Original Research

Development and Validation of an Instrument to Assess Clinical Competencies in the Management of Self-Limiting Health Conditions (Psal-Brazil)

Audinei de Sousa Moura [ID], Noemia Urruth Leão Tavares [ID], Wellington Barros da Silva [ID], Rodrigo Fonseca Lima [ID], Rafael Santos Santana [ID]

Abstract

Background: The management of self-limiting health conditions (PSAL) is a service generally performed by professional pharmacists in community pharmacies, which directly impacts in the reduction of demand for other levels of care in the public health system. To achieve this, pharmacists must invest in their continued education in order to further develop their clinical skills. **Objective:** To develop and validate a clinical skills assessment instrument to be used to train pharmaceutical professionals and undergraduate students to manage self-limiting health conditions. **Methods:** Firstly, the assessment instrument was developed, based on a literature review. Then, the instrument was validated using the Delphi Method. Experts were invited to evaluate the instrument on five criteria. For content validation, the Content Validation Index (CVI) was calculated and items were considered validated if the CVI ≥ 0.80. For internal consistency analysis, Cronbach's Alpha was used. **Results:** Of the 26 invited experts, 19 participated in the first round and 17 in the second. Items (13) Monitoring and (14) Verbal communication, from the initial version, did not reach consensus in terms of objectivity (0.79) and clarity (0.79), respectively. After the changes suggested by the experts were made, a second round was carried out, in which all items reached consensus, CVI ≥ 0.80. Other suggestions were accepted and the final version of the instrument addressed 15 questions to analyze the quality of the service and one question to assess the level of clinical skills development, as initial, intermediate or advanced. The Cronbach's Alpha average increased significantly from the first to the second round. **Conclusion:** The PSAL-BRASIL assessment instrument was validated with a desirable level of consensus and demonstrated a level of internal consistency classified as almost perfect, seeking to be a reference in the development of clinical skills necessary for pharmaceutical care of self-limiting health conditions.

Keywords: pharmaceutical care; surveys and questionnaires; validation studies; clinical pharmacy; pharmaceutical education

INTRODUCTION

The management of self-limiting health conditions (referred to as PSAL in Portuguese) is a service generally performed by a professional pharmacist in accordance with patient demand in community pharmacies. In the performance of said service, the usual procedure is to identify the causes and characteristics of the disorders presented, so that pharmacological and non-pharmacological interventions can be carried out as well as the identification of warning signs that require referral to other professionals or health services, when needed.[1] Studies show that the management of PSAL in the community pharmacy by a trained professional has a direct impact on reducing the demand for other levels of care in the public health system, with a decrease in the demand for medical consultations for minor symptoms from 21.6% to 61.3%, and success rates ranging from 68% to 94%.[2,3,4]

To this end, pharmacists must invest in their continued education in order to further develop their clinical skills, which not only helps them to establish a bond of trust with the patient but also directly impacts the rational use of over-the-counter medicines, as the patient will only use whatever is most effective for the amount of time necessary.[5] The development of clinical skills is possible through taking lessons and training courses that use active learning methodologies as well as participating in projects with experimental activities in pharmaceutical care, such as simulations.[6,7]

Studies show that realistic simulations prepare professionals for clinical practice, by bringing benefits such as the development of clinical and critical reasoning and increased safety, thus assisting in decision making processes, in the establishment of action plans and in the monitoring of results and interventions.[8]

Audinei de Sousa MOURA. Evidence and Pharmaceutical Studies Laboratory. Pharmacy Department, Faculty of Health Sciences, University of Brasília, Brazil. moura.audinei@gmail.com

Noemia Urruth Leão TAVARES. Evidence and Pharmaceutical Studies Laboratory. Pharmacy Department, Faculty of Health Sciences, University of Brasília, Brazil. noemialtavares@unb.br

Wellington Barros da SILVA. Federal University of Sergipe, Center for Biological and Health Sciences, Department of Physiology. São Cristóvão, Sergipe. wbarros@ufs.br

Rodrigo Fonseca LIMA. Evidence and Pharmaceutical Studies Laboratory. Pharmacy Department, Faculty of Health Sciences, University of Brasília, Brazil. rodrigo.fonseca@unb.br

Rafael Santos SANTANA*. Evidence and Pharmaceutical Studies Laboratory. Pharmacy Department, Faculty of Health Sciences, University of Brasília, Brazil. rafael.santana@unb.br

Simulations, as active learning methodologies, are essential in pharmacy training, as they are known to improve student satisfaction in regards to the matter under study, to increase safety in care, to increase effectiveness in solving problems related to medications as well as to improve interpersonal relationships between professionals and patients.[9]

There are few scientific studies that validate assessment tools for pharmaceutical clinical skills. Therefore, the goal of this study was to develop and validate a clinical competence assessment instrument for pharmaceutical professionals and undergraduate students in managing self-limited health conditions.

METHODS

Study design

This is a methodological development study, with a descriptive character and a qualitative approach. A process of development and validation of the assessment instrument entitled **PSAL-BRASIL: Assessment of Clinical Competencies for the Management of Self-Limiting Health Conditions** was carried out in two parts, namely: (1) methodological development of the instrument; and (2) validation by a panel of experts using the Delphi method, according to the steps described below.

Stage I - Methodological Development of the Assessment Instrument

The methodological development of the assessment instrument was carried out in Brasília, Federal District, Brazil, from December 2021 until February 2022. The first stage consisted of the development of the instrument's initial proposal based on a broad review of the literature on the topic as well as the vast number of studies previously carried out within the scope of the "Evidence-Based Pharmacy" project.[10-14]

Preparation of the Assessment Instrument

The instrument was developed by the team of researchers from the Evidence and Pharmaceutical Studies Laboratory of the University of Brasília (LEFAR-UnB), which had already published a series of clinical guidelines for pharmaceutical care in self-limiting health conditions (<https://www.lefarunb.com.br/diretrizes-cl%C3%ADnicas>).

The instrument and previous guidelines had their structure divided into stages recommended by national projects to be followed in pharmaceutical care, starting with a preliminary stage of (1) welcoming the patient, followed by the stages of (2) case assessment, (3) establishment of a care plan and (4) monitoring guidelines.[1] In addition, questions about verbal and non-verbal communication were included in the questionnaire. The instrument was developed to be applicable to the management of different types of self-limiting health conditions.

Review of the Instrument's Content

Focus group meetings to review the content of the instrument were held with expert researchers in the field, in order to adapt the instrument for use in assessing clinical skills in realistic simulations of the management of self-limiting health conditions.

Based on the skills to be developed by pharmaceutical professionals to care for patients in the context of a pharmaceutical consultation, the content of the instrument was reviewed by laboratory members and then tested by the group itself. Furthermore, pre-tests were carried out with groups of pharmacy professionals and students to improve the instrument for its practical use.

Stage II - Validation of the Assessment Instrument

The validation of the instrument followed the Delphi Method of content validation by experts, which was chosen due to its advantages, such as the possibility of flexible application in different regions at the same time, as well as the application to specialists in the area with different backgrounds and the guarantee of anonymity, so that thoughts and opinions would not be influenced by peer pressure and prejudice. In order for there to be credibility, reliability and validity of the results found, methodological rigor is necessary in applying the method.[15,16]Although there is no specific checking system for the Delphi Method, the study was prepared based on the standard recommendations of **Guidance on Conducting and Reporting Delphi Studies (CREDES)** reports.[17]

Expert panel selection

The experts were selected based on research carried out in scientific articles in the area, as well as in the CV database available on an online platform (Lattes Platform – CNPq). For this, pharmaceutical professionals with experience and/or publication of scientific articles in the area of interest were selected. The sample was formed by convenience so that pharmacists from all regions of Brazil were invited to participate in the research via email, and, when necessary, there was a second attempt at getting in touch through a messaging app. The snowball sampling technique was applied and experts who participated in the validation were invited to nominate other experts who met the inclusion criteria.[18]

It is noteworthy that participants with expertise in the researched subject were included in the sample: pharmacists with experience in managing self-limiting health conditions or postgraduate pharmacists with research in the areas of pharmaceutical care, clinical pharmacy, management of self-limiting health conditions and/or pharmaceutical prescription. Researchers involved in the development of this research were not included in order to avoid conflict of interest.

In total, 26 pharmacists were invited, including PhD and Master's title holders and specialists. In the first contact made, each selected pharmacist was sent a Cover Letter, containing an explanation of the research project and formalizing the invitation to join the experts' panel. The Free Prior Informed Consent Term (known as TCLE in Portuguese) was sent as an attachment, which should be completed and returned alongside their email response, in order to guarantee the confidentiality of the instrument developed.

After agreeing to participate in the panel, the electronic form was sent to the experts with an initial part, which contained sociodemographic questions, and the questionnaire to validate the instrument, with specific instructions for evaluation and completion. In order to guarantee anonymity in the evaluations of the instrument, the experts were not aware of the other participants' answers.

Data collection

The criteria used to evaluate the attributes of each question in the assessment instrument were:[20,21]

● **Representativeness** – The ability of the item to represent the content of the domain as described in the theoretical definition. To what extent does each instrument item measure the clinical skills referenced by the assessment?

● **Clarity** – The item is written in a clear, simple and unambiguous way. How clear is the item to you?

● **Objectivity** – Allows timely response. How objective is the item in relation to the skill it is intended to assess?

● **Accuracy** – Each assessment item is distinct from the others, they cannot be mistaken among themselves.

● **Relevance** – Does not imply an attribute that differs from what was defined.

Each of the instrument's questions was followed by the criteria to be evaluated with scores represented by the numbers 1, 2, 3 and 4. Therefore, a value of one (1) indicates that the criterion was not met by the question, and a value of four (4) indicates that the criterion was fully met by the question. Space was provided for experts to suggest ways to improve the item.

The Delphi technique

The Delphi technique was applied in rounds, there being established a minimum of two rounds, which continued until a consensus was reached among experts. In the first round, the instrument validation form mentioned above was made available to the judging experts, in which they were invited to complete and send the response within a maximum period of 20 days, which was extended for another 10 days, so that the greatest number of experts could participate.

The items with possible answers on a scale of 1 to 4 were condensed into a dichotomous scale of YES or NO, so that the answers corresponding to numbers 1 and 2 were considered negative (NO), indicating that the question did not reach the criterion judged, and answers with numbers 3 and 4 were considered positive (YES), indicating that the criterion was reached satisfactorily by the question.

Items with subjective responses were summarized to generate a list of experts' comments on each question and the comments were analyzed individually. These comments were taken into account when reviewing the instrument's evaluative items.

Definition of Consensus

A level of consensus among experts is defined as reaching 80% or more agreement for each question. For this purpose, the Content Validation Index (CVI) was calculated from the ratio between the number of "3" or "4" responses and the total number of responses so that the items were considered validated if the CVI presented a value greater than 0.80.[22]

Second round

After evaluating the responses from the first round and defining the level of consensus regarding the questions, a second round of the Delphi technique was applied, in which a second version of the form was sent to the experts. The items were modified to meet the comments made by the experts, considering that acceptance of the suggestion was moderated by the researchers who developed the instrument.

The judging experts had to evaluate these items using the same previous criteria (representativeness, clarity, objectivity, accuracy and relevance); in the second round there was no space for comments on the items. The deadline given to experts to respond in this round was a maximum of 10 days. Periodic reminders were sent to obtain as many responses as possible within the given period.

If there was still disagreement and consensus was not reached on any of the items (CVI < 0.80), new rounds would be initiated, depending on the level of divergent responses and the number of items not approved. This way, the stopping point would be the consensus of all items (regardless of the number of rounds).

Statistical methods

The items present in the assessment instrument were analyzed quantitatively based on the calculation of the CVI, as previously described, in each of the rounds of the Delphi Method. The data obtained were exposed using descriptive statistics, based on the calculation of the mean and the percentage.

As a measure of consistency between evaluators, an internal consistency measure was performed using the Cronbach's Alpha method calculated using the R software.[23] To interpret the Alpha coefficient, the following categories were considered: almost perfect (> 0.8), substantial (between 0.61 and 0.8), moderate (between 0.41 and 0.60), reasonable (0.21 and 0.40) and low (<0.21).[24]

Ethical aspects

The research project was approved by the Research Ethics Committee of the Faculty of Health Sciences (CEP/FS) of the University of Brasília, on December 16, 2021, with the approval opinion number 5,171,224 (CAAE: 42517920.9. 0000.0030).

RESULTS

Methodological Development of the Assessment Instrument

The methodological development stage resulted in an assessment instrument entitled **PSAL-BRASIL: Assessment of Clinical Competencies for the Management of Self-Limiting Health Conditions**, which was constructed with 15 questions to analyze the quality of the service: Hospitality (1), Assessment (3), Care Plan (8), Monitoring (1) and Communication (2), in addition to a question to evaluate the simulated pharmacist's

general performance level (clinical skills), as presented in Table 1.

Table 1. Evaluation domains and questions of the PSAL-BRASIL: Assessment of Clinical Competencies for the Management of Self-Limiting Health Conditions instrument

Evaluation Domain	Assessment Instrument Questions
Hospitality	1. Hospitality and presentation
Assessment	2. Definition of the health condition
	3. Pharmaceutical history
	4. Measurement of vital signs; Physical and laboratory examinations
Care Plan	5. Therapeutic goals and objectives
	6. Prevention and health promotion actions
	7. Non-pharmacological interventions
	8. Pharmacological intervention (necessary)
	9. Pharmacological intervention (effective)
	10. Pharmacological intervention (safe)
	11. Guidelines for using medications
	12. Warning signs and referrals
Monitoring	13. Monitoring
Communication	14. Verbal communication
	15. Non-verbal communication
Clinical skills	16. General evaluation
SOURCE: Elaborated by the authors.	

The instrument was developed with a three-point assessment scale, the aim of which was to allow simplicity in the examiner's response. The evaluation of the clinical performance of the simulation participant, the simulated pharmacist, was defined based on whether or not each of the evaluated items was fulfilled, so the judgment would be: (0) Did not perform – indicating that the simulation participant did not perform the aforementioned step of care; (1)

Performed incompletely – indicating that they performed, but not satisfactorily or completely and (2) Performed satisfactorily – indicating that the participant met completely the skill measured by the item.

Validation of the Assessment Instrument

Characterization of the expert panel

26 pharmacists were recruited from the five geographic regions of Brazil. Of those invited, 19 agreed to participate in the first round and sent the evaluation of the instrument, which represents a return rate of 73%. In the second round, 17 experts sent their responses, a return rate of 89% of the first round participants.

When characterizing the place of professional activity, there was a predominance of pharmaceutical researchers in the area (university professors), followed by clinical and community pharmacists, which is a positive aspect, due to

their daily coexistence with pharmaceutical care services. The characterization of the participants is described in Table 2.

Development of the Delphi Technique

The results obtained in each of the validation rounds using the Delphi Technique and the data referring to the calculation of internal consistency (Cronbach's Alpha) for each criterion evaluated are described in Table 3.

It can be noted in the previous table that most of the questions reached a favorable consensus among experts greater than 80%, except for items (13) Monitoring, which did not reach consensus on the objectivity criterion (79%), and item (14) Verbal communication, which did not reach consensus in terms of the clarity criterion (79%). The topics most discussed in the experts' comments and suggestions are described in Table 4.

Chart 1 below highlights the changes that were made by the team responsible for developing the instrument, based on the evaluation of the experts' suggestions.

The order of the items on verbal and non-verbal communication (which became items 14 and 15) was changed, as their location in the Hospitality stage was questioned by the experts, as it was understood that communication occurs throughout the service, and therefore, must be evaluated at the end of the simulation. The items were placed in their own category. A new electronic validation form was then created and sent in a second round to the experts. In the second round, all proposed items reached consensus (Table 3).

The effect of the experts' evaluations and comments was positive and the results were reliable for evaluating each of the criteria. The mean Cronbach's Alpha increased significantly from the first round (alpha = 0.745,IC(95%): 0.586-0.904) to the second round (alpha = 0.896, IC(95%): 0.853-0.939). The final version of the PSAL-BRASIL assessment instrument is represented in chart 2.

DISCUSSION

The instrument developed in this research, in the form of a standardized and validated questionnaire, seeks to be a reference in the training of pharmaceutical professionals and pharmacy graduates in the assessment of clinical skills for managing self-limiting health conditions (PSAL), also assisting in decision making to pharmaceutical prescription. Content validation for online courses has been successfully used in studies, in order to obtain an improvement in educational intervention.[25] There is also evidence that the use of protocols for the care of PSAL in community pharmacy increases patient safety, being, therefore, a contribution by the pharmacist to the public health system, as it assists in supported self-care or even in the process of responsible self-medication.[2]

The Delphi Technique is widely used in pharmaceutical practice research, validations with this technique can be found in articles that seek to develop standardized counseling instruments for young people when prescribing pharmaceutical contraceptives,[26] to establish a consensus

Table 2. Characterization of the experts who participated in the validation process using the Delphi Method				
Characteristic	**First Round Participants (N= 19)**		**Second Round Participants (N = 17)**	
	%	**n**	**%**	**n**
Gender				
Female	78,9%	15	82,4%	14
Male	21,1%	4	17,6%	3
Age				
20 - 30 years	42,1%	8	47,1%	8
31 - 40 years	36,8%	7	35,3%	6
41 - 50 years	21,1%	4	17,6%	3
Level of academic training				
PhD title holder	78,9%	15	76,5%	13
Master's title holder	15,8%	3	17,6%	3
Specialization	5,3%	1	5,9%	1
Time working as a professional				
Less than 5 years	21,1%	4	23,5%	4
6 to10 years	21,1%	4	23,5%	4
11 to 20 years	47,4%	9	41,2%	7
21 to 30 years	10,5%	2	11,8%	2
Region of Brazil in which they perform				
Southeast	36,8%	7	35,3%	6
Midwest	26,3%	5	23,5%	4
North East	26,3%	5	29,4%	5
North	5,3%	1	5,9%	1
South	5,3%	1	5,9%	1
Type of institution of activity				
Public	73,7%	14	70,6%	12
Public and Private	15,8%	3	17,6%	3
Private	10,5%	2	11,8%	2
Place of professional activity				
College Professor	68,4%	13	70,6%	12
Clinical Pharmacist	15,8%	3	17,6%	3
Community Pharmacist	10,5%	2	11,8%	2
Pharmacist Manager	5,3%	1	0%	0

SOURCE: Elaborated by the authors

Table 3. Summary of the Content Validation Index (CVI) in the first (1st) and second (2nd) round of the Delphi Technique and Cronbach's Alpha.										
SOURCE: Elaborated by the authors										
Assessment Instrument Questions	**Criteria**									
	Representativeness		**Clarity**		**Objectivity**		**Accuracy**		**Relevance**	
	1st	**2nd**	**1st**	**2nd**	**1st**	**2nd**	**1st**	**2nd**	**1st**	**2nd**
1. Hospitality and presentation	0,89	1,00	0,84	1,00	0,84	0,94	1,00	0,94	0,84	1,00
2. Definition of the health condition	0,95	1,00	0,84	1,00	0,84	0,94	0,95	0,94	0,95	1,00
3. Pharmaceutical history	0,95	1,00	0,89	1,00	0,89	0,88	0,95	0,94	1,00	1,00

4. Measurement of vital signs; Physical and laboratory examinations	1,00	1,00	0,89	1,00	0,95	0,94	0,95	0,94	1,00	1,00
5. Therapeutic goals and objectives	1,00	1,00	0,95	1,00	0,89	0,94	1,00	1,00	0,95	1,00
6. Prevention and health promotion actions	1,00	1,00	0,89	1,00	1,00	1,00	1,00	1,00	1,00	1,00
7. Non-pharmacological interventions	1,00	1,00	0,84	1,00	0,95	1,00	1,00	1,00	0,95	1,00
8. Pharmacological intervention (necessary)	1,00	1,00	1,00	0,94	0,89	1,00	1,00	1,00	0,95	1,00
9. Pharmacological intervention (effective)	1,00	1,00	0,95	0,94	0,95	1,00	1,00	1,00	0,95	0,94
10. Pharmacological intervention (safe)	1,00	1,00	1,00	0,94	0,95	1,00	1,00	1,00	0,95	1,00
11. Guidelines for using medications	1,00	1,00	0,95	0,94	1,00	0,94	1,00	0,94	0,95	0,94
12. Warning signs and referrals	1,00	1,00	0,95	1,00	0,89	0,94	1,00	0,94	0,95	0,94
13. Monitoring	1,00	1,00	0,84	1,00	0,79*	1,00	1,00	1,00	1,00	1,00
14. Verbal communication	0,84	1,00	0,79*	1,00	0,89	1,00	1,00	1,00	0,95	1,00
15. Non-verbal communication	0,89	1,00	0,84	1,00	0,95	0,94	1,00	0,94	0,95	1,00
16. General evaluation	1,00	0,94	0,95	0,82	0,84	0,88	1,00	0,94	1,00	0,94
Cronbach's Alpha	**0,90**	**0,95**	**0,74**	**0,87**	**0,75**	**0,88**	**0,55**	**0,91**	**0,79**	**0,87**
Internal consistency	Almost perfect	Almost perfect	Substantial	Almost perfect	Substantial	Almost perfect	Moderate	Almost perfect	Almost perfect	Almost perfect

* Items with CVI<0.80 that did not reach consensus in the first round

Table 4. Summary of comments and suggestions from experts on the PSAL-BRASIL assessment instrument in the first round of the Delphi Technique	
Comment category	**Quantity (N = 163)**
Rewrite (105)	
Include term	42
Separate or merge item	26
Explain term	19
Delete term	8
Rewrite item	10
Evaluation (19)	
Change rating scale terms	11
Describe the evaluation criteria	8
Clarity (18)	
Improve item understanding	14
Change or describe a term	4
Structure (16)	
Change order of items	16
Grammar (04)	
Grammatical corrections	4
Objectivity (01)	
Make the item more objective	1

SOURCE: Elaborated by the authors

Chart 1. Initial and final version of the questions of the PSAL-BRASIL: Assessment of Clinical Competencies for the Management of Self-Limiting Health Conditions instrument.

First Round Version	Second Round Version
Did they greet the patient? Did they introduce themselves and explain the service adequately?	Have they greeted the patient, introduced themselves and explained the service adequately?
Did they clearly define or confirm the health condition?	Have they clearly defined or confirmed the patient's **self-limiting health condition** or **chief complaint**?
Did they use the INDICO technique or take a correct pharmaceutical history, using essential questions to evaluate the condition?	Have they carried out the **pharmaceutical anamnesis** correctly, using techniques (such as **INDICO***) or essential questions to assess the clinical picture?
Did they perform adequate physical/laboratory examinations and/or check vital signs (if applicable)?	Have they measured the patient's **vital signs** or performed other physical/laboratory **exams** appropriately (if applicable)?
Did they clearly define the therapeutic objectives/goals for management?	Have they clearly defined the therapeutic **objectives/goals** for managing the health condition?
Did they adequately carry out prevention and health promotion actions?	Have they advised on measures to **prevent** new episodes of the current situation and **health promotion** actions?
Did they correctly indicate non-pharmacological interventions such as health practices and products?	Have they correctly indicated **non-pharmacological** interventions to manage the current situation, such as health practices and products?
Did they recommend a medication necessary to the treatment?	Have they recommended a pharmacological treatment **necessary** to the management of the self-limiting health condition?
Did they select the most effective pharmacological treatment for the patient?	Have they selected the most **effective** pharmacological treatment available for the self-limiting health condition?
Did they select the safest pharmacological treatment for the patient?	Have they selected a **safe** pharmacological treatment for the patient?
Did they correctly guide the patient on how to use medications (dosage, care, possible events, etc.)?	Have they correctly guided the patient on how to use **the medication(s)**?
Did they know how to identify warning signs and/or carry out referrals appropriately?	Have they known how to analyze the **warning signs** and, when necessary, how to carry out **referrals** appropriately?
Did they guide the patient on the correct way to self-monitor and/or schedule a new appointment to reevaluate the health problem?	Have they defined with the patient the best way to **evaluate results** (self-monitoring or active monitoring by the pharmacist)?
Verbal communication: Did they use open and closed questions at the appropriate time? Did they speak clearly to the patient without using technical jargon or explaining technical terms when necessary?	**Verbal communication:** Have they spoken clearly to the patient, without the use of technical jargon or explaining technical terms when necessary?
Non-verbal communication: Were non-verbal expressions such as gestures, posture, active listening, empathy, non-violent communication and other communication resources well used?	**Non-verbal communication:** Were non-verbal communication expressions and skills such as gestures, posture, attentive gaze, active listening and empathy used appropriately?
In general, evaluate the performance of the simulated pharmacist:	In general, what is the level of performance of the clinical skills demonstrated by the simulated pharmacist: (At this stage, the sum of the previous questions must be carried out and, according to the score, a level of skills development must be assigned)
☐ Bad	
☐ Reasonable	☐ 00-10 points - Initial Skills (introductory phase)
☐ Good	☐ 11-20 points - Intermediate Skills (development phase)
☐ Very Good	☐ 21-30 points - Advanced skills (improvement phase)
☐ Excellent	

SOURCE: Elaborated by the authors.

Chart 2. Final version of the "PSAL-BRASIL: Assessment of Clinical Competencies for the Management of Self-Limiting Health Conditions" instrument.

PSAL-BRASIL: Assessment of Clinical Competencies for the Management of Self-Limiting Health Conditions
This instrument aims to evaluate the clinical skills presented by participants in the development of a simulated clinical case regarding the management of self-limiting health conditions.
In this step, you will evaluate the skills demonstrated by the simulated pharmacist.
Fill out instructions, use value:
0. Did not perform - When the pharmacist did not perform the step indicated in the item
1. Performed incompletely - When the pharmacist did not perform one or more steps of the item or when they performed it unsatisfactorily
2. Performed satisfactorily - When the pharmacist performed the item completely
NOTE: Not applicable - It should only be used when an item does not apply to the clinical case in question and in these cases **a score of 2 points should be assigned**.

	0 1 2
Previous Stage – Hospitality:	0 1 2
1. Have they greeted the patient, introduced themselves and explained the service adequately?	☐ ☐ ☐
Stage 1 – Evaluation:	0 1 2
2. Have they clearly defined or confirmed the patient's **self-limiting health condition** or **chief complaint**?	☐ ☐ ☐
3. Have they carried out the **pharmaceutical anamnesis** correctly, using techniques (such as **INDICO***) or essential questions to assess the clinical picture?	☐ ☐ ☐
4. Have they measured the patient's **vital signs** or performed other physical/laboratory **exams** appropriately (if applicable)?	☐ ☐ ☐
Stage 2 – Care Plan:	0 1 2
5. Have they clearly defined the therapeutic **objectives/goals** for managing the health condition?	☐ ☐ ☐
6. Have they advised on measures to **prevent** new episodes of the current situation and **health promotion** actions?	☐ ☐ ☐
7. Have they correctly indicated **non-pharmacological** interventions to manage the current situation, such as health practices and products?	☐ ☐ ☐
8. Have they recommended a pharmacological treatment **necessary** to the management of the self-limiting health condition?	☐ ☐ ☐
9. Have they selected the most **effective** pharmacological treatment available for the self-limiting health condition?	☐ ☐ ☐
10. Have they selected a **safe** pharmacological treatment for the patient?	☐ ☐ ☐
11. Have they correctly guided the patient on how to use **the medication(s)**?	☐ ☐ ☐
12. Have they known how to analyze the **warning signs** and, when necessary, how to carry out **referrals** appropriately?	☐ ☐ ☐
Stage 3 – Monitoring:	0 1 2
13. Have they defined with the patient the best way to **evaluate results** (self-monitoring or active monitoring by the pharmacist)?	☐ ☐ ☐
Communication:	0 1 2
14. Verbal communication: Have they spoken clearly to the patient, without the use of technical jargon or explaining technical terms when necessary?	☐ ☐ ☐
15. Non-verbal communication: Were non-verbal communication expressions and skills such as gestures, posture, attentive gaze, active listening and empathy used appropriately?	☐ ☐ ☐
16. In general, what is the level of performance of the clinical skills demonstrated by the simulated pharmacist: (At this stage, the sum of the previous questions must be carried out and, according to the score, a level of skills development must be assigned)	
☐ 00-10 points - Initial Skills (introductory phase)	
☐ 11-20 points - Intermediate Skills (development phase)	
☐ 21-30 points - Advanced skills (improvement phase)	

*Pharmaceutical anamnesis technique using the acronym **INDICO**: Patient **i**dentification; **N**ature of signs and symptoms; **D**uration; Have they **i**nitiated any treatment; **C**omorbidities; and **O**ther situations.

on diagnostic criteria,[27] to determine resources necessary to reduce medication errors in intensive care[28] and in the search for characteristics necessary to provide good services in community pharmacies.[29]

In this research, experts were selected based on their experience with the topic covered and research practice in the area studied, using references in literature and research centers. The experts who agreed to participate in the process were invited to nominate other individuals who they considered capable of participating in the panel, using a sampling technique called snowball. According to the literature, this type of sampling is important to access groups considered difficult to research, as well as when there is no way of specifying the number of individuals in the sample.[18]

Of the 26 experts invited to participate in the validation, 73% (19) answered the first round questionnaire. Note that the experts' response rate was consistent with the literature, in which this observed rate is, on average, 80%.[19] In a literature review, it was observed that the number of experts who agreed to participate in the first round varied between five and 161.[15] In the second round, we achieved a significant return of the questionnaires, in comparison to the first round, of 89% (17/19), higher than that observed in the literature, given that, on average, expert returns drop to only 50%.[19] Another study shows a similar decrease from the first to the second round, where 14 and 12 experts participated, respectively.[28]

In the first round of the Delphi, it was observed that 14 of the 16 items reached consensus among experts, which was promising in comparison to other studies. An article that validated the content, using the Delphi technique, of an online course on the use of antibiotics for respiratory tract infections developed for pharmacists and community doctors, obtained consensus in the first round on only 4 of the 8 items evaluated.[25] This was observed also in the development of a questionnaire on the adherence of asthmatic patients, in which of the 31 items evaluated, only 13 reached consensus in the first round.[30]

Item (13) Monitoring was assessed with low objectivity (CVI = 0.79), as it had more than one question in the same item, so the item was rewritten to condense the question into one. Item (14) Verbal communication was evaluated with low clarity (CVI = 0.79), to improve understanding, the question was summarized, removing the part considered ambiguous. In the literature, problems with the clarity of items under validation were also observed, this occurred because the items did not make clear which criteria the evaluator should use to judge the performance of that action.[31]

The items on non-verbal and non-verbal communication activities reached consensus in the second round. Studies show that communication assessment is essential during clinical care; however, a literature review noted a scarcity of validated instruments capable of assessing communication skills, as well as on questioning how the teaching and assessment of these skills has been introduced in the training of health professionals and which instruments are used for this purpose.[32] This reinforces the importance of PSAL-BRASIL by including questions about communication skills in clinical training.[25]

In the second round, all questions in the assessment instrument achieved consensus on the five criteria evaluated (CVI ≥ 0.80). Contrary to what occurred in another study, in which two of the seven cases evaluated were not validated.[25] As proposed in the methodology of this research, the items would be submitted to the necessary number of rounds until reaching consensus and, in this case, two rounds were sufficient. The same cannot be observed in other studies in which several rounds are sometimes necessary.[26,28,33]

After the experts' suggestions, a change was made to the last question of the instrument, regarding the student's general performance. As they considered the assessment of performance on a five-point Likert scale to be very subjective, the new proposal required the summation of the score obtained in each activity performed by the simulated pharmacist in the previous 15 questions, so that the total points would be translated into initial, intermediate and advanced clinical skills levels.[34] Thus, when the majority of responses were "0. Did not perform", it was considered that the student assessed still presented initial skills and when most of the answers were "2. Performed satisfactorily", it was considered that the student being evaluated had advanced skills.

A psychometric analysis confirmed the existence of internal consistency based on the Cronbach's Alpha calculation. In the first round, the Cronbach's Alpha average was 0.745 (IC (95%): 0.586-0.904), increasing significantly in the second round to 0.896 (IC(95%): 0.853-0.939), this value is considered almost perfect. A similar increase was observed in the validation of an instrument with scales of clinical criteria for the clinical diagnosis of carpal tunnel syndrome, in which Cronbach's Alpha increased from 0.86 in the first round to 0.91 in the second.[27]

In the literature, models of questionnaires and checklists were found, such as, for example, an assessment tool for the development of clinical skills in pharmaceutical care, using the OSCE method (Objective Structured Clinical Examination – ECOE, in Portuguese),[35] forms to be used as support in the pharmaceutical dispensing of prescribed medications[36] and in the standardization of indicators for pharmacotherapeutic monitoring in outpatients.[37] As well as the development and validation of a checklist to assist the pharmacist in preparing a patient care intervention report (PaCIR, in Portuguese).[33]

However, there is a lack of validated instruments that target self-limiting health conditions in the context of community pharmacies. Therefore, the questions developed in this instrument we propose will allow for the development of skills that boost the pharmacist's confidence while greeting the patient appropriately, identifying health problems and, thus, drawing up a care plan. Moreover, the pharmacist will be able to define alongside the patient which actions help monitor the complaint, in order to improve self-care. The development of clinical skills during graduation and the continued training of professionals are demands perceived by academics and pharmacists themselves, who feel insecure in carrying out clinical activities.[38,39]

In order for the development of clinical skills to be possible, it is necessary to use tools that can objectively measure these skills. To achieve this, it is important to establish assessment instruments that are reliable and reproducible. The assessment of clinical skills must also have an educational and training nature, so that students can learn from the tests and receive feedback, which lead to the further development of their knowledge and skills. Clinical simulations are expanding tools and as these simulations become necessary and accessible, training and undergraduate courses will need to adopt assessment practices that provide better evidence of the effectiveness of the content, as opposed to merely subjective assessments.[40-42]

Therefore, the goal of the present instrument is to bring professionals greater clarity and security in the pharmaceutical service process. In this way, it allows the student under training to practice skills that are required in the clinical context, as well as to receive feedback on their actions with simulated patients, as a measure to avoid the wear and tear and unpredictability of real patients.[43] The use of standardized patients for the simulation of pharmaceutical services enables the standardization of teaching-learning, which allows the student to make mistakes in an academic context, so that the error does not harm real patients and takes place in an environment where it can be evaluated and improved.[35]

Even though it is widely used in the literature, the Delphi method is not free of limitations. Potential biases may occur in the selection of the expert panel and the limited response time for the forms, in addition to the lack of determination of the methodology prior to the study, are limitations that should be consider. To minimize these effects in the present study, measures were adopted, such as clearly defining the goal of the study, clearly determining the criteria for selecting experts, defining consensus, noting the need for rounds until consensus is reached as well as the insurance of anonymity. Moreover, the development process of the initial questionnaire, the changes made to the items after each round and the final model of the instrument were addressed.[15,26]

CONCLUSION

The PSAL-BRASIL assessment instrument was validated by a panel of experts and achieved consensus on all items assessed after two rounds, as well as high internal consistency in the final version. In this way, the instrument achieved good acceptance among specialists and seeks to be a reference in the assessment of clinical skills. In the teaching-learning process using simulations, the assessment of these skills must stimulate clinical practice, allow feedback to students, and be consistent with the skills being assessed.

References

1. Conselho Federal de Farmácia. [Pharmaceutical services directly aimed at the patient, family and community contextualization and conceptual framework]. Brasília;CFF;2016. ISBN 978-85-89924-20-7.
2. Amador-Fernández N, Benrimoj SI, Lima AOL, García-Cárdenas V, Gastelurrutia MÁ, Berger J, et al. Strengthening patients' triage in community pharmacies: A cluster randomised controlled trial to evaluate the clinical impact of a minor ailment service. PLoS One. 2022;17(10):e0275252-e0275252. https://doi.org/10.1371/journal.pone.0275252
3. Lee R, McCarthy L. Canadian "minor ailments" programs: Unanswered questions. Can Pharm J. 2015;148(6):302-4. https://doi.org/10.1177/1715163515611144
4. Paudyal V, Watson MC, Sach T, Porteous T, Bond CM, Wright DJ, et al. Are pharmacy-based minor ailment schemes a substitute for other service providers? British Journal of General Practice. 2013;63(612):e472-e481. https://doi.org/10.3399/bjgp13X669194
5. Lima SHP de, Silva DCS, Silva GV, Melo LGA, Oliveira LAC, Bezerra L JC, et al. Cuidados farmacêuticos no manejo de problemas de saúde autolimitados: gripe / Pharmaceutical care in the management of self-limited health problems: influenza. Brazilian J Dev. 2022;8(7):50516-24. https://ojs.brazilianjournals.com.br/ojs/index.php/BRJD/article/view/50127
6. Mendonça SAM, De Freitas EL, De Oliveira DR. Competencies for the provision of comprehensive medication management services in an experiential learning project. PLoS One. 2022;12(9):e0185415. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0185415
7. Mesquita AR, Souza WM, Boaventura TC, Barros IMC, Antoniolli AR, Silva WB, et al. The Effect of Active Learning Methodologies on the Teaching of Pharmaceutical Care in a Brazilian Pharmacy Faculty. PLoS One [Internet]. 2015;10(5):e0123141. https://doi.org/10.1371/journal.pone.0123141
8. Araújo M, Barros VA, Lima AB. A simulação realística como ferramenta de ensino em uma pós-graduação de farmácia clínica: relato de experiência. IJHE - Interdiscip J Heal Educ. 2017;2(2). https://ijhe.emnuvens.com.br/ijhe/article/view/347
9. Morais YJ, Santos VRC, Soler O. Realistic simulation as a mediator of the teaching-learning process in undergraduate Pharmacy: systematic review. Res Soc Dev. 2021;10(10):e241101018783-e241101018783. https://rsdjournal.org/index.php/rsd/article/view/18783
10. Costa AP, Reis TM, Santana RS. Elaboração de diretriz clínica para o cuidado farmacêutico na febre article info abstract. 2022;12(03):54550-3. https://doi.org/10.37118/ijdr.24038.03.2022
11. Costa, AP, Alves BMCS, Silva DLM, Martins RLM, Silva FA, Zimmermann IR, et al. Clinical guidelines for smoking cessation: comparative analysis with AGREE II. BRASÍLIA MÉDICA, 2022.

12. Lima BFR, Alves BMCS, Tavares NUL, Lima RF, Ginani VC, Reis TM, et al. Quality appraisal of clinical guidelines for the management of constipation according to AGREE II instrument. Res Soc Dev [Internet]. 2022;11(3):e57911327086-e57911327086. https://rsdjournal.org/index.php/rsd/article/view/27086

13. Vaz JMA, Alves BMCS, Duarte DB, Marques LAM, Santana RS. Quality appraisal of existing guidelines for the management of headache disorders by the AGREE II's method. Cephalalgia. 2022;42(3):239-49. https://doi.org/10.1177/03331024211037297

14. Costa AP, Alves BMCS, Silva DLM, Martins RLM, Silva FA, Zimmermann IR, et al. Diretrizes clínicas para cessação do tabagismo: análise comparativa com o agree ii. Brasília Med 2022;59(Anual):1-11. https://doi.org/10.5935/2236-5117.2022v59a285

15. Jaam M, Awaisu A, El-Awaisi A, Stewart D, El Hajj MS. Use of the Delphi technique in pharmacy practice research. Res Soc Adm Pharm [Internet]. 2022;18(1):2237-48. https://doi.org/10.1016/j.sapharm.2021.06.028

16. Staykova MP. Rediscovering the Delphi Technique: A Review of the Literature. Adv Soc Sci Res J. 2019;6(1):218-29. https://journals.scholarpublishing.org/index.php/ASSRJ/article/view/5959

17. Jünger S, Payne SA, Brine J, Radbruch L, Brearley SG. Guidance on Conducting and REporting DElphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review. Palliat Med. 2017;31(8):684-706. https://doi.org/10.1177/0269216317690685

18. Vinuto J. A amostragem em bola de neve na pesquisa qualitativa. Tematicas. 2014 22(44):203-20. https://econtents.bc.unicamp.br/inpec/index.php/tematicas/article/view/10977

19. Olsen AA, Wolcott MD, Haines ST, Janke KK, McLaughlin JE. How to use the Delphi method to aid in decision making and build consensus in pharmacy education. Curr Pharm Teach Learn. 2021;13(10):1376-85. https://doi.org/10.1016/j.cptl.2021.07.018

20. Rubio D, Berg-Weger M, Tebb S, Lee E, Rauch S. Objectifying content validity: conducting a content validity study in social work research - Documento - Gale Academic OneFile. Soc Work Res. 2003; 27(2):94-111. https://gogale.ez54.periodicos.capes.gov.br/ps/i.do?p=AONE&u=capes&id=GALE%7CA105367299&v=2.1&it=r

21. Vituri DW, Matsuda LM. Validação de conteúdo de indicadores de qualidade para avaliação do cuidado de enfermagem. Rev da Esc Enferm da USP. 2009;43(2):429-37. https://doi.org/10.1590/s0080-62342009000200024

22. Alexandre NMC, Coluci MZO. Validade de conteúdo nos processos de construção e adaptação de instrumentos de medidas. Cien Saude Colet. 2011;16(7):3061-8. https://doi.org/10.1590/s1413-81232011000800006

23. Cronbach LJ. Coefficient alpha and the internal structure of tests. Psychometrika. 1951;16(3):297-334. https://link.springer.com/article/10.1007/BF02310555

24. Landis JR, Koch GG. The Measurement of Observer Agreement for Categorical Data. Biometrics. 1977;33(1):159.

25. Estrela M, Roque F, Silva TM, Zapata-Cachafeiro M, Figueiras A, Herdeiro MT. Validation of the eHealthResp online course for pharmacists and physicians: A Delphi method approach. Biomed Pharmacother. 2021;140:111739. https://doi.org/10.1016/j.biopha.2021.111739

26. Meredith AH, Wilkinson TA, Campi JA, Meagher CG, Ott MA. Use of the Delphi Method to Enhance Pharmacist Contraceptive Counseling Materials. J Pharm Pract. 2021;34(5):678-84. https://doi.org/10.1177/0897190019894146

27. Graham B, Regehr G, Wright JG. Delphi as a method to establish consensus for diagnostic criteria. J Clin Epidemiol. 2003;56(12):1150-6. https://doi.org/10.1016/s0895-4356(03)00211-7

28. Bourne RS, Shulman R, Jennings JK. Reducing medication errors in critical care patients: pharmacist key resources and relationship with medicines optimisation. Int J Pharm Pract. 2018;26(6):534-40. https://doi.org/10.1111/ijpp.12430

29. Grey E, Harris M, Rodham K, Weiss MC. Characteristics of good quality pharmaceutical services common to community pharmacies and dispensing general practices. Int J Pharm Pract. 2016;24(5):311-8. https://doi.org/10.1111/ijpp.12253

30. Nassar RI, Saini B, Obeidat NM, Basheti IA. Development and validation of the Adherence to Asthma Medication Questionnaire (AAMQ). Pharmacy Practice. 2022;20(2):2673. https://doi.org/10.18549/PHARMPRACT.2022.2.2673

31. Vituri DW. Desenvolvimento e validação de um instrumento para avaliação da qualidade do cuidado de enfermagem. MS thesis. Universidade Estadual de Maringá, 2007.

32. Araújo DCSA, Menezes PWDS, Cavaco AMDN, Mesquita AR, Lyra Júnior DP. Instrumentos para avaliação de habilidades de comunicação no cuidado em saúde no Brasil: uma revisão de escopo. Interface - Comunicação, Saúde, Educação. 2020;24:1-13. https://doi.org/10.1590/INTERFACE.200030

33. Clay PG, Burns AL, Isetts BJ, Hirsch JD, Kliethermes MA, Planas, et al. PaCIR: A tool to enhance pharmacist patient care intervention reporting. Journal of the American Pharmacists Association: JAPhA. 2019;59(5): 615-23. https://doi.org/10.1016/j.japh.2019.07.008

34. Smith SR. AMEE guide no. 14: outcome-based education: part 2-planning, implementing and evaluating a competency-based curriculum. Medical teacher 1999;21(1):15-22.

35. Galato D, Alano GM, França TF, Vieira AC. Exame Clínico Objetivo Estruturado (ECOE): Uma experiência de ensino por meio de simulação do atendimento farmacêutico. Interface: Communication, Health, Education. 2011;15(36):309-19. https://doi.org/10.1590/S1414-32832010005000032

36. Rocha KSS, Santos SC, Boaventura TC, Santos Júnior GA, Araújo DCSA, Silvestre CC, et al. Development and content validation of an instrument to support pharmaceutical counselling for dispensing of prescribed medicines. Journal of Evaluation in Clinical Practice. 2020;26(1):134-41. https://doi.org/10.1111/JEP.13102

37. Lima TM. Desenvolvimento e validação de indicadores para avaliação da qualidade do acompanhamento farmacoterapêutico.

Diss. Universidade de São Paulo, 2018. http://www.teses.usp.br/teses/disponiveis/9/9139/tde-09112018-102237/pt-br.php

38. Coelho MMA, Mesquita AR, Lima MG. Perceptions of Pharmacy students about their competences for professional practice in community pharmacy. Brazilian Journal of Pharmaceutical Sciences. 2022;58. https://doi.org/10.1590/S2175-97902020000318730

39. Mills E, Laaksonen R, Bates I, Davies G., Duggan C. Self-assessment of competence in a community pharmacy setting. Pharmacy Education. 2005;5(3):63-7. https://doi.org/10.1080/15602210500282491

40. Antomarchi J, Delotte J, Jordan A, Tran A, Bongain A. Development and validation of an objective structured assessment of technical skill tool for the practice of vertex presentation delivery. Archives of Gynecology and Obstetrics.2014;290(2):243-7. https://doi.org/10.1007/S00404-014-3204-X/FIGURES/1

41. Chipman JG, Schmitz, CC. Using Objective Structured Assessment of Technical Skills to Evaluate a Basic Skills Simulation Curriculum for First-Year Surgical Residents. Journal of the American College of Surgeons. 2009;209(3):364-370.e2. https://doi.org/10.1016/J.JAMCOLLSURG.2009.05.005

42. Wass V, van der Vleuten C, Shatzer J, Jones R. Assessment of clinical competence. The Lancet. 2001; 357(9260):945-9. https://doi.org/10.1016/S0140-6736(00)04221-5

43. Troncon LEA. Utilização de pacientes simulados no ensino e na avaliação de habilidades clínicas. Medicina (Ribeirão Preto). 2007;40(2):180-191. https://www.revistas.usp.br/rmrp/article/view/315/316