



## RESEARCH ARTICLE

**EVALUATION OF NORMAL PHARMACEUTICAL CARE SERVICES FOR ASTHMA PATIENTS**

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**ABSTRACT**

To study the pharmaceutical care services on asthma related quality of life. As asthma is associated with an enormous social, psychological, and economic burden, various patient education programs have been developed to improve outcomes, including quality of life. The authors evaluated the effectiveness of community pharmacy-based interventions on lung function, health-related quality of life, and self management in asthma patients in a 12-month controlled intervention study in 26 intervention and 22 control pharmacies. Pharmacies opted whether to take part as intervention or control pharmacies. According to this, patients (ages 18-65) with mild to severe asthma attending the pharmacies were allocated to the intervention (n = 161) or control group (n = 81), respectively. Intervention patients were educated on their disease, pharmacotherapy, and self management; inhalation technique was assessed and, if necessary, corrected. Pharmaceutical care led to significantly improved inhalation technique. Asthma-specific quality of life and the mental health summary score of the SF-36 improved significantly in the intervention group. At 12 months, the intervention group showed significant improvements with regard to evening peak flow, self-efficacy, and knowledge.

**KEYWORDS:** Asthma, Pharmaceutical Care, Quality of Life, Patient Education.**INTRODUCTION:**

Asthma is still one of the major health problems world-wide. Asthma is one of the major health problems in industrialized countries.<sup>1,2</sup> As asthma is associated with an enormous social, psychological, and economic burden, various patient education programs have been developed to improve outcomes, including quality of life. Although new pharmacological agents and therapeutic guidelines have been developed over the past years, no major improvements in terms of morbidity and mortality could be established.<sup>3</sup> Patient education programs are frequently conducted by physicians or nurses and usually take place in clinical settings.<sup>4</sup> However; there are few data about long-term effectiveness. To achieve permanent improvements, it is necessary to provide patient education on a regular ongoing basis. Pharmacists have become more and more active in patient care over the past years and can demonstrate a positive impact on the outcomes of drug therapy in asthma patients.<sup>5,6</sup> Pharmaceutical care is a concept to optimize drug therapy, minimize drug-related problems, and improve self management and quality of life of patients. The pharmacist is part of the health care team, and extensive communication between pharmacist, physician, and patient is necessary to achieve defined health outcomes.<sup>6,7</sup> They estimated the net benefit for the American health care system due to the implementation of pharmaceutical care to be approximately \$40 billion. The present study is the first controlled trial to investigate the impact of pharmaceutical care for asthma patients in Germany. Asthma continues to be under-diagnosed and

under-treated, it's appropriate management requires correct diagnosis, assessment of severity, proper management including appropriate medication, patient education, and a written action plan, ongoing monitoring, appropriate follow-up, and specialty referral where appropriate. The guidelines for treatment of asthma recommend greater involvement of the patients in the management of their diseases.<sup>2</sup> Self management of asthma is reported to reduce its incidence and improve patients' quality of life.<sup>3,4</sup>

Self-management skills should be developed through education of the patients about asthma and its appropriate treatment by health care professionals. Pharmacists can educate patients by providing information about asthma medications and by demonstrating how to use inhaled medications and peak flow meters. They can help patients to understand their asthma management plan. In addition, pharmacists can monitor medications use and refer patients with poor control of asthma to physicians for medical care.<sup>5</sup>

A longitudinal non-controlled intervention study was conducted in Germany involving 183 asthma patients reported a significant improvement in clinical parameters (peak flow, clinical symptoms, asthma severity), and humanistic outcomes (quality of life, self-efficacy, knowledge, adherence, inhalation technique) as a result of the provided pharmaceutical care services.<sup>12</sup> Shaw et al. conducted a study in New Zealand to assess a community pharmacy-based pharmaceutical care service. In this study, one hundred patients were enrolled, 431 medication

related problems were identified, of these, 66.1% were related to noncompliance. There were improvements in control of symptoms and peak flow readings in the majority of patients and a significant improvement in quality of life.<sup>13</sup> A non-controlled study was conducted in Indiana to assess an asthma disease state management program that included point-of-care testing in the form of peak flow meters. This program was developed by an independent community pharmacy. In this study, patients who completed one year in the program had a 77% decrease in hospitalization and 78% decrease in emergency department visits compared with year prior to enrollment in the program.<sup>14</sup>

These studies were conducted in developed countries and established the clinical, economic and humanistic viability of pharmaceutical care on asthma patients. However, there is lack of information regarding the implementation of pharmaceutical care services in developing countries and its value. Studies carried out in several developing countries including Sudan have shown that prescribing and dispensing practices were frequently irrational and illogical with many inappropriate prescribing practices. Pharmaceutical care practice is intended to meet a need in the health care system that has arisen due to the increase in complexity of drug therapy and the significant level of drug-related morbidity and mortality associated with drug use. Therefore, the introduction of pharmaceutical care is required in developing countries to aid in the resolution of medication-related problems. The existence of variations in pharmaceutical care models and practices among countries were also reported.<sup>16</sup>

Asthma is a chronic disease of the airways characterized by airway inflammation, increased responsiveness to a variety of stimuli, and airway obstruction that reverses spontaneously or as a result of appropriate therapy. Symptoms of asthma include cough, wheeze, and tightness of chest, shortness of breath and increased sputum production. Due to rapid industrialization and urbanization, the prevalence of asthma is likely to increase rapidly in the coming years. The increase is likely to be dramatic in India, which is projected to become the most populous nation by 2050. An absolute 2% increase in the prevalence of asthma in India would result in an additional 20 million people with the disease. Medication regimens for patients with asthma are particularly vulnerable to adherence problems because of the chronic nature of the disease, the use of multiple medications, and the periods of symptoms remission. As drug experts, pharmacist can influence adherence to therapy by providing patient education<sup>6</sup>. A study by Tullio demonstrated the impact of pharmacist's patient education on improving compliance with asthma through a controlled, patient-blinded study<sup>17</sup>.

While considerable evidence exists demonstrating the worth of pharmaceutical care on a variety of patient outcomes, little has been provided on the impact of pharmaceutical care on QoL of asthma patients as an end-point in the health care process<sup>18</sup>. More evidences on the impact of pharmaceutical care on subjective outcomes, specifically quality of life are needed. Therefore, the department of pharmacy practice, after consultation with the concerned physician, planned to conduct a study on the impact of pharmaceutical care on quality of life of patients with asthma.

This study aims at the outcome of providing pharmaceutical care services for asthma patients through on active partnership between clinical pharmacist and patients for an optimal pharmacotherapy and a better quality of life.

#### **METHODS:**

##### **SETTING:**

All of the 465 community pharmacies in the city of Hamburg (population 1.7 million) were asked to enter the study either as an intervention or control pharmacy; 26 and 22 pharmacies, respectively, agreed to participate. Intervention pharmacies were asked to deliver pharmaceutical care in one-to-one meetings in counseling rooms.

##### **PARTICIPANTS:**

At the beginning of the study, the intervention pharmacies were trained to provide pharmaceutical care and were introduced to the study protocol. Training of the intervention pharmacist comprised medical, pharmaceutical, and pharmacological knowledge (5 hours), communication skills (6 hours), and the use of the study protocol and documentation forms (2 hours). In contrast to other patient education programs in primary care, pharmaceutical care is an individual approach. Pharmacists did not follow a predefined educational program but aimed to detect and solve individual drug- and health-related problems. The control pharmacies received an introduction to the study protocol only.

##### **SAMPLE SIZE:**

Minimum sample sizes for different potential analyses were calculated using the methods described by Cohen<sup>10</sup> with a predetermined alpha level of  $\alpha = 0.05$ , a power  $1 - \beta = 0.8$ , and an effect power ranging from  $d = 0.3$  to  $d = 0.6$ . According to these calculations, the smallest sample size can be estimated at 121 cases for a Pearson's 2 test ( $df = 3$ ) and at about 23 cases for a two-way analysis of

variance with repeated measurements for two groups (intervention and control).

#### **PATIENTS' ASSESSMENT:**

The intervention and control pharmacies recruited 161 and 81 patients, respectively. Asthma patients were identified by means of their medication or by patients' self-report. Patients gave written informed consent, which was developed in cooperation with the data protection agency in Hamburg. Afterward, patients and pharmacists asked the physicians in attendance ( $n = 120$ , general practitioners, internal medicine and pulmonary specialists) for their willingness to cooperate. The diagnosis was confirmed by the physician by means of spirometry results. The Medical Research Council Dyspnea Scale (Medical Research Center-MRC of Great Britain, 1960) was used to assess dyspnea severity (none to severe: 0-4), and asthma severity (mild to severe: 1-3) was classified according to German Asthma Guidelines.<sup>21</sup> In addition, patient stated their self-perceived asthma severity and dyspnea at 6 and 12 months in accordance with the same criteria. Lung function data were reviewed independently by two experienced chest physicians. In case of insufficient or apparently incorrect data, physicians were asked to provide flow volume curves. These patients' data were reassessed by the chest physicians. Data that still could not be interpreted have been excluded. In addition, the chest physicians checked the lung function data and asthma severity for consistency. After 6 and 12 months, this procedure was repeated.

#### **DATA COLLECTION AND INTERVENTIONS:**

Meetings between pharmacists and patients in the intervention group were scheduled at 6-week intervals (overall, 9 meetings within 12 months). During these meetings, the pharmacists assessed and, if necessary, corrected patients' inhalation techniques. In addition, pharmacists detected and solved drug- or health related problems in cooperation with the patient and the physician

(Table I). To improve self-management, study patients were instructed to use a peak flow meter provided for the study and an asthma diary on a regular basis. The control group received traditional care. At baseline and after 6 and 12 months, quality-of-life questionnaires, a self-efficacy questionnaire, and an asthma knowledge questionnaire were administered to all patients.

#### **OUTCOME MEASURES:**

To demonstrate the impact of pharmaceutical care, the following outcome measures were chosen. To monitor lung function, forced expiratory volume in 1 second (FEV1) and peak expiratory flow rates were measured. The percentage change in FEV1 from baseline was used as a clinical outcome.<sup>3</sup> Peak expiratory flow rates were measured by patients at home and on consulting dates in the pharmacy as a means of self-monitoring. The peak flow measures under pharmacists' supervision were recorded in the monitoring plan. In addition, study patients' diaries (peak flow measurements twice a day) were analyzed. For statistical analysis, the mean of 5 consecutive morning and evening values at baseline and at 6 and 12 months, respectively, was taken. A 7-point checklist was used to score the inhalation technique. For each correct step, 1 point was assigned, and the sum score of the inhalation technique was documented. The SF-36 and the German version of the Living with Asthma Questionnaire<sup>22,23</sup> were applied to measure generic and asthma-specific quality of life, respectively.

A constructed self-efficacy scale based on parts of a standardized generic self-efficacy questionnaire<sup>14</sup> and some disease-specific items was employed to investigate any changes of patients' perceptions in their self-management skills and ability to deal with the disease. The asthma knowledge questionnaire, which focuses on basic information about the disease and drug therapy, was developed in cooperation of chest physicians, clinical psychologists, and clinical pharmacists involved in this study.

Table 1: Drug-Related Problems and Solutions (case reports from intervention pharmacies)

Problem	Example	Solution
Need for additional drug therapy	Patients without inhaled corticosteroid but needing one	Referral to physician
Inappropriate dosage form inhaler	Patients unable to use a metered dose inhaler	Use of dry-powder inhaler or breath-activated device
Dosage too low	Patients using the inhaled corticosteroid every other day	Information on the proper and regular use
Dosage too high acting	Patients with excessive use of short-acting beta2 agonists	Information on the use of controller and reliever medication Use of spacer and mouth rinsing
Adverse drug reaction caused	Patients with sore throats or thrush by the use of inhaled corticosteroid	Switch to paracetamol if possible Patients were informed on the differences between inhaled and oral corticosteroid
Interactions	Self-medication with NSAIDs	
Compliance	Patients refusing the use of inhaled corticosteroids due to the fear of systemic side effects	

**STATISTICAL ANALYSIS:**

Statistical computations were performed on 164 patients using statistical analysis systems (SAS® version 6.12, SPSS® version 8.0, STATISTICA® version 5.1H; all for Windows NT). To examine various hypotheses concerning the effect of pharmaceutical care, it was necessary to take different statistical techniques into consideration. A variety of tests were considered according to the assumptions used in the tests (e.g., uni- and multivariate distribution, covariance/variance). The ones chosen were those with the most power for each type of hypothesis.

The comparability of uniquely measured demographic data (e.g., gender, age, age of onset, allergic status, etc.) between the intervention and control group was investigated by Pearson’s  $\chi^2$ , Student’s independent *t*-test, Mann-Whitney’s U-test, or Wald-Wolfowitz’s runs test, while the repeatedly measured outcome parameters (e.g., spirometric data, physiological and psychological scales) were analyzed by single comparisons within the general mixed models (SAS® 1990; proc-mixed) or Cochran-Mantel- Haenszel’s  $\chi^2$ -test, respectively, which were used to evaluate the effectiveness of intervention. All scales and subscales derived from the repeatedly administered questionnaires (quality of life, selfefficacy, and knowledge) were linearly transformed to a percentage scale ranging from 0 to 100. Low values are associated with

a low characteristic of the measured construct and vice versa.

For all statistical analysis, the two-tailed alpha level was predetermined on  $\alpha = 0.05$ . The hypotheses on parameters concerning the trend of the intervention and the control group over time (e.g., lung function, quality of life, self-efficacy, knowledge, and inhalation technique) were investigated using general mixed models (SAS® 1990; proc-mixed) or the nonparametric Cochran-Mantel-Haenszel’s  $\chi^2$  test if any assumption of the mixed models was violated.

**RESULTS:**

At the beginning of the study, the intervention pharmacies recruited 161 patients, and the control pharmacies recruited 81 patients. After the application of the study criteria (intervention and control group: patient-pharmacist meeting at baseline and meetings after 6 and 12 months were mandatory; intervention group only: no more than two missed meetings in a row and no more than three meetings missed within 12 months), 101 patients remained in the intervention group and 63 patients served as controls. To control for confounders and biases, a wide range of baseline characteristics and outcome measures were recorded and tested for group differences. The only significant differences at baseline were physicians in attendance and type of asthma (Table II). Significantly more patients ( $n = 28, 45.2\%$ ) in the control group were

treated by a chest physician than in the intervention group ( $n = 29$ , 28.7%). In only 6 (10%) patients in the control group was allergic asthma diagnosed against 28 (31.1%) in the intervention group ( $p = 0.009$ ). At entry, there were no significant differences regarding the outcome measures.

Hence, it seems justified to deduce that the observed significant changes in the outcome measures were due to the intervention. Patients mentioned mainly the lack of interest (29.5%,  $n = 23$ ) or the lack of time (22%,  $n = 17$ ) as reasons to discontinue.

Table 2: Baseline Characteristics of Intervention and Control Group

Variable	Intervention Group ( $n = 101$ )		Control Group ( $n = 63$ )		$p$ -Value
Mean (SD) of age (years) <sup>a</sup>	46.3	(11.4)	45.9	(12.5)	0.976
Sex (%) <sup>b</sup>					0.394
Female	66	(65.4)	37	(58.7)	
Male	35	(34.6)	26	(41.3)	
Employment status (%) <sup>b</sup>					0.508
Employed	61	(62.9)	31	(57.4)	
Unemployed	36	(37.1)	23	(42.6)	
Smoking status (%) <sup>b</sup>					0.156
Current smoker	28	(28.9)	10	(18.2)	
Ex-smoker	31	(32.0)	15	(27.3)	
Nonsmoker	38	(39.1)	30	(54.5)	
Asthma severity (%) <sup>b</sup>					0.814
1—mild	47	(50.0)	30	(49.2)	
2—moderate	35	(37.2)	25	(41.0)	
3—severe	12	(12.7)	6	(9.8)	
Mean (SD) of asthma severity	1.63	(0.7)	1.61	(0.7)	
Type of asthma (%) <sup>b</sup>					0.009
Allergic	28	(31.1)	6	(10.0)	
Nonallergic	21	(23.3)	16	(26.7)	
Mixed type	41	(45.6)	38	(63.3)	
Physician in attendance (%) <sup>b</sup>					0.01
General practitioner	50	(49.5)	16	(25.8)	
Specialist in internal medicine	22	(21.8)	18	(29.0)	
Chest physician	29	(28.7)	28	(45.2)	
Mean (SD) of age when asthma was diagnosed (years) <sup>a</sup>	32.1	(15.1)	32.2	(16.2)	0.838
Mean (SD) of duration of asthma since onset (years) <sup>a</sup>	13.7	(11.4)	13.7	(11.2)	0.884
Mean (SD) of FEV <sub>1</sub> % VC <sup>c</sup>	67.6	(15.7)	70.5	(14.7)	0.266

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FEV<sub>1</sub> % VC, percentage forced expiratory volume in 1 second of vital capacity (Tiffeneau index). Numbers do not always add up to total because of missing data.

a. Mann-Whitney U-test.

b. Pearson's  $\chi^2$  test.

c. Student's  $t$ -test

#### LUNG FUNCTION, DYSPNEA, AND ASTHMA SEVERITY:

Although the FEV<sub>1</sub> was clearly increased in the intervention group at 6 months (+11.4% vs. +4.5% changes from baseline in the control group), no significant difference in comparison to the control group could be established at 12 months.

Peak expiratory flow rates measured in the pharmacy remained unchanged. In the intervention group, the morning values recorded in patients' diaries remained unchanged, but the evening values increased significantly. The changes in dyspnea and asthma severity rated by physicians were not significant. In contrast, the patients in the intervention group perceived a significant within-group improvement of asthma severity from 6 to 12 months. These improvements are differed significantly from the control group at 12 months.

#### INHALATION TECHNIQUE, KNOWLEDGE, AND SELF-EFFICACY:

Inhalation technique improved significantly in the intervention group. Though no significant change with regard to knowledge of asthma and drug therapy could be determined at 6 months, at 12 months, the knowledge in the intervention group was significantly improved. Self-efficacy was improved in the intervention group at 6 ( $p = 0.019$ ) and 12 months ( $p = 0.001$ ).

#### QUALITY OF LIFE:

In the intervention group, the mental summary scale of the SF-36 improved significantly while the physical summary scale indicated no change. Significant improvements could be established for the intervention group in the summary score and all subscales of the Living with Asthma Questionnaire: physical symptoms, psychological distress, and functional status.

#### LIMITATIONS OF THE STUDY:

The tendencies for improvements in the control group with regard to some outcomes measured at 6 months might indicate that even the control pharmacists engaged in counseling activities. Due to ethical considerations, it did not seem appropriate to stop control pharmacists from intervening if a drug-related or health-related problem became evident.

#### DISCUSSION:

The findings show that pharmaceutical care performed in community pharmacies has a clear, positive impact on the patients' asthma management and quality of life. Moreover, it could be demonstrated that pharmaceutical care is feasible and highly accepted by the patients as a long-term service in primary care.

The small changes in lung function are consistent with the results found in other studies.<sup>15</sup> Although FEV<sub>1</sub> in the intervention group was clearly but not statistically significantly increased at 6 months by 11.4%, a decrease to the control level at 12 months could be observed. Reasons for this remain unclear. A 12% increase in FEV<sub>1</sub> indicates a significant improvement regarding airflow obstruction.<sup>33</sup> So, we regard the 11.4% improvement in FEV<sub>1</sub> during the first 6 months as clinically significant. Though the lung function data indicate no changes at 12 months, one cannot conclude that patient education programs are not effective as morbidity comprises additional parameters (e.g., hospitalizations). Therefore, it is questionable whether measuring FEV<sub>1</sub> only three times during a period of 1 year accurately reflects morbidity.

As in previous studies, it could be demonstrated that pharmacists may improve patients' inhalation techniques.<sup>16</sup> Although this is just a technical aspect of patient education, it is one of the prerequisites for achieving positive outcomes of drug therapy as up to 60% of the patients do not use their inhalers correctly.<sup>17</sup>

Beyond this, the pharmacists' interventions aimed to provide patients with deeper insights into their disease and drug therapy. Therefore, the disease- and health-related problems were discussed in individual counseling sessions. It is arguable whether improved knowledge will lead directly to increased self-management in asthma patients,<sup>18</sup> but it is definitely a good basis for safe and rational drug use.

One of the most important conditions for the patient's ability to cope with asthma is his or her self-confidence with respect to his or her own capabilities to effectively alter the disease process. Therefore, the detected improvement in self-efficacy is a predictor of long-term patient compliance. This might be important in practice, particularly when patients are confronted with a deterioration of their asthma.<sup>19,20</sup>

The increased knowledge and self-efficacy might have led to the positive impact on quality of life. Patients who know more about the disease and drug therapy and perceive more control of their asthma are better prepared to cope with the burden of asthma.<sup>21,22</sup> Probably, these changes in disease perception and attitudes are reflected by the substantially enhanced quality of life. There is only a low correlation between increases in quality of life and lung function in patients with asthma and chronic obstructive pulmonary disease.<sup>23,24</sup> On the other hand, the subscales of the Living with Asthma Questionnaire show a clear relationship to asthma severity.<sup>25</sup> It is possible that the increases in quality of life might indicate a reduction in asthma symptoms.<sup>26-29</sup>

We conclude that the interventions have laid a basis for appropriate drug use, health attitudes, and health behavior that improves the self-management abilities and quality of life in asthma patients. Based on these results, it deems promising to conduct further research into long-term outcomes and the pharmacoeconomical impact of pharmaceutical care programs.<sup>31-36</sup>

#### CONCLUSION:

The pharmacist's role and place in the health care structure has changed, and new opportunities have emerged. Results from this study provide evidence that through providing structured, co-operative, patient oriented Pharmaceutical Care, Pharmacists can help patients with reactive airway disease achieve desired health outcomes, optimize health related quality of life in realistic economic parameters. Our recommendation is: Pharmaceutical care would have maximum impact if its effect on patients' outcomes could be demonstrated in community pharmacies by well trained pharmacist. Community pharmacies have the capacity to rapidly implement programs system wide. However, for programs to be integrated into these pharmacies, a rigorous change in pharmacy education in Egypt will be necessary.

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