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ALSATION Study Protocol: Romanian Translation of Three Health Literacy Surveys

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Abstract. Access to the internet and online resources changes the concept of health and increases people's autonomy. In this context, Health Literacy (HL) is a critical determinant of health-related choices. At World Health Organization (WHO) level, M-POHL (Action Network on Measuring Population and Organizational Health Literacy of WHO-Europe) created and validated on European population four questionnaires: digital HL (HLS19-DIGI), communication HL (with doctors from health care services - HLS19-COM-P-Q11 long version and HLS19-COM-P-Q6 short version), online navigation HL (HLS19-NAV), and vaccination HL (HLS19-VAC). Based on the expertise of the team, the present study aimed to report the study protocol for Romanian translation, culturally adapting and psychometric testing the following three M-POHL health literacy tools: HLS19-DIGI, HLS19-NAV, and HLS19-COM-P-Q11, HLS19-COM-P-Q6. We will conduct a qualitative descriptive study design in seven steps to translate and adapt the HLS19-DIGI, HLS19-NAV, and HLS19-COM-P-Q11, HLS19-COM-P-Q6 to the Romanian speakers. The study will begin with the translation of English (En)-Romanian (Ro) (2 researchers involved) (step 1), followed by the evaluation of the translation by a bilingual researcher independent of the two researchers who did the En-Ro translation (step 2), the translation of Ro-En (2 researchers but not those in step 1; step 3), the evaluation of the translation by a bilingual researcher independent of the two researchers who did the Ro-En translation (step 4), evaluation of the translation of the tool in an expert group (step 5), pilot testing on a sample of the target population (step 6) and full psychometric testing of the version resulting from step 6 (step 7).

Keywords. Health literacy (HL), Survey, Translation, Validation.

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1. Introduction

Access to the internet and to the resource's available online changes the concept of health and increases people's autonomy. In this context, Health Literacy (HL) is a critical determinant of health-related choices. Low levels of health literacy are associated with poorer health [1,2], unhealthy behaviour and more visits to healthcare services [3,4]. A high proportion of people have low HL, with a clear social gradient for HL [4].

At the World Health Organization (WHO) level, M-POHL (Action Network on Measuring Population and Organizational Health Literacy of WHO-Europe) has activities to assess literacy in the context of health. Among the objectives, M-POHL includes conducting regular, high-quality, internationally comparative surveys on health literacy, health literacy systems and organisations, collecting and analysing data on organisational health literacy (structures, processes and capacities conducive to health literacy). Data from the European Health Literacy Knowledge Survey show that almost half of the Europeans surveyed (Romania did not participate in this study) have inadequate or problematic health knowledge. Poor health literacy skills are associated with riskier behavior, poorer health, less self-management, and more hospitalization and costs [5].

Under the umbrella of M-POHL, specific tools have been developed, validated and applied to measure four relevant specific aspects of HL (https://m-pohl.net/tools): (1) Digital HL (HLS19-DIGI) [6], (2) HL of communication (with doctors of health care services - HLS19-COM-P-Q11 Long version and HLS19-COM-P-Q6 Short version) [7], (3) HL internet browsing (HLS19-NAV) [8-10], and (4) Vaccination HL (HLS19-VAC). There is evidence on different aspects of health literacy in European countries [4].

The present study aimed to present the study protocol for Romanian translation, cultural adaptation, and psychometric testing three health literacy M-POHL tools from the area of expertise of the research team, namely HLS19-DIGI, HLS19-NAV, and HLS19-COM-P-Q11, and HLS19-COM-P-Q6.

2. Materials and Methods

The translation and cultural adaptation of the questionnaires will be done applying the methodology described by HSRI (Human Services Research Institute, USA) [11] and following the methodology recommended by Sousa and Rojjanasrirat [12].

Table 1 summarizes the steps that apply to each instrument. The procedures that will be followed are presented in Table 2.

Table 1. ALSATION study: steps and description.

Step	Description
1	Translating the tool from En to Ro (2 experienced researchers from academia with different backgrounds). The first translator must have knowledge of medical terminology and tool construction, and the second translator must be familiar with colloquial phrases, slang and jargon regarding digital literacy, idiomatic expressions and emotional terms. The approach will generate two translated versions containing words and sentences that cover both medical language and ordinary spoken language with its cultural nuances.
2	Evaluation of the translation by a bilingual researcher independent of the two researchers who made the initial translation. At this stage, ambiguities and discrepancies of words, sentences and meanings are evaluated. The identified discrepancies are discussed and resolved by a group consisting of the two researchers who made the initial translation, the third researcher and at least two other members of the research team. This group must reach a consensus and will report the preliminary Ro versions.
3	Translate the preliminary version of the tool from Ro to En. Use different two

Step	Description
	researchers/translators with the characteristics described in step 1.
4	Apply the approach presented in step 2 for comparing the translated versions from Ro to En relative to the original version of the tool. At this stage, the similarity of the instructions, elements and response format is assessed in terms of wording, item structure, meaning and relevance. Repeat steps 1 to 4 as many times as necessary till solve all ambiguities and discrepancies. Alternatively, only elements that do not retain their original meaning are retranslated and translated back.
5	Evaluate the translation of the tool in an expert group (targeted number is 10). We will evaluate clarity of instructions, items, and response possibilities. The experts will be invited to assess each element of the instrument in terms of *content relevance* (1 = not relevant; 2 = somewhat relevant; 3 = relevant but requires minor changes; 4 = very relevant. Items classified as 1 or 2 will be revised [13]); *sharpness* (1 = blurry, 2 = item needs review; and 3 = very clear); and *necessity* (1 = non-essential; 2 = useful but not essential; and 3 = essential). The content validity index will be calculated at the element level (I-CVI, CVI=content validity) and at the S-CVA/Ave scale level (mean calculation method) [14]. The items with $0.70 \leq$ I-CVI (relevance of items) ≤ 0.79 will be review [15], and those with I-CVI<0.70 will be removed [16]; S-CVA/Ave ≥ 0.90 shows excellent content validity [15]. The process will continue until acceptable indices of validity are obtained or eliminated. The final version will be analyzed in terms of content (internal validity) by calculating the kappa coefficient [17], the minimum acceptable coefficient to be considered a good tool being 0.60, excellent above 0.74.
6	Pilot testing on a sample of the target population (targeted sample size: 10-40 participants). At this stage, each participant evaluates the instructions and elements of the instrument using a dichotomous scale (clear or unclear). For evaluations in the "blurry" category, participants are asked to provide suggestions on how to rewrite to make the language clearer. We will reassess items and elements of the instrument that at least 20% of the sample consider unclear [18].
7	Full psychometric testing of the version resulting from step 6 (targeted sample size: minimum 10 subjects per instrument scale item. What do we evaluate? At least one of the following (1) reliability of internal consistency; (2) stability reliability (test-retest reliability); (3) the validity of the construction (convergent and/or divergent, discriminatory validity).

Table 2. ALSATION study: main procedures.

Step	Procedure
1	Criteria for identifying potential participants for translation: • Language skills En (minimum level C1) and Ro (mother tongue); • Experience in the field (medicine, sociology, public health, applied informatics in medicine or related fields); • Previous experience in questionnaire translation or questionnaire-based research: if possible previous translation experience (questionnaires or other research materials) in the previous listed areas. Participants must give their consent. Benefits (fees or other benefits – e.g. inclusion in the research team) and delivery times are established.
2	Two researchers (other than those in step 1) will be invited to take part in the activities of this step. Eligibility criteria: • Language skills En (minimum level C1) and Ro (mother tongue), and • Experience in questionnaire research.
3	The criteria for translators are those described in Step 1. The people involved in Step 1 cannot be involved in this step.
4	Identical as procedure described in Step 2.
5	Eligibility criteria for the Expert Group participants: • Experience in the field (medicine, sociology, public health, applied informatics in medicine or related fields); • Previous experience in questionnaire-based research; • Availability of active participation.
6	Eligibility criteria: • It is part of the target group, represented by the general population; •The mother tongue is Romanian; • Has the ability to understand what reads in Romanian; • Preferable, has the necessary skills to use online tools. To capture all demographic and socio-cultural groups, at least two trained researchers will help the potential participants in this process. How to identify participants: • Individual invitations of research team members – convenient snowball – those who participate are asked to invite 1-2 more acquaintances/colleagues/family members/neighbors; • Groups – social media platforms (e.g., Facebook etc.); • Invitations – Professional social media platforms / patient groups / patients etc.
7	Eligibility criteria: • It is part of the target group, represented by the general population; • The mother tongue is Romanian; • She/He can understand what he reads in Romanian; • She/He has the necessary skills to use online tools.

Step	Procedure
	How to identify participants: • Students: regardless of field of study, form of schooling, sex or other criteria (reliability of stability); • Participants in activities intended for the general population: leisure, health (cross-country, health education), screening, etc.; • Support groups and patient associations; • General population.

The ethical approval has been received from the Ethics Committee of the Iuliu Haţieganu University of Medicine and Pharmacy Cluj-Napoca (approval number AVZ152/29 July 2024) and the signed informed consent was waived.

3. Results, Discussion and Conclusion

Brief Health Literacy Screen [18] and Single-Item Literacy Screener (SILS) [19] are available surveys to measure health literacy, but none have a validated Romanian version. The HLS-EU-Q16 is the only HL survey translated and validated in Romania, that reflects the Romanian reality in 2019 [20]. The HLS-EU-Q16 assesses literacy according to the definition that existed at the time of development, a definition that is not valid anymore. M-POHL captures better the current definition of HL and offer instruments able to evaluate several dimensions of HL. The M-POHL results showed that almost half of the Europeans surveyed have inadequate or problematic health literacy knowledge and skills [21]. Poor health literacy skills are associated with riskier behavior, poorer health, less self-management, and more hospitalization and costs [22].

Romanian versions of the targeted M-POHL surveys on HL can enhance the assessment of health literacy achievements within the Romanian population, who did not take part in the validation of M-POHL surveys. Romanian versions of targeted M-POHL surveys will provide valid tools tailored to cultural and linguistic requirements of the Romanian population. The translated and validated versions will be instruments capable of evaluating specific aspects of digital health literacy, potentially leading to increased participation and accurate responses. This is crucial, as language and cultural nuances can affect how individuals comprehend and respond to survey questions [23]. Enhancing health literacy assessment through a translated survey can provide valuable insights into the health literacy levels of the Romanian population, information that is essential for developing targeted interventions and policies to improve health outcomes and reduce health [24] in the context of digital health and care in [25].

Translating the health literacy survey into Romanian is a necessity that will offer a tailored approach to assessing health literacy achievements within the Romanian population. This initiative aligns with the broader goal of promoting health literacy as a fundamental aspect of improving health knowledge, skills, and behaviors, ultimately leading to better health outcomes for the Romanian population.

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