

Enabling Patient Health Improvements through COPD (EPIC) Medicines Optimisation within Community Pharmacy: a prospective cohort study

Abstract

Objectives

To improve patients' ability to manage their own COPD through greater understanding of COPD and its treatment, increased use of self-care management plans, and assessment of inhaler technique within a community pharmacy setting

Design - Multicentre prospective cohort study

Setting – UK Community Pharmacies within one CCG area within the UK

Participants 190 COPD patients at 14 GP practices with high incidence of COPD related hospital admissions attended an initial consultation and follow up consultation within the pharmacy.

Interventions - Eligible patients received 2 consultations 8-12 weeks apart with a suitably trained pharmacist or pharmacy technician. The consultations included CAT/MRC COPD assessment, smoking cessation advice, inhaler technique assessment, COPD monitoring, and pharmacotherapy and lifestyle education.

Main outcome measures CAT score, MRC and inhaler technique were measured at the initial and follow up consultation.

Results

The reduction in mean CAT score at 8-12 weeks post community pharmacy intervention was statistically significant (Change in mean score -1.0, $p=0.0003$). The number of patients who reported a clinically important decrease of ≥ 2 points in their CAT score was also significant ($P=0.0001$). Twenty-six per cent (108/413) of inhaler devices were being used unsatisfactorily when initially assessed. This decreased to 3.4% (14/413) after the patients were taught how to use their inhaler devices within the same consultation. Overall, the inhaler technique used by patients improved for 93.7% (208/222) inhaler devices which were originally assessed as being used sub-optimally. This improvement was maintained for 76.9% (163/222) inhaler devices at follow-up.

Conclusions

A COPD consultation within a community pharmacy setting can improve COPD health status and optimise their inhaler technique as well as identify other interventions, including vaccination and pulmonary rehabilitation. The input of community pharmacy professionals should be considered in COPD pathway redesign.

Introduction

In the UK, 835,000 people are diagnosed with Chronic Obstructive Pulmonary Disease (COPD), although an estimated 2,200,000 people are thought to remain undiagnosed.¹ Despite the availability of national and international guidelines, the management of COPD remains sub-optimal; COPD is the second largest cause of emergency admission in the UK, accounting for one in eight (13,000) emergency admissions to hospital.² Prescribing of Long Acting Muscarinic Antagonist (LAMA) and Inhaled Corticosteroid / Long Acting Beta-2 Agonist (ICS/LABA) inhalers in England's primary care sector is significant, with just six drugs in these two classes accounting for £583million of drug expenditure in 2015. However this may reflect significant over-prescribing of ICS/LABAs in patients with mild-moderate airway obstruction and infrequent exacerbations, and under-use of LAMAs.³ A recent study has also found that patients' use of inhalers has not improved for 40 years, prompting an "urgent" need for new approaches to patient education.⁴ In addition, there has recently been a significant increase in the number of new inhaled drugs and inhaler devices.⁵ This has created an opportunity for community pharmacy staff to optimise patient's medication through education to improve adherence and understanding. Previous work by Bsheti *et al* demonstrated that community pharmacies could successfully deliver inhaler optimisation education to patients with asthma, which was maintained at follow up and was associated with an improvement in asthma control.⁶

As the majority of COPD patients are managed in primary care, community pharmacies seem an ideal place to improve the management of COPD. Two community based projects have assessed the impact of enhanced inhaler technique training on COPD control, which have reported a trend towards an improvement in COPD health status measured by the COPD Assessment Test (CAT), although both were confounded by low follow up rates of 17%¹⁰ to 28%¹¹. The Greater Manchester Community Pharmacy Inhaler Technique Service reported that an improvement in inhaler technique was maintained over a 3-4 month period in 77.1% and 59.0% of asthma and COPD patients using MDI and Dry Powder Inhalers respectively.¹¹ Wright *et al* demonstrated that community pharmacies could provide a cost effective intervention for COPD patients which improved their EQ-5D score, however showed no improvement in CAT or British Medical Research Council (MRC) dyspnoea scores.⁷ Both CAT score and MRC score provide a useful and accurate tool for measuring quality of life and breathlessness in COPD patients and can be used to measure disease progression and the impact of intervention and are advocated in the GOLD COPD guidelines.^{8,9} This study reviews the impact of a community pharmacy led COPD service on patients' health status using MRC and CAT scores as the main outcome measure.

Methods

The EPIC project targeted COPD patients at 14 GP practices within a close geographical area over a period of 4 months. The GP practices were chosen based on high rates of hospital admissions and accident & emergency attendances for COPD. An estimated 2,600 COPD patients were registered within these practices based on QOF data for 2013/14. A new COPD 'preferred' drug formulary and treatment algorithm, based on the GOLD 2015 COPD guidelines⁹ was developed and approved for use across primary and secondary care within the area studied.

Two 2-hour evening training sessions were provided on 25th January and 2nd March 2016 for Pharmacists and Pharmacy Technicians from 24 community pharmacies on COPD, its treatment, self-management, inhaler technique and promoting healthy lifestyle. This was supported by a comprehensive COPD information folder, consultation guide and inhaler technique training pack, that were developed for this service.

Patients were recruited directly into the service by pharmacy staff, identified through presentation of a prescription for inhalers, searching through patient records and speaking to the individual patients. Letters were also sent by GP practices to patients who were on their COPD register who had an MRC of 2,3 or 4 encouraging them to attend their community pharmacy for a consultation. Eligible patients received two consultations 8-12 weeks apart with a trained pharmacy professional (pharmacist or pharmacy technician) (see table 1). Patients symptoms were assessed at baseline using a CAT score and MRC score questionnaire, recommended assessment in the GOLD COPD guidelines.⁹ Patients' CAT scores can range from 0-40; the higher the score the bigger the impact

on a patient's health status. A shift of 2 points or more on the CAT score is deemed a clinically relevant change in health status.¹⁰ MRC score indicates the level of disability caused by a patient's breathlessness. A score of 3 or more indicates the patient's breathlessness is having a significant impact on patient's life and the patient should be referred to pulmonary rehabilitation. Details of the consultation were automatically sent to the patient's GP via a standardised letter template in PharmOutcomes® (data capture software) indicating that the patient had visited the pharmacy for a consultation. If the pharmacy identified any interventions required to optimise a patient's COPD management, such as vaccination or pulmonary rehab, a separate referral letter was sent to the practice to outline that the practice should check records and take action if necessary.

Table 1 Content of initial and follow up consultation

Consultation Content
<ul style="list-style-type: none"> • Assessment of COPD severity using CAT / MRC score and combined COPD assessment • Smoking status, brief advice and signposting to relevant service • Assessment of inhaler technique with teaching of correct technique and re-check technique, using In-Check DIAL inspiratory flow meter and supply of spacer where appropriate. Inhaler technique was assessed as being <i>Optimal</i> (all 7 steps on a checklist performed correctly), <i>Satisfactory</i> (some minor errors, but no major errors that would significantly impact on drug delivery, or <i>Unsatisfactory</i> (at least one major error).¹³ • Assessment of adherence, patient understanding of medication and provision of advice tailored to the patient to explain what the medication, what is for, how it works, and the potential side-effects and how to minimise them • How to identify exacerbations and what to do • Lifestyle and self-care advice relevant to COPD patients • Intervention to ensure patient has been offered vaccination, pulmonary rehabilitation and has relevant printed information – The British Lung Foundation 'Living with COPD' booklet. • Patient feedback

At each consultation, data were entered onto PharmaOutcomes® including patient demographics, GP practice, smoking status, CAT score, MRC score and inhaler technique assessment outcome. Following advice from NHS West Yorkshire Research and Development Team, the project was deemed a service evaluation, and therefore formal ethical approval was not required.

Data were extracted anonymously from PharmOutcomes®. Data distribution were examined using box plots then differences in patient CAT and MRC scores were analysed using parametric tests (paired t test and paired z-test for two proportions). All tests were conducted using Stata® version 9, using a significance level of $P < 0.05$.

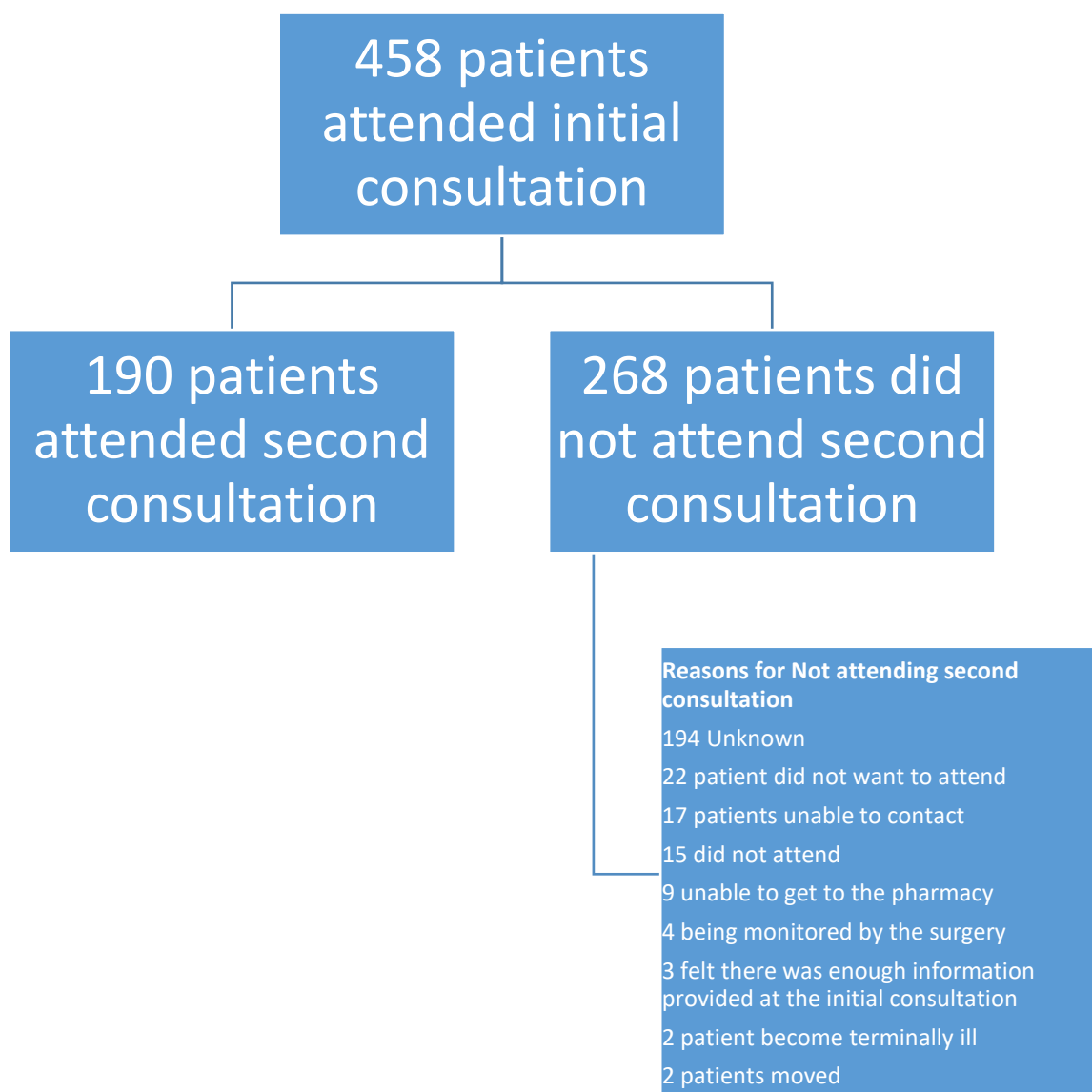
Results

A total of 463 patients attended an initial consultation at the pharmacy; 190 (41.0%) went on to have a follow up consultation between 8-12 weeks (See figure 1). No difference in mean age, initial CAT score and initial MRC score were seen in those patients who did and did not attend the follow up appointment. Patients were more likely to attend follow up if recruited into the service by the pharmacy staff than if referred by the GP (47.4% cf 38.4%).

Loss to follow up

The percentage of patients who were not followed up at 8-12 weeks after the initial consultation per GP practice varied from 23.1% to 95.7% (mean 56.7%). The proportion of patients who did not have a follow up appointment ranged from 13-100% per pharmacy (median 67%). The reason for loss to follow-up was not known for 79.1% of patients; the remainder are reported in figure 1.

Figure 1. Follow-up of patients throughout the project



Demographics of patients attending initial and follow up consultation

Data were available for comparison at baseline and 8-12 week follow up for 190 patients (see table 2). There was no difference in characteristics of all patients attending the initial consultation compared to those who attended both the initial and follow-up consultation, although patients who attended for follow-up were more likely to have received advice on anxiety at the initial consultation. The age range of people attending both consultations varied from 44-90 years old (median 72); comprising 48.9% (93) males and 51.1% (97) females. Thirty-three percent (62) were smokers, 56% (107) ex-smokers and 28% (53) had a smoker in the house. Thirty-four percent of patients (64/190) did not recall having their pneumococcal vaccination and 7% (14/190) their flu vaccination.

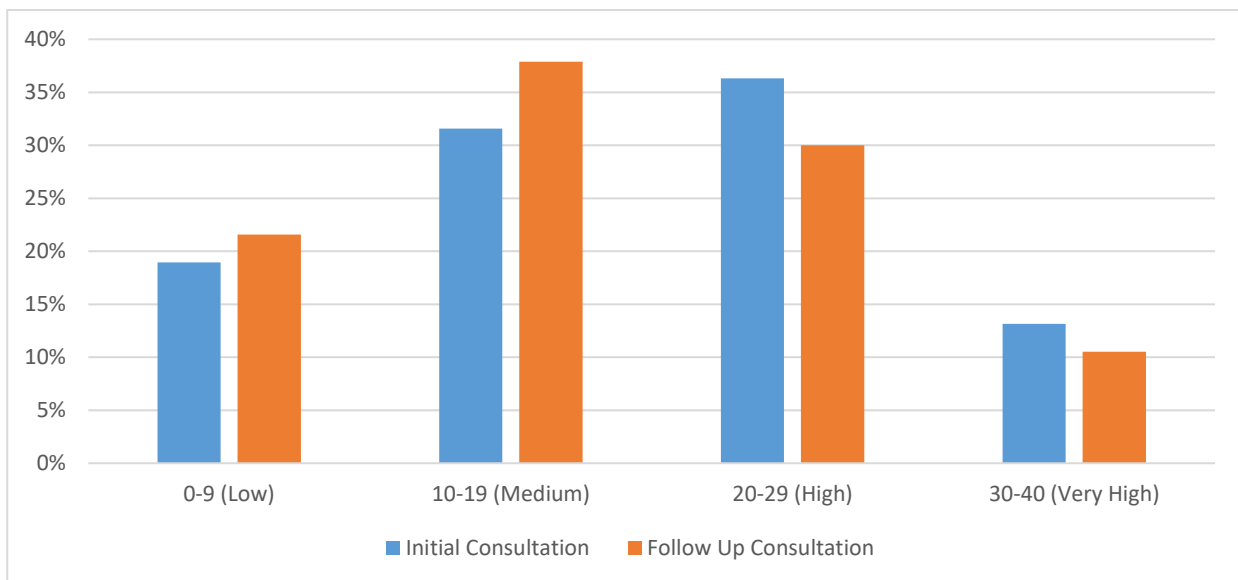
Table 2 Descriptive Statistics for patients attending initial and follow up consultations

		Data for all patients who attended the initial consultation (n=458)		Data for patients who attended both the initial and follow up consultations. (n=190)	
Age	Range	40-105		44 -90	
	Median	72		72	
Gender	Male	51.2%	242	48.9%	93
	Female	45.7%	216	51.1%	97
Smoking status	Smokers	27.7%	131	33%	62
	Ex Smokers	54.3%	257	56%	107
	Smoker in the House	24.3%	115	26%	53
Patient has had pneumococcal vaccine					
	Yes	63.4%	300	66.3%	126
	No	16.7%	79	13.7%	26
	Don't know	16.7%	79	20.0%	38
Patient has had Influenza Vaccination					
	Yes	88.4%	418	92.6%	176
	No	8.2%	39	7.4%	14
	Don't know	0.2%	1	0	0
Number of Inhalers used by patient					
	1	16.7%	79	17.4%	33
	2	49.9%	236	47.9%	91
	3	33.0%	156	34.2%	65
	4	0.4%	2	0.5%	1
Type of Medication used by patient					
	SABA	90.4%	414	91.6%	174
	ICS	11.8%	54	10.5%	20
	LABA	14.0%	64	11.6%	22
	LAMA	57.2%	262	60.5%	115
	LAMA/LABA	12.9%	59	13.2%	25
	ICS/ LABA	49.8%	228	52.1%	99
	Aminophylline/Theophylline	1.3%	6	1.1%	2
	Carbocysteine	5.2%	24	6.3%	12
	Other	1.5%	7	1.6%	3
Medication advice provided to patient		98.3%	450	96.3%	186
Advice provided on recognition of COPD exacerbation		99.3%	455	97.9%	190

Advice on action to take during COPD exacerbation	97.2%	445	98.4%	187
Advice on diet provided to patient	95.4%	437	99.5%	189
Advice on anxiety provided	68.3%	313	75.8%	144
BLF patient information provided	96.7%	443	97.9%	186

CAT Score

Figure 2 CAT Score at Initial and Follow up Consultation for the patients who attended both consultations (n=190)



The initial mean CAT score for patients who attended both consultations was 18.7 (SD 8.85). A significant improvement in health status was achieved (reduction in mean CAT score) at 8-12 weeks post community pharmacy intervention (mean CAT score 17.7, SD 8.88 (Change in mean CAT score -1.0; $p=0.0003$) (see figure 2). The number patients with medium to high impact of COPD symptoms at baseline (CAT score of >10) who improved to have a low impact of symptoms (CAT score of <10) was not significant ($P=0.545$). However the number of patients who reported a clinically important improvement in COPD health status (decrease of ≥ 2 points in their CAT score) was significant ($P= 0.0001$).

Table 3 Changes in CAT score in patients who had a change to their inhaler technique

Inhaler Technique following education	CAT score clinically improved (reduction in score by ≥ 2 units)	CAT score clinically worsened (increase in score by ≥ 2 units)	No Clinical change	Total
Improved	34	15	39	88
No change	30	12	41	83
Worsened	3	7	9	19
TOTAL	67	34	89	190

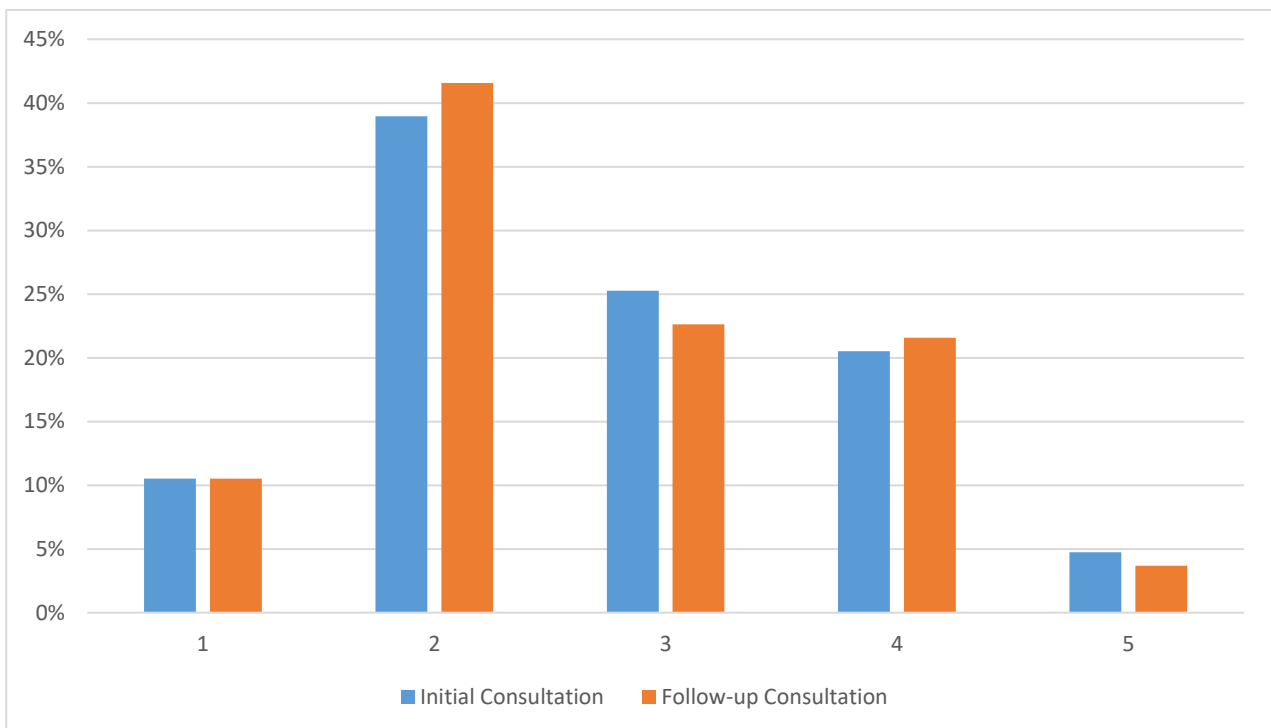
Table 4 Changes in CAT score in patients who had a change to their inhaler device

Inhaler device changed	CAT score clinically improved (reduction in score by ≥ 2 units)	CAT score clinically worsened (increase in score by ≥ 2 units)	No Clinical change	TOTAL
Yes	21 (41.2%)	10 (19.6%)	20 (39.2%)	51
No	46 (33.1%)	24 (17.2%)	69(49.6%)	139
Total	67 (35.3%)	34 (17.9%)	89 (46.8%)	190

MRC Score

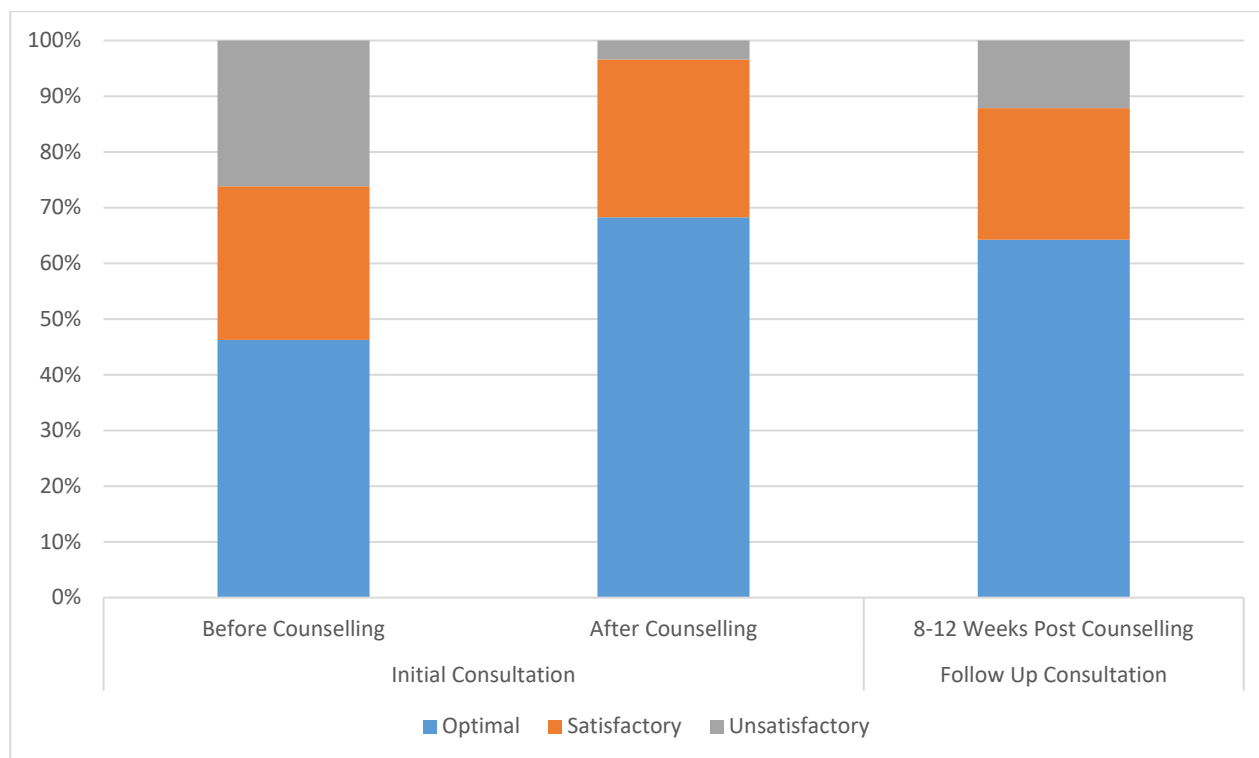
At 8-12 week follow-up, no significant difference in mean MRC score (-0.04, $p=0.381$), or the proportion of patients who moved from clinical categorisation of more breathless (MRC ≥ 3) to less breathless (MRC ≤ 2) (+4%, $p=0.536$) was observed (See figure 3).

Figure 3 MRC score at initial and follow up Consultation (n=190)



Inhaler Technique

Figure 4 Comparison of inhaler technique before and after counselling and at 8-12 week follow up



At follow-up 11.1% patients had decreased the number of inhaler devices that they used compared with 7.4% who had increased their number of inhaler devices. Most patients used two or three inhaler devices (see table 2). At baseline, 46% (190/413) of inhaler devices used were assessed as being used with optimal inhaler technique, and 26% (108/413) were being used unsatisfactorily. After training during the initial consultation, 68% (281/413) of devices were assessed as achieving optimal technique and only 3.4% (14/413) continued to be unsatisfactory. Overall, the inhaler technique used by patients improved for 93.7% (208/222) inhaler devices which were originally assessed as being used sub-optimally. The improvement was maintained for 76.9% (163/222) inhaler devices at follow-up (see figure 4).

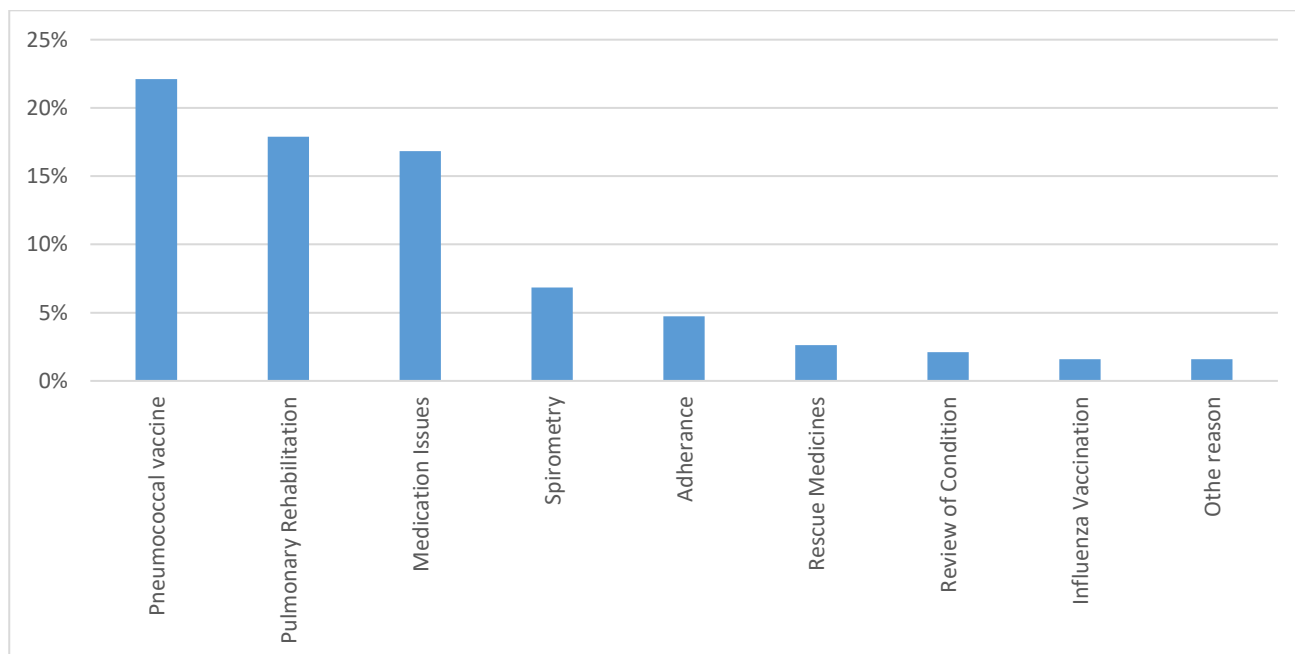
Of the patients whose inhaler technique improved following training at the baseline consultation, 34 (38.6%) achieved a clinically important improvement in health status (reduction in CAT score ≥ 2 units), which was more than experienced a clinically meaningful deterioration in health status (15 (17.0%) patients) (see table 3).

Following inhaler technique education, a change in inhaler device was recommended for 32 (16.8%) patients; 20 of these patients (10.5%) had a change to device at follow up. A further 31 (16.3%) patients had a change made to an inhaler device who had not been referred to the GP by the community pharmacy professional. In total, 51 (26.8%) patients had received a change to at least one of their devices since their previous visit (see table 4). Forty-four patients had one new type of inhaler device and seven patients had two new types of inhaler devices. Patients who had a change in inhaler device were more likely to achieve a clinically important improvement in health status (reduction in CAT score ≥ 2 units) than get worse.

Referral to General Practice

Most patients were referred to their GP for pneumococcal vaccination (22.0% (42/190)), pulmonary rehabilitation (17.9% (34/190)) and issues with their inhaler device (16.8% (32/190)) (see figure 5).

Figure 5 Reason for onward referral to GP post consultation



Referral to other services

28 out of the 95 patients eligible (MRC \geq 3) were referred for pulmonary rehab. Seven patients (4%) were referred to a stop smoking service.

Patient Feedback

The majority of patients had a positive experience of the service and learned more about their condition and treatment (see table 5). Positivity was slightly higher in those who attended both initial and follow up consultation.

Table 5 Patient feedback following consultation

	Feedback from patients only attending the initial consultation (n=458)		Feedback from patients attending both the initial and follow up consultations (n=190)	
	%	n	%	n
Patient felt they had a better understanding of COPD following the consultation	90.9%	430	95.3%	181
Patient felt they Understood their different medication following the consultation	92.2%	436	95.8%	182
Patient stated they would use the service again	88.2%	417	92.6%	176
Patient stated that they would recommend the service to others	90.9%	430	94.2%	179

Discussion

Pharmacy staff can support patients with COPD to improve their health status (measured by CAT score) using a consultation tailored to suit the patient. Inhaler technique taught during the consultation was maintained at 12 weeks post consultation. It appeared that patients were more likely to attend follow up if recruited by the pharmacy directly rather than referred by the GP practice and if they provided positive feedback at the first consultation. The reason for this is unclear and further work to explore this should be undertaken.

These findings are different to a previous study by Wright et al who showed no significant difference in CAT score, despite a difference in EQ-5D.⁷ A recent systematic review demonstrates that incorrect inhaler technique is frequent and has not improved over the past 40 years.⁴ It calls for new approaches to education; the results of this, and previous studies suggest that community pharmacy may be able to offer an appropriate setting.⁶

Our study suggests that a COPD consultation within a community pharmacy setting can improve a patient's inhaler technique and COPD health status, as well as identifying other interventions such as need for vaccination and pulmonary rehabilitation. The input of community pharmacy professionals should be considered in COPD pathway redesign. The patient's GP practice acted as a gatekeeper within the study. The implementation of any recommendations was reliant on the GP practice acting on the pharmacy staff suggestions. Direct referral by pharmacy staff to other services such as pulmonary rehabilitation would be beneficial to avoid unnecessary extra work for GPs, provided that relevant pharmacy staff had access to patient records to contribute rather than duplicate work.

This intervention was conducted in addition to usual care, and so it is therefore difficult to ascertain whether these results are attributable to the pharmacy staff intervention or intervention conducted elsewhere. However our data show that where a positive impact was made on a patient's treatment by improving inhaler technique, or switching inhaler device, then this more likely to achieve improvements in health status than a deterioration. Where no active changes to inhaler technique or inhaler device prescribed was made, patients were also more likely to achieve a clinically meaningful improvement in COPD health status. The reasons for this are speculative, but could be the result of the education provided by pharmacy professionals on COPD, pharmacotherapy, lifestyle management, with support from written patient information materials. Patient feedback is supportive of this, with the vast majority of patients reporting they had better understanding of COPD and their medicines following the consultation

A large proportion of patients failed to attend the follow up appointment at the pharmacy, although the follow-up rate was higher in our study than in other similar community pharmacy studies.^{7,10,11} The reasons for this are unclear, but may be that the patients thought that they had obtained sufficient information at the initial consultation, that they had not seen the benefit from it, that they were invited for various check-ups elsewhere or some other reason. Further work to explore this would be beneficial.

One concern from our study is the relatively low referral rate based on the number of issues identified during the consultation. For example referral rates for vaccination, stop smoking services and pulmonary rehabilitation were lower than expected for the number of patients where these issues were identified. The reasons for this were not collected, but may be due to patients declining onward referral. Further research may be required to establish the true reasons for lower than expected referral rates.

"What this paper adds"

- COPD has significant impact on both patients and the health service with patients frequently experiencing exacerbations and hospital admission. Previous studies have shown community pharmacy to provide cost-effective intervention in patients with COPD and improve quality of life with no improvement in CAT score.

- This study suggests that a COPD consultation within a community pharmacy setting can improve a patient's CAT score and optimise their inhaler technique as well as identify other interventions eg vaccination and pulmonary rehabilitation
- The input of community pharmacy professionals should be considered in COPD pathway redesign

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