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Pharmacist-led intervention study to improve inhalation technique in asthma and COPD patients

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Abstract

Rational and aims Inhaled therapy is the mainstay of treatment in patients with asthma and chronic obstructive pulmonary disease (COPD). For effectiveness of pharmacotherapy, correct use of medication is required. The aims of this study were to survey the quality of inhalation technique in patients and to determine the effect of a single intervention in community pharmacies by means of standardized procedures.
Methods A total of 757 patients with asthma or COPD were randomly selected by 55 community pharmacies. At baseline, patients were interviewed and their inhalation technique was assessed with a 21-items checklist. Any error was recorded and, if necessary, patients were instructed in the proper use of their device. After 4–6 weeks, demonstration of inhalation technique was repeated in the community pharmacies and a pre–post comparison was performed.
Results A total of 597 patients (78.9%) made at least one mistake in performing the inhalation technique at baseline. This number dropped to 214 (28.3%) from the first to the second appointment. All patients did benefit from the pharmacists' intervention regardless of their former training experiences.
Conclusions Inhalation technique of asthma and COPD patients is poor. In daily practice, community pharmacy-based pharmacists are well suited to significantly supplement doctor-based education in inhalation technique.

Introduction

Chronic obstructive lung diseases like asthma and chronic obstructive pulmonary disease (COPD) are accompanied by a major burden of symptoms, health care utilization, lost of productivity and cost of medications on the individual and society. Although effective drugs and evidence-based guidelines have been developed, no major change in morbidity and mortality can be recognized and data indicate that asthma and COPD in most patients are not well controlled [1]. One reason can be found in the inability of patients to use their inhaler devices correctly [2].

The mainstay of asthma and COPD treatment is by inhalation of medication to the site of the disease process. The major advantage of inhalation therapy is that drugs are delivered directly into the airways, achieving higher local concentrations with significantly less risk of systemic side effects [3]. The deposition pattern of inhaled drug in the respiratory tract is determined by a complex interaction between the device, the aerosol formulation and the patient's inhalation technique [4]. The use of an inhaler device involves a complex series of steps, which need to be performed correctly. Failing to perform one or more steps correctly can substantially reduce delivery and hence effectiveness, and safety of medication [5]. Further difficulties occur because proliferation of inhaler devices has resulted in a confusing number of choices, and patients are rarely prescribed just one inhaled medication. Each inhaler type has unique operating instructions and requires different ways of handling. This additionally creates the possibility of confusion among patients and increases errors in usage [6].

Several studies have demonstrated that 50–80% of patients fail to use their inhaler devices correctly [7–11]. Patients are often not aware that they use their inhaled medication inadequately, and overestimate their own abilities [12]. Incorrect use of inhalation devices may lead to uncontrolled disease state, unwanted side effects and can also cause higher treatment costs. According to Fink and Rubin, 5–7 Mio. $US are annually wasted in the USA because of inhaler misuse [5].

National and international guidelines for asthma and COPD management state that inhalation technique should be assessed

regularly, and corrected if inadequate [3,13–15]. Regarding these recommendations, there is a need of studies to explore the effectiveness and frequency of patient education and consider interventions to improve inhalation technique [4]. Our study objectives therefore were to survey the quality of inhalation technique in patients with asthma or COPD and to determine the effect of a single intervention on inhalation technique in community pharmacies by means of standardized procedures.

Methods and materials

The study was run over 3 months from August till October 2007. It was designed as a prospective multi-centre intervention study. Intervention comprised pharmaceutical counselling on correct inhalation technique. For evaluation of the intervention effect, a pre–post comparison was reasonable because controlled studies have clearly shown a positive effect of pharmacists' intervention on inhalation technique, and also its acceptance by patients [16–19]. In Germany, institutional review board approval has been waived when all patients receive the intervention like in this study.

Setting and study population

By means of a regular newsletter, the study idea with a call for participation was sent to a mailing list, to which around 4000 community pharmacists (CPs) from throughout Germany interested in pharmaceutical care (PC) have subscribed. Inclusion criterion for CPs was successful completion of the certified continuing education programme in PC for patients with asthma/COPD. Germany-wide this is a 9-hour standardized curriculum based on the recommendations of the Federal Chamber of Pharmacists in Germany. An extra training was not provided. Recruited CPs were provided with a project folder containing the study description as well as all necessary and supporting material to conduct the study (e.g. prepared letter to inform eligible patients by mail, patient handouts, several sheets of the standardized patient interview as well as of the checklist to assess inhalation technique, Appendixes 1 and 2). Pharmacists were additionally provided with the *Manual – Pharmaceutical Care for Asthma Patients* [20]. This manual contains information on correct inhalation technique of different types of devices as well as master copies to provide written information including pictures for patients, among others. CPs were asked to recruit 15 (maximum 30) asthma or COPD patients. Patients should be at least 18 years old, use inhalation medications on a permanent (daily) basis and have signed the consent form. Eligible patients could be identified upon prescription of inhalation drugs and/or upon patient data on file in the pharmacy. Patients were informed about the study either directly at the respective study pharmacy, by writing letters, or by telephone contacts. Pharmacists made appointments with interested patients asking them to bring along all their inhalation medications at the first visit in the pharmacy.

Quality check of inhalation technique

At baseline (t_1), standardized patient interviews were conducted to record basic data like age, gender, diagnosis, duration of disease, number of prescribed inhalation medications and instructions on inhalation technique received in the past. Subsequently, they were asked to demonstrate inhalation technique. Inhalation technique of only one drug was demonstrated; primarily the inhaled corticosteroid (ICS) was chosen because in contrast to non-ICS drugs additional aspects are important to avoid adverse drug events (e.g. rinse out mouth/eat something after use of glucocorticoid). No further specifications according the choice of drug were made. To assess inhalation technique, a 21-items checklist had been developed, which could be used for all types of inhalation devices i.e. metered-dose inhaler (MDI), MDI plus spacer, breath-actuated MDI and dry-powder inhaler (DPI). Assessed were overall condition of device (3 items), preparation of inhalation (3 items), inhalation technique (11 items; note: step 11 comprises 3 items on the inhalation checklist) and termination of inhalation (4 items). Along with the patient performing the inhalation, each single step should be marked as been performed correctly or incorrectly by the pharmacist. In that, not all steps were relevant for each inhaler system, for example, shaking the inhaler in case of a DPI, non-relevant steps should be marked as correct. If necessary, patients were instructed once in the proper use of their device and inhalation technique. They were given the opportunity to practise the procedure again in the pharmacy. Written instructions could be provided as supplement. At the end of the first consultation, a second appointment (t_2) 4–6 weeks later was made asking the patient to demonstrate inhalation technique again in the pharmacy. Inhalation checks (at t_1 and t_2) had to be performed with the same inhalation system/drug by each patient.

Community pharmacists were paid for their involvement: €20 for a complete documentation of a patient when documentation forms were submitted till the end of September 2007, and €15 when documents were submitted till the end of October 2007.

Sample size estimation

Calculation of sample size was carried out with the programme G*Power Version 3.0.5 (http://www.downloadforge.com). The basis of calculation was literature data stating incorrect use of inhalation medications in 50–80% of patients, on average 65% [7–11]. Correspondingly, 35% of patients performed inhalation correctly. This number ($P = 0.35$) was used as baseline value (t_1) for computation of the sample size. The objective was defined as an 18% difference, equivalent to an increase of more than 50%, in the number of patients who perform inhalation without making any mistake. An average percentage of 43% of discordant pairs was taken as basis for calculation. The calculated odds ratio amounted to OR = 2.3. The McNemar test in the exact version (binomial distribution) was used for calculation. Alpha was defined as 0.05, and beta as 0.8.

Based on these assumptions, the resulting number of study participants per subgroup amounted to $n = 91$. The smallest relevant subgroup was the one comprising participants in the German asthma and COPD disease management programmes. Nationwide, the number of participants enrolled in these programmes has been estimated at 10–15%. This resulted in a theoretically required total case number of $n = 607$ up to $n = 910$, on average 759 study participants to be included in the study.

Statistical evaluation

The primary effect variable was reduction of the number of patients who make errors when inhaling their medication. The

secondary effect variable was reduction of the average number of errors per patient. Analysis of study data was performed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA). The chi-squared test according to McNemar was performed to measure the effect variables, if data were dichotomous. With metric data, the *t*-test was performed for paired random samples, because due to the selected before–after comparison a dependence of data was given. According to data scaling, comparison of two subgroups was performed by means of chi-squared test in case of dichotomous data, and by means of *U*-test according to Mann–Whitney in case of ordinal scaled data. In case of metric data, independent sample *t*-test was used, and if there were more than two classes, simple variance analyses were run for interval scaled data. As a matter of principle, an error probability of less than 5% was demanded ($P < 0.05$). Testing was always performed two-sidedly.

Results

In total, 74 CPs were recruited. Before baseline assessment, 19 pharmacists withdrew from the study because of lack of time, staff shortages, illness or difficulties in patient recruiting, resulting in a final number of 55 CPs. Altogether, 781 patients were included in the study. This was on average 14.2 patients per pharmacy. Twenty-four patients were excluded from evaluation because they were under 18 years of age (11 patients), had changed to another inhalation medication (6 patients), did not show up for their second appointment (5 patients), or because t_1 was assessed after the pharmacist's intervention (1 patient). One patient died during the study period. Thus, 757 study participants became part of the evaluation.

Basic characteristics of study population

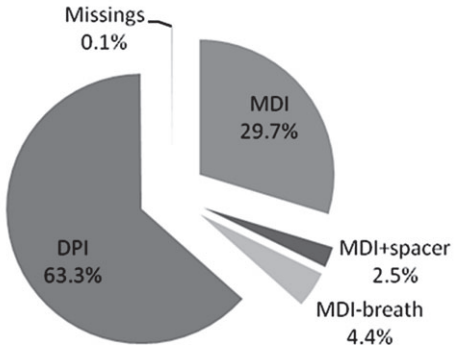
An overview of basic characteristics of the study population is shown in Table 1. In addition, 67.1% of patients stated that they were treated medically directly after diagnosis. Further 14.7% stated that therapy started up to 5 years after diagnosis. The average duration until starting pharmacotherapy was up to 3 years after diagnosis.

Table 1 Basic characteristics of study population ($n = 757$)

Gender	Male	298 (39.4%)
	Female	456 (60.2%)
	Missing data	3 (0.4%)
Age in years (mean)		61.0 (SD: 15.2, range 18–94)
Education in years	9 or less	362 (47.8%)
	10 or 11	232 (30.7%)
	12 or more	146 (19.3%)
	Missing data	17 (2.3%)
Indication	Asthma	380 (50.2%)
	COPD	184 (24.3%)
	Mixed disease state	109 (14.4%)
	Miscellaneous	7 (0.9%)
	Unknown	66 (8.7%)
	Missing data	11 (1.5%)
Duration of disease in years	≤1	83 (11.0%)
	2–5	163 (21.5%)
	6–10	143 (18.9%)
	11–15	84 (11.1%)
	≥16	267 (35.3%)
	Missing data	17 (2.2%)
Duration of inhalation therapy in years (mean)	≤1	102 (13.5%)
	2–5	179 (23.6%)
	6–10	153 (20.2%)
	11–15	82 (10.8%)
	≥16	228 (30.1%)
	Missing data	13 (1.7%)
Participation in a disease management programme	Yes	65 (8.6%)
Number of instruction sessions (training experience)	None	93 (12.3%)
	1	342 (45.2%)
	2	174 (23.0%)
	3 and more	148 (19.6%)
Number of different inhalation medications	1	292 (38.6%)
	2	330 (43.6%)
	3	107 (14.1%)
	4 and more	26 (3.4%)
	Missing data	2 (0.7%)

Data are presented as absolute and relative numbers (*n* or %), mean and standard deviation values (SD).

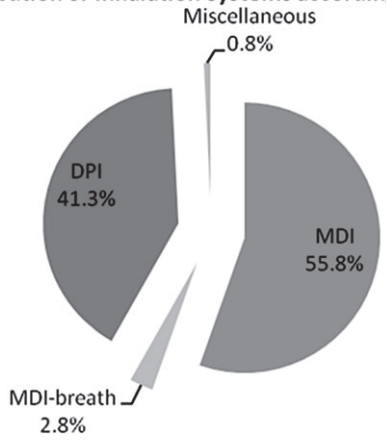
Distribution of inhalation systems used for inhalation check



Distribution of inhalation systems (Study)

Type	No. absolute	No. relative (%)
DPI	479	63.3
- Turbuhaler	(157)	(20.7)
- Diskus	(149)	(19.7)
- Novolizer	(68)	(9.0)
- Handihaler	(40)	(5.3)
- Aerolizer	(31)	(4.1)
- ...	(...)	(...)
MDI	225	29.7
MDI + SPACER	19	2.5
MDI BREATH-ACTUATED	33	4.4
MISSING DATA	1	0.1
TOTAL	**757**	**100.0**

Distribution of inhalation systems according to GIDE



Distribution of inhalation systems (GIDE)		
Type	No. absolute*	No. relative (%)
DPI	2.287.119	41.3
- Turbuhaler	(609.471)	(26.7)
- Diskus	(513.030)	(22.4)
- Handihaler	(364.678)	(16.0)
- Inhalator M	(268.443)	(11.7)
- Novolizer	(253.857)	(11.1)
- ...	(...)	(...)
MDI	3.089.222	55.8
MDI BREATH-ACTUATED	157.276	2.8
MISCELLANEOUS	43.387	0.8
TOTAL	**5.533.617**	**100.0**

DPI = Dry-powder inhaler, MDI = Metered-dose inhaler, Miscellaneous = e.g. Respimat® Inhaler
*) Number of prescribed items between August and October 2007.

Figure 1 Distribution of inhalation systems in our study compared with nationwide claims data (GIDE) [21].

Of study participants, significantly more men than women, 12.3% stated that they had never received an introduction into correct usage of their inhalation medications. A total of 45.2% patients had attended one instruction session on how to perform correct inhalation technique, 23.0% indicated two and 19.6% three or more sessions (Table 1). More than 55% of patients had already attended an instruction session in a doctor's office, 27% in a pharmacy and 9% in a hospital. Concerning the nature of instruction experienced, multiple answers could be given. According to that, study participants had most often demonstrations (38.9%) and oral instructions (31.0%). Reading of package insert or practising under guidance of an expert was mentioned less often (17.6% and 12.0%, respectively).

More than 80% of study participants indicated that they were currently using one (38.6%) or two (43.6%) different inhalation medications at the same time. The minority of patients took three, four or more than four different inhalation medications (14.1% and 3.4%, respectively, Table 1). Figure 1 shows the distribution of inhalation systems used by study participants for the inhalation check. DPI is broken down per type of device, and the five leading DPI devices are shown. In addition, the distribution of prescribed inhalation systems during the study period in Germany according to data of the German Institute for Drug Use Evaluation (GIDE) is shown [21]. The five most frequently prescribed DPI devices are listed as well.

Quality of inhalation technique

At baseline (t_1), 597 patients (78.9%) made at least one error in performing their inhalation. This number dropped to 214 (28.3%) from the first to the second appointment ($P < 0.001$) (Fig. 2).

Absolute and relative frequencies of possible sources of errors are shown in Table 2. The average number of errors dropped from 2.5 to 0.5 per patient ($P < 0.001$). Quality of inhalation technique showed no significant dependencies on different inhaler devices. Evaluations were done for general inhalation systems (MDI, MDI + spacer, MDI-breath and DPI, Table 3), as well as for specific types of MDI-breath and DPI devices, respectively.

Furthermore, evaluation of quality of inhalation technique showed no significant dependencies, neither on socio-demographic characteristics like age, gender or education nor on time since diagnosis of the disease.

Patients who stated at study entry that they had never received a training in correct inhalation technique made more errors in performing inhalation at baseline than those who have had one or more instruction sessions before the study (3.2 vs. 2.4 errors, $P = 0.001$). However, after intervention there was no significant difference between groups observable and the mean error rate was similar for both groups (0.6 vs. 0.5 errors) (Table 4).

The pharmacists' average (median) time needed to assess the inhalation technique and to perform the intervention including documentation was 13 (15) minutes.

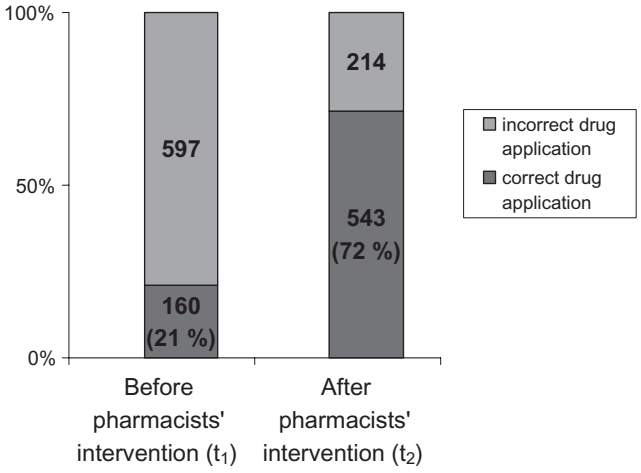


Figure 2 Number (%) of correct and incorrect inhalation check performances at t_1 and t_2 ($n = 757$).

Discussion

This study has shown that almost 80% of patients with chronic lung diseases in ambulatory care made one or more errors when inhaling their medication. A one-time, standardized intervention by qualified pharmacists has shown to significantly improve patients' inhalation technique. The percentage of patients making errors was reduced by 65% to 28.3% from the first to the second appointment. The average number of errors dropped from 2.5 to 0.5 per patient. All patients did benefit from the pharmacists' intervention regardless of their former training experiences.

In the literature, there is consistency that a high percentage of patients have poor inhalation technique. Checklists used for inhalation technique assessment thereby differ between studies. They were mostly limited to a few important points to be checked or specific to a single type of inhaler. Hence and in general, comparing results between different studies and settings remain difficult. In the present study, a newly developed checklist was used. This checklist can be used to assess patients' performed

Table 2 (Relative) Frequency of individual errors in $n = 757$ patients at t_1 and t_2

	t_1		t_2	
Possible sources of error	*n*	%	*n*	%
Hold breath after inhaling (5–10 seconds)	271	35.8	63	8.3
Exhale through pursed lips or nose (Refers to the moment after drug inhalation and holding breath)	228	30.1	50	6.6
Lean head slightly back (MDI)	170	22.5	47	6.2
Exhale (normally) (Refers to the moment before starting drug inhalation)	167	22.1	33	4.4
Wipe saliva off mouthpiece (DPI)	161	21.3	44	5.8
Rinse out mouth/eat something after use of corticosteroid	136	18.0	17	2.2
Inhale slowly and deeply (MDI, MDI-breath, MDI + S) or quickly and deeply (DPI) (Refers to the way of inhalation)	135	17.8	33	4.4
Shake well before use (usually for MDI, MDI-breath, MDI + S)	83	11.0	7	0.9
MDI-breath and DPI: Inhale with forceful breath(s) (Refers to the beginning of inhalation)	79	10.4	24	3.2
Perform steps correctly to make the device ready to use (e.g. pull lever, attach spacer) (MDI-breath, MDI + S, DPI)	74	9.8	11	1.5
Cleanliness satisfactory	74	9.8	11	1.5
Hold device correctly (MDI, MDI-breath, MDI + S: Hold mouthpiece down, DPI: usually horizontally)	66	8.7	13	1.7
Avoid exhaling into device	57	7.5	14	1.8
Close lips (tightly for MDI-breath and DPI)	56	7.4	11	1.5
MDI: Spray and inhale at the same time, as exception also for Jethaler® device (DPI)	40	5.3	9	1.2
Close device immediately	33	4.4	5	0.7
Device technically functional	12	1.6	0	0.0
MDI + S: Release in spacer and inhale directly (<3–5 seconds)	6	0.8	3	0.4
Device components fit together	6	0.8	0	0.0
Remove locking cap	4	0.5	2	0.3
Release the device (MDI-breath)	2	0.3	1	0.1

Data are presented as absolute (*n*) and relative number of patients (%).
If no specific device is mentioned, single items were relevant for all types of inhalation devices. In case that single items had to be considered when using specific inhalation device(s), only these devices are explicitly mentioned.
DPI, dry-powder inhaler; MDI, metered-dose inhaler; MDI-breath, breath-actuated MDI; MDI + S, MDI plus spacer.

Table 3 Average number of correct steps at t_1 and t_2 depending on type of inhalation device

Type of device	Number of patients	Mean number of correct steps (max. 21)		*P*-value
		t_1	t_2	
MDI	225	18.3	20.4	<0.001
MDI + spacer	19	19.0	20.9	<0.001
MDI breath-actuated	33	19.2	20.7	<0.001
DPI	479	18.6	20.5	<0.001
Missing data	1	–	–	–
Total	757	18.5	20.5	<0.001

DPI, dry-powder inhaler; MDI, metered-dose inhaler.

Table 4 Quality of inhalation technique at t_1 versus t_2 depending on prior training experience

Patient subgroups	Number of patients (%)	Number of patients with incorrect execution (%)		Mean number of errors per patient	
		t_1	t_2	t_1	t_2
Patients without prior instruction in inhalation technique	93 (12.3%)	84 (11.1%)	31* (4.1%)	3.2	0.6*
Patients with prior instruction in inhalation technique	664 (87.7%)	513 (67.8%)	183* (24.2%)	2.4	0.5*
Total numbers	757 (100.0%)	597 (78.9%)	214* (28.3%)	2.5	0.5*

*Compared with t_1: $P < 0.001$.

inhalation technique with all different types of inhalation systems. The 21-items checklist allows detailed assessment of every single step of inhalation device usage.

The most common errors detected in the study were similar to those found in other studies, for example, failure to hold breath after inhalation, inappropriate inspiration flow and failure to shake the canister before use [7,9,11,22]. In consequence to the detailed assessment of inhalation technique, other sources of errors were reported frequently, like failure to lean head slightly back (MDI), failure to wipe saliva off mouthpiece (DPI) and failure to rinse out mouth/eat something after using an ICS. These errors were also found to be relevant because they may have an impact on effectiveness as well as safety of the inhaled medication. Results showed no significant dependencies on different inhaler devices. In contrast to other studies [8,23,24], the frequently observed errors in our study were mostly device-independent like failure to breath-hold after inhalation. Regarding this point, it has to be stated that identifying differences between devices was no study objective, and the chosen study design presumably did not have the power to find possible differences. Similar to other studies, we found no significant dependencies on socio-demographic data like age, gender or education [11,23,25]. Quality of inhalation technique was also independent of the number of inhaled medications. Because of practicability reasons, the different types of inhalation devices used by a patient were not recorded by CPs, and quality of inhalation technique was only assessed for one inhalation device per patient. Therefore, we do not know whether parallel usage of different types of inhalation systems (MDI + DPI) may increase error rate in patient usage versus usage of the same type of inhalation system (MDI + MDI or DPI + DPI).

In case of errors, patients are in need to be educated in correct inhalation technique. Pharmacists' intervention comprised step-by-step demonstration of correct inhalation technique, verbal instructions as well as practical exercises. These methods in educating patients have shown to be effective, leading to an improved inhalation technique [26–28].

Based on our study data, no answer can be given whether the positive effect of intervention on inhalation technique will sustain for a longer period, like in our 12 months PC studies on asthma [18,19]. Presumably, it would be necessary to repeat such intervention on a regular basis. A further limitation of the study is that a selection bias cannot be fully excluded because such offers are usually accepted more frequently by motivated patients rather than by unmotivated patients. Furthermore, any inhalation training session that might have taken place outside the pharmacy in the period of 6 weeks (between t_1 and t_2) was not recorded; but this would only have distorted the results false-positively. However, this error is probably negligible with respect to the size of effect found. Finally, the results show that such one-time interventions are not sufficient for all patients to learn how to perform error-free inhalation technique. Additional follow-up instructions and exercises would probably increase the number of patients who inhale their medication without making any mistake. However, even then, probably not all patients would be capable of performing proper inhalation technique in the long run.

The results presented here have a high practice relevance. They have shown that there is a clear need for a specific and probably regularly repeated training of patients to ensure correct inhalation technique. Implementation of this service in daily community pharmacy practice is therefore highly recommended, and qualified CPs are in an ideal position to perform these tasks. The results, in addition to the results of our PC studies on asthma [18,19], gave German pharmacists the opportunity to contribute to the revision of the German disease management guideline for asthma [14]. For the first time, pharmacists are now involved in the asthma care

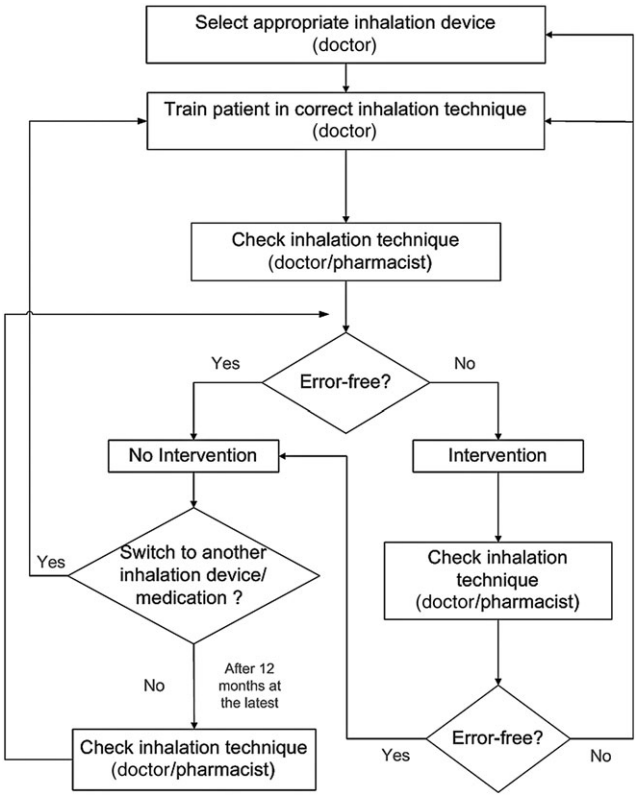


Figure 3 Ensuring correct inhalation technique (according to German Disease Management Guideline for Asthma, 2009 [14]).

process in Germany supporting ensurance of correct inhalation technique in close collaboration with the prescribing doctors. In Fig. 3, the algorithm is shown that was agreed on by doctors and pharmacists.

Accordingly, evaluation of inhalation technique should be done on a regular basis with instructions adjusted to the patients' needs. When the doctor prescribes an inhalation device for the first time or when a switch to another device is necessary, he educates the patient in correct use of the device. Shortly after the first instruction (within 4 weeks) evaluation of inhalation technique should be repeated by the doctor or the pharmacist. Patients who inhale without making any mistake should repeat this process once a year or when they switch to another inhalation device/medication. Patients who make mistakes in carrying out their inhalation should receive instructions in the pharmacy. If this does not lead to an error-free inhalation technique, remedial training should be given by the doctor and his asthma/COPD team. Implementing these services in close collaboration between doctors and pharmacists would substantially support effective and safe pharmacotherapy, and reduce wasted resources.

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References

1. Rabe, K. F., Adachi, M., Lai, C. K., Soriano, J. B., Vermeire, P. A., Weiss, K. B. & Weiss, S. T. (2004) Worldwide severity and control of asthma in children and adults: the global asthma insights and reality surveys. *Journal of Allergy and Clinical Immunology*, 114, 40–47.
2. Crompton, G. K., Barnes, P. J., Broeders, M., *et al.* (2006) The need to improve inhalation technique in Europe: a report from the Aerosol Drug Management Improvement Team. *Respiratory Medicine*, 100, 1479–1494.
3. Global Initiative for Asthma (GINA) (2008) *Global strategy for asthma management and prevention*. Update 2008. Available at: http://www.ginasthma.org (last accessed February 2010).
4. Brocklebank, D., Ram, F., Wright, J., Barry, P., Cates, C., Davies, L., Douglas, G., Muers, M., Smith, D. & White, J. (2001) Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature. *Health Technology Assessment*, 5, 1–149.
5. Fink, J. B. & Rubin, B. K. (2005) Problems with inhaler use: a call for improved clinician and patient education. *Respiratory Care*, 50, 1360–1374.
6. van der Palen, J., Klein, J., van Herwaarden, C., Zielhuis, G. & Seydel, E. (1999) Multiple inhalers confuse asthma patients. *European Respiratory Journal*, 14, 1034–1037.
7. Carrion, V. F., Maya, M. M., Fontana, S. I., Diaz, L. J. & Marin, P. J. (2000) [Inhalation technique in patients with chronic respiratory diseases]. *Archivos De Bronconeumologia*, 36, 236–240.
8. Girodet, P. O., Raherison, C., Abouelfath, A., Lignot, S., Depont, F., Moore, N. & Molimard, M. (2003) [Real-life use of inhaler devices for chronic obstructive pulmonary disease in primary care]. *Therapie*, 58, 499–504.
9. Larsen, J. S., Hahn, M., Ekholm, B. & Wick, K. A. (1994) Evaluation of conventional press-and-breath metered-dose inhaler technique in 501 patients. *Journal of Asthma*, 31, 193–199.
10. Molimard, M., Raherison, C., Lignot, S., Depont, F., Abouelfath, A. & Moore, N. (2003) Assessment of handling of inhaler devices in real life: an observational study in 3811 patients in primary care. *Journal of Aerosol Medicine*, 16, 249–254.
11. Shrestha, M., Parupia, H., Andrews, B., Kim, S. W., Martin, M. S., Park, D. I. & Gee, E. (1996) Metered-dose inhaler technique of patients in an urban ED: prevalence of incorrect technique and attempt at education. *American Journal of Emergency Medicine*, 14, 380–384.
12. Erickson, S. R., Horton, A. & Kirking, D. M. (1998) Assessing metered-dose inhaler technique: comparison of observation vs. patient self-report. *Journal of Asthma*, 35, 575–583.
13. German Medical Association, National Association of Statutory Health Insurance Physicians, & Association of the Scientific Medical Societies in Germany (2006) *National disease management guideline for COPD*. Available at: http://www.versorgungsleitlinien.de/themen/copd (last accessed February 2010).
14. German Medical Association, National Association of Statutory Health Insurance Physicians, & Association of the Scientific Medical Societies in Germany (2009) *National disease management guideline for asthma*. Available at: http://www.versorgungsleitlinien.de/themen/asthma (last accessed February 2010).
15. Global Initiative for Obstructive Lung Disease (GOLD) (2007) *Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease*. Available at: http://www.goldcopd.com (last accessed February 2010).

16. Armour, C., Bosnic-Anticevich, S., Brillant, M., Burton, D., Emmerton, L., Krass, I., Saini, B., Smith, L. & Stewart, K. (2007) Pharmacy Asthma Care Program (PACP) improves outcomes for patients in the community. *Thorax*, 62, 496–502.
17. Cordina, M., McElnay, J. C. & Hughes, C. M. (2001) Assessment of a community pharmacy-based program for patients with asthma. *Pharmacotherapy*, 21, 1196–1203.
18. Mangiapane, S., Schulz, M., Mühlig, S., Ihle, P., Schubert, I. & Waldmann, H. C. (2005) Community pharmacy-based pharmaceutical care for asthma patients. *Annals of Pharmacotherapy*, 39, 1817–1822.
19. Schulz, M., Verheyen, F., Mühlig, S., Müller, J. M., Mühlbauer, K., Knop-Schneickert, E., Petermann, F. & Bergmann, K. C. (2001) Pharmaceutical care services for asthma patients: a controlled intervention study. *Journal of Clinical Pharmacology*, 41, 668–676.
20. Mangiapane, S., Schulz, M. & Verheyen, F. (2005) [Pharmaceutical Care Manuals. Issue 2: Asthma], 4th edn. Eschborn: GOVI Publisher & Co.
21. Schussel, K. & Schulz, M. (2006) Prescribing of COX-2 inhibitors in Germany after safety warnings and market withdrawals. *Pharmazie*, 61, 878–886.
22. Rau, J. L. (2006) Practical problems with aerosol therapy in COPD. *Respiratory Care*, 51, 158–172.
23. Golpe, G. R., Mateos, C. A. & Soto, F. I. (2001) [Inadequate technique in the use of inhalers in patients seen at a pneumology clinic]. *Anales De Medicina Interna*, 18, 69–73.
24. Hesselink, A. E., Penninx, B. W., Wijnhoven, H. A., Kriegsman, D. M. & van Eijk, J. T. (2001) Determinants of an incorrect inhalation technique in patients with asthma or COPD. *Scandinavian Journal of Primary Health Care*, 19, 255–260.
25. Gray, S. L., Williams, D. M., Pulliam, C. C., Sirgo, M. A., Bishop, A. L. & Donohue, J. F. (1996) Characteristics predicting incorrect metered-dose inhaler technique in older subjects. *Archives of Internal Medicine*, 156, 984–988.
26. Basheti, I. A., Reddel, H. K., Armour, C. L. & Bosnic-Anticevich, S. Z. (2005) Counseling about turbuhaler technique: needs assessment and effective strategies for community pharmacists. *Respiratory Care*, 50, 617–623.
27. Ekedahl, A. (1996) Open-ended questions' and 'show-and-tell'-a way to improve pharmacist counselling and patients' handling of their medicines. *Clinical Pharmacology and Therapeutics*, 21, 95–99.
28. Self, T. H., Brooks, J. B., Lieberman, P. & Ryan, M. R. (1983) The value of demonstration and role of the pharmacist in teaching the correct use of pressurized bronchodilators. *Canadian Medical Association Journal*, 128, 129–131.

Appendix I: patient interview

Patient Interview – VITA Project (to be filled out by the pharmacist)

Patient code:	_____ (Pharmacy code + Patient number)	**Date:**	. . 2008
Year of birth:	19	**Gender:**	☐ male ☐ female

How many years did you attend school?

☐ 8-9 years ☐ 10-11 years ☐ 12-13 years ☐ other: ____ years

Diagnosis: ☐ Asthma ☐ COPD ☐ Mixed form ☐ unknown

When were you diagnosed with the disease?

Year ____

Are you participating in a structured healthcare programme for asthma/COPD?
(Disease management programme for asthma/COPD)

☐ no ☐ yes ⇨ since when? (e.g. 04/2007) /

Since when have you been using inhalation medication?

Since / (e.g. 05/2003)

Where was the use of inhalation medication explained to you?
(Please mark an "x" for all that apply)

☐ Physician's office ☐ Pharmacy ☐ Not explained ☐ Other: ____

How were you instructed in the use of your inhalation medication?
(Please mark an "x" for all that apply)

☐ Oral instructions
☐ Practical demonstration
☐ Practice under the guidance of an expert
☐ Printed *Instructions for Use* of the respective system
☐ Other: ____

How many instruction sessions have you had until now to use the inhalation medication?

☐ none ☐ 1 ☐ 2 ☐ 3 or more

How many different inhalation medications do you regularly use to control your asthma/COPD disease at the present time?

☐ 1 ☐ 2 ☐ 3 ☐ 4 or more

Which inhalation asthma/COPD medications do you use?
(You can also retrieve the information from your customer/patient database)

☐ Anticholinergic drug	e.g. ipratropium
☐ Beta 2 agonist (short-acting)	e.g. salbutamole, fenoterole, terbutaline
☐ Beta 2 agonist (long-acting)	e.g. formoterole, salmeterole
☐ Inhalation corticosteroid (ICS)	e.g. budesonide, ciclesonide, fluticasone
☐ Mast cell stabiliser	e.g. cromoglicine acid
☐ Combination drug	e.g. salmeterole/fluticasone
☐ Other, specifically:	____

Remarks:

Appendix II: checklist – correct use of inhalation medication

Correct Use of Inhalation Medication - Checklist					
Patient code: — — — —		**Medication:**		®	
Inhalation system:		☐ Metered dose inhaler – breath-actuated (MDI-breath)			
☐ Metered dose inhaler (MDI)		☐ Dry powder inhaler (DPI)			
☐ Metered dose inhaler+spacer (MDI+S)		☐ Other:			
Demonstration of inhalation by patient		**Appointment 1**		**Appointment 2**	
Date		. .2007		. .2007	
Condition of the device		correct*	incorrect	correct*	incorrect
1	Device technically functional	☐	☐	☐	☐
2	Device components fit together	☐	☐	☐	☐
3	Cleanliness satisfactory	☐	☐	☐	☐
Preparation		correct*	incorrect	correct*	incorrect
4	Remove locking cap	☐	☐	☐	☐
5	Shake well before use (usually for MDI, MDI-breath, MDI+S)	☐	☐	☐	☐
6	Perform steps correctly to make the device ready to use (e.g. pull lever, attach spacer) (MDI-breath, MDI+S, DPI)	☐	☐	☐	☐
Inhalation		correct*	incorrect	correct*	incorrect
7	Hold device correctly (MDI, MDI-breath, MDI+S: Hold mouthpiece down, DPI: usually horizontally)	☐	☐	☐	☐
8	Exhale (normally)	☐	☐	☐	☐
9	Close lips (tightly for MDI-breath and DPI)	☐	☐	☐	☐
10	Lean head slightly back (MDI)	☐	☐	☐	☐
11	MDI: Spray and inhale at the same time, as exception also for Jethaler® device (DPI)	☐	☐	☐	☐
	MDI-breath and DPI: Inhale with forceful breath(s)	☐	☐	☐	☐
	MDI+S: Release in spacer and inhale directly (<3-5 sec.)	☐	☐	☐	☐
12	Inhale slowly and deeply (MDI, MDI-breath, MDI+S) or quickly and deeply (DPI)	☐	☐	☐	☐
13	Hold breath after inhaling (5-10 sec.)	☐	☐	☐	☐
14	Exhale through pursed lips or nose	☐	☐	☐	☐
15	Avoid exhaling into device	☐	☐	☐	☐
Conclusion		correct*	incorrect	correct*	incorrect
16	Wipe saliva off mouthpiece (DPI)	☐	☐	☐	☐
17	Release the device (MDI-breath)	☐	☐	☐	☐
18	Close device immediately	☐	☐	☐	☐
19	Rinse out mouth/eat something after use of glucocorticoid	☐	☐	☐	☐
Time Needed (in minutes, e.g. 11.5)		,		,	
Other (other errors, comments)					
Appointment 1:		Appointment 2:			

*Correct is when the patient does not make an error during the inhalation demonstration or when the source of error does not exist for the respective medication. © Center for Drug Information and Pharmacy Practice, Federal Union of German Associations of Pharmacists, Berlin