree" to "completely agree"). The questionnaire was translated from German to Romanian by two native Romanian speakers fluent in German. Each translator independently translated the questionnaire from German to Romanian and afterwards they met together with study coordinator (CB) and discussed in a consensus meeting the translation. Afterwards a professional translator re-translated the Romanian version of the questionnaire into German and differences were discussed with one of the authors of the original questionnaire (IS). The final version was presented to five clinicians who also gave their opinion about the final form of the questionnaire thus resulting the final version that was administered. The translated instrument proposed for validation is presented below (Table 1).

Demographic data

Alongside with the questionnaire the physician filled in general data about included patients such as age, gender, diagnosis, current treatment and also data about the history of patient (if he/she had treatment with anticoagulants how long did the patient take them, his risk scores for hemorrhage, etc.).

Table 1
Adapted Romanian SDM-Q-9 version

Item	Possible answers						
Medicul meu m-a informat explicit că trebuie luată o decizie	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu a vrut să știe exact de la mine cum doresc să particip la decizie.	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu mi-a comunicat că pentru acuzele mele există opțiuni diferite de tratament.	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu mi-a explicat în detaliu avantajele și dezavantajele opțiunilor de tratament	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu m-a ajutat să înțeleg toate informațiile.	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu m-a întrebat ce opțiune de tratament prefer.	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu și cu mine am cântărit riguros diferitele opțiuni de tratament.	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu și cu mine am selectat împreună o opțiune de tratament.	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat
Medicul meu și cu mine am căzut de acord asupra modului în care vom proceda de acum înainte.	Total neadevărat	În mare măsură neadevărat	Mai degrabă neadevărat	Mai degrabă adevărat	Mai degrabă adevărat	În mare măsură adevărat	Total adevărat

Data analysis

Differences between continuous variables were analyzed using non-parametric tests if the distribution was not normal or with t-test if the distribution was normal. Differences between ordinal variables were analyzed using non-parametric tests (Mann Whitney U test). Differences between nominal variables were analyzed using chi-square tests. Internal consistency of the scale was assessed with Cronbach's alpha. In order to reduce the dimension of the scale, principal components analysis (PCA) with varimax rotation was performed, extracting components with Eigenvalues > 0.5. SPSS version 16 software for Windows was used for statistical analysis.

RESULTS

Population sample

In this study a total number of 665 questionnaires were filled in (324 questionnaires (48.7%) in a hospital setting and 341 online (51.3%), anonymous. As a particularity for the online survey, some patients declared that they were the legal guardian for the child that was patient with autoimmune disease and have completed the SDM-Q-9 questionnaire as such (this is why there are some patients that have age below 18 years in the online survey). Table 2 summarizes the main descriptive data of the study.

Table 2
Descriptive data about sample included

Variable	Whole group (n = 665)	Hospital questionnaires (n = 324)	Online questionnaires (n = 341)	P values
Age (years)	50 (5-95)	68 (18-95)	38 (5-68)	p<0.001
Gender distribution (n = 659)	437 females (66.3%)	152 females (47.8%)	285 females (83.6%)	p<0.001
Disease duration (years)	6 (0-50)	9 (0.5-33)	6 (0-50)	p<0.001
Educational level (n = 644)	59 elementary school (9.2%)	52 elementary school (17.2%)	7 elementary school (2.1%)	p<0.001
	86 gymnasium (13.4%)	77 gymnasium (25.4%)	9 gymnasium (2.6%)	
	224 high school (34.8%)	128 highschool (42.2%)	96 highschool (28.2%)	
	275 college (42.7%)	46 college (15.2%)	229 college (67.2%)	
Social status (n = 649)	435 urban (67%)	149 urban (48.4%)	286 urban (83.9%)	p<0.001
Marital status (n = 645)	388 Married (60.2%)	185 Married (60.9%)	203 (59.5%)	p<0.001
	47 Divorced (7.3%)	15 Divorced (4.9%)	32 (9.4%)	
	85 Widower (13.8%)	86 (28.3%)	3 (0.9%)	
	121 Single (18.8%)	18 (5.9%)	103 (30.2%)	
Diagnosis (n = 658)	423 autoimmune diseases (64.3%)	82 (25.9%)	341 (100%)	p<0.001
	235 atrial fibrillation (35.7%)	235 (74.1%)	0 (0%)	

On the third and fourth column percentages in the brackets refer as from total hospital questionnaires or online questionnaires available. Mann-Whitney U tests were used for continuous variables and Chi-square tests for categorical variables. In Romanian Educational system elementary School represents 1st to 4th grade, gymnasium represents 5th to 8th grade, Highschool represents 9th to 12th grade.

Internal consistency of the questionnaire

There was a very good completion rate of SDM-Q-9 over 98% for all items. Ceiling effect (calculated as percent of patients that completely agreed) ranged from 29.2-50.8% – Q1-50.8%, Q2-34.1%, Q3-35.3%, Q4-40.2%, Q5-39.2%, Q6-29.6%, Q7-29.2%, Q8-31.0%, Q9-45.7%. Item difficulties (defined at the cut-off 2.5 – midpoint on 0-5 Likert point scale) were above this threshold and ranged between 2.7 and 3.8. Reliability analysis showed a very high Cronbach α of 0.95 (Table 3). Corrected item correlations were good ranging from 0.64 to 0.89. Inter-item correlation matrix is given in the table below (Table 4).

Ceiling effect for anonymous questionnaires ranged from 16.1% to 38.4% (Q1-38.4%, Q2-28.7%, Q3-25.2%, Q4-30.2%, Q5-27.9%, Q6-16.1%, Q7 19.9%, Q8-19.6%, Q9-26.7%) and were lower compared to the observed ceiling effect for questionnaires that were administered in the clinical setting.

Table 3
Reliability analysis

Item	Discrimination (corrected item-total correlations)	Difficulty in completion	Cronbach's α if item is deleted
Q1	0.64	3.8	0.96
Q2	0.81	3.3	0.95
Q3	0.81	3.1	0.95
Q4	0.85	3.3	0.95
Q5	0.82	3.4	0.95
Q6	0.87	2.7	0.95
Q7	0.64	2.8	0.95
Q8	0.89	2.8	0.95
Q9	0.84	3.4	0.95

Table 4
Inter-Item Correlation

Item	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Q1		.671	.531	.564	.599	.528	.557	.541	.564
Q2	.671		.691	.724	.736	.695	.708	.712	.695
Q3	.531	.691		.759	.671	.754	.769	.759	.665
Q4	.564	.724	.759		.803	.751	.780	.748	.749
Q5	.599	.736	.671	.803		.715	.721	.728	.769
Q6	.528	.695	.754	.751	.715		.883	.875	.764
Q7	.557	.708	.769	.780	.721	.883		.903	.782
Q8	.541	.712	.759	.748	.728	.875	.903		.809
Q9	.564	.695	.665	.749	.769	.764	.782	.809	

Descriptive analysis of the questionnaire answers: Factor structure

Comparing the questionnaire used in the Hospital setting and the one being used online, there were no differences regarding Cronbach's Alpha (0.92 and 0.95, respectively).

The original questionnaire in German had one component explaining the variance and therefore for validation of the Romanian version this should

have been the same. We have performed a Principal Component Analysis (PCA). First, we have evaluated the Kaiser-Meyer-Olkin (KMO) measure that reached 0.94 in our sample (above 0.85). Bartlett's test of sphericity was significant and indicated therefore that factor analysis is appropriate in the sample (χ^2 (36) = 6343, $p < 0.001$). Two components showed Eigenvalue above 0.50, explaining in total 82.18 % of variance for SDM-Q-9 questionnaire (74.8% first component and 7.3% second component). The rotated component matrix is given (varimax rotation) in the table below. As observed, Item 1 and item 2 would load in the 2nd component while the last 7 items would load in the 1st component (Table 5, loads over 0.50 are in bold).

Table 5
Rotated component matrix (varimax rotation)

Item	Component 1	Component 2
Q1	0.24	0.91
Q2	0.56	0.68
Q3	0.77	0.36
Q4	0.75	0.47
Q5	0.66	0.56
Q6	0.88	0.28
Q7	0.88	0.32
Q8	0.89	0.30
Q9	0.76	0.42

DISCUSSION

In the present study, the Romanian translation of SDM-Q-9 questionnaire was validated on patients with both autoimmune diseases and atrial fibrillation. Until now, this is the first instrument in Romanian that assesses SDM process. Also, this is the first study not only meant to psychometrically test the SDM-Q-9 in Romania, but, likewise, to measure SDM in Romania, since there hasn't been any study on the status quo of SDM in Romania yet.

The process for translation and validation was performed using international guidelines [13]. The Romanian version had good internal consistency (evaluated by Cronbach α coefficient that was 0.96, similar with previous validation reports in the literature (for the Spanish validation it was 0.89 [9] or 0.94 for Hebrew adapted SDM-Q-9-psy [11])). Corrected item correlations were good ranging from 0.64 to 0.89 with low corrected item correlations for item 1 and item 7, similar with previous reports in the literature. For example, in Spanish SDM-Q-9 validation, item 1 obtained the lowest item-total correction of 0.27, but the remaining showed values between 0.52 and 0.82 similar to those found in Romanian validation [9].

PCA found a one-factorial solution with the first factor showing an Eigenvalue above 1, but the first item had the lowest loading. Similar data were also reported in the literature. There seems to be an issue with item 1, given the fact that it is less correlated with the other items. When factors showing Eigenvalues above 0.5 are taken into account, a two-factorial solution is found with the first factor comprising item 2 to 9 and second factor with the first item. For example, the Spanish validation found a two-factorial solution with the second factor comprising the first item [9] and also Dutch validation found one factor solution but item 1 and item 9 had the lowest loadings [10].

There are some limitations. Patients were recruited both with online survey/within hospital clinical setting and, therefore, the sample may not be representative for the entire Romanian population. However, being a multicentric study, it comprised

hospitals from all around the country. Additionally, patients from all areas were recruited and they had similar educational level and social status compared with the rest of Romanians. Another limitation is the fact that ratings from the hospital survey were non-anonymous, and as such there is higher risk for social desirability bias.

In conclusion, SDM-Q-9 is a useful tool, validated in Romania, and can it be used in Internal Medicine/Rheumatology setting as well in Cardiology units. Nevertheless, this questionnaire can be used on a larger scale in Romania in order to evaluate the SDM process. In addition, evaluation of this translated tool should also be performed in special clinical settings like Oncology units where SDM is more complex.

Conflict of interest disclosure: The authors confirm that there is no conflict of interest.

Introducere. *Decizia împărtășită (SDM) este o problemă din ce în ce mai importantă din punctul de vedere al interacțiunii dintre medic și pacient. Până în prezent nu a fost realizat un studiu care să evalueze punctul de vedere al pacienților din România în privința SDM. Scopul studiului este de a evalua parametrii versiunii traduse în română a chestionarului de decizie împărtășită SDM-Q-9.*

Materiale și metode. *A fost realizat un studiu multicentric transversal în 8 centre din România. Pacienții recrutați au fost printre cei care s-au prezentat la spital pentru fibrilație atrială sau boli de colagen. În același timp, pacienții din Societatea Pacienților cu Boli Autoimune au participat la evaluare prin completarea datelor online și anonim. Toți participanții au completat versiunea tradusă în română a SDM-Q-9.*

Rezultate. *Au fost completate 665 de chestionare, 324, 48.7% în spital și 341, 51.3% online. Versiunea tradusă în limba română a avut o consistență internă bună (coeficientul Cronbach α de 0.96). Corelațiile corectate inter-itemi au fost bune, ele variind între 0.64 și 0.89 cu cele mai mici valori pentru itemii 1 și 7. Analiza factorială a găsit o soluție unifactorială (similar cu alte date din literatură), însă primul item a avut cea mai mică încărcare.*

Concluzii. *Chestionarul de decizie împărtășită SDM-Q-9 este un instrument util care poate fi utilizat în context clinic în această țară.*

Correspondence to: Paul Balanescu, M.D, "Colentina" Hospital, Internal Medicine, 19-21 Ștefan cel Mare Street, Bucharest Romania
E-mail: plbalanescu@gmail.com

REFERENCES

1. GÄRTNER FR, BOMHOF-ROORDINK H, SMITH IP, SCHOLL I, STIGGELBOUT AM, PIETERSE AH. *The quality of instruments to assess the process of shared decision making: A systematic review.* PLoS One. 2018;**13**(2):e0191747.
2. TERWEE CB, PRINSEN CAC, CHIAROTTO A, WESTERMAN MJ, PATRICK DL, ALONSO J, BOUTER LM, DE VET HCW, MOKKINK LB. *COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study.* Qual Life Res. 2018;**27**(5):1159-1170.

3. PRINSEN CAC, MOKKINK LB, BOUTER LM, ALONSO J, PATRICK DL, DE VET HCW, TERWEE CB. *COSMIN guideline for systematic reviews of patient-reported outcome measures*. Qual Life Res. 2018;**27**(5):1147-1157.
4. MOKKINK LB, DE VET HCW, PRINSEN CAC, PATRICK DL, ALONSO J, BOUTER LM, TERWEE CB. *COSMIN risk of bias checklist for systematic reviews of patient-reported outcome measures*. Qual Life Res. 2018;**27**(5):1171-1179.
5. SIMON D, SCHORR G, WIRTZ M, VODERMAIER A, CASPARI C, NEUNER B, et al. *Development and first validation of the shared decision-making questionnaire (SDM-Q)*. Patient Educ Couns. 2006;**63**:319–327.
6. SCHOLL I, KRISTON L., DIRMAIER J., HÄRTER M. *Comparing the nine-item Shared Decision-Making Questionnaire to the OPTION Scale – an attempt to establish convergent validity*. Health Expectations. 2015;**18**:137–150.
7. KRISTON L, SCHOLL I, HÖLZEL L, SIMON D, LOH A, HÄRTER M. *The 9-item shared decision making questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample*. Patient Education and Counseling, 2010; 80: 94–99.
8. ALVAREZ K, WANG Y, ALEGRIA M, AULT-BRUTUS A, RAMANAYAKE N, YEH YH, et al. *Psychometrics of shared decision making and communication as patient centered measures for two language groups*. Psychol Assess. 2016;**28**(9):1074–86.
9. DE LAS CUEVAS C, PERESTELO-PÉREZ L, RIVERO-SANTANA A, CEBOLLA-MARTÍ A, SCHOLL I, HARTE M. *Validation of the Spanish version of the 9-item Shared Decision-Making Questionnaire*. Health Expect. 2015;**18**(6):2143-53.
10. RODENBURG-VANDENBUSCHE S, PIETERSE AH, KROONENBERG PM, SCHOLL I, VAN DER WEIJDEN T, LUYTEN GP, et al. *Dutch translation and psychometric testing of the 9-Item Shared Decision Making Questionnaire (SDM-Q-9) and Shared Decision Making Questionnaire-Physician Version (SDM-Q-Doc) in primary and secondary care*. PLoS One. 2015;**10**(7):e0132158.
11. ZISMAN-ILANI Y, ROE D, SCHOLL I, HARTE M, KARNIELI-MILLER O. *Shared decision making during active psychiatric hospitalization: Assessment and Psychometric Properties*. Health Commun. 2016:1–5.
12. BAICUS C, DELCEA C, DIMA A, OPRISAN E, JURCUT C, DAN GA. *Influence of decision aids on oral anticoagulant prescribing among physicians: a randomised trial*. Eur J Clin Invest. 2017;**47**(9):649-658.
13. RUIZ-AZAROLA A, PERESTELO-PÉREZ L. *Citizens' participation in health: education and shared decision-making*. SESPAS Report 2012. Gaceta Sanitaria, 2012; **26** (Suppl. 1): 158–161.

Received January 15, 2019