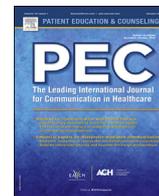




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Evaluation of a structured pharmacist-led inhalation technique assessment service for patients with asthma and COPD in Norwegian pharmacies

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ABSTRACT

Objective: To investigate whether the inhalation technique improved among patients with asthma and chronic obstructive pulmonary disease after an Inhalation Technique Assessment Service (ITAS), and to assess the patients' and pharmacists' perceptions of ITAS.

Methods: This uncontrolled, pre-post study included 405 patients recruited from 42 Norwegian pharmacies. Inhalation technique was assessed by trained pharmacists before ITAS (baseline), directly after (follow-up 1) and three months after ITAS (follow-up 2), and analyzed statistically using SPSS. Perceptions of ITAS were assessed using a questionnaire.

Results: 488 ITAS were performed. At baseline, 8% of the inhalation technique demonstrations were rated as optimal and 31% as acceptable. Following ITAS, this increased to 72% (optimal) and 86% (acceptable). At follow-up 2 inhalation technique remained significantly higher than baseline (optimal: 52%, acceptable: 75%). The median rate of wrong steps decreased from 25% (baseline) to 0% (follow-ups). The usefulness of ITAS was rated 4 on a 5-point Likert scale.

Conclusion: Inhalation technique improved significantly after ITAS for both new and experienced users and all assessed devices. The technique remained significantly improved at follow-up 2. ITAS was well accepted by pharmacists and patients.

Practice implications: ITAS can contribute to significant improvements in inhalation technique among patients using inhaler devices.

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1. Introduction

Asthma and chronic obstructive pulmonary disease (COPD) patients rely on inhaled medications for disease management. Many patients risk sub-optimal effect of their medication due to incorrect use [1–7]. Previous studies have shown that inhaler technique education leads to improved inhalation technique, and that community pharmacists are in a particularly good position to provide such education since they are easily accessible primary health care professionals [8–10]. Studies so far have generally evaluated

interventions conducted exclusively for specific studies or in limited geographical areas. Hence, results may not be representative of similar interventions implemented in real-life routine practice. Based on good results from studies in community pharmacies it has been argued that inhalation technique interventions involving community pharmacists should be trialed at a national level [10].

Finland was the first European country to implement a national asthma program (10-year program 1994–2004), that also included a pharmacy program to check and correct inhalation technique as well as giving patients information on the overall effects of their medication [11]. Since 2005 Danish pharmacies have been providing a national standardized inhalation technique assessment service (ITAS), to improve inhalation technique among patients [12]. Haahtela et al. reported that the Finnish program led to decreased burden of asthma, but did not report on the impact on patients' inhalation technique [11]. Kaae et al. have documented experiences with implementation of ITAS in Denmark, focusing on patients' experiences and how provision and sustainability of the

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service was influenced [12–15]. To our knowledge, no studies have investigated the effect of a pharmacy-based service on patients' inhalation technique after implementation of a national service.

To improve inhalation technique, the Norwegian health authorities allocated funds in the 2016 National Budget to reimburse ITAS in pharmacies. On the initiative of the Norwegian Pharmacy Association a standardized pharmacist-led ITAS (“*Inhalasjonsveiledning*”) was developed to detect and correct errors in patients' inhalation technique, to ensure that the patients knew when to use their inhaler(s) and give practical information regarding the device. In March 2016 ITAS was implemented in Norway for patients using inhalers to treat asthma or COPD. By the end of 2016 a total of 41,159 services had been performed in 825 of the 868 pharmacies in Norway.

The aims of the study were to investigate whether the inhalation technique improved among asthma and COPD patients after receiving a standardized ITAS, and to assess the patients' and pharmacists' perceptions of the service.

Primary outcome measures:

- Proportion of patients performing all steps correct (optimal technique [1]) and all critical steps correct (acceptable technique) before and after ITAS.
- Rate of wrong steps and rate of wrong critical steps before and after ITAS.

Secondary outcome measure:

- Patients' and pharmacists' perceptions of the usefulness of ITAS.

2. Methods

2.1. Study design

This uncontrolled pre-post study was conducted between September 2016 and March 2017 in 42 pharmacies in 16 of the 19

counties in Norway. Pharmacies were selected based on the following criteria: minimum two certified pharmacists to provide ITAS, regular provision of ITAS and all major pharmacy-owners represented. Each study-pharmacy recruited patients to the study during a three weeks period.

All patients (≥ 16 years) who were eligible to receive ITAS (medical diagnosis of asthma/COPD and a prescribed inhaler device), and who decided to accept ITAS, were offered to participate in the study. No inhaler devices sold in Norway were excluded, except if the patient used an inhalation-chamber. Patients could be included in the study with up to three different inhaler devices, and received one ITAS per device. Inhalation technique was measured immediately before ITAS (baseline), immediately after ITAS (follow-up 1) and three months after ITAS (follow-up 2). It was likely that follow-up 2 would coincide with the patient's next medication refill as doctors in Norway routinely prescribe for three months when prescribing medicines against a chronic condition. It was not possible to control for factors that might influence the patient's inhalation technique between follow-up 1 and follow-up 2 (e.g. additional visits to a pharmacy/physician). As ITAS is a government-paid service intended for all eligible patients, it was considered unethical to conduct a randomized controlled trial with a non-service control group.

All data were handled anonymously and the patients included in the study signed a written, informed consent form prior to participation. The study was approved by the Data Protection Official for Research (Reg. No. 49405).

2.2. Pharmacist training

ITAS is provided by certified pharmacists who have completed a standardized training program including e-learning courses, workshops to practice how to correct inhalation technique and communication skills, an ITAS manual and 18 device-specific fact-sheets. Since ITAS mainly focuses on technical advice, the pharmacists are encouraged, but not obliged, to complete e-learning on asthma and COPD treatment. The study-pharmacists

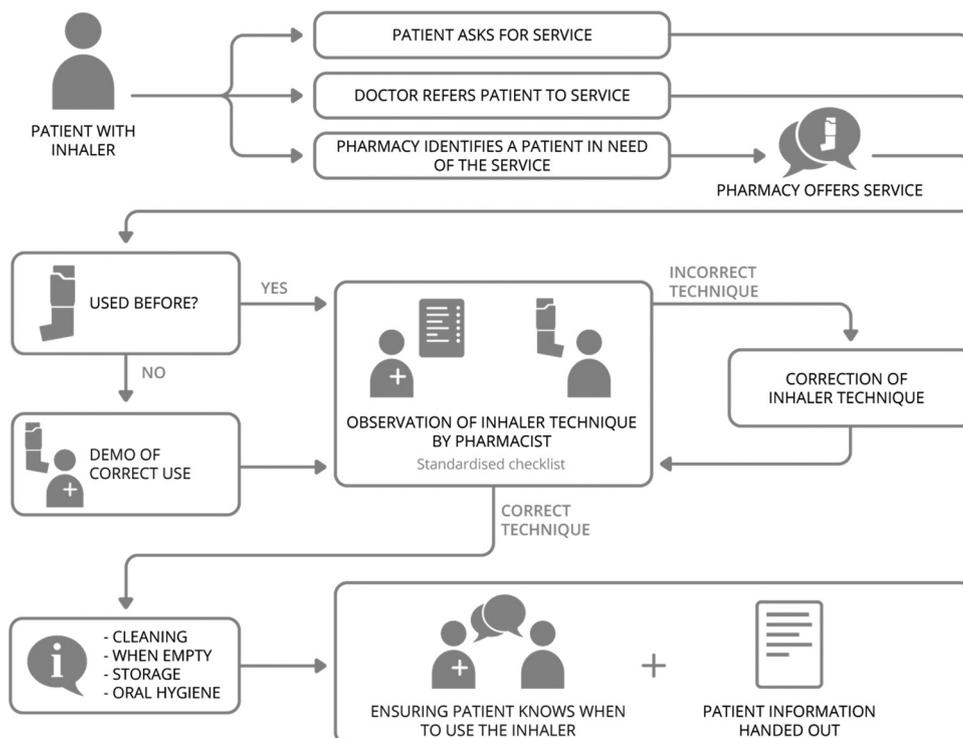


Fig. 1. Flow diagram of Inhalation Technique Assessment Service in Norwegian pharmacies.

also attended a one-day training session, focusing on study procedures and how to use the study checklists.

2.3. Description of inhalation technique assessment service (ITAS)

Patients prescribed any inhaler device approved by the Norwegian Medicines Agency for the treatment of Asthma or COPD may request ITAS, or have the service recommended by their general practitioner or pharmacist (Fig. 1). ITAS is available for both new and experienced users of inhaler devices. Experienced users start by demonstrating their inhalation technique to the pharmacist. Patients with no prior experience are first shown correct use by the pharmacist before the patient demonstrates his/her technique. The pharmacist addresses issues about the patient's use of the inhaler, and repeats the counseling cycle with patient demonstration and pharmacist correction, if necessary. The pharmacist also asks questions to clarify the patient's needs for further individualized information (e.g. differences between types of inhalation medication (i.e. reliever vs. controller) and when to use them, how to store and clean the device and the importance of good oral hygiene). A device-specific fact-sheet is available to facilitate the information. Finally, a written information leaflet summarizing the individualized information is handed out to reinforce any corrections in inhaler technique.

2.4. Development of checklists and definition of incorrect use

To develop specific checklists and to define critical steps for each inhaler device, a literature search was carried out. Critical steps were defined according to Giraud et al., as steps that, if not performed correctly, could substantially affect dose delivery [1]. In cases where no references were available, checklists for similar inhaler devices were adapted based on a critical review of the manufacturers' product information leaflet. The specific checklists are presented in Supplementary Table.

The number of steps and critical steps varied between the different inhalers, hence rate of wrong steps (RWS) and rate of wrong critical steps (RWCS) were used to analyze the magnitude of errors corrected by ITAS. RWS has been defined by Choroa et al. as the number of inhalation technique wrong steps divided by the total number of recommended steps [16]. For RWCS the definition was adjusted as number of inhalation technique wrong critical steps divided by the total number of critical steps.

Previous studies often use dichotomous measures like the proportion of patients with all steps correct [1,17,18] or with wrong steps below a defined threshold [4,19,20]. To enable a comparison with other studies (despite different checklists), the variables optimal technique and acceptable technique were used. The study-pharmacists were not aware of which steps were assigned as critical.

2.5. Data collection

Data was collected by the study-pharmacists during routine care. The patients demonstrated their inhalation technique to the study-pharmacists who used device-specific checklists (9–13 steps) to record whether each step was demonstrated "correctly" or "incorrectly". Patients with no prior experience with the inhaler device were given time to read the package leaflet before demonstrating their baseline inhalation technique. The patients used their own inhaler device to demonstrate inhalation technique, either by inhaling a dose of the medication or simulating use (according to the ITAS guide). The study-pharmacists reported the patients' inhalation technique immediately after the assessment using an electronic form.

At the completion of ITAS, patients' and study-pharmacists' perceptions of the usefulness of ITAS (including gained knowledge,

understanding of practical aspects and when to use the medication) were explored using a questionnaire with responses rated on a 5-point Likert scale. The patients also answered questions regarding patient characteristics (age, sex, diagnosis) and rated their own inhalation technique before and after receiving ITAS on a visual analogue scale (VAS) from 1 to 10. The pharmacists answered the questionnaire electronically. Patients could either answer the questionnaire electronically by using a computer at the pharmacy or by receiving a link on their cell-phone, or by a paper copy returned in a sealed envelope to the pharmacy within a week.

Analyzing inhalation technique before and after ITAS provides an indication on the usefulness of the service. However, the impact of the service can be questioned unless patients acknowledge the service as beneficial. A questionnaire answered by pharmacists and patients provides insight on how these groups perceive the usefulness of the service.

2.6. Statistical analysis

Statistical analyses were performed using IBM SPSS (Statistical Package for the Social Sciences) version 24. The data were not normally distributed (Shapiro–Wilk tests of normality) and statistical analyses were therefore performed using non-parametric tests. Wilcoxon test was used to analyze differences in continuous variables between baseline, follow-up 1 and follow-up 2, using median and interquartile range (IQR). McNemar test was used to assess differences in categorical dichotomous variables (all steps/critical steps correct) between baseline, follow-up 1 and follow-up 2. For comparison between new and experienced users, Mann–Whitney *U* Test for independent samples was used. The data was analyzed collectively for all types of inhaler devices representing the entire study population (not categorized per pressurized metered-dose inhalers or dry powder inhalers). In addition, the proportion of patients with all steps correct and all critical steps correct also included the device-specific results for each inhaler used in >5% of services. Data from the patient questionnaires were used to analyze potential associations between patient characteristics and errors in inhalation technique. For this analysis, only one inhaler device was included per patient (in case of multiple inhalers, the device first demonstrated was included). The Independent-samples Mann–Whitney *U* test was used for categorical dichotomous variables (sex, diagnosis, above/below 65 years), while correlations between age and errors in inhalation technique were analyzed using the Spearman's correlation coefficient (ρ). Differences with *p* values < 0.05 were considered statistically significant.

3. Results

3.1. Study population

In total, 405 asthma and COPD patients receiving ITAS were included in the study. All participants had their inhalation technique assessed before ITAS (baseline) and immediately after ITAS (follow-up 1) on the day of inclusion. Among these, 324 patients (80%) returned the patients' perceptions of usefulness questionnaire (number of patients with complete information on both study ID and age/sex/diagnosis were 278/277/284 respectively). Three months after ITAS, 238 (59%) patients returned for follow-up 2. Of these, 19 were excluded due to missing information, leaving 219 (54%) patients included in analyses at follow-up 2.

Twelve pharmacies from each of the three major pharmacy-chains in Norway, five outpatient hospital pharmacy departments and one independently owned pharmacy were included in the study. All 42 participating pharmacies had two or more ITAS-certified pharmacists who recruited patients for the study.

3.1.1. Study sample for assessment of inhalation technique

During the three weeks of inclusion 488 ITAS conducted with 405 different patients (65% of all ITAS performed in the study pharmacies) were included in the study. The inhaler device was new to the patient in 65 of the ITAS, while 423 services were performed with experienced users. There were 327 patients who received the service for one inhaler, 73 patients for two inhalers and five patients for three inhalers. At follow-up 2 the data included 250 (51%) assessments of inhalation technique. An overview of the recruitment process is presented in Fig. 2.

The data includes 14 of the 16 inhaler devices sold in Norway. Table 1 shows the distribution of different inhaler devices at follow-up 1 and follow-up 2.

3.1.2. Study population for patients' perceptions of usefulness

Patient characteristics for the 324 patients who returned the patient questionnaire are presented in Table 2.

3.2. Primary outcome: improvement in inhalation technique

The patients frequently demonstrated errors in their inhalation technique. The proportions of assessments where patients demonstrated optimal inhalation technique and acceptable inhalation technique increased from baseline to follow-up 1 and follow-up 2 (Table 3). Separate analyses of the different inhaler devices showed similar improvements in inhalation technique across devices (Fig. 3).

3.2.1. Rate of wrong steps

There were significant reductions in median RWS and median RWCS between baseline and follow-up 1. Patients' inhalation technique remained significantly better than baseline at follow-up 2 (Fig. 4a and b). The Kruskal–Wallis H test showed no significant differences between the inhaler devices for any of the measure points ($p > 0.05$). Experienced users showed significantly better

Table 1

Distribution of the different types of inhaler devices assessed in the study.

Inhaler device	Baseline/Follow-up 1 (N = 488) Percentage (N)	Follow-up 2 (N = 250) Percentage (N)
Diskus	30% (146)	32% (79)
Turbuhaler	23% (111)	24% (61)
Aerosol suspension	11% (54)	10% (25)
Aerosol solution	8% (39)	8% (19)
Ellipta	8% (38)	6% (15)
Respimat	8% (37)	8% (19)
Breezhaler	5% (23)	5% (12)
HandiHaler	3% (13)	4% (9)
Autohaler suspension	2% (10)	2% (4)
Genuair	1% (5)	1% (2)
Nexthaler	1% (5)	1% (2)
Spiromax	1% (5)	1% (2)
Forspiro	<1% (1)	<1% (1)
Autohaler solution	<1% (1)	0
Easyhaler	0	0
Twisthaler	0	0

Due to rounding, percentages do not add up to 100%.

inhalation technique than first-time users at baseline. The differences between the groups were reduced after ITAS (Fig. 5a and b).

Separate analysis of errors in inhalation technique among the participants with available patient characteristics showed a positive correlation between age and wrong steps in the inhalation technique, with rho ranging from 0.136 to 0.245, $p \leq 0.023$ (N = 278). Sex and diagnosis did not show any significant associations with in inhalation technique.

3.3. Secondary outcome: usefulness of ITAS

On average, the patients who answered the questionnaire scored their baseline inhalation technique as 7.2/10 and their inhalation technique at follow-up 1 as 9.4/10 on the VAS. A

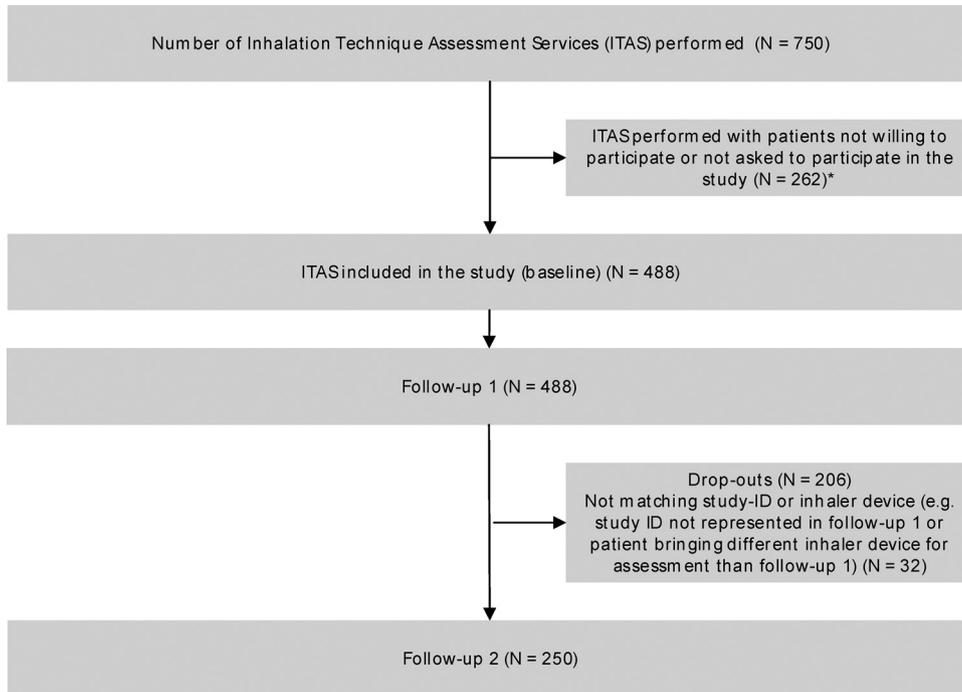


Fig. 2. Flow diagram of total number of Inhalation Technique Assessment Services (ITAS) performed in the 42 study pharmacies, number of ITAS included in the study and drop-outs.

*Only the number of services performed and the number of patients who accepted to participated in the study were recorded. Hence details regarding how many patients who were considered ineligible or for other reasons not invited are not available.

Table 2
Characteristics for patients answering the questionnaire regarding perceptions of the usefulness of ITAS (N = 324).

	Percentage (N)
Age	
17–64	50 (163)
65–94	47 (151)
Unknown age	3 (10)
Median (IQR) ^a	64 (49–72)
Sex	
Female	64 (206)
Male	33 (108)
Missing	3 (10)
Indication for inhalation medicine	
Asthma	59 (191)
COPD	19 (62)
Asthma and COPD	14 (46)
Don't know	7 (22)
Missing	1 (3)

^a Presented as years, not as percentage (N). Abbreviations: COPD: chronic obstructive pulmonary disease, IQR: interquartile range, ITAS: inhalation technique assessment service.

majority of the patients (79%) would like to receive ITAS again if they were prescribed a new inhaler device, and 55% of the patients would like to receive the service again for the same inhaler device. The patients' and pharmacists' ratings of their perceived benefit of ITAS are presented in Table 4 and 5, respectively

4. Discussion and conclusion

4.1. Discussion

This study investigated whether the Norwegian pharmacist-led ITAS succeeds in correcting errors in inhalation technique directly after the service, and if improvements are maintained after three months. The results confirmed that the structured educational intervention available nationwide can be provided with good results as a part of the daily routine in pharmacies. Existing literature supports that interventions including patients demonstrating their technique followed by corrections by a health care provider, are superior to verbal and written information or demonstration alone [21–24].

Previous studies have used various study designs with regards to checklists, inhaler devices, definitions of inhaler misuse and number of repeated feedback [1,4,18,19,24–30]. A recent review by Mahon et al. investigating errors in inhaler technique points out that lack of standardization among studies is a challenge for drawing conclusions about the scale of incorrect use [31]. However, substantial improvements are common regardless of methods used, and devices assessed [1,5,16,19,21,27,31–33]. In the present study, the proportion of patients with optimal and acceptable technique increased from baseline (8% and 31% respectively) to follow-up 1 (72% and 86%) and follow-up 2 (52% and 75%). When looking at other studies with similar

Table 3
Proportion of assessments with optimal and acceptable inhalation technique at baseline, follow-up 1 and follow-up 2 (N = 250).

	Baseline	Follow-up 1 ^a	p-value	Follow-up 2 ^b	p-value
Optimal technique (All steps correct)	8%	72%	<0.001	52% ⁱ	<0.001
Acceptable technique (All critical steps correct)	31%	86%	<0.001	75% ⁱⁱ	<0.001

P-value refers to comparison of follow-up with baseline. ⁱSignificant decrease from follow-up 1 (p < 0.001). ⁱⁱSignificant decrease from follow-up 1 (p = 0.037). The table includes data from participants who completed both follow-ups.

^a Measured directly after ITAS.

^b Measured three months after ITAS without further instruction of inhalation technique.

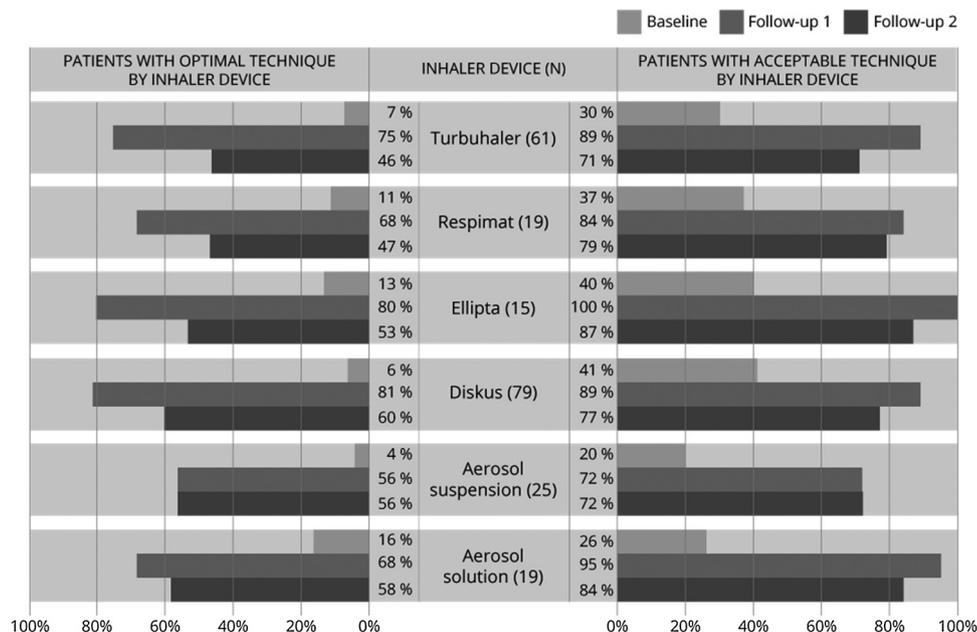


Fig. 3. Proportion of patients with optimal inhalation technique and acceptable inhalation technique before and after Inhalation Technique Assessment Service (ITAS) for the most frequently used inhaler devices. For all the inhaler devices, there were significant improvements from baseline to the two subsequent measures. Optimal technique; baseline and follow-up 1: p ≤ 0,003, baseline and follow-up 2: p ≤ 0,039. Acceptable technique; baseline and follow-up 1: p ≤ 0,012, baseline and follow-up 2: p ≤ 0,021).

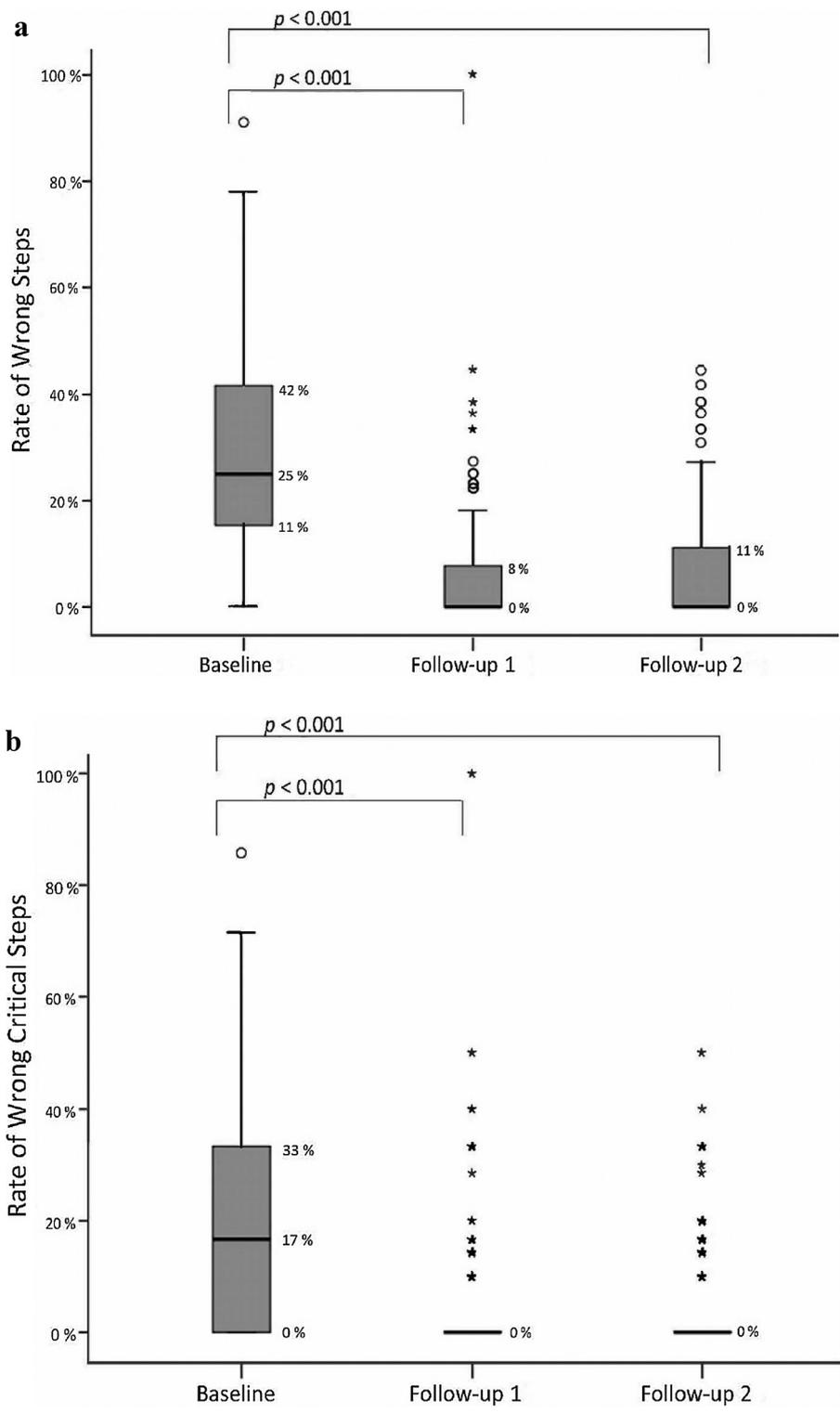


Fig. 4. (a) Boxplot illustrating the rate of wrong steps (RWS) and distribution of RWS (boxes and whiskers) at baseline, follow-up 1 and follow-up 2. N = 250. Box represents 25–75 percentiles and dark line the median. o: Outliers. -: Extreme values. (b) Boxplot illustrating the rate of wrong critical steps (RWCS) and distribution of RWCS (boxes and whiskers) at baseline, follow-up 1 and follow-up 2. N = 250. Box represents 25–75 percentiles and dark line the median. o: Outliers. -: Extreme values.

interventions, the proportion of patients with correct use increased from 17% [17] and 24% [1] at baseline to 61% [17] and 79% [1]. Although previous research cannot be compared directly to the current study, the absolute increases seen in these studies were in the same range as our finding. Other studies focusing on the reduction of incorrect inhaler technique found that proportion of patients performing minimum one error was

reduced from 63% and 79% at baseline to 20% and 28% respectively after training [18,34].

Our study indicates that both new and experienced users of inhaler devices may benefit from ITAS. Separate analysis of RWS for experienced and new users, demonstrated frequent errors at baseline and large improvements after ITAS in both groups. Interestingly, Kaae et al. found that first-time and experienced

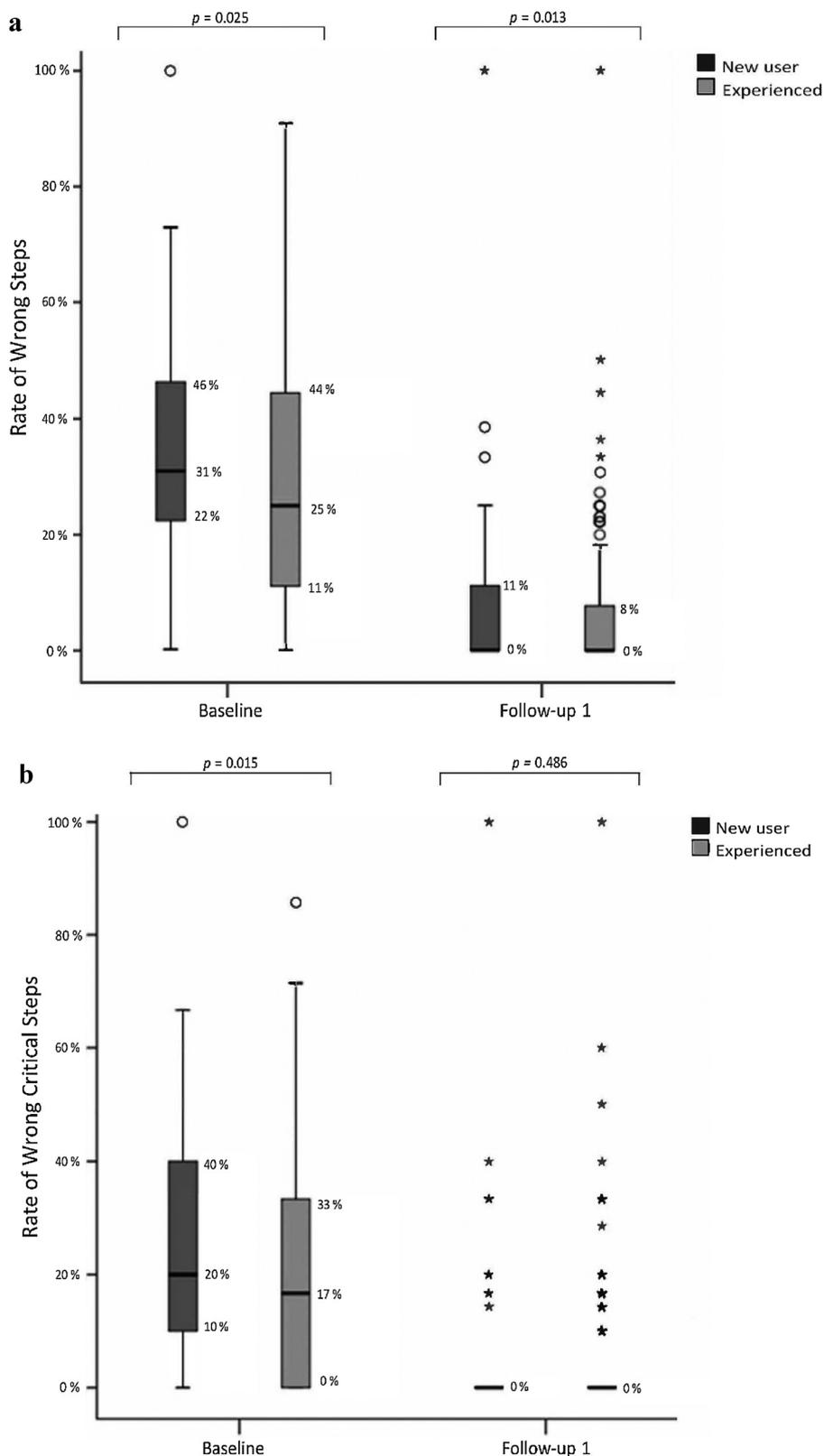


Fig. 5. (a) Boxplot illustrating rate of wrong steps (RWS) and distribution of RWS for new and experienced users of the inhaler device at baseline and follow-up 1. N = 488. Box represents 25–75 percentiles and dark line the median. o: Outliers. -: Extreme values. (b) Boxplot illustrating rate of wrong critical steps (RWCS) and distribution of RWCS for new and experienced users of the inhaler device at baseline and follow-up 1. N = 488. Box represents 25–75 percentiles and dark line the median. o: Outliers. -: Extreme values.

users in Denmark had different motivation for accepting ITAS. While new users wanted to learn correct use of the device, most experienced users did not feel any need for the service but still accepted to receive the service [15]. Later, Kaae et al. found that

both these groups generally found the service meaningful despite their diverging opinion initially [12]. Users of inhaler devices often misperceive the correctness of their own inhalation technique and tend to overestimate this. Press et al. found that while 96% of

Table 4
Patients' rating of their perceived benefit of Inhalation Technique Assessment Service (ITAS).

	N	Median (IQR)
To what extent did ITAS give you:		
... increased knowledge about cleaning the inhaler	261	4 (3–5)
... increased knowledge about storage of the inhaler	247	4 (3–5)
... increased knowledge about how to see when inhaler is empty	257	4 (3–5)
... increased understanding of when to use the inhaler	256	4 (3–5)
To what extent ...		
... was the output of the service worth the time spent?	307	5 (4–5)
... did the pharmacist communicate information in an understandable way?	313	5 (4–5)
All in all, how satisfied are you with ITAS	318	5 (4–5) ¹
To what extent do you think ITAS was useful for you	313	4 (4–5)

Rated on a 5-point Likert scale where 1: to a very little extent, 2: to a little extent, 3: to some extent, 4: to a great extent, 5: to a very great extent. ¹: Extremely dissatisfied, 2: very dissatisfied, 3: somewhat satisfied, 4: very satisfied, 5: extremely satisfied.

Table 5
Pharmacists' rating of their perceived benefit of Inhalation Technique Assessment Service (ITAS) for patients.

	N	Median (IQR)
To what extent do you think ITAS gave the patient:		
... increased knowledge about cleaning the inhaler	413	3 (2–4)
... increased knowledge about storage of the inhaler	357	3 (2–4)
... increased knowledge about how to see when inhaler is empty	391	3 (2–4)
... increased understanding of when to use the inhaler	435	3 (2–4)
For this inhaler, to what extent do you think ITAS was useful for the patient	488	4 (3–5)

Rated on a 5-point Likert scale where 1: to a very little extent, 2: to a little extent, 3: to some extent, 4: to a great extent, 5: to a very great extent.

Diskus users expressed confidence in use, 76% used it wrong [24]. By making patients aware of their own errors, services such as ITAS might lead to more accurate perceptions among patients about their own inhalation technique. Based on the post-ITAS questionnaire, we found that the patients' own baseline score was in average 7.2/10, whereas the mean score after ITAS was 9.4/10. The patient perception correlates with the pharmacists' evaluation, reporting median 75% correct steps at baseline (RWS: 25%) and median 92% correct steps after ITAS (RWS: 8%). This indicates that most patients acknowledged their own errors in baseline-inhalation technique after ITAS.

This study was limited to three months of follow-up, and ITAS seems to successfully reduce incorrect use during this period. Previous research indicate that improvement of inhalation technique is likely to last much longer than three months [28,35]. Although the inhalation technique remained significantly better compared to baseline throughout the study period there was a significant reduction in correct use from follow-up 1 to follow-up 2. According to literature, a decline during the first three months is expected if the training is not repeated [27,33]. However, provision of written information to reinforce corrections can counteract such a relapse. In the current study, individualized information leaflets were used to reinforce the corrections during ITAS. According to Basheti et al. it can be even more effective to place such information on a label attached to the inhaler device, since information attached to the device is more visible to the patient every time the inhaler device is used [36]. A challenge is still adherence to the recommended corrections. A study in Denmark found that although participants accepted the corrections suggested by the pharmacy-staff, they had difficulties remembering all the instructions and to inhale precisely as told [12]. Both guidelines [37] and previous studies emphasize the need to reeducate patients, partly because many patients need repetition to succeed and partly because inhalation technique deteriorates over time [22,27,35,38–40].

ITAS does not exclusively consist of observation and correction of inhalation technique, the pharmacist also provides individualized information about principles for use and practical aspects.

Patients rated the service as useful and expressed that the information was communicated in an understandable manner, indicating a high level of satisfaction. Results from the patient questionnaire showed that 79% of the participants would like to use the service again if they were prescribed a new type of inhaler device. At the same time, patients acknowledged the benefit of repetition as 55% would like to receive ITAS again for the same inhaler device. Pharmacists in our study scored lower than patients regarding perceived benefit of the service. Kaae et al. studied the implementation of ITAS in Denmark and found that individual staff members showed a non-justified lack of belief in their own competencies [41]. This perception may explain the lower score from the pharmacists.

One of the strengths with the current study is that it reflects a real-life setting. The pharmacists participated in the study during normal working hours in addition to other tasks in the pharmacy. The patients were recruited during standard practice, including their personal inhaler devices. All the major pharmacy owners are represented, and patients were recruited from a wide geographical area. The age distribution of the study-population is similar to the general population using inhalation medication for asthma and COPD (data openly available in the Norwegian Prescription Database). However, older patients are slightly overrepresented in the study (47% ≥65 years in the study vs. 40% in the general population using inhalation medication).

Furthermore, as ITAS was evaluated as it was practiced in real life, patients were included with up to three different inhalers. Hence results from up to three ITAS have been included for patients with multiple inhalers. A precondition for inclusion of multiple inhaler devices was the use of different device-specific checklists to assess inhaler technique. For the analysis, we assumed independency between inhalation technique assessment for different devices. However, patients with general inhalation technique problems will contribute relatively more if these are included with more than one device. Furthermore, using multiple inhaler devices may increase the risk of incorrect use [42–44]. For analysis of associations between patient characteristics and errors

in inhalation technique only one measurement per patient was included (first inhaler device demonstrated). A limitation for the analyses is that patient characteristics only are available for the participants who returned the patient questionnaire.

Garcia-Cardenas et al. assessed the effect of a pharmacist intervention and found that inhalation technique improved for the control group as well as for the intervention group during the first three months after baseline [28]. Consequently, with the absence of a control group one can argue that the improved inhalation technique three months after receiving ITAS may in part be due to other factors than ITAS (e.g. gaining experience, reading patient information leaflet or asking advice by health care professionals). This potential bias cannot be eliminated completely. However, we found that both new and experienced users had difficulties using their inhaler device. Even though experienced users had significantly better baseline results than new users, inhalation technique improved significantly for both groups after ITAS. Moreover, the service seems to even out differences in inhalation skills between new and experienced users. Although causality cannot be determined, the large improvement in inhalation technique following ITAS for both groups indicates that the improvement is mainly related to ITAS rather than gained experience with use. However, it would be interesting to compare our results with a control group, to analyze the differences in inhalation technique with time.

The inhalation technique was observed by pharmacists certified to deliver ITAS and not objective researchers. This was done to facilitate the study within the daily provision of the service already in place, and to enable participation of patients from a wide geographical area. Observations performed by the study pharmacists may vary more than if one or a few objective researchers had observed inhalation technique for all participants. To minimize observer bias, device-specific checklists were used, and the study-pharmacists were blinded to which steps were defined as critical. The pharmacists reported anonymously to neutral researchers. Hence, pharmacists had little incentive to report in a manner that could make them appear “better”. As only pharmacies with regular provision of ITAS during the first months after roll-out were included, the observed pharmacist perceptions may not be representative of the perceptions of pharmacists with less experience with the service.

4.2. Conclusion

This study confirms that a considerable proportion of asthma and COPD-patients visiting Norwegian pharmacies demonstrate a suboptimal inhalation technique, regardless of inhaler device. At baseline, only 8% of the demonstrations were evaluated as optimal inhalation technique. The inhalation technique improved significantly after ITAS (72% with optimal technique), which is in line with existing literature. Median rate of wrong steps was reduced from 25% at baseline to 0 after ITAS. Without further counseling, scores on inhalation technique had declined to some extent three months after ITAS compared to scores immediately after ITAS. Experienced users had significantly better inhalation technique compared to new users at baseline, but ITAS seems to even out the differences in inhalation technique between these two groups.

4.3. Practice implications

The Norwegian standardized pharmacist-led service ITAS shows a great potential to improve inhalation technique for patients with asthma and COPD. Given the large improvements in inhalation technique among patients receiving ITAS, regardless of age, inhaler device or experience, ITAS should be offered routinely to all users of inhalation medication.

Role of funding sources

The Norwegian Pharmacy Association were involved in decisions regarding study design and recruitment of participating pharmacies for the study. The Norwegian Pharmacy Association was also involved in the decision to submit the article for publication, and co-authored the article. Analysis and interpretation of data were carried out without involvement from the funding sources.

The Norwegian Community Pharmacy Foundation supported the participating pharmacies financially with a compensation for time spent, and had further than that no other involvement.

Conflict of interest

None.

Authors' contributions

KWR has made substantial contributions to the following: acquisition of data, analysis and interpretation of data, drafting the article, and approved the final version to be submitted.

SWR has made substantial contributions to the following: the conception and design of the study, revising the drafted article critically and approved the final version to be submitted.

PKF has made substantial contributions to the following: the conception and design of the study, revising the drafted article critically and approved the final version to be submitted.

HA has made substantial contributions to the following: the conception and design of the study, acquisition of data, revising the drafted article critically and approved the final version to be submitted.

RH has made substantial contributions to the following: the conception and design of the study, acquisition of data, analysis and interpretation of data, revising the drafted article critically and approved the final version to be submitted.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.pec.2018.05.018>.

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