ORIGINAL RESEARCH ARTICLE



Effectiveness of an educational intervention on different types of errors occurring during inhaler therapy use in COPD patients during a Pulmonary Rehabilitation Program

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Background: Inhaled drug therapy is an essential treatment in Chronic Obstructive Pulmonary Disease (COPD) patients as it reduces symptoms, exacerbation rate and mortality risk. Errors in inhaler use can affect drug delivery to the lungs and minimize treatment benefits. The aim of the study was to evaluate the effect of a nurse-lead educational intervention on inhaler use in a group of patients with COPD during a Respiratory Rehabilitation Program. Methods: COPD patients attending a Respiratory Rehabilitation Unit for a pulmonary rehabilitation program participated in the educational training program. The nurse-lead educational intervention included a specific checklist used to evaluate each patient's inhalation technique. Errors were scored and classified as device-dependent, device-independent and critical one. Patients completed a pre and post-intervention survey to compare pre and post nurse-lead educational intervention results.

Results: One-hundred twenty-three COPD patients attending a Respiratory Rehabilitation Unit participated in the training program. A high frequency of total errors has been found at baseline (72.1%) whose critical errors represented 35%, irrespective of the severity of airway obstruction, the length of disease history and the educational level. The structured educational intervention resulted in changes on patients' attitudes and skills on inhaler use with a significant reduction in the frequency of all types of errors (P-value < 0.01), particularly total and critical errors (35% and 12.9%, respectively), but not completely eliminated them.

Conclusions: Patient training in the use of the inhaler and regular review of the patient's competence in using the devices by health care professionals remains a crucial aspect of effective inhalation therapy regardless of the disease trajectory. These interventions are feasible and may impact the ability to engage patients in the chronic care journey.

Key words: COPD, inhaler, errors, educational intervention

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Introduction

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of morbidity and mortality worldwide, leading to increased economic and social burden. It is a common, preventable and treatable disease characterized by persistent respiratory symptoms and airflow limitation [1]. Inhaled therapy is the cornerstone of the treatment for COPD. This therapy has been showed to reduce symptoms (especially dyspnea), frequency and severity of exacerbations, improve health status, increase exercise capacity, and prolong survival [2]. Recent advances in inhaler technology have resulted in a wide variety of devices designed to optimize drug delivery, ensure consistent efficacy, and enhance patient adherence [3]. However, several studies have reported that many patients with asthma and COPD do not use their inhalers correctly. This improper use can significantly reduce drug delivery to the lungs and diminish treatment efficacy, leading to a submoptimal control of their disease [4]. It is challenging and almost impossible to identify the "perfect device", as some errors are recurrent with specific devices, while others are commonly reported across various inhaler types. This has led to the categorization of errors into devicedependent and device-independent [5].

Promoting patient education and engagement is increasingly acknowledged as a way to address the challenge of chronic conditions and as a key component of patient-centered models of sustaining healthcare.

However, to date, no study has evaluated the impact of educational training on inhalers technique that specifically address the different types of possible errors encountered in patients with COPD. The aim of the study was to evaluate the effectiveness of a nurse-lead educational intervention on inhaler use in a group of patients with COPD during a Pulmonary Rehabilitation Program.

Material and Methods

This single-centre, prospective, observational study included a cohort of patients with COPD defined as per the GOLD guidelines [1], attending the Respiratory Rehabilitation Unit of the Istituti Clinici

Scientifici Maugeri IRCCS in Pavia (PV) (from 2018 to 2019) for a pulmonary rehabilitation program. Inclusion criteria were a diagnosis of COPD as assessed with pulmonary function test [1], in a clinically stable phase of their disease, prescribed with inhaler therapy for at least one month before hospitalization. Exclusion criteria were the concomitant presence of orthopedic condition limiting hand movements, neuromuscular diseases, cognitive disorders and/or dementia. Patients with a tracheostomy were also excluded. The study was approved by the Maugeri IRCCS Ethics Committee (Prot-CE n.2172) and all participants were informed of the purpose of the study and gave their written consent to participate. This present study was in line with the principles of the Declaration of Helsinki.

Data collection

We collected baseline characteristics of the participants, including demographic information such as age, sex, level of education and presence of a caregiver; smoking habits; need for oxygen supplement; use of benzodiazepines; knowledge of own pathology and duration of diagnosis; hospital admissions in the previous year; type of drugs and inhaler used and who first explained the inhaler technique. A checklist was used to assess patients' inhalation technique as defined for each inhaler from the package leaflet (Supplementary Table 1). The examination was conducted before the training session and at the end of hospitalization after at least two sessions. Each device requires a specific sequence of actions to ensure proper drug delivery to the lungs. Patients were requested to take a puff of their usual inhaler using their usual inhalation technique, which was observed for each item and scored by an experienced nurse trained in the management of inhalers. The nurse was asked not to give any instructions before the test.

According to the literature, errors were classified as: [6-7]

Device-independent: actions that are not dependent on the design of the device, such as not exhaling before inhaling, inhaling through the nose or not holding the breath for a few seconds after inhaling.

- Device-dependent: actions related to manual device management, such as not shaking the MDI device before use, or cover the air intake holes with fingers.
- Critical: actions that significantly affected dose delivery to the lungs; this is equivalent to a complete absence of dose delivery.

Critical errors included not removing the device's cap from the mouthpiece, failure to inhale through the mouthpiece for all devices, manoeuvring despite no dose remaining on the dose counter, and for:

- pMDI: poor synchronization between hand actuation and inhalation
- Breezhaler®/Handihaler®: failure to insert capsule, failure to press and release buttons, powder remaining in the capsule at the end of inhalation
- Diskus®: failure to slide the lever
- Respimat®: lack of cartridge in the device, failure twisting the base, poor synchronization between hand actuation and inhalation
- Turbuhaler®: failure to hold the inhaler upright when turning the handle (tolerance ±45°), failure to turn the handle clockwise and then counterclockwise until "click"
- Genuair®: do not check the colour of the window before (green) and after (red) inhalation, do not press and release the green button before inhalation
- Nexthaler[®]: do not open the cap fully until feedback sounds, do not check the dose counter after inhalation
- Ellipta®: do not open the cap fully until feedback sounds

Based on the checklist used for each inhaler, a more detailed breakdown of error types is available in the Supplementary Table 1.

Educational session

All the participants attended one hour training session provided by an experienced registered nurse working in Pulmonary ward, who provided general information on COPD in terms of clinical features and management and on the main drugs used as inhalation therapy. Nurses participating to the study had themselves been trained by expert pulmonologists involved in the study (AC and PC). An update meeting for refresher training and any other questions was scheduled every ten days until the end of the study. Slides were used to illustrate the concepts, including simple and clear terms so that all subjects enrolled in the study could understand their meaning; images and videos were also projected to make a positive impression on the patients and help them remember the concepts. There was also a practical demonstration of the correct sequence of action for each device to ensure proper use of them and optimize drug delivery to the lungs. The educational course lasted one hour and was replied every week, so that each patient could attended at least two sessions during the hospitalization lasting in general three weeks for the rehabilitation program. All partecipants attended at least one educational meeting, regardless of whether or not they used their device with or without errors at baseline.

Statistical analysis

Statistical analysis was performed using SPSS. A Shapiro-Wilk test was used to assess the normality of distribution for all variables. Continuous variables with non-normal distribution were reported as medians (1st quartile; 3rd quartile), while those with normal distribution were expressed as means \pm standard deviation (SD). Categorical variables were reported as number and percentage (%). Categorical variables were compared using the χ^2 test or the Fisher exact test and continuous variables with the t test or the nonparametric Mann-Whitney test. The frequency of errors was determined based on actual observations of total number of inhalers used, as some used more than one inhaler.

Results

Baseline characteristics

One hundred and twenty-three patients were enrolled in the study. Their baseline characteristics

Table 1. Baseline characteristics of patients.

Baseline characteristics		N /123 (%)
Age		69 (± 9.2)
Gender	Male	76 (61.8%)
Education level	Primary school	35 (28.5%)
	Secondary school	32 (26.0%)
	High school	46 (37.4%)
	Degree	10 (8.1%)
Live alone		39 (31.7%)
Smoking habit	Current	15/121 (12.4%)
	Ex	83/121 (68.6%)
GOLD stages	I	16 (13.0%)
	II	36 (29.3%)
	III	36 (29.3%)
	IV	35 (28.5%)
Number of devices used	> 1	17 (13.8%)
Time from COPD diagnosis	1 year	14/114 (12.3%)
	2-5 years	35 /114 (30.7%)
	> 5 years	65/114 (57.0%)
Oxygen-therapy		59/121 (48.8%)
A/D treatment		28/121 (23.1%)
Awareness of own disease		92 (74.8%)
Previous pulmonologist consultation		101 (82.1%)
Hospitalization in the previous year	0	55/120 (45.8%)
	≥1	65/120 (54.2%)
Who first explained inhaler technique	None	9/115 (7.8%)
	Doctor	70/115 (60.9%)
	Paramedic	36/115 (31.3%)

^{*}Data are presented as number and relative percentage (%); age is expressed as mean and standard deviation (SD); GOLD stages were defined according to reference [1].

are listed in Table 1. The mean age was 69 (SD \pm 9,2) years, with a majority of patients being males, exsmokers and having a diagnosis of COPD for more than 6 years. GOLD classes were equally represented among patients. Thirty-one (25,2%) patients declared to be unaware of their disease and 22 (17,1%) had never consulted a pulmonologist, receiving their first inhaler prescription from their general practitioner.

Nearly half of the patients were on long-term oxygen therapy and 65/123 (54.2%) had been hospitalized at least once in the previous year. A univariate analysis comparing patients with no hospitalizations in

the previous year to those with at least once hospitalization showed no statistically significant differences in baseline characteristics except for a higher prevalence of long-term oxygen prescription in the hospitalized group (P value < 0,001) (Supplementary Table 2).

Errors

The prevalence of errors was calculated based on observations of 140 inhalers used by 123 enrolled patients, with 17 of them using two different inhalers, thereby, treated as additional participants. At baseline,

Table 2. Stratification of critical errors on baseline characteristics of patients.

	Critical Error	Critical Error	
Baseline Characteristics	NO	YES	P
Age	69 (64.2-76)	72.5 (67-77.5)	ns
Gender	47/37 (56.0/44.0%)	36/20 (64.3/35.7%)	ns
Live alone	54 (56.8%)	41 (43.2%)	ns
A/D treatment	23 (76.7%)	7 (23.3%)	0.04
Knowledge of own disease	62 (59.6%)	42 (40.4%)	ns
COPD diagnosis from more than one year	71 (60.7%)	46 (39.3%)	ns
At least one hospitalization in the previous year	43 (58.1%)	31 (41.9%)	ns
Someone already explained inhaler technique	62 (56.1%)	50 (43.9%)	ns
Low educational level	43 (51.2%)	33 (58.9%)	ns

^{*}Age is expressed as a mean and interquartile range (IR); gender is considered male/female; low schooling level is considered primary and secondary school.

Table 3. Frequency of all type of errors before and after the educational program.

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Errors	Baseline (T0)	Post training (T1)	P
Total errors	101 (72.1%)	49 (35.0%)	< 0.01
Device dependent errors	24 (17.1%)	6 (4.3%)	<0.01
Device independent errors	89 (63.6%)	39 (27.9%)	<0.01
Critical errors	49 (35.0%)	18 (12.9%)	<0.01
No errors	39 (27.9%)	91 (65.0%)	<0.01

^{*}Data are expressed as absolute number and relative percentage (%) calculated on the total number of observation (n.140). To, before educational training; T1, after educational training.

72.1% of inhalers were used with at least one error (101/140) of which, 63,6% were device-independent errors and 35% of them (49/140) were critical errors. Patients who did not make any critical errors were more likely to be on anxiety/depression (A/D) treatment (P value < 0,04); no other statistically significant differences were found between those making critical errors and those who did not (Table 2). The distribution of critical errors did not different significantly among the GOLD stages.

Educational intervention

As shown in the Table 3, the educational session significantly reduced the frequency of all type of errors. There was a statistically significant increase in the percentage of maneuvers performed with no errors from 27.9% to 65% after the educational session. However,

even after the rehabilitation program, 35% of inhalers were still used with at least one error, including 12.9% classified as critical errors.

Device

The distribution of different inhalers used by the enrolled patients is detailed as follows: MDI with spacer 14 (10%), MDI 26 (18,6%), Turbohaler 4 (2,9%), Handihaler/Breezhaler 17 (12,1%), Diskus 1 (0,7%), Ellipta 32 (22.9%), Genuair 22 (15.7%), Respimat 15 (10,7%) and Nexthaler 9 (6.4%). Notably, 17/123 (13,8%) patients used a combination of two different devices.

Figure 1 and Figure 2 show the prevalence of device-dependent and critical errors respectively, according to the device used as well as the changes in prevalence following the training session.

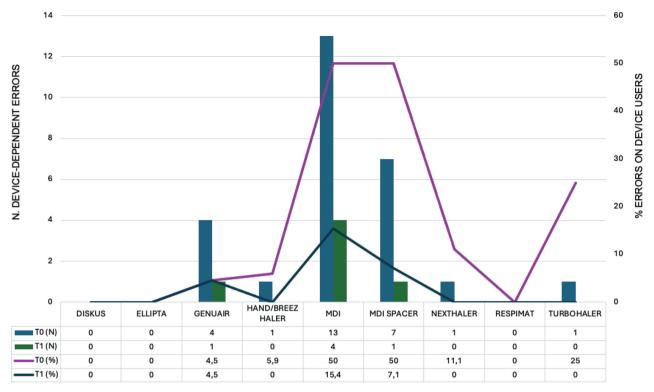


Figure 1. Prevalence of device-dependent errors before (T0) and after (T1) educational training session. Columns represent the number of device-dependent errors according to the device used; lines represent the relative percentage.

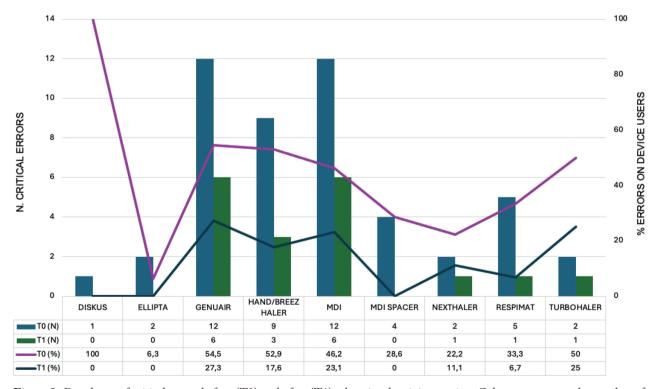


Figure 2. Prevalence of critical errors before (T0) and after (T1) educational training session. Columns represent the number of critical errors according to the type of inhaler used; lines represent the relative percentage.

The most common device-dependent errors were associated to MDI and MDI used with spacer, while with the most frequently used device, Ellipta, showed no device-dependent errors. Critical errors were mostly associated with Genuair (54% of patients using it) and MDI (46% of users).

Overall, patients expressed great appreatiation and satisfaction of the educational program provided.

Discussion

Our study showed that a nurse-led dedicated educational program on inhaler use significantly improved the competencies of COPD patients admitted to a rehabilitation center for a pulmonary rehabilitation program compared to the pre-educational program period, with an overall reduction of all types of errors; however, one-third of patients still made some errors. According to the literature, inhaler device usage is associated with a high prevalence of overall and critical errors, ranging from 50-100% and 14-92%, respectively [8]. Our study found that before the educational intervention, 72.1% of inhalers were used with at least one error, and 35% of them with at least one critical error, despite the majority of enrolled patients (92%) report having received instructions on inhaler use at the time of their first prescription. We observed an increase in errors in patients who were on average older, with a lower educational level, and less aware of their condition, even if no statistical difference was shown on these variables. Interestingly, our study found a consistent distribution of errors overall, regardless of the severity of airway obstruction (GOLD stage) and the time to the first diagnosis of COPD. This emphasizes the need to regularly assess patients' inhaler technique, regardless of their chronic disease duration or the time they use the device. Therefore, as clinicians, we should not assume that longer disease history will necessarily guarantee better inhaler technique.

Furthermore, no significant differences were found between patients who made critical errors and those who did not, except for a higher prevalence of A/D treatment in the latter.

Anxiety and depression often affect patients with COPD and have been shown to be associated with

lower treatment adherence, as well as an increased risk of COPD exacerbations and mortality [9-12]. However, no study has explored the possible impact of treating these symptoms on the improvement of inhaled therapy use. We hypothesized that pharmacological therapy, by reducing symptoms, could help people cope better with activities of daily living, including the use of inhaled therapy.

Interestingly, the distribution of patients making critical errors did not differ between patients who had been hospitalized in the previous year and those who had not. This last finding is in contrast with Molimard's results [6], which described a significant association between critical errors and hospitalization due to severe exacerbations of COPD in a large outpatients cohort. However, our analysis included hospital admission for all causes in the previous year, including those related to pulmonary rehabilitation. Thus, we cannot draw conclusions about the potential impact of incorrect inhaler use on severe exacerbations requiring hospitalization based on our data. Nevertheless, it is worth noting that there was no difference in error rates between the two patient groups, despite at least one hospitalization in the previous year, which could have provided an opportunity to learn or improve inhaler technique. We also acknowledge that possible confounding factors may have affected our results, such as the actual adherence of the patient to the therapy prior to enrolment.

Even though it remains unknown to date whether a correlation exists between "non-critical errors" and clinical outcomes, the role of "critical error", which significantly compromises dose delivery to the lung and correlates with a worse disease outcome is well known [13]. The novelty of our study was to accurately identify and classify "critical errors" and "non-critical errors" in both "device-dependent" and "device-independent" contexts during a pulmonary rehabilitation program.

Critical errors, which ultimately prevent the drug from reaching the lungs properly, accounted for over a third of the identified errors. Their prevalence varied among the different devices as well as the impact of education training differed according to the device used. These findings emphasize the need for more effective educational training, particularly during pulmonary rehabilitation programs, retraining and guidance on device choice when results are not as expected.

A literature review showed that errors associated with inhaler devices have been linked to adverse outcomes for patients and an increased economic burden on healthcare systems. It is therefore essential to consider the benefits of educational interventions on inhaler use, due to the potential positive impact on patients, healthcare systems and society [7].

The educational intervention carried out at our center significantly reduced all type of inhalation technique errors, with error-free inhaler usage increasing from 27.9 to 65% after the educational session. As reported in the literature, there are several studies supporting a significant improvement in inhaler technique following an educational intervention [14-16]; however, despite the improvement, a significant percentage of patients still made errors at the end of the educational sessions during a pulmonary rehabilitation program.

Device-independent errors were the most prevalent at both the beginning (T0) and end (T1) of the program, suggesting the need for a more focused training and investment in addressing this type of error.

The device-independent error is related to the user's understanding of the technique rather than the design of the device. There are two important points to consider. First, providing a single explanation of the technique at the time of the first prescription is unlikely to be enough to ensure optimal understanding. Refresher training of the patient in the use of the inhaler and regular review of the patient's competence in the use of the treatment by health-care providers is a crucial aspect of treatment effectiveness. Second, it's important to ensure that the healthcare professional teaching the patient are experienced and knowledgeable about the correct use of inhalers, as a recent study showed that many clinicians lack of adequate knowledge about the correct use of inhalers [17].

In our study we observed a noticeable difference in the rates of device-dependent and critical errors among the various devices used, as shown in Figure 1 and Figure 2. Nowadays, there are numerous different devices available, the most commonly used in our study were MDI, Ellipta and Genuair. Ellipta had the fewest number of critical errors, all completely corrected after the educational sessions. This is in line with previous

studies reporting Ellipta as an easy to use device and highly appreciated by COPD patients [18]. However, it is important to note that the absence of critical errors does not necessarily mean that the drug is completely inhaled and delivered to the lung, as with DPI this also depends on the patient's peak inspiratory flow (PIF), a parameter that we did not assess [19-21]. On the other hand, Genuair, Handihaler/Breezhaler and MDI (with and without the addition of a spacer) had the highest number of critical errors and only half of them were corrected by the educational interventions (Figure 2). This was likely due to the large number of actions these devices require to be used properly, as well as the coordination skills required for the use of MDI [22]. Therapy optimisation may include routine training in inhaler technique and assessment of the patient's inhalation skills. Switching to a different type of inhaler that is easier for the patient to use correctly should be considered to achieve optimal outcomes if errors persist; however, switching options should be a shared decision that also considers patient preferences, device size, and treatment regimen. Further research is needed to quantify the impact of inhaler switching on achieving COPD treatment outcomes [23].

Patient education is an essential step for self-management and engagement of patients in their medical journey, especially for patients with older age and less education. Educational training on inhalers technique should be an integral part of the pulmonary rehabilitation program since by enhancing understanding and skills, effective education can empower patients to take control of their disease, ultimately improving health outcomes.

Our study has some limitations. First, the single-center design may have limited the results. Second, the external validity is limited as the results might be different in other centers and not generalizable. Third, we did not correlate knowledge skills acquired after the training with clinical outcomes due to the short time point of assessment of our study. However, the high rate of participant satisfaction and the absence of associated costs make this educational intervention a potentially valuable tool to improve patients' self-management and support its potential for routine use during pulmonary rehabilitation programs. Further research is

needed to evaluate the effectiveness of nurse-led educational programs on inhaler use and their impact on the long-term clinical outcomes of COPD patients.

Conclusion

Providing education intervention on how to use inhalers was effective in changing attitudes of patients, creating awareness and knowledge of inhalation technique, reducing the number of total and critical errors even if it does not eliminate them completely.

These results emphasize the need for regular monitoring and training on inhaler usage for COPD patients throughout their medical journey. Educational intervention on inhaler use should be considered as part of the rehabilitation program.

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Supplementary files

Table S1. Inhalers checklist.

MDI	YES	NO
Remove the cap from the mouthpiece		
Shake the inhaler		
Hold your device away from your mouth and breathe out deeply		
Hold the inhaler upright with the mouthpiece at the bottom		
Place the mouthpiece between your teeth and close your lips tightly around it, with the tongue flat under it.		
Start breathing in slowly through your mouth while pressing down firmly on the top of the pressurised container to release one puff		
Keep breathing in slowly and deeply for as long as possible		
Remove the inhaler from your mouth		
Hold your breathe for 5 second then breath out slowly		

MDI with spacer	YES	NO
Remove the cap from the mouthpiece of the inhaler and the spacer		
Shake the inhaler		
Attach the spacer to the inhaler		
Breathe out as slowly and deeply as possible		
Place the mouthpiece of the spacer between your teeth and close your lips tightly around it, with the tongue flat under it.		
Start breathing in slowly while pressing down firmly on the top of the inhaler to release one puff in the spacer		
Keep breathing in slowly and deeply as you can		
Remove the spacer from your mouth		
Hold your breathe for 5 second then breath out slowly		

DISKUS	YES	NO
Open the cap of the device		
Slide the lever fully until you hear a click.		
Hold your device away from your mouth and breathe out deeply		
Place the mouthpiece between your lips and breath in deeply		
Remove the mouthpiece from your mouth and hold your breath for about 10 seconds		
Breathe out slowly		
Slide the lever to its original position until you hear a click and then close your device.		

TURBOHALER

Remove the cover from the device

Hold your device upright with the red grip at the bottom

Without holding the mouthpiece, turn the red grip as far as it will go in one direction

Then turn it as far as it will go in the other direction. You should hear a click sound

Hold your device away from your mouth and breathe out gently

Place the mouthpiece between your lips and breath in deeply

Remove the mouthpiece from your mouth and breath out gently

Replace the cover tightly after use

HANDIHALER/BREEZHALER Remove the cap from the device and open the mouthpiece Take one capsule and put it into the inhaler Close the mouthpiece until you hear a click Hold the inhaler upright. Pierce capsule by firmly pressing both side buttons at the same time Hold your device away from your mouth and breathe out deeply Place the mouthpiece between your lips and breath in deeply Remove the mouthpiece from your mouth and hold your breath for about 10 seconds Open the mouthpiece and remove the empty capsule, then close it

ELLIPTA	YES	NO
Slide the cover down until you hear a click		
Hold your device away from your mouth and breathe out deeply		
Place the mouthpiece between your lips and breath in deeply		
Remove the mouthpiece from your mouth and hold your breath for about 3-4 seconds		
Breathe out slowly		
Close the inhaler		

Remove the cap from the mouthpiece

Hold the inhaler horizontally with the mouthpiece facing you and the button on top

Press the button down and release it to load your dose

Check the control window turned from red to green

Hold your device away from your mouth and breathe out deeply

Place the mouthpiece between your lips and breath in strongly until you hear a click

Take the inhaler out of your mouth

Hold your breath for as long as possible

Slowly breathe out away from the inhaler

Make sure the control window is now red

Push the protective cap back onto the mouthpiece after each use

NEXTHALER	YES	NO
Hold the device in the upright position and slide the cover down until you hear a click		
Hold your device away from your mouth and breathe out deeply		
Place the mouthpiece between your lips without covering the air vent with the fingers		
Breath in quickly and deeply		
Take the inhaler out of your mouth		
Hold your breath for 5-10 seconds or as long as is comfortable		
Breathe out slowly		
Replace the cover over the mouthpiece. Check the dose counter has reduced by one		

RESPIMAT	YES	NO
Keep the cap closed and turn the clear base until you hear a click		
Open the cap until it snaps fully open		
Hold your device away from your mouth and breathe out deeply		
Close your lips around the mouthpiece without covering the air vents		
While taking a slow, deep breath through your mouth, press the dose-release button and continue to breathe in slowly for as long as comfortable		
Hold your breath for 10 seconds or for as long as comfortable		
Breathe out slowly		
Close the cap		

Table S2. Stratification of hospital admission in the previous year on baseline characteristics of patients.

Baseline characteristics	Hospital admission in the previous year	No hospital admission in the previous year	P
Age	70,29	69,70	ns
Male	31 (56,4%)	43 (66,2%)	ns
Live alone	17 (30,9%)	21 (32,3%)	ns
Oxygen-therapy	16 (29,6%)	42 (65,6%)	<0,001
Awareness of own disease	41 (74,5%)	53 (81,5%)	ns
Someone first explained inhaler technique	50 (94,3%)	54 (90,0%)	ns
Length of diagnosis >1 year	43 (86,6%)	55 (90,2%)	ns
Low educational level	36 (65,5%)	31 (47,7%)	ns
GOLD I	9 (14,1%)	6 (10,9%)	ns
GOLD II	17 (26,6%)	18 (32,7%)	ns
GOLD III	19 (29,7%)	16 (29,1%)	ns
GOLD IV	19 (29,7%)	15 (27,3%)	ns

Age is expressed as mean, low educational level means primary and secondary school.