Patient Preferences on Participation in Chronic Obstructive Pulmonary Disease Practice-based Research in a Community Pharmacy Setting

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Abstract

Objective: To investigate patient preferences on community pharmacist-led practice-based research to inform the development of a multi-site, practice-based research protocol.

Methods: Paper surveys were administered at the point-of-care to patients eligible to participate in a COPD disease state management (DSM) program. Eligibility was determined based on fill history and the survey was completed anonymously. Descriptive statistics are reported.

Results: A total of 22 individuals were recruited to participate during the five months of data collection, and 12 participated (55% response rate). When asked if their pharmacist could play a role in improving the patient's COPD control, 92% of patients agreed or strongly agreed. A majority of patients (92%,) agreed that they would be interested in participating in pharmacist-led COPD research study that lasted at most 6 months, with 75% of patients agreeing to meet with the pharmacist up to 30 minutes during each appointment.

Conclusions: This patient perceptions study demonstrated that the majority of COPD patients were willing to participate in pharmacy research at their local community pharmacy and viewed a reasonable length of study duration of 6 months with 30 minutes per pharmacy visit.

Keywords: COPD; Community pharmacy services; Medication therapy management

Introduction

A growing public health concern, chronic obstructive pulmonary disease (COPD) is expected to reach the fourth leading cause of death worldwide by 2030, an increase from its rank of sixth leading cause of death in 1990 [1]. With roughly 12.7 to 14.7 million adults over the age of 18 having a physician diagnosis of COPD in the United States in 2013, the social and economic strain caused by COPD is significant [2]. Of all care related to COPD, it is estimated that COPD exacerbations account for the greatest proportion of the total of COPD burden on the healthcare system [1]. Appropriate immunizations, medical treatment, and appropriate inhaler use can prevent COPD exacerbations as well as effectively manage symptoms [3].

Inhaled medications are the backbone of COPD management. To ensure optimal symptom control, patients must be adherent and they must self-administer their inhalers correctly [4]. However, many COPD patients fail to control symptoms due to inappropriate inhaler technique [5]. This is largely due in part to the vast range of inhalers available to patients and concomitant use of multiple inhalers, each having unique techniques associated with their administration [5,6]. Studies have demonstrated that between 50-80% of individuals do not use their inhaler devices correctly [4]. For this reason, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommends the monitoring of patients' pharmacotherapy, namely their medication adherence and inhalation technique [7]. In addition, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines recommends that the pharmacist play a key role in COPD management, and can decrease patient adverse effect and improve quality of care.

A recent stakeholder's summit on expanding the role of the pharmacist in managing COPD in the U.S. found that pharmacists can play a multitude of roles in the care of patients with COPD [5]. This group of patient advocates, health plans (U.S. third-party insurers), academia, and other health care professionals determined there are 3 potential roles for the pharmacist:

· Improving adherence and compliance to medication regimens

· Incorporating pharmacists into support groups, education programs, and smoking cessation programs

· Providing medication regimen reviews

In general, the pharmacist is uniquely positioned to improve COPD care due to their expertise in medication use. But, it is the community pharmacist that represents the largest potential for access to care for patients suffering from COPD, as about 95% of the United States population lives within 5 miles of a community pharmacy [8].

To date several large, multi-site research trials outside the United States (U.S.) have been examined the pharmacist's impact on COPD outcomes [4,9-14]. However, this research cannot be extrapolated directly to the U.S. as there are fundamental differences between single and multi-payer systems that present unique challenges in workflow, availability of pharmacist time, and patient perceptions of

what constitutes pharmacist-delivered care. In order to appropriately develop a large, multi-site research study on community pharmacist impact on COPD, a patient perceptions study on participation in community pharmacy practice-based research was conceived. The purpose of the present research is to determine patient perceptions on the design of on community pharmacist-led COPD DSM research.

Methods

Study sample

Participants were recruited to fill out the survey based on fill history of maintenance COPD medications at the two community pharmacy sites. Inclusion criteria included age older than 18 years of age, patient-reported diagnosis COPD, and the patient being present on pick-up of the COPD maintenance medication. Exclusion criteria included patients who were pregnant or breastfeeding, residing in a nursing home or assisted living facility, patient-reported significant problem with vision, hearing, or speech, and inability to read or write.

Study design

This study is a prospective patient perception survey. A taskforce was assembled to design the survey instrument that included two community pharmacists, a community pharmacy resident, and a college of pharmacy faculty member. The survey was piloted on a convenience sample of non-pharmacists prior to use.

Practice setting

The study was conducted at Mac's Pharmacy, an independent pharmacy with two locations in eastern Tennessee. One site is located in Knoxville and the other is located in Powell, a suburb of Knoxville. According to the American Lung Association, Tennessee is ranked third in age-adjusted prevalence of COPD in adults by state in 2011 [2]. Additionally, hospitalizations related to COPD in the U.S. are highest in the geographical area represented by the Mississippi Delta, Deep South, and Appalachia –the state of Tennessee being a central component of all three [12].

Data collection and analysis

Data were collected from 10/21/2014 until 4/1/2015. After identification of an eligible patient by a trained pharmacy technician or pharmacist, the patient was asked to participate in the survey and read a statement of consent. This study and informed consent was approved by the institutional review board (IRB) at the University of Tennessee Health Science Center (Memphis, TN). Descriptive statistics were computed using SPSS v. 22.

Results

Of the 22 individuals who were identified by study personnel as eligible to participate in the survey, 12 (55%) completed the survey. The average age was 64, and ages ranged from 42-76 years. There were 7 females and 5 males. All subjects were Caucasian. There was an average of 2 inhalers per individual, with an average of 8 medications and 8 co-morbid health conditions per patient. The average participant smoked 1.25 packs per day for an average of 15 years and ranged from 2.5 packs per day for 50 years to complete lifetime abstinence from smoking. Within the last 12 months a total of 27 exacerbations were recorded, with an average of about 2 exacerbations per individual.

Table 1 details the responses used to the patient survey. When asked if a pharmacist could play a role in improving the patient's COPD control, 11 patients agreed or strongly agreed (92%). Regarding patient perceptions of participation in practice-based research at the community pharmacy, again 92% of patients agreed or strongly agreed

(n=11) that they would participate in future COPD management research despite the potential for inconvenience to the patient.

Several questions assessed convenience of pharmacist-led research from the patient's perspective. Patient's perceived preference for length of the pharmacist-patient COPD management appointment demonstrated that 75% of patients surveyed were willing to meet between 16-30 minutes per visit, and 42% (n=5) would approve of an appointment lasting between 31-45 minutes. All participants indicated they agreed or strongly agreed that they would be willing to be inconvenienced if the total interaction time with the pharmacist exceeded what was stated if in the end it benefited their overall health. Similarly, 11 participants (92%) indicated they would participate in a future pharmacist-led research study, despite any inconvenience, if the overall health improvement was achieved by the conclusion of the study. The majority of participants indicated they would agree to participate in the research for up to 6 months (n=7), and meet the pharmacist up to once each month (n=9). Slightly less (42%) patients indicated they would agree to participate in a research study that lasted up to 12 months (n=5). Although privacy was not a concern for participation, time and travel were noted as possible barriers for patient participation.

Discussion

Our study's aim was to explore COPD patient perceptions of participation in research at their local community pharmacy to inform a future research protocol set in the Appalachian region of the U.S. As community pharmacies operate outside of health-systems or medical practices, the concept of pharmacy-led research for a specialized area such as COPD may be perceived as inappropriate by some patients and present a barrier for study enrollment. However, this study demonstrated positive perceptions exist for both the impact a pharmacist may have on COPD control, as well as establishing patient willingness to participate in research at their local community pharmacy. To our knowledge, this is the first research of its kind evaluating patient perceptions of pharmacist-led research of any kind.

Recent studies of the community pharmacist's impact on COPD conducted in Europe and Asia have yielded positive, but modest results. A recent trial in Germany examined the effect a community pharmacist can have on inhaler technique [4]. A total of 597 out of 757 patients (78.9%) made at least one mistake while performing their inhalation technique at baseline. This number decreased to 214 (28.3%) in a follow-up appointment a month later after being instructed regarding appropriate use of their inhaler device by a community pharmacist after the baseline assessment. After 4-6 weeks of interventions, the study concluded that community pharmacists are well suited to greatly supplement and improve inhalation technique. A retrospective study aimed to evaluate the impact of an educational program provided by community pharmacists in Japan on correct and consistent inhalation technique to patients found a decrease in the frequency of COPD exacerbations and an increase in adherence [14]. However, at the end of the study health related quality of life (HRQOL) was not statistically different from baseline. One of the most notable trials to date, the PHARMACOP trial was conducted in Belgium and aimed at assessing the effectiveness of community pharmacists as part of a pharmaceutical care program for patients with COPD over 3 months [11]. The interventions again focused on inhalation technique and adherence to therapy improvement. Endpoints were assessed at baseline, month 1, and month 3. Results showed that a community pharmacist providing one-on-one counseling improved both inhalation technique and adherence compared to a "usual care." However, the patient humanistic

Survey Responses	Total Recorded Responses				
Question	SA	A	N	D	SD
1. I believe pharmacists are capable of helping me manage and control my chronic obstructive pulmonary disease (COPD).	5	6	0	1	0
2. Time is a major barrier for me to participate in a research study.	1	6	2	3	0
3. Travel time or travel inconveniences are a major barrier for me to participate in a research study.	1	6	2	2	1
4. Personal fear of participating in a research study is a major barrier for me.	1	1	1	7	2
5. Privacy concerns are a major barrier for me to participate in a research study.	0	2	2	7	1
6. I would participate in a research study even if it was inconvenient for me but it concluded with an improvement in my COPD management and improvement in my overall health and quality of life.	4	7	0	1	0
7. What is the maximum amount of time (in minutes) for a single visit you would be willing to meet with a pharmacist to discuss appropriate inhaler technique and develop a plan to improve your health and quality of life.	0-15	16-30	31-45	46-60	>60
	3	5	1	2	1
8. If the interaction took longer than my maximum time allotment listed above but could improve my health and quality of life, I would still be willing to participate.	4	8	0	0	0
9. If I did partake in a research study, I would be willing to physically come back to the community pharmacy and meet with a pharmacist for subsequent visits to discuss my disease state, inhaler usage, and overall health.	Weekly	Monthly	Every Other Month	Every 3rd Month	
	2	7	1	2	
10. If I did partake in a research study, I would be willing to participate in a study for a maximum of:	Three Months	Six Months	Twelve Months	>Twelve Months	
	1	6	3	2	

Note: (SA) Strongly Agree, (A) Agree, (N) Neutral, (D) Disagree, (SD) Strongly Disagree.

Table 1: Survey responses.

outcome scores (reported by guideline-recommended and validated assessment tools) were not statistically improved compared to the control group. This study too concluded that community pharmacists are capable of improving adherence and compliance and should be encouraged to engage in COPD care.

When exploring the feasibility of designing and implementing a future COPD study in the U.S., one must consider not only the development of a scientifically sound methodology, but also the feasibility of patient recruitment and participation. In particular, the length of data collection and number of patients recruited can reduce the likelihood of a type II error. Based on our study results, it would be feasible to target customers of a given community pharmacy in Eastern Tennessee to enroll in a prospective, randomized control trial to evaluate community pharmacist impact on COPD outcomes over 6 months with monthly, 30 minute appointments.

There were several limitations in the study. Due to variations in workflow demands recruitment did not always occur, especially during peak busy times or when staffing levels were low. Although over half of the eligible patients participated, the overall number of participants was low and would have benefited from a longer recruitment window or enrollment of other sites. Lastly, it may be possible that a type of selection bias occurred during recruitment, as those who consented to perform survey-based research may be more willing to take part in practice-based research.

Conclusion

This study demonstrates that a sample patient population of two community pharmacies in Eastern Tennessee had the desire to participate in practice-based research at their local community pharmacy. As community pharmacists are accessible and have a proven positive effect on COPD treatment adherence and inhaler technique, they are uniquely positioned to improve patient outcomes and demonstrate cost effectiveness to third-party payers within the U.S. Future research protocols should enroll COPD patients at their local community pharmacy, with a recommended study duration of 6 months and monthly 30 minute pharmacist appointments.

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