Original Research

Use of secret simulated patient followed by workshop based education to assess and improve inhaler counseling in community pharmacy in Jordan

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Abstract

Objectives: To assess inhaler technique demonstration skills of community pharmacists located in Amman, Jordan via incorporating the trained secret simulated patient (SSP) approach. Secondly, to evaluate the effectiveness of a 2-hour educational workshop focused on SSP feedback.

Methods: This cross-sectional study involved community pharmacies located in Amman, Jordan. Initially, a trained SSP was involved to enact baseline visits requesting advice on how to use Ventolin® (a pressurized metered-dose inhaler; pMDI) and Pulmicort® (a Turbohaler inhaler, TH). Immediately after each visit, the SSP completed an inhaler technique evaluation form with inhaler checklists based on previously published checklists (consisting of 9 and 10 items for pMDI and TH respectively). The SSP invited all participating pharmacists to a 2-hour workshop that included feedback on their demonstration skills, and the second evaluation of their inhaler technique. The workshop included a summary of the initial visits' results highlighting pharmacists' performance.

Results: Sixty pharmacies were visited and 120 inhaler assessments were completed. During baseline assessment, pharmacists scored an average of 4.5 out of 9 for pMDI and 4.9 out of 10 for TH. Only 11 pharmacists (18.3%) attended the workshop. During the workshop, inhaler technique demonstration skills significantly improved, as scores improved from 5.4 (SD 1.6) to 7.8 (SD 0.9) (p=0.008) and from 4.6 (SD 2.5) to 9.9 (SD 0.6) (p=0.003) for pMDI and TH respectively.

Conclusions: The SSP approach revealed a lack of ability to demonstrate correct inhaler technique for pMDI and TH inhalers by community pharmacists in Amman, Jordan. A focused educational workshop based on SSP feedback improved inhaler technique significantly.

Keywords

Administration, Inhalation; Metered Dose Inhalers; Dry Powder Inhalers; Professional Practice; Community Pharmacy Services; Pharmacies; Pharmacists; Patient Education as Topic; Checklist; Patient Simulation; Cross-Sectional Studies; Jordan

INTRODUCTION

Pharmacists are taking leading roles in optimizing therapy and patient education since the drug interventions are being the leading health intervention in modern time along with the growing population of patients with chronic diseases.[1] Asthma is a growing global health problem and a leading cause of fatal respiratory attacks and unnecessary medication costs.[2] Jordan is following the global trend, with the prevalence of asthma being doubled over the last 20 years.[3]

Inhaled therapy is the cornerstone in the management of asthma due to its direct, localized delivery of drugs to the airways with minimal systemic side effects.[4] The most commonly used inhaler devices in asthma treatment are the pressurized metered-dose inhalers (pMDIs), being cheapest compared to other devices.[4] Other devices include dry powder inhalers (DPI) such as the Turbohaler (TH), Diskhaler, and Accuhaler, which consist of powdered drug formulations dispersed into particles by the inspiration of the dose. Regardless of the type of inhaler device, patients need training on the correct inhaler technique as it has been shown that over 50% of patients do not use their inhaler devices correctly.[5-7] In Jordan, it has been estimated that only 20% of asthmatic patients are able to use their inhalers correctly.[8] Furthermore, inappropriate inhaler technique is associated with poor asthma outcomes and avoidable treatment costs.[5,6,8,9] Previous research has shown that few pharmacists are able to demonstrate correct inhaler technique for certain inhaler devices (Accuhaler and TH).[10] Interestingly, patients made errors similar to those of the community pharmacists.[10] The similarity between the pharmacists' and patients' inhaler technique errors indicated that their cause could be the lack of pharmacists' knowledge, or they could be device-specific problematic steps that are not easy to perform.[10]

Pharmacists have a key role in educating and counseling patients on optimizing inhaler technique and asthma management, particularly in the community settings.[9,11] In Jordan, pharmacists educate patients on medications as they are purchased, but previous studies have shown suboptimal counselling practices in this area, globally and in Jordan, presenting an important issue that calls for improvement.[10-16] Thus, it is important to investigate and evaluate means of good practice reinforcement to support pharmacists in delivering their role in regard to appropriate inhaler use and necessary patient counseling.[11,17,18]

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Traditionally, training programs relied primarily on workshops without a mean of reinforcement and feedback to secure transfer of skills acquired into practice. Studies have suggested that workshops alone might be insufficient to induce behavior or practice changes.[11,17-20] Adding reflective feedback regarding participants' performance in their workplace can have a positive impact.[21]

Moreover, secret simulated patient (SSP) method is used in pharmacy research world to assess practice in different settings including the community setting.[16,21,22] It relies on capturing a realistic description of the practice using a trained individual (a single simulated patient) or individuals (numerous simulated patients) who conduct a covert visit to a pharmacy enacting a scenario to test staff members without being aware of the SSP's identity.[23,24] Secret simulated patient approach is being used increasingly as a mean of reinforcing and supporting practice improvements by guiding focused and tailored education.[15,20,22,25] Use of SSPs has been reported previously in the literature for evaluation of health professionals.[26-28] Many studies outlined an improvement in pharmacist's performance dealing with non-prescription medicines supply, but the potential to demonstrate such benefits in empowering pharmacists to actively improve asthma patients' inhaler technique and reduce implications of improper inhaler use is yet to be studied.[26-30]

Simulation-based assessment is effective, confined to the "shows how" level of Miller's pyramid.[31] Miller's Pyramid of assessment provides a framework for assessing clinical competences and can assist in matching learning outcomes, including clinical competencies with expectations of what the learner should be able to do at any stage.[31]

The primary aim of this study was to investigate the dispensing and additional therapeutic recommendation practices, including inhaler demonstration skills for Ventolin® (a pMDI) and Pulmicort® (a TH) of pharmacists working in community pharmacies located in Amman, Jordan via incorporating the trained SSP approach (phase 1). The secondary objective was to evaluate the effectiveness of a follow-up 2-hour blended educational workshop for pharmacists (phase 2) focusing on the assessed outcomes obtained via the SSP visit (conducted in phase 1).

METHODS

Study settings

This cross-sectional study was conducted between May and November 2017. A research assistant visited pharmacies prospectively and obtained consent from an authorized representative (pharmacy owner or manager) from each pharmacy. Each individual staff member at each involved pharmacy was also invited to provide informed consent; those who did not wish to participate were offered to wear a badge as such they would not be approached by the study team. Details about the scenario and the time of the visits were not revealed to pharmacy staff members. A SSP was trained to perform the study visits in a standard way. To avoid detection, the SSP was not connected in any way to the research assistant responsible for pharmacy recruitment and did not work previously at any of the pharmacies included in the study. Nevertheless, pharmacies were urged to report if they suspect a SSP visit at any point in the study. The study was piloted in five pharmacies at convenient locations to assess the feasibility of the method and standardize the simulation process.

Visits were audio-recorded using a hidden microphone in order to validate the assessment completed by the SSP. Recordings were assessed by two independent investigators to minimize assessor bias. The audio-recordings also served to measure the duration of each visit.

Study design

This study was conducted in Amman, the national capital of Jordan, were 1,568 community pharmacies are located (at the time of study conduct).[32] The study consisted of two phases: a baseline assessment via a SSP visit to randomly selected community pharmacies in Amman (phase 1), followed by a follow-up 2-hour blended educational workshop for pharmacists (phase 2) focusing on the assessed outcomes obtained via the SSP visit (conducted in phase 1).

Phase 1- Baseline assessment

A male clinical pharmacist in his twenties who acted as the SSP was trained to enact the scenario. Two of the authors (EE and EH) delivered a training session over two hours which focused on theoretical and practical aspects of enacting SSP scenarios. These included how to manage situations that could emerge in the process of enacting the scenarios. The SSP entered pharmacies asking for advice on how to use a pMDI namely Ventolin® and a TH namely Pulmicort®. The SSP used specific scenarios such as: "I have been prescribed these two inhalers but I am not sure how to use them appropriately, no one mentioned anything to me on this". He was instructed to show that he is stressed and confused. To authenticate the scenario, the SSP had a fabricated prescription detailing the dose and frequency of each inhaler.

The SSP assessed the visit using a pre-designed evaluation form consisting of previously published checklists. The evaluation was completed by the SSP observing the pharmacists demonstrate the pMDI and TH technique, then recording their correct steps against the checklist outside the pharmacy immediately after the visit. A total score out of 9 and 10 was calculated for the pMDI and TH respectively according to the steps obtained correctly for each inhaler.[4] In addition to inhaler technique, the content of patient counseling with respect to the number of puffs to be used, frequency of administration, recommended storage, what to do if a dose was missed and many other details were also evaluated. Details of the pharmacy visits were also noted including pharmacy type (chain vs. independent), location and number of waiting customers. Time and day of the visit, duration of the visit, gender and the estimated age of the pharmacists were also recorded.

Phase 2- Workshop and feedback

Pharmacists visited during the first phase were invited to a two-hour workshop about patient counseling on the proper use of inhalers. Invitation of pharmacists was performed

Table 1. Characteristics of pharmacists during the initial visits (n=60)

Pharmacy Characteristics	n (%)
Type of pharmacy	
Chain	24 (40)
Independent	36 (60)
Dispensary load *	
None	20 (33.3)
Low (1-2 customers waiting)	17 (28.3)
Moderate (3-5 customers waiting)	13 (21.7)
Busy (> 5 customers waiting)	10 (16.7)
Visit time	
Morning shift	26 (43.3)
Evening shift	34 (56.7)
Pharmacy personnel Characteristics	
Gender	
Male	37 (61.7)
Female	23 (38.3)
Age group	
20-29	31 (51.7)
30-39	23 (38.3)
40-49	4 (6.7)
>50	2 (3.3)

*Classification is based on classification of Berger et al.[37]

personally by the SSP who handed a formal invitation letter from the faculty of pharmacy at the University of Jordan (signed and stamped by the dean) to the pharmacists two weeks before the educational workshop. The formal letter included the purpose of the workshop, why the invited pharmacist was chosen to participate, proposed time, date and location of the workshop. The date and time discussed was agreed to best fit with the study pharmacists when the SSP delivered the invitation. At the time the invitation letters were delivered, pharmacists' phone numbers were obtained to confirm the invitation three days before the workshop and on the same day of the workshop (as requested by the pharmacists to be reminded of the workshop date and place).

In order to determine whether the pharmacy staff detected the SSP visits, a special form was prepared and provided to the attending pharmacists. The pharmacists were asked to complete the form with details of all suspected visits. Suspected visits were excluded from data analysis.

Pharmacists' inhaler technique for both pMDI and TH were evaluated before the start of the educational workshop session. A feedback summary presenting the baseline assessment results provided from the SSP visit to the pharmacy was provided and deficits in inhaler technique and counseling process were discussed with each pharmacist. This was followed by a focused blended educational session using a PowerPoint presentation on asthma and correct inhaler technique, a video presenting an active demonstration of inhaler technique for pMDI and TH devices. The workshop also involved one on one training and small group discussions regarding correct technique of the inhaler devices involved in the study and peer demonstration of inhaler technique.

At the end of the workshop, inhaler technique of participating pharmacists was also evaluated to assess the effect of the educational workshop session on pharmacists' correct inhaler technique. Pharmacists were then asked to complete a short survey to express their views about the material presented in the workshop and its usefulness.

Table 2. Percentage of pharmacists (n=60) who correctly demonstrated each step of the inhalation technique checklist at baseline.

Steps	Percentage
pMDI	
Remove mouthpiece cover and shake	78.3
Hold inhaler upright	80.0
Exhale to residual volume	23.3
Keep head upright or slightly tilted	20.0
Place mouthpiece between teeth and lips	70.0
Inhale slowly and press canister	75.0
Continue slow/deep inhalation	18.3
Hold breath for 5 seconds	40.0
Close inhaler	33.3
Turbohaler	
Open inhaler	80.0
Keep inhaler upright	35.0
Rotate grip anti-clockwise and then back until click	85.0
Exhale to residual volume	18.3
Exhale away from mouthpiece	15.0
Place mouthpiece between teeth and lips	63.3
Inhale forcefully and deeply	83.3
Hold breath for 5 seconds	43.3
Exhale away from mouthpiece	18.3
Close inhaler	40.0

Ethics approval

Ethical approval was obtained from the Institutional Review Board (IRB) at the University of Jordan Hospital (reference no. 235/2014).

Data analysis

All statistical analyses were conducted using the SPSS version 23. Categorical and continuous values were expressed as frequency (percentage) and mean (SD) respectively. The comparison between the groups was conducted using Mann Whitney test (to compare between two independent groups), Kruskal Wallis (to compare between at least three independent groups), Wilcoxon signed ranked test (to compare between two related groups) and chi-square test to compare categorical variables. Pearson correlation was used to find correlations between two continuous variables (correlation between visit duration and total score for both inhalers). A two-sided p-value <0.05 was considered to be statistically significant.

RESULTS

Sixty visits were undertaken including 120 assessments. Each pharmacy (n=60) was visited once. Table 1 summarizes the characteristics of the study visits. Majority of the visits involved independent pharmacies and often were of nil to low dispensary load. The average duration of the visits was 5.1 (SD 2.0) minutes. The majority of pharmacy personnel visited were males, aged below 40 years old. None of the SSP visits were identified by the participating pharmacists.

Baseline assessment

None of the pharmacists were able to demonstrate all steps for both pMDI and TH correctly. On average, pharmacists scored 4.5 (SD 2.1) out of 9 for pMDI and 4.9 (SD 1.9) out of

Table 3. Information provided by the participating pharmacists to the secret simulated patient (SSP) during the initial visit.

Information provided	pMDI	Turbohaler
Number of puffs	46 (77)	40 (67)
Frequency of administration	48 (80)	42 (70)
What to do if a dose was missed	1 (2)	0
Where to store the inhaler device	0	0
Benefits of taking the medication as recommended	7 (12)	4 (7)
Duration of therapy	4 (7)	2 (3)
Onset /peak effect	4 (7)	2 (3)
Additional directions*	5 (8)	18 (30)
Side effects/warnings	2 (3)	9 (15)
Emphasis of the importance of correct inhaler technique	6 (10)	5 (8)
Asking patient to re-demonstrate inhaler technique	3 (5)	2 (3)

*Additional directions included: for the Turbohaler (Pulmicort®), 'Wash mouth and gargle as it contains steroid, not to wash the inhaler with water, and not to stop the medication before doctor advice'; for the pMDI (Ventolin®),'shake the inhaler for 5 seconds with the metal canister inserted' and 'Prime inhaler if used for first time'.

10 for TH. Table 2 presents the frequencies of pharmacists demonstrating correctly each step for both pMDI and TH.

For pMDI, pharmacy personnel did not demonstrate correctly steps relevant to exhalation of residual volume or maintaining slow and deep inhalation. For TH, often steps relevant to residual volume exhalation before and after use was not demonstrated correctly.

Information provided by the pharmacy personnel are presented in Table 3. Most often, only the number of puffs and frequency of administration were highlighted to the SSP.

Investigating factors that may affect pharmacists' inhaler technique score for both pMDI and TH indicated that visit time was the only factor that significantly influenced inhaler technique demonstration skills (inhaler technique score). Pharmacists who were visited during the evening shifts had higher inhaler technique scores for both the pMDI and TH, compared to those visited during the morning shift (Table 4).

Workshop and feedback

Out of 60 pharmacy personnel involved in the study and invited to participate in the workshop, fifteen pharmacists (25%) were interested in taking part in the educational workshop. Thirty-four (56.7%) refused participation due to being busy or having previous work commitments. Some refused to give a reason and others were lost from contact. Eventually, only 11 attended the workshop. For both inhalers, the average inhaler technique score pre-workshop was 5.4 (SD 1.6) and 4.6 (SD 2.5) for pMDI and TH respectively. Post-workshop assessments showed a significant improvement in inhaler technique with average scores of 7.8 (SD 0.9) and 9.9 (SD 0.6), p=0.008 and p=0.003, Wilcoxon signed ranked test, for pMDI and TH respectively.

With regards to pharmacists' performing correctly the individual steps in the inhaler technique checklists for both the pMDI and TH, most steps were demonstrated correctly during the post-workshop assessment (Table 5).

Attendants expressed positive views on the workshop; over 90% of the pharmacists agreed or strongly agreed that the

Table 4. Investigating factors associated with pharmacists' inhaler technique demonstration skills (inhaler technique scores) for both pMDI and Turbohaler (TH).

	MDI Score out of 9 Mean (SD)	p-value	Turbohaler Score out of 10 Mean (SD)	p-value
Pharmacy type *		0.181		0.643
Chain	5.0 (2.3)		4.7 (2.2)	
Independent	4.2 (2.0)		4.9 (1.8)	
Dispensary load **		0.623		0.249
Nil	4.6 (1.4)		5.2 (1.7)	
Low (1-2 customers waiting)	3.7 (2.3)		4.3 (2.2)	
Moderate (3-5 customers waiting)	4.8 (2.3)		4.9 (2.0)	
Busy (> 5 customers waiting)	5.4 (1.7)		5.1 (1.7)	
Visit time *		*0.009*		*0.012*
Morning shift	3.7 (2.0)		4.2 (2.0)	
Evening shift	5.1 (2.0)		5.4 (1.7)	
Visit duration in minutes #	R = 0.232	0.074	R=0.179	0.172
Gender *		0.789		0.828
Male	4.5 (2.0)		4.8 (2.2)	
Female	4.6 (2.2)		4.9 (1.5)	
Age group **		0.666		0.304
20-29	4.8 (2.0)		5.1 (1.9)	
30-39	4.2 (2.2)		4.5 (2.0)	
>40	4.3 (2.0)		5.2 (1.8)	

*P value was calculated using Mann Whitney test, ** p value was calculated using Kruskal Wallis test. # P value was calculated using Pearson correlation

Table 5. Percentage of pharmacists correctly demonstrating each step of inhalation technique before and after educational workshop.

	Before educational workshop	After educational workshop
pMDI		
Remove mouthpiece cover and shake	36.4	72.7
Hold inhaler upright	100	100
Exhale to residual volume	54.5	81.8
Keep head upright or slightly tilted	18.2	63.6
Place mouthpiece between teeth and lips	100	100
Inhale slowly and press canister	36.4	72.7
Continue slow/deep inhalation	27.3	72.7
Hold breath for 5 econds	63.6	100
Close inhaler	100	100
Turbohaler		
Open inhaler	90.9	100
Keep inhaler upright	36.4	100
Rotate grip anti-clockwise and then back until click	72.7	100
Exhale to residual volume	27.3	100
Exhale away from mouthpiece	0.0	90.9
Place mouthpiece between teeth and lips	81.8	100
Inhale forcefully and deeply	27.3	90.9
Hold breath for 5 seconds	27.3	100
Exale away from mouthpiece	9.1	100
Close inhaler	81.8	100

workshop increased their awareness of asthma patients' need of learning correct inhaler technique and the importance of having correct inhaler technique demonstration skills. They also agreed that the workshop material was organized well (81.8%), balanced (81.8%), and was of right length (81.8%). All Attendants expressed that they would be interested in attending follow-up, more advanced workshops, on this subject and other counseling subjects.

DISCUSSION

According to the assessment of inhaler technique counseling skills in community pharmacies via the SSP approach, pharmacists in Jordan showed suboptimal practice, as they were unable to demonstrate correct inhaler technique. This was the case for the older device, the pMDI, and the newer device, the TH. Being consistent with previously published results from Jordan and neighboring countries, these results call for quick action.[14,15,20,33,34] This problem is not limited to Jordan or countries with a developing pharmacy profession. Deficiencies in inhaler counselling skills amongst pharmacists have become evident in the literature worldwide, including countries with a well-established pharmacy profession.[16,19]

There is a wide consensus in published pharmacy practice studies on the notion that training and continuous education programs are needed to improve suboptimal inhaler counselling practice.[9,12,13,15,19,33] However, the features of training methods and content that is necessary to transfer and sustain skills into practice have been increasingly questioned.[11,18,19] This study derived an accurate baseline assessment of inhaler counseling practice and outlined to the pharmacy personnel specific practice deficiencies that did not meet expectations. Feedback provided by the SSP on inhaler technique demonstration skills of involved pharmacists was effective. The method used to assess pharmacists' demonstration skills and behaviors in this study was at the "Does" level of Miller's pyramid. Not only did the study employ "ordinary" simulated patients, but ones that were unknown to the research subjects (pharmacy personnel) to act as real patients (or family members) genuinely seeking advice about asthma medications. Such an approach, in addition to the feedback and focused educational workshop that followed to support inhaler counseling in the community setting in Jordan, was found effective.

The educational workshop conducted in this study was unique in two ways. Firstly, tailored feedback by the SSP highlighting the identified problematic areas in inhaler technique demonstration skills and practice was effective. Secondly, providing corrective information via lecture format, group discussions and peer demonstration of inhaler technique allowed focused and targeted fine-tuning of clinical practice in this area, which could facilitate skill implementation.[28,29] Pharmacists showed favorable attitudes towards the SSP feedback and training. Inhaler technique scores improved significantly on assessment after the workshop. Thus, SSP feedback coupled with tailored education via continuous workshops, could play an important role in practice change and its sustainability when pharmacists return to their community pharmacies.

Nevertheless, the veracity of the comprehensive implementation of this study observations merits discussion. Pharmacists often express positive views on training but they don't often voluntarily seek profession development goals.[1,8,19] Numerous strategies to optimize the number of attendants to the workshop were employed; the workshop was conducted at the University of Jordan, in central Amman, which allows for an easy access location and a complimentary lunch was provided for attendants. Pharmacists were informed that they would receive an official certificate for attendance. Informative and official invitation letters were hand-delivered to the involved pharmacists. Furthermore, reminder phone calls were carried out; pharmacists were called to confirm attendance

a day before the workshop date. This necessitates seeking prompt ways to reach and motivate pharmacists to attend educational workshops and to enhance continuous professional development pursue. Potentially, developing training programs using self-directed learning through online access or mobile applications may be a possible way to tackle a lack of motivation or difficulty of travelling around to attend educational workshops. In addition, continuous education can be linked to practice license renewal or financial incentives. Continuous professional development has become a driving feature of pharmacy practice.[1]

In Jordan, there are 3,214 community pharmacies serving the community across the country, of which 56 are chain pharmacies incorporating around 300 branches, and the remainder are independent pharmacies. No continuous professional development or education requirements for pharmacy license renewal are in force yet.[35] Increasingly, pharmacies, particularly chains, are enhancing pharmaceutical care through allocating a special counseling area and offering continuous training programs to their employees. Of noteworthy, no difference was identified in this study between the performance of pharmacists working in a chain or an independent pharmacy. Our study echoes previous published studies calling to mandate continuous education programs to enforce inhaler counseling in the community settings.[8,9,12,13,15,33]

Variations between the individual steps in the TH and MDI technique can lead to variations in results. Looking closely at the MDI and TH individual steps performance by the pharmacists, it can be noted that a greater percentage of pharmacists correctly demonstrated each step of TH technique after the educational workshop (almost all steps been reached by all the pharmacists). Only 3 of the 9 steps of pMDI inhaler technique were correctly demonstrated by 100% of pharmacists after the educational workshop. This indicates that future educational workshops need to focus further on pharmacists' MDI individual step performance.

This study comes with limitations. While 60 pharmacies were visited by the SSP, only 11 pharmacists attended the workshop. This small number of voluntary participants may limit the conclusion driven by this intervention. In addition, due to this small number of pharmacists who attended the workshop, it was not plausible to assume that practice improvement would be sustainable without repeated measures and multiple educational interventions. Thus, comparative controlled future studies should focus on investigating the magnitude of subsequent practice change with and without repeated visits and educational interventions. Additionally, it is essential to explore factors predicting subsequent practice improvement and to understand the long-term effectiveness and generalizability of this study's results. Although results from studies that use one or a few simulated patients may be more limited and less generalizable than studies that use greater numbers of individuals to conduct the SSP visits, most studies were found to use few SSPs.[36] Moreover, the voluntary nature of participation in the study workshop might have resulted in involving pharmacy personnel who are most likely to perform better and have more commitment to educational programs. Recruitment strategies in future studies should be broadened and should focus on health promotion campaigns and endorsement by official pharmacy profession bodies or enterprise. This may ensure the recruitment of a large, randomized sample of pharmacists drawn from various backgrounds and practice settings in Jordan. However, researchers should be aware that this might introduce performance bias as pharmacists would become aware of the SSP visits, moving into a hyper vigilant state.

CONCLUSIONS

Using the SSP approach to assess community pharmacists' inhaler technique demonstration skills is effective. Providing focused feedback by the SSP through a tailored educational workshop was found promising in optimizing pharmacists' inhaler technique demonstration skills. The results of this study suggest that the SSP approach followed by the focused educational workshops could become an essential feature in the future in auditing pharmacist performance and enhancing inhaler technique counselling in the community setting. However, the effect on practice and long term sustainability of the assessment and educational approach proposed in this study is still in need of further development.

CONFLICT OF INTEREST

None declared.

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