Cross-cultural adaptation and validation of the Recognizing And Addressing Limited Pharmaceutical Literacy (RALPH) interview guide in community pharmacies

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A B S T R A C T

Background: The RALPH (Recognizing and Addressing Limited PHarmaceutical Literacy) interview guide makes it possible to identify patients with limited pharmaceutical knowledge and to assess their skills in the functional, communicative, and critical health literacy domains.
Objective: (s): To perform a cross-cultural validation of the RALPH interview guide in Spanish population; to conduct a descriptive analysis based on patients' responses.
Methods: A cross-sectional study of patients' pharmaceutical literacy skills was conducted in three stages: systematic translation, administration of the interview and analysis of psychometric properties. The target population included adult patients (≥18 years) who attend one of the participating community pharmacies in Barcelona (Spain). Content validity was evaluated by an expert committee. Viability was assessed in the pilot test, and reliability was assessed using internal consistency and intertemporal stability. Construct validity was assessed by factor analysis.
Results: A total of 103 patients were interviewed at 20 pharmacies. Cronbach's alpha values based on standardized items ranged between 0.720 and 0.764. For the longitudinal component, the ICC test–retest reliability was 0.924. The factor analysis was verified by KMO (0.619) and Bartlett's test of sphericity (*P*-value <0.05). The definitive RALPH guide translated into Spanish maintains the same structure as the original. Some expressions were simplified, and the questions on the comprehension of warnings or specific instructions for use, contradictory information and shared decision-making were reformulated. Pharmaceutical literacy skills were seen to be most limited with regard to the critical domain. The responses of the Spanish patients were in agreement with the original results of the RALPH interview guide.
Conclusions: The RALPH interview guide in Spanish complies with the requirements viability, validity, and reliability. This tool may be able to identify the low pharmaceutical literacy skills of patients coming to community pharmacies in Spain, and its use may also be extended to other Spanish-speaking countries.

1. Introduction

Limited health literacy has become a major public health issue in recent years.[1] The World Health Organization's Shanghai Declaration of 2015, which established the United Nations Sustainable Development Goals 2030, placed particular emphasis on promoting health literacy in order to improve and empower individual health. Although there is no overall unanimous definition of health literacy, the ones available follow the same principles.[2] For example, Dodson et al. (2015) defines it as 'the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health. Health literacy includes the capacity to communicate, assert and enact these decisions'.[3] Raising the levels of health literacy requires the involvement of the entire society, as people receive and access ever more information, especially through the Internet.[4] Specific skills are required based on content and context. Vervloet et al. (2018) uses the term *pharmaceutical literacy* to refer to the skills needed in the context of patients' use of medicines dispensed in community pharmacies.[5] In their article, they developed the RALPH

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Abbreviations

RALPH	*Recognizing and Addressing Limited PHarmaceutical Literacy*
WHO	*World Health Organization*
ATC	*Anatomical Therapeutic Chemical Classification System*
ISPOR	*International Society for Pharmacoeconomics and Outcomes Research*
ICC	*Interclass Correlation Coefficient*
PCA	*Principal Component Analysis*
KMO	*Kaiser-Meyer-Olkin Test*
SD	*Standard Deviation*
CBUB	*University of Barcelona's Bioethics Commission*

(Recognizing and Addressing Limited PHarmaceutical Literacy) interview guide, to identify patients with limited pharmaceutical knowledge and to assess their skills in three sequential domains of health literacy: the functional domain, which includes basic-level skills for understanding medical instructions, such as handling medications; the communicative/interactive domain, which covers the advanced cognitive skills that allow patients to actively participate in health-related interactions by requesting, seeking and understanding information; and finally the critical domain, the most complex level, which refers to patients' ability to analyse health-related information and apply it to their own situation, as well as to participate in shared decision-making.[1,6,7] RALPH thus differs from other instruments developed to assess medication literacy or health literacy skills, since most of them focus only on the functional level and are self-completed by patients.[6–10] Developed in community pharmacies throughout the Netherlands, the RALPH interview guide is a practical, straightforward tool written in English which can be incorporated into the daily practice of pharmacists during the dispensing process.[6]

Pharmacists collaborate with the health authorities to guarantee the public's access to medicines and health products and to promote their safe, effective, efficient and responsible use. In Spain, problems with polypharmacy in the elderly with chronic illnesses are frequent but, on many occasions, they can be anticipated and avoided.[11] To respond to this need, a patient-centered care model is also emerging in Spanish community pharmacies. This model is supported by the accessibility of pharmacies (99% of the population have one in their local town) and their role as a venue for social communication where people discuss their health problems. Today a wide variety of professional pharmacy services are on offer, such as chronic disease management, disease prevention, and transition-of-care coordination. These new services are expanding the functions and responsibilities of community pharmacists in their daily practice.[12]

The inclusion of evidence-based protocols and guides is necessary to standardize and improve the quality of pharmaceutical care services, as a part of an integrated health system, and to guarantee the safe, effective, and responsible use of medication.[13–15] For this reason, in our geographical setting, it is crucial to provide Spanish-language versions of tools validated and used in other countries.

The main objective of the present study was to perform a cross-cultural validation of the RALPH interview guide for assessing the pharmaceutical literacy skills of patients in community pharmacies in a Spanish population. In addition, a descriptive analysis of patients' responses was carried out.

2. Materials and methods

2.1. Study design and setting

Cross-sectional study conducted in community pharmacies of the city of Barcelona (Catalonia, Spain). Barcelona is the second most populous city in Spain, with 1,628,936 inhabitants, distributed in 10 neighborhoods.[4] This high population and its distribution make it possible to reflect different realities and situations, and thus ensure greater heterogeneity for the cross-cultural validation.

2.2. Instrument

RALPH is an English-language interview guide tested against a reference standard.[6] It consists of 10 questions framed in the three pharmaceutical literacy domains: questions 1–3 related to the functional domain, 5–7 to the communicative domain, and questions 4 and 8–10 to the critical domain. Polytomous response data are obtained. All questions are linked to the patient's own medication, so patients (together with the pharmacist) should select one of their medications at the beginning to serve as a guideline for the interview. To facilitate the recording of patients' responses, possible answers are pre-printed on the interview guide.[5]

Participants were required to provide data on socio-demographic variables of interest including age, gender, and educational level. As for clinical variables, the initial prescription date of the target medicine and the total number of medicines prescribed to the patient were also recorded. For data management, all medicines were classified according to the Anatomical Therapeutic Chemical (ATC) index.[16]

2.3. Sampling

The target population included adult patients (≥18 years) who attended one of the participating community pharmacies. Patients with severe physical or psychological problems or those who did not agree to participate were excluded, as were those who did not collect the medication in person. A minimum sample size of 30 patients was considered sufficient for piloting (95% confidence, 0.1 probability)[17] distributed among six community pharmacies to guarantee sampling heterogeneity. The calculation of the sample size needed to identify a problem or undesirable event in the pilot study was based on a prior probability; according to the formula developed by Viechtbauer et al.[18] for pilot studies, the confidence value (from 0 to 1, ideally greater than 0.95) and the probability (a value from 0 to 1) of the event to be evaluated should be determined a priori.[19] In order to ensure that the population was representative, sampling was stratified by proportional allocation. The total number of interviews was distributed proportionally according to the population of each of the 10 districts of the city of Barcelona.[20] The pharmacies were contacted by telephone until the number required in each district was obtained, with the corresponding number of interviews.

2.4. Procedure

The study was conducted in three stages: translation, administration of the interview, and the analysis of the psychometric properties (Fig. 1).

2.4.1. Translation

The RALPH was translated into Spanish in accordance with the Principles of Good Practice for the Translation and Cultural Process for Patient-Reported Outcomes Measures developed by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) task force.[21] After receiving authorization from the author of the original RALPH interview guide,[5] the English version was first independently translated into Spanish by one researcher and one uninformed translator, both native Spanish speakers, to obtain T1 and T2 versions respectively. T1-2 was then obtained after reviewing and reconciling T1 and T2, and resolving any discrepancies with the translator's reports. Two English native independent researchers who were unaware of the original self-report measure performed the back translation (BT1 and BT2 versions). A committee comprising experts from the fields of
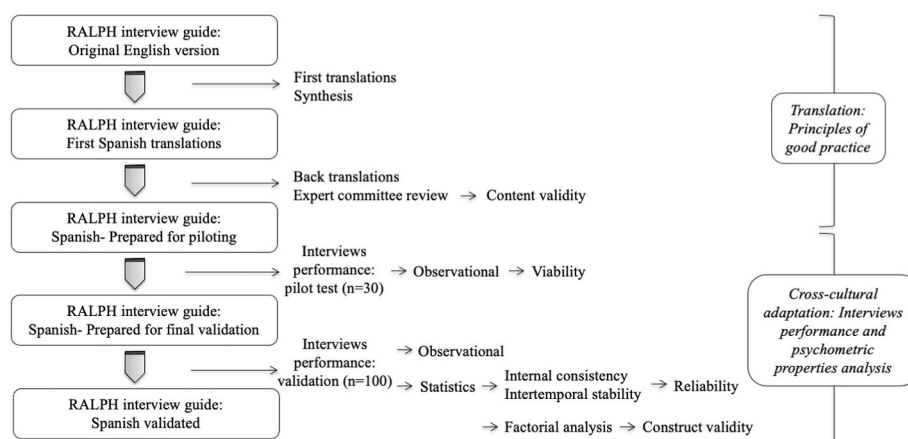
Fig. 1. The study procedure, conducted in three main stages: translation, interviews performance and the psychometric properties analysis.

pharmacy education, hospital pharmacy and community pharmacy harmonized all translations and evaluated the content validity, until the first version of the RALPH guide in Spanish was produced and prepared for piloting.

2.4.2. Administration of the interviews

Interviews were performed first to assess viability through the pilot test (n = 30), and subsequently for the final validation study (n = 100). The participating pharmacists were fully informed of the purpose of the study, the handling of the guide, and the requirement for confidentiality and informed consent of those participating. They were also given the corresponding translated RALPH interview guide (prepared either for piloting or for the final validation respectively), an instruction sheet, and the consent sheet for patients. As the RALPH is a guide, it was not necessary to read the questions literally or in the preset order. The interviews were conducted by the pharmacist when the patient went to collect their own medication, as per usual. The conversation thus took place during the dispensing process. Finally, pharmacists were asked to complete a short questionnaire about their experiences with RALPH.

2.4.3. Analysis of psychometric properties

This analysis was performed in accordance with Schreiber guidance for exploratory factor analysis.[22] To ensure the adaptation of the RALPH guide to the new cultural context and the new target population, it had to meet the requirements of validity, viability and reliability.[23] As mentioned, content validity was evaluated by an expert committee in order to prepare the RALPH guide for piloting. Then, the pilot test was performed to assess viability through the observational criteria. Once all necessary interviews had been completed during the final validation process, the statistical analysis was performed.[24,25] To assess reliability, internal consistency and intertemporal stability were tested. The internal consistency reliability was calculated by Cronbach's alpha statistical analysis to evaluate the relations between the elements of the interview guide. Cronbach's alpha coefficient is considered the simplest and best-known way of measuring internal consistency and is the first approach used for validating the construct of a scale. It should be considered as a measure of the correlation of the items that make up the scale, and its determination is indicated in one-dimensional scales of three to twenty items.[26] A Cronbach's alpha based on standardized items of >0.7 is indicative of reliable results.[23] Intertemporal stability was tested using the interclass correlation coefficient (ICC) by a test-retest (two-way random effects model, single measure), since at least 10% of the total sample must be re-tested.[27] Interviews were re-conducted in the same way as before, applied to the same medication, when patients returned to the pharmacy. Based on the 95% confidence interval, reliability was considered poor with ICC values < 0.5, moderate with values between 0.5 and 0.75, good with scores between 0.75 and 0.9, and

excellent with scores >0.90.[28] The construct validity was assessed by exploratory factor analysis, grouping the responses according to subscales. The Varimax method for matrix rotation was selected, and the number of factors was determined considering the three domains, as in the original RALPH. A principal component analysis (PCA) was previously performed in order to determine the relevance of the factor analysis. Those items whose saturation was more than 0.35 were retained. A Kaiser-Meyer-Olkin (KMO) score of ≥ 0.5 indicated that the factor analysis was acceptable, as well as a significant result (P-value <0.05) on Bartlett's sphericity test.[29]

2.5. Statistical analysis of patients' responses

Descriptive statistics assuming normality of distribution were used. Means and standard deviations (SD) for quantitative variables were considered, and percentages for qualitative variables (nominal or ordinal). For comparisons of qualitative variables the Chi-squared χ2 test, Fisher's test and linear-by-linear association were calculated. For quantitative variables for two or more subgroups, the Student-t test and analysis of variance (ANOVA) were used respectively. Since the number of possible pre-established responses changes depending on the item, it was necessary to standardize the variables according to the criteria described by Koster et al.[6] In order to compare the Spanish patients' responses with those described by Koster et al.[6] using the original RALPH interview guide in Dutch patients, response options were also dichotomized. This descriptive analysis of the percentage of correct answers should serve as a starting point for future studies. Thus, responses from the functional domain (questions 1–3) were classed as correct or incorrect and the option "the patient does not know" was included as incorrect. The possible responses for question 4 from the communicative domain were also scored using the same criteria as correct or incorrect. Critical domain responses (questions 5–7) and the rest from the communicative domain (8–10) were dichotomized as easy or difficult. The option "not searching for information" was included as difficult. To compare the percentage of correct answers provided by the Spanish patients with those described by Koster et al.,[6] a two-proportion z-test was applied to determine whether the two samples differ significantly in specific characteristics.[30] A P-value <0.05 was considered statistically significant. All the data analyses were processed using SPSS version 24.0.

2.6. Ethical considerations

This study was approved by University of Barcelona's Bioethics Commission (CBUB), Institutional Review Board (IRB00003099). The study complies with the principles of the Declaration of Helsinki. All patients gave written informed consent before the interviews. They were

informed that their participation was voluntary and confidential, and were provided with a study information sheet. No data that could identify patients were collected in accordance with the ethics committee protocol.

3. Results

3.1. Cultural adaptation and psychometric properties

As mentioned, the RALPH interview guide in Spanish prepared for the piloting was obtained after harmonization by the expert committee. To ensure content validity, once the translation process was completed, it was checked that the BT1 and BT2 versions agreed with the original guide. The non-coincident terms were considered synonymous and nuances were introduced to make the guide more comprehensible to the Spanish population.

The translated RALPH interview guide was considered feasible (viability) after six community pharmacies participated in the pilot test (n = 30). The time required was correct (5–10 min), but it was necessary to add an introduction before the questions, and also to simplify and adapt certain expressions while retaining the original meaning. In question 4, a footnote was added clarifying the definition of a reliable source.

After conducting the interviews with a total of 103 patients, the reliability analysis indicated that the Spanish version of the RALPH guide had acceptable internal consistency since the Cronbach's alpha value based on standardized items was 0.759 (range 0.720–0.764). For the longitudinal component, the ICC test–retest reliability was 0.924, indicating an excellent result. The factor analysis was appropriate, since it was verified by the results of KMO (0.619) and Bartlett's test of sphericity (P-value <0.05). After standardizing the variables, the questions distributed among the three domains that make up the original RALPH coincided with the Spanish version, with three exceptions: question 3 was placed in the critical domain instead of the functional domain, and questions 4 and 10 moved from the critical domain to the functional domain and the communicative domain respectively.

3.2. Analysis of patients' responses

During the final validation study, a total of 103 patients were interviewed at 20 pharmacies distributed throughout the city of Barcelona, from January 2020 to January 2021. Each of the 20 participating pharmacists interviewed from three to six patients. Table 1 displays patients' socio-demographic and clinical variables.

The socio-demographic characteristics of the Spanish interviewees were similar to those described by Koster et al.[6] Mean age was 67.6 years (SD = 15.2) in the RALPH-English study versus 66.5 years (SD = 15.3) in the current study. In the RALPH-English study, 43.9% of the population

Table 1
Socio-demographic and clinical variables.

Total sample, (N = 103)	
Age, Mean (SD)	66.53 (15.33)
Gender, N (%)	
Female	59 (57.3)
Male	44 (42.7)
Level of education, N (%)	
No schooling	13 (12.7)
Primary school	26 (25.5)
Secondary school	29 (28.4)
University studies	34 (33.3)
Time since initial prescription date of the target medication, N (%)	
<1 year	11 (11.2)
≥1 year	92 (88.8)
Number of prescribed medications, N (%)	
<5	56 (54.9)
≥5	46 (45.1)

were men (versus 44%) and 40.6% had non-formal/low educational level (versus 38.2% with no schooling/primary school).

Most of the medication chosen as the guideline for the interview by the participants (89% of cases) was for chronic medical conditions, since the patients had been taking it for more than a year. Almost half (45%) had multiple medications (treated with five or more drugs). Lipid modifying agents and angiotensin-converting enzyme (ACE) inhibitors were the most chosen medication (both 11.7%). Table 2 contains the patients' responses to the RALPH interview guide in Spanish, prepared for final validation. The questions follow the same order and structure as the original RALPH interview guide, as well as the same answer options. The vast majority of patients (91–96%) knew the indications and frequency/time of use of their medication; however, 36% could not answer when they were asked about their understanding of warnings or specific instructions for use (question 3), and 10% answered this question incorrectly. The responses to question 4 should also be highlighted, since a considerable percentage of patients stated that they did not seek further information (18%) or consult reliable sources (6%) upon receiving contradictory information. Most of those who did seek information from reliable sources had asked the physician or pharmacist. This response is in agreement with those obtained to questions 5 and 6, where 62–65% of patients stated that it was very easy for them to ask health professionals about their doubts or concerns regarding their medication. In addition 37–43% of patients found it very or quite easy to obtain information in words they understood, to judge its applicability and reliability, and also to participate in shared decision-making. In summary, the reason that patients adduced for not participating in the assessment of the information of their medication was that they trusted their health care professional. As for the analysis of the socio-demographic variables, no significant differences were observed according to patients' gender or age. Older patients had notably more difficulty finding information (question 7, F-value = 3.437, P-value <0.05) and in participating in shared decision-making (question 10, F-value = 3.266, P-value <0.05). Significant differences were also observed according to patients' responses and their level of education (linear-by-linear association <0.05). A higher level of education was linearly correlated with easier information assessment, except for questions 4 and 10. Regarding the clinical variables, no significant differences were detected between patients' responses and the number of medicines prescribed or their initial prescription time.

When comparing the percentage of correct answers of the Spanish patients with those obtained by Koster et al.,[6] no significant differences were observed on most of the items (Table 3). However, Spanish patients had a significantly higher number of correct answers in assessing information reliability (question 9, z = 4.30 P-value <0.005) and shared decision-making (question 10, z = 2.95, P-value <0.005). In contrast, for the understanding of warnings or specific instructions for use (question 3), the percentage of correct answers among the Spanish patients was significantly lower (z = 4.74, P-value <0.005).

3.3. RALPH interview guide: the validated Spanish version

The definitive RALPH guide translated into Spanish maintains the same structure as the original: 10 questions framed in the three pharmaceutical literacy domains, linked to the patient's own medication. It contains a section on socio-demographic and clinical variables of interest. At the beginning, a summary of the instructions presented to the participating pharmacists was added to simplify their use. Some expressions were also reformulated, taking care not to change their meaning. Finally, the questions about understanding the warnings or specific instructions for use (question 3), contradictory information (question 4) and shared decision-making (question 10) had to be rewritten due to cultural differences, and in accordance with the observational and statistical results.

Table 2
Patients' responses to the RALPH interview guide in Spanish language, prepared for final validation. Total sample N = 103.

RALPH questions	Health literacy domain	Patients' responses n (%)		
		Correct	Incorrect	Patient does not know
1. Indication for use	Functional	94 (91.3)	7 (6.8)	2 (1.9)
2. Frequency/timing of medication use	Functional	99 (96.1)	4 (3.9)	–
3. Understanding of warning or specific instruction for use	Functional	56 (54.4)	10 (9.7)	37 (35.9)
		Searching information in reliable source	Searching information in non-reliable source	Patient does not search
4. Contradicting information	Critical	78 (75.7)	6 (5.8)	19 (18.4)
		Very easy	Quite easy	Quite difficult	Very difficult	Patient does not participate

RALPH questions	Health literacy domain	Very easy	Quite easy	Quite difficult	Very difficult	Patient does not participate
5. Asking questions	Communicative	67 (65.0)	28 (27.2)	6 (5.8)	2 (1.9)	–
6. Addressing concerns	Communicative	64 (62.1)	31 (30.1)	6 (5.8)	2 (1.9)	–
7. Finding information	Communicative	38 (36.9)	33 (32.0)	20 (19.4)	4 (3.9)	8 (7.8)
8. Assessing information applicability	Critical	25 (24.5)	33 (32.4)	29 (28.4)	8 (7.8)	7 (6.9)
9. Assessing information reliability	Critical	26 (25.5)	32 (31.4)	27 (26.5)	11 (10.8)	6 (5.9)
10. Shared decision making	Critical	37 (36.3)	44 (43.1)	8 (7.8)	6 (5.9)	7 (6.9)

Table 3
Percentage of correct answers in the RALPH-Spanish version compared to the original RALPH interview guide,[6] and the significance according to the *P*-value.

RALPH questions	RALPH – Spanish % correct answers (N = 103)	RALPH – Original % correct answers (N = 508)	Significance (*P*-value)
1 Indication for use	91.3	85.4	–
2. Frequency/timing of medication use	96.1	95.9–91.3	–
3. Understanding of warning or specific instruction for use	54.4	74.7	p < 0.05
4. Contradicting information	75.7	70.1	–
5. Asking questions	92.2	90.9	–
6. Addressing concerns	92.2	87.8	–
7. Finding information	68.9	60.6	–
8. Assessing information applicability	56.3	50	–
9. Assessing information reliability	56.3	36	p < 0.05
10. Shared decision making	78.7	64.7	p < 0.05

4. Discussion

This is a study of the linguistic validation of the Spanish version of the RALPH interview guide that involved its protocolized translation and cultural adaptation, and an analysis of its psychometric properties. The validated Spanish version complies with the requirements of viability, validity and reliability (both internal consistency and inter-temporal stability). Occasionally, the translated guide was difficult to follow during the cultural adaptation process, and the participating pharmacists required some training. For this reason, a brief introduction was added to the final version, and some expressions were clarified and reduced, always taking care to maintain the original meaning. In this process, a clear, easily manageable tool was created for use at Spanish community pharmacies.

Interestingly, questions about understanding warnings or specific instructions for use (question 3) and contradictory information (question 4) had to be rewritten. The analysis of the patients' responses indicated that these questions had the highest rates of the answer "the patient does not know". This may show that the interviewers or patients had different interpretations or did not understand the questions correctly. In fact, many interviewers shared their doubts, especially regarding question 4. Furthermore, the answers to question 3 were not consistent with the answers to the other functional domain questions, since the high percentage of patients who "did not know" reduced the percentage of correct answers. Consequently, significant differences were found with respect to the responses described by Koster et al.[6] This is supported by the construct validity study carried out using factor analysis, since both questions 3 and 4 were placed in a new domain that

did not correspond to the original. Nor did the question on shared decision-making (question 10) remain in the expected domain during factor analysis. Question 10 also raised doubts of interpretation among pharmacists during the interview process, which may have led to an artificially high percentage of correct answers; indeed, the differences with respect to the Dutch patients in the original were significant, and for this reason an example was added in question 10 in order to adapt it to the reality of the new target population.

On the other hand, the lack of correlation observed between patients' socio-demographic and clinical characteristics and their pharmaceutical literacy skills may indicate that the RALPH interview guide can be applied in all populations. However, although the study was designed to ensure sample variability, pharmacists were able to choose the patients they interviewed due to the need to combine the interviews with the daily tasks of each pharmacy. This could be interpreted as a limitation of the study and may restrict the extrapolation of the data to other contexts, but it also allowed pharmacists to identify the patient profile that they consider in greatest need of attention: namely, the elderly with chronic diseases, frequently with multiple medications. This patient profile is in fact increasing within the Spanish primary-care population and is associated with greater morbidity and healthcare needs.[31,32] In addition, the medications chosen during the interviews are indicated for the most common diseases in primary health care, such as hypertension and hypercholesterolemia.[33]

Taken together, it can be concluded that the pharmaceutical literacy skills of the patients interviewed were adequate in both functional and communicative domains, that is, that they were able to understand instructions about their medication and to express their concerns. Their

pharmaceutical literacy was more limited in the critical domain, for instance when judging the information they found in the press or on the internet. Indeed, searching on the internet, contrasting information and shared decision-making are situations where older people tend to have more difficulties.[33,34] As shown in Table 3, the results agree with those observed by Koster et al.,[6] except for the reformulated questions 4 and 10. The differences in Question 9 (assessing information reliability) may be due to the fact that the terms "reliable" and "relevant" were more difficult for the Spanish-speaking interviewers to differentiate. Therefore, the percentages of correct answers to both question 8 (information applicability) and question 9 (information reliability) were the same for the Spanish version, but not for the original. It is important to note that the patients' data are descriptive, since the sample size established in this study is intended to validate the interview guide. It should also be borne in mind that the patients who attend the community pharmacy are not representative of the general primary care population, as they do not include, for example, the homeless and people living in nursing or residential homes.

As stated above, Spanish pharmacists' impressions of the RALPH interview guide were positive. The concerns they raised were mainly to do with specific doubts, or suggestions of ways to simplify certain aspects. If pharmacists are able to identify low pharmaceutical literacy on the part of their customers, the dispensing process will be improved.

When the validated version of the RALPH guide in Spanish is available, the interviews should be conducted in a large sample in order to identify areas for improvement in the Spanish population. Validation of the guide in Spanish will also permit its use in other Spanish-speaking countries. This tool will be particularly useful in many settings: in patients who require special attention (e.g., in elderly people with multiple medications), in the provision of specific professional pharmaceutical services in community pharmacies, in both national and international studies to evaluate a population's pharmaceutical literacy skills, and in the implementation of public health interventions. Finally, as an interview guide, it can be adapted to the needs of different healthcare professionals. It can therefore be used in other settings outside the community pharmacy – for example, in primary care centers – where assessing patients' pharmaceutical literacy is important.

5. Conclusions

This validated version of RALPH interview guide in Spanish complies with the requirements of viability, validity and reliability (both internal consistency and intertemporal stability). This tool may be able to identify the low pharmaceutical literacy skills of patients coming to community pharmacies in Spain, and its use may also be extended to other Spanish-speaking countries. The descriptive results indicated that more limited pharmaceutical literacy skills were observed regarding the critical domain. The responses of Spanish patients were in agreement with the results of the original RALPH interview guide.

Author statement

MAC and PM developed the design of the study. MA-M acquired the data and drafted the manuscript. All authors contributed to data analysis, revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Formatting of funding sources

Data sharing statement

The dataset used is available from the corresponding author upon request.

Declaration of competing interest

The authors report no conflicts of interest for this work.

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