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## Original Research

# Training and standardization of simulated patients for multicentre studies in clinical pharmacy education

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### Abstract

**Objective:** To evaluate the training and standardization methods of multiple simulated patients (SPs) performing a single scenario in a multicenter study.

**Methods:** A prospective quasi-experimental study, using a multicenter approach, evaluated the performance of five different individuals with the same biotype during a simulation session in a high-fidelity environment. The SPs training and standardization process consisted of four steps and six web or face-to-face mediated: Step 1: simulation scenario design and pilot test. Step 2: SPs selection, recruitment and beginning training (Session 1: performance instructions and memorization request.) Session 2: check the SPs' performances and adjustments). Step 3 and session 3: training role-play and performance's evaluation. Step 4: SPs' standardization and performances' evaluation (Sessions 4 and 5: first and second rounds of SPs' standardization assessment. Session 6: Global training and standardization evaluation. SPs performance consistency was estimated using Cronbach's alpha and ICC.

**Results:** In the evaluation of training results, the Maastricht Simulated Patient Assessment dimensions of SPs performances "It seems authentic", "Can be a real patient" and "Answered questions naturally", presented "moderate or complete agreement" of all evaluators. The dimensions "Seems to retain information unnecessarily", "Remains in his/her role all the time", "Challenges/tests the student", and "Simulates physical complaints in an unrealistic way" presented "moderate or complete disagreement" in all evaluations. The SPs "Appearance fits the role" showed "moderate or complete agreement" in most evaluations. In the second round of evaluations, the SPs had better performance than the first ones. This could indicate the training process's had good influence on SPs performances. The Cronbach's alpha in the second assessment was better than the first (varied from 0.699 to 0.978). The same improvement occurred in the second round of intraclass correlation coefficient that was between 0.424 and 0.978. The SPs were satisfied with the training method and standardization process. They could perceive improvement on their role-play authenticity.

**Conclusions:** The SPs training and standardization process revealed good SPs reliability and simulation reproducibility, demonstrating to be a feasible method for SPs standardization in multicenter studies. The Maastricht Simulated Patient Assessment was regarded as missing the assessment of the information consistency between the simulation script and the SPs provision.

### Keywords

Patient Simulation; Simulation Training; Education, Pharmacy; Pharmacists; Clinical Competence; Clinical Decision-Making; Educational Measurement; Reproducibility of Results; Brazil

## INTRODUCTION

Health training using simulated patients (SPs) is increasing in pharmacists' education, essentially aimed to broaden students' clinical skills.<sup>1-4</sup> The use of SPs provides safe clinical settings for student training and can also be advantageous for researching their competencies. Different health conditions can be simulated and distinct individuals can be recruited to perform the same scenario.<sup>5</sup> To assess the competencies of community pharmacists in minor ailments, such as headache and acute gastroenteritis complaints, as well as in emergency contraception counselling, researchers have used SPs.<sup>6-10</sup>

In addition to high-fidelity simulation environment, defined as "a controlled learning environment that closely represents reality" the training and standardization of SPs are important to have an accurate reproduction of clinical scenarios.<sup>11,12</sup> In research, the training quality is a determinant of success because of the risk of bias introduced by the SPs. Strictly trained and validated SPs are critical for the simulation experience to be consistent with the objectives proposed.<sup>12-16,17</sup> They must present repeated and reliable performances to ensure the equivalence and realism of the simulation experience for each participant.<sup>18</sup> The clinical, social, emotional, and psychological aspects must be virtually the same in all simulations even though the acting persons are different.<sup>16</sup> The reliability of SPs should be assessed using recommended psychometric methods, such as the Maastricht Simulated Patient Assessment instrument, widely used in medical education for SPs standartization.<sup>17,19</sup>

To make use of SPs, accurate methodologies are needed to accomplish SPs training and standardization, thus ensuring the necessary reproducibility of the scenario being played.<sup>18,20</sup> Generally, authors do not report the training required in enough detail for replication by other educators and researchers willing to use SPs.<sup>18</sup> In multicenter research, methods for training and standardizing SPs are

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even more important, as they may reduce bias and decrease the costs and time to develop the required SPs accuracy. As far as we know, there are no studies that have evaluated the training and standardization of SPs in a multicenter study with large distances between the centers' locations. The present study aimed to evaluate the training and standardization methods of multiple SPs performing a single scenario in a multicenter study, helping those interested in the best use of SPs for clinical pharmacy education and research.

## METHODS

This study followed a quasi-experimental prospective design and was described considering the checklist of quality studies with SPs.<sup>20</sup> It took place between July and November 2019 and aimed to evaluate the performance of five different women with the same biotype, and representing one SP in a high-fidelity simulation environment. The study consisted of a national multicenter approach, which involved one federal university per administrative Brazilian region: São João Del-Rei University (Southeast region); Federal University of Pará (North region); Federal University of Piauí (Northeast region); Federal University of Mato Grosso do Sul (Midwest region) and the Federal University of Rio Grande do Sul (South region). The study was carried out in geographic regions with cultural and oral expression (e.g. pronunciation) differences, putting an additional challenge in SPs to perform the same simulated scenario.<sup>21</sup>

To develop the training and standardization of SPs methodologies, a literature search identified at least four different methods, presented in Online appendix.<sup>22-25</sup> From here the research team developed by an iterative consensus a study methodology comprising several steps. The simulation scenario involved a female patient, 28 years old, and working full-time as a secretary in an accounting office; she was married and a mother of a 2-years-old boy. She seeks care from a pharmacist while experiencing mild allergic rhinitis and no other medical conditions. She is lucid, time- and space-oriented, active, collaborative, and quite talkative. The SPs wore casual clothes (t-shirt and jeans) and no makeup. The final scenario included features intended to reduce student clinical performance bias such as season, hour and room temperature indication. Considering the environmental, cultural, and social differences between the five administrative Brazilian regions, a pilot simulation test was carried out in each research center to confirm all scenario features. All simulated encounters were videotaped.

The SPs training and standardization process consisted of six steps and five sessions the early in person at the last at a distance (online). The group of SPs consisted of individuals with the same background degree (pharmacy) and included two graduates and three postgraduates (Master and PhD), aged between 21 and 30 years. None of the SPs had previous experience as simulation actors. After scenery design, the SPs training and standardization methods were developed including reliability and reproducibility assessments.<sup>26-31</sup> In the first step, the simulation scenario

was developed by the research team according to quality simulation guidelines. On step 2, each research center recruited a candidate to act as an SP, following the characteristics established on the scenario. Session one, web meeting occurred 7 days before the session 2, the candidates signed the Informed Consent Term (ICT) according to the standards of best practice (SOBP) of the Association of Standardized Patient Educators (ASPE).<sup>32</sup> In session 2 the training phase began, was individual and face-to-face in each research center. The purpose was to check the SPs' performances and make regional and cultural adjustments in each region. One researcher performed the pharmacist with the each SP. After the simulation, oral and written feedback on each SP performance was provided. All simulations were recorded, videos analyzed, and changes in performance discussed.

The Step 3, as well as the next steps, were online meetings of 120 to 180 minutes with all five SPs and two researchers. The objective was to finish the training and start the standardization of the SPs. The session 3 occurred one month after the second one. The simulations clinical interview with one researcher as pharmacist and the SPs were repeated in this sequence: Southeast, South, Midwest, and Northeast. After each simulation and before the next one occurred the training of performance's evaluation with: 1) a qualitative self-assessment of performance was given by the SP, 2) a qualitative evaluation was done by the other four SPs and the two researchers (on this sequence) followed by feedback of performance adjustments and an objective assessment using Maastricht Simulated Patient Assessment Instrument of the five SPs by the seven participants. During the third session it was possible identify good role-playings in Maastricht Simulated Patient Assessment Instrument evaluation with incorrect or missed information or either the new data included by SPs. So one block to "content fidelity" was designed to cover this construct facet of a good role-playing. The five new items were submitted to external peers and educational experts and were evaluated separately of Maastricht Simulated Patient Assessment Instrument, Table 1.

In step 4, the objective was SPs' standardization and performances' evaluation. The session 4, with all five SPs and one researcher as a pharmacist, lasted about 180 minutes. The web meeting took place within a week of the third session, to give SPs enough time to prepare the necessary adjustments. Simulated interviews occurred in the same way as in session 3, but fifteen days apart and the performances' evaluations were done individually after all simulations. The evaluation results and the individual feedbacks were sent by e-mail. The full set of taped simulations was scored for each SP by 3 independent raters (First round of evaluation). Fifteen days after session 4, the Session 5 took place with the same process protocol (Second round of evaluation).

The Maastricht Simulated Patient Assessment instrument was used to evaluate the SPs' standardization.<sup>19</sup> It comprises 20 items divided by two main blocks:

Table 1. Simulated patient performances' assessment using Maastricht Simulated Patient Assessment <sup>12</sup> and the additional questions about fidelity of scenery content

Variable <sup>1</sup>	First Round of Evaluation			Second round of Evaluation		
	% (n)	Cronbach alfa	ICC 95%	% (n)	Cronbach affa	ICC95%
SP appears authentic		0.568	0.598 [-0.334: 0.925]		0.699	0.696 [0.124:0.940]
Moderate agreement	51.4 (18)			37.1 (13)		
Complete agreement	48.6 (17)			62.9 (22)		
SP might be a real patient		0.614	0.616 [-0.130:0.925]		0.758	0.735 [0.271:0.947]
Moderate agreement	48.6 (17)			42.9 (15)		
Complete agreement	51.4 (18)			57.1 (20)		
SP is clearly role-playing		0.936	0.934 [0.810: 0.987]		0.844	0.855 [0.531:0.972]
Complete disagreement	22.9 (8)			22.9 (8)		
Moderate disagreement	45.7 (16)			77.1 (27)		
Not applicable	31.4 (11)			-		
SP appears to withhold information unnecessarily		0.820	0.827 [0.487:0.966]		0.837	0.806 [0.446: 0.961]
Complete disagreement	40.0 (14)			45.7 (16)		
Moderate disagreement	60.0 (21)			48.6 (17)		
SP stays in his/her role all the time		0.722	0.722 [0.190:0.945]		0.879	0.874 [0.637:0.975]
Complete disagreement	40.0 (14)			-		
Moderate disagreement	60.0 (21)			-		
Not applicable	-			2.9 (1)		
Moderate agreement	-			42.9 (15)		
Complete agreement	-			54.3 (19)		
SP is challenging/testing the student		0.871	0.881 [0.641:0.977]		0.978	0.97 [0.935:0.996]
Complete disagreement	34.3 (12)			28.6 (10)		
Moderate disagreement	65.7 (23)			68.6 (24)		
Not applicable	-			2.9 (1)		
SP simulates physical complaints unrealistically		0.815	0.817 [0.446:0.964]		0.878	0.845 [0.565:0.969]
Complete disagreement	48.6 (17)			40.0 (14)		
Moderate disagreement	51.4 (18)			60.0 (21)		
SP appearance fits the role		0.338	0.314 [-0.764:0.857]		0.861	0.852 [0.577:0.971]
Complete disagreement	2.9 (1)			-		
Moderate disagreement	5.7 (2)			-		
Moderate agreement	51.4 (18)			48.6 (17)		
Complete agreement	40.0 (14)			51.4 (18)		
SP answers questions in a natural manner		0.697	0.720 [0.112:0.947]		0.771	0.789 [0.346:0.960]
Moderate agreement	65.7 (23)			62.9 (22)		
Complete agreement	34.3 (12)			37.1 (13)		
SP starts conversation with the student(s) during the time-out		0.808	0.815 [0.451:0.964]		0.947	0.943 [0.836:0.984]
Not applicable	45.7 (16)			2.9 (1)		
Moderate agreement	-			62.9 (22)		
Complete agreement	54.3 (19)			34.3 (12)		
Additional items to Maastricht Simulated Patient Assessment Instrument: scenario content's fidelity						
1 - Relevant scenario information was missing and would be made available by the patient's spontaneous speech						
Complete disagreement	14.3 (1)	0.734	0.665 [0.195:0.937]	57.1 (4)	0.881	0.891 [0.672:0.979]
Moderate disagreement	42.9 (3)			42.9 (3)		
Not applicable	42.9 (3)					
2- Scenario information was spontaneously made available that would only be provided upon direct questioning						
Complete disagreement	42.9 (3)	0.804	0.818 [0.445:0.965]	14.3 (1)	0.855	0.854 [0.567:971]
Moderate disagreement	28.6 (2)			71.4 (5)		
not applicable	28.6 (2)			-		
Moderate agreement	-			14.3 (1)		
3 - The PS showed that it did not memorize the content correctly and thus modified or introduced new information in the standardized scenario						
Complete disagreement	14.1 (1)	0.702	0.672 [0.119:0.933]	57.1 (4)	0.833	0.845 [0.532:0.970]
Moderate disagreement	57.1 (4)			42.9 (3)		
Not applicable	28.6 (2)			-		
4 - The PS was vague in its responses when it should have been objective						
Complete disagreement	57.1 (4)	0.805	0.793 [0.458:0.960]	71.4 (5)	0.845	0.814 [0.441:0.964]
Moderate disagreement	28.6 (2)			28.6 (2)		
Not applicable	14.3 (1)			-		
5 - The PS was objective in its responses when it should have been vague						
Complete disagreement	71.4 (5)	0.682	0.784 [0.665:0.934]	71.4 (5)	0.734	0.694 [0.195:0.937]
Moderate disagreement	28.6 (2)			14.3 (1)		
Not applicable				14.3 (1)		

Variables with Likert scale: complete disagreement, moderate disagreement, not applicable, moderate agreement and complete agreement. Showed only cells with values.

<sup>1</sup>Variables with Likert scale: complete disagreement, moderate disagreement, not applicable, moderate agreement and complete agreement. Showed only cells with values

"Authenticity during the consultation" and "Feedback after the consultation". All the questions of authenticity were represented in the first column of Table 1. Each item is rated on a 5 points scale, running from complete disagreement to complete agreement. The questions related to feedback were withdrawn from our study since the simulated patient did not perform the students' feedback. While the research team was aware of the wide dissemination and use of Maastricht Simulated Patient Assessment, it was also discussed the need to evaluate SPs fidelity to the scenario content i.e. to assess ad-hoc deviations from the proposed script. Since the simulated patient did not provide feedback to students after the simulation, the questions related of it in Maastricht Simulated Patient Assessment were not used on this study.. The closing web-meeting the "Evaluation of SP perceptions on the training programme" Instrument was applied to explore the perceptions of the SPs about the usefulness and acceptability of the training method.<sup>33</sup> This questionnaire is divided into 3 blocks: A. My experience as an educator, B. My experience with the SP training workshop, C. My rating of the training workshop (scale of 1 to 10), and D. Any additional comments of own experiences in peer and self-evaluation during the SP workshop.<sup>33</sup> The standardization process were evaluated by consistency of SPs performance. It was estimated using Cronbach's alpha, with alpha values between 0.70 and 0.90 considered acceptable.<sup>26</sup> SPs scores correlations were also assessed by the intraclass correlation coefficient (ICC). ICC values were considered poor if  $<0.4$ ; satisfactory to good if  $0.4 < ICC < 0.75$ ; and excellent if  $ICC \geq 0.75$ .<sup>34</sup> The data analysis consisted of descriptive statistics, with estimates of proportions and percentiles. All analyses were performed in IBM SPSS v24 and used a statistical significance of 95%.

The study was conducted according to the guidelines of the Declaration of Helsinki and the provisions of the National Health Committee of Brazil. The study received approval by the Research Ethics Committee Involving Humans of the Dona Lindu Midwest Campus of the Federal University of São João Del-Rei (CEPCCO No. 2,853,052).

## RESULTS

The Table 1 shows the results of Maastricht Simulated Patient Assessment dimensions. The first round of evaluation dimensions "it seems authentic", "can be a real patient" and "answered questions naturally", presented moderate or complete agreement in 100.0% of the simulations; "seems to retain information unnecessarily", "remains in his role all the time", "challenges/tests the student", and "simulates physical complaints in an unrealistic way" presented moderate or complete disagreement in 100.0% of the simulations. "It is clearly role-playing" presented complete disagreement in 22.9% of the simulations, moderate agreement in 45.7% of the simulations, and was not applicable in 31.4% of the simulations. "Appearance fits the role" showed complete disagreement in 2.9%, moderate disagreement in 5.7%, moderate agreement in 51.4%, and complete agreement in 40.0% of the simulations.

In the second round, "appears authentic", "might be a real patient", "answers questions naturally" and "appearance

fits the role" showed moderate or complete agreement for 100% of the simulations; "is clearly role-playing" and "simulates physical complaints unrealistically" showed moderate or complete disagreement for 100% of the simulations; "Appears to withhold information unnecessarily" showed complete disagreement, showed moderate disagreement or was not applicable in 45.7%, 48.6%, and 5.7% of the simulations, respectively; "stays in her role all the time" was not applicable, showed moderate agreement or showed complete agreement in 2.9%, 42.9%, and 54.3% of the simulations, respectively; "is challenging/testing the student" showed complete or moderate disagreement or was not applicable in 28.6%, 68.6% and 2.9%, of the simulations, respectively; and "starts a conversation with the student(s) during time-out" showed was not applicable, showed moderate agreement or showed complete agreement in 2.9%, 62.9%, and 34.3%, respectively (Table 1).

The Cronbach's alpha value in the first round varied from 0.338 to 0.936, and the ICC values from 0.314 to 0.934. In the second round of simulations, there was an improvement in the Maastricht Simulated Patient Assessment parameters, in which all the Cronbach alphas increased (0.699 to 0.978). The same was observed for the ICC values (0.424 to 0.978), indicating good agreement between the raters regarding the simulation parameters observed. The additional block comprised of five items to assess the SPs fidelity to the scenario content presented in the first round Cronbach's alpha values between 0.682 to 0.808 and ICC values varying from 0.665 to 0.815. In the second round of simulations, the Cronbach's alpha values increased (0.734 to 0.947) and the same was observed for ICC (0.694 to 0.943), indicating in this case the scale good internal consistency as well as the agreement between the raters.

The results of the perception questionnaire applied at the final step showed that SPs were satisfied with the training method and standardization process (Table 2). The overall average score received for the training program was 8.6 out of 10. Three SPs said they had improved in terms of their role-play authenticity, while two had improved information retention, and one had not forgotten the role details. Two SPs said the training helped them understand how to improve the simulation for clarity and indicated "I learned by watching other people's performance." There were no negative comments about the training method.

## DISCUSSION

This study was developed to assess a training process for SPs standardization within multiple simulation centers for research purposes, seeking to achieve equivalent SPs calibration to avoid bias on later research stages. Health simulation involving human actors interacting with students has been used as a method for assessing health professionals' competence.<sup>35</sup> Some pharmacy courses have implemented simulation in their curriculum as a way to optimize the training process.<sup>36</sup> However, the use of SPs for research education in multiple and different settings requires greater precision in SP training and performance, looking for controlling the possibility of scenario bias introduced by the SPs.<sup>37</sup>



Table 2. Self-perception questionnaire for SPs training and standardization<sup>27</sup>

Questionnaire items	Always % (n)	Frequently % (n)	Sometimes % (n)	Occasionally % (n)	Never % (n)
My experience in school, university or college					
I have assessed my work/performance in private in a formal manner previously in pre-university education	20.0 (1)	40.0 (2)	-	40.0 (2)	-
I have assessed my colleagues' work in private in a formal manner in pre-university education	-	60.0 (3)	-	20.0 (1)	20.0 (1)
I have self-assessed my work performance openly in front of my peers (class) during pre-university education	-	60.0 (3)	-	20.0 (1)	20.0 (1)
I have self-assessed my colleagues' work performance openly in front of peers (class) during pre-university	20.0 (1)	40.0 (2)	-	20.0 (1)	20.0 (1)
SP training workshop: my experience					
I felt shy when providing feedback on myself to the group	20.0 (1)	40.0 (2)	-	20.0 (1)	20.0 (1)
I learned many things that I did wrong when I did the self-assessment	60.0 (3)	20.0 (1)	20.0 (1)	-	-
I felt awful when I was providing feedback to others on their performance	-	-	-	40.0 (2)	60.0 (3)
I learned many things when my peers/doctors evaluated me which I would never have thought of myself	60.0 (3)	20.0 (1)	20.0 (1)	-	-
I felt uncomfortable when others were providing feedback on my performance	-	-	20.0 (1)	60.0 (3)	20.0 (1)
I felt harassed when others were providing feedback on my performance	-	-	20.0 (1)	60.0 (3)	20.0 (1)
I used the points shown during self and peer assessment to improve my performance at practice CSU session	40.0 (2)	60.0 (3)	-	-	-
Any specific aspect that I was able to improve on when the self-assessment and peer assessment was done on role play					
Authenticity of role	60.0 (3)	20.0 (1)	20.0 (1)	-	-
Withholding information	20.0 (1)	60.0 (3)	20.0 (1)	-	-
Forgetting the role	20.0 (1)	40.0 (2)	40.0 (2)	-	-

Knowing the need to standardize SPs for research purposes and to obtain reliable results, authors developed a possible procedure for multi-centered studies, evaluating its efficacy and reliability. The method considered the large distances between study centers and the use of SPs with cultural discrepancies, looking to reduce funding costs, travel and time restrictions or lower availability of SPs for displacement.<sup>21,38-41</sup> In the literature, it was possible to identify at least four different standardization methods, referred previously.<sup>22-25</sup> Their authors presented the necessary SP production components, with variable depth and perceived differences. Our standardization protocol incorporated most recommendations of the previous approaches, aligning in a single and clear study protocol the designed options (Figure 1).

According to the SOBP of the ASPE, training can be performed in various formats (e.g., face-to-face, online, or combined).<sup>32</sup> In the context of multicenter studies, considering the difficulty of face-to-face meetings, the combined format was chosen, with study results showing it was an adequate option. Candidates were recruited following the criteria established by the ASPE SOBP.<sup>32</sup> Characteristics such as age appropriateness for the role and proximity to the pharmacy area were respected in the study. Sending the scenario to the prospective SPs in advance may have contributed to easier memorization of the script content. The SPs were required to remember the relevant facts and the background of their scripting function to achieve good performance.<sup>37</sup> A relevant point was the inclusion of the SPs in all steps of the study: this allowed for direct interaction and knowledge exchange between the five SPs. This feature of SPs working together and with other staff was reported as a key point for simulation improvement.<sup>37</sup> All SPs received individual

feedback, which also helped to improve performance by discussing the necessary adjustments.<sup>32</sup> Studies have identified that feedback was a valuable tool to increase understanding and consolidate information.<sup>42,43</sup> Another important aspect of our study was the SPs observation and assessment of the performance of their peers, which helped self-assessment and self-reflection. The usefulness of self-assessment in improving learning has been demonstrated.<sup>44</sup> The use of videos to evaluate personal and peer performance, as used in this assessment method, seemed to be effective. Previous studies have shown that videos can truly improve performance.<sup>38</sup>

The development of a training method is incomplete or prone to criticism if there is no measurement of the reliability of the training procedure. The responses obtained by the 'augmented' Maastricht Simulated Patient Assessment instrument were analyzed regarding internal consistency and reliability using Cronbach's alpha and ICC. Results showed good values for both statistics on SP performance, indicating each SP in this group resembled each other.

The assessment of a new training method should also include an investigation of the participants' acceptance. The questionnaire on the SPs' perceptions of the standardization process, showed that SPs were satisfied with the training program and recognized the importance of standardized outcomes.<sup>33</sup> The two training rounds seemed to be adequate for achieving reliability in SPs performance.

Despite the recognized importance of Maastricht Simulated Patient Assessment, it is our opinion this instrument needs a revision to include a dimension that can be named as "consistency of the information provided".<sup>19</sup> Although using

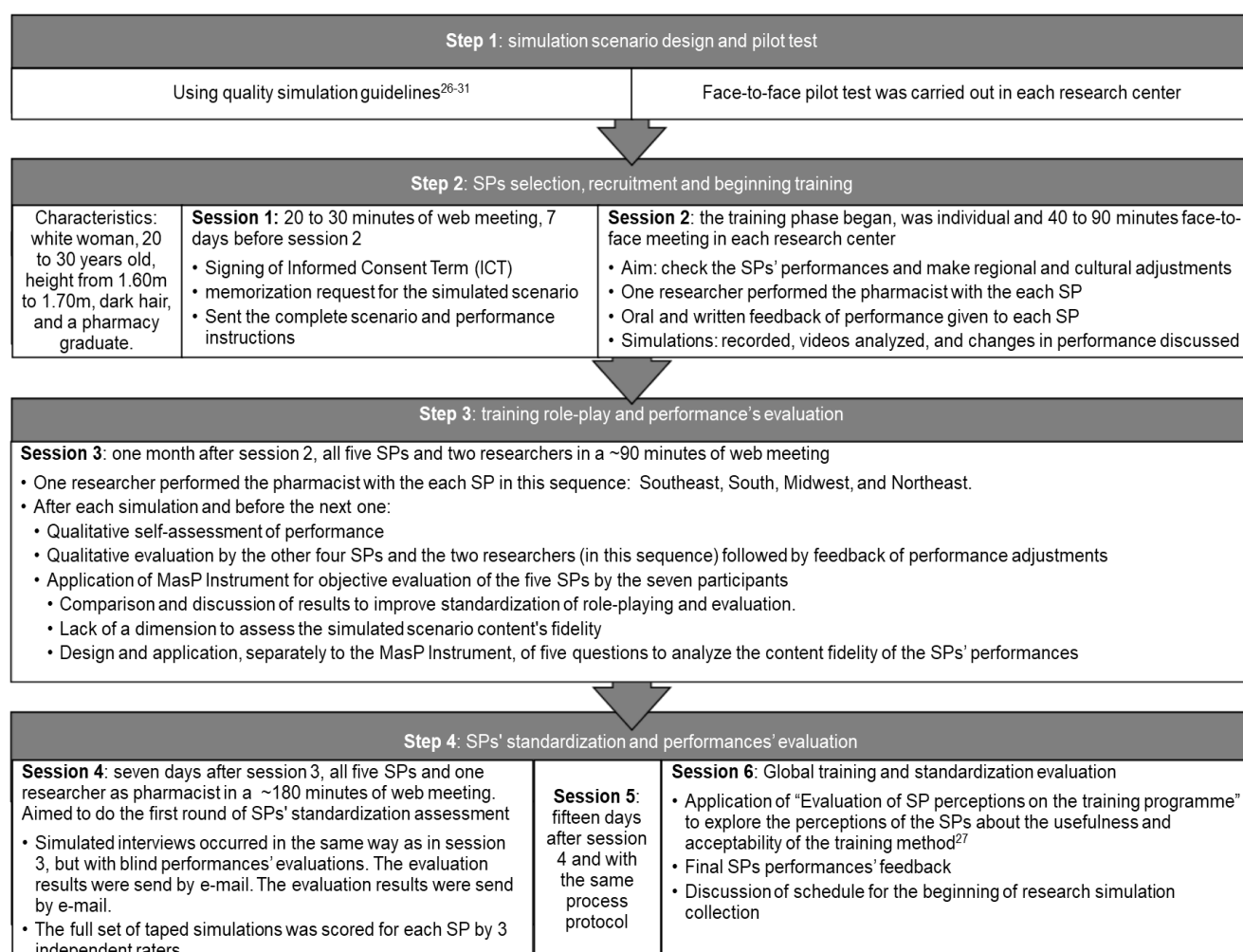


Figure 1. Proposed method for training and assessment of simulated patient in multicenter studies

a small size study, the reliability tests were satisfactory for this new Maastricht Simulated Patient Assessment block. We also adapted the instrument to our study by removing the feedback block, following other studies that showed some very specific items in Maastricht Simulated Patient Assessment that were irrelevant to some research institutions and objectives.<sup>19</sup> Perera *et al.*, 2015 adapted the Maastricht Simulated Patient Assessment to their study context, while Bouter *et al.*, 2013 proposed a new Maastricht Simulated Patient Assessment-based instrument called Simulated Patient Nijmegen Assessment (NESP), that focused only on feedback.<sup>33,45</sup> Due to the nature of the instrument, organized by independent blocks, it was possible to withdraw one and add a new one as a first attempt to expand the Maastricht Simulated Patient Assessment scope.

This study presents several limitations. The risk of bias by the evaluator is inherent in this type of study. However, Figure 1 shows that the bias control measures were taken as training and standardization of the evaluators in step 3; blinding of the evaluators in steps 4 and 5 and, finally, the analysis of internal consistency by Cronbach's alpha and by the intraclass correlation coefficient (ICC). Given the great geographic distance between simulation centers, there may have been details that were not directly controllable by the

research team, such as details of the set layout, including personal features (e.g. makeup, clothing) and room organization (e.g. furniture, lighting, and interpersonal distance). The homogeneity of the SPs features such as paralanguage was also not possible to control, although a pilot test was performed in each region. The sample size was quite small for results generalization and additional studies using the procedure in multiple locations should be performed with larger SPs samples and using different clinical situations.

## CONCLUSIONS

This study developed a feasible method for training simulated patients when multicenter studies are carried out. The procedure was reliable, knowing the equivalency between SPs performance rigor, and took into consideration the cultural differences between SPs from different regions, accounting also for its validity. The study also proposed an instrument development, associated with the missing SPs assessment dimension regarding the consistency of the information provided by the SPs concerning the simulation script, a possible Maastricht Simulated Patient Assessment block subject to a subsequent validation.

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## CONFLICT OF INTEREST

The authors have no conflicts of interest to declare in this paper.

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