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An evaluation of a multi-site community pharmacy–based chronic obstructive pulmonary disease support service

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Abstract

Objectives Chronic obstructive pulmonary disease (COPD) is a progressive chronic condition that can be effectively managed by smoking-cessation, optimising prescribed therapy and providing treatment to prevent chest infections from causing hospitalisation. The government agenda in the UK is for community pharmacists to become involved in chronic disease management, and COPD is one area where they are ideally located to provide a comprehensive service.

This study aims to evaluate the effect of a community pharmacy–based COPD service on patient outcomes.

Methods Patients in one UK location were recruited over a 10-week period to receive a community pharmacy–based COPD support service consisting of signposting to or provision of smoking-cessation service, therapy optimisation and recommendation to obtain a rescue pack containing steroid and antibiotic to prevent hospitalisation as a result of chest infection. Data were collected over a 6-month period for all recruited patients. Appropriate clinical outcomes, patient reported medication adherence, quality of life and National Health Service (NHS) resource utilisation were measured.

Key findings Three hundred six patients accessed the service. Data to enable comparison before and after intervention was available for 137 patients. Significant improvements in patient reported adherence, utilisation of rescue packs, quality of life and a reduction in routine general practitioner (GP) visits were identified. The intervention cost was estimated to be off-set by reductions in the use of other NHS services (GP and accident and emergency visits and hospital admissions).

Conclusions Results suggest that the service improved patient medicine taking behaviours and that it was cost-effective.

Introduction

Chronic obstructive pulmonary disease (COPD) is normally a progressive disease, which is most frequently associated with smoking.[1] Currently the fourth biggest killer worldwide, it will be third by 2020.[2] COPD has 5-year survival rates of 78% for men and 72% for women with mild disease, which reduces to 30% and 24% respectively in severe disease.[3] It is estimated that up to a quarter of adults over the age of 40 have some form of mild airway obstruction,[4] and this correlates closely to the proportion of the population known to smoke. Within the UK the cost of COPD to the National Health Service (NHS) was estimated to be between £805M and £870M in 2009,[5] and this is largely due the cost of treating and managing the disease and hospital bed days associated with exacerbations of the condition.

COPD presents as a limitation of airflow that is not fully reversible and results from fibrosis and loss of elasticity of small airways, destruction of alveoli as they eventually lose their ability to repair and the permanent production of mucus as a non-specific immune response.[6] Clinical diagnosis of COPD is made on the basis of shortness of breath

(dyspnoea), chronic sputum production or cough, and history of exposure to a known risk factor. Once diagnosed, the severity is then based on the extent of airflow obstruction (GOLD Standards): stage 1 (mild, forced expiratory volume in 1 s (FEV_1) ≥ 80% of predicted), stage 2 (moderate, FEV_1 50–80% of predicted), stage 3 (severe, FEV_1 30–50% of predicted) and stage 4 (very severe, FEV_1 <30% of predicted), and treatment is prescribed accordingly.[1]

Smoking cessation is usually the first stage in the management of COPD, and following this, yearly influenza vaccinations should be offered due to the reduced ability of their lungs to respond to infections.[7] All COPD patients should be prescribed inhaled short-acting beta agonists or muscarinic antagonists to increase lung capacity. As FEV worsens, then long-acting beta-agonists and muscarinic antagonists are introduced as combination therapy with the final option being to introduce inhaled corticosteroids.[7] The effectiveness of this approach is determined by the patient's ability to use an inhaler correctly[8] and by their willingness to use it as agreed with the prescriber.[9] Devices such as the In-Check Dial (Clement Clarke International, Harlow, UK) are available to ensure that the type of inhaler selected for a patient is appropriate for their pulmonary function.[10] Evidence suggests that interventions to improve patient use of their inhalers can significantly improve the management and care of patients with COPD.[11] It has been recommended in the UK that the inhaler technique and medication for all patients with COPD are reviewed on a yearly basis[12] and that a COPD assessment test (CAT)[13] be used to measure any changes resulting from this.

Severe exacerbations of COPD are one of the main causes of hospital bed days,[14] and hence guidance suggests that patients who frequently experience exacerbations should be given antibiotics and oral corticosteroids to be kept at home (rescue packs) to prevent deterioration.[7]

With medication central to the effective management of COPD and smoking cessation the first part of the process, the community pharmacist is ideally located to undertake a more proactive role in the care of such patients. Community pharmacists frequently provide smoking cessation services or can signpost patients to them. Researchers have reported that community pharmacy services for patients with COPD should focus on drug adherence, influenza vaccination, smoking cessation and inhaler technique.[15]

A small pilot study reported in Canada in 2012 to test whether community pharmacists can contribute to the management of patients with COPD and utilising many of the approaches described by Mehuys[15] demonstrated patient and physician acceptability and that appropriate recommendations can be made to improve therapy.[16] The significant time required to deliver the service was identified as a barrier, and consequently appropriate funding was stated to be required.[16]

One large-scale controlled service evaluation based on 212 Dutch community pharmacies (107 intervention and 105 control) where 3757 patients received a comprehensive intervention to improve sup-optimal drug use demonstrated that such a service reduced the need for steroids and antibiotics in the intervention arm, reduced medicine wastage and improved selection of inhaler device.[17] A single-blind, randomised controlled study conducted in 170 community pharmacies within Belgium over a 3-month period with 734 patients demonstrated improvements in adherence, inhalation score and reductions in hospitalisation.[18]

Within the UK there is growing evidence for community pharmacy–based interventions to improve medicines support for patients with COPD[19,20]; however, no evaluations have effectively captured costs or effect on quality of life. Within a budget-constrained health system, it is no longer sufficient to demonstrate the effectiveness of a service and although an outpatient hospital pharmacy–based COPD management service has been demonstrated to be cost-effective,[21] there is no similar evidence for such a community pharmacy–based service.

The aim of this paper is therefore to describe the effectiveness of a community pharmacy–based COPD service delivered from a wide variety of community pharmacies and to provide an initial indication as to the cost-effectiveness of the intervention.

Method

Following advice from the Nottingham NHS Research Ethics Committee, the project was deemed a service evaluation, and therefore formal ethical approval was not required. Written confirmation supporting this decision was provided by UEA ethical committee. The COPD service was delivered from September 2012 to June 2013 and located in Boots UK, Co-operative, Lloyds and Rowland pharmacies.

Pharmacist recruitment and training

All 34 pharmacies belonging to the four companies in the Wirral in the North West of England provided the service and were included in the evaluation. One pharmacist from each pharmacy attended a 1-day training course, which they were then responsible for cascading to the remaining colleagues in store. All pharmacy staff involved in service delivery were provided with distance learning materials for pre-reading; completion of which was compulsory.

Patient identification and recruitment

A variety of methods was utilised to identify patients suitable for the service. Leaflets were located in pharmacies to enable patients to self-present. Potentially suitable patients were

identified through pharmacy medication records, and the service was then discussed with them when they presented for their repeat prescription. Patients who were interested were given an information form to take away and consider. Additionally, the service was promoted to relevant primary healthcare professionals local to the pharmacy who subsequently provided potentially appropriate patients with a referral to the service.

Presenting patients were asked to confirm their diagnosis and where there was any uncertainty, the pharmacist was expected to confirm with the GP practice prior to recruiting. All patients completed a consent form prior to participation. Only patients presenting within the first 10 weeks of the service initiation were included within the service evaluation.

COPD service

The service involved supporting patients to stop smoking (if appropriate), helping patients to recognise symptoms of exacerbations and enabling them to respond, e.g. through rescue packs. The service aimed to improve medicines adherence, through the provision of advice on how to use inhalers and ensuring that patients were using the most appropriate inhaler device. General lifestyle advice was also provided where necessary.

Consented patients were screened, and the following information obtained:

- Patient demographics
- CAT score[13]
- Medical Research Council dyspnoea score[22]
- Appropriateness of current inhaler (In-Check Dial meter recommendation).

The pharmacist discussed the initial assessment with the patient and provided the following interventions as deemed necessary:

- Medication counselling
- Lifestyle advice
- Stop smoking service (if patients were receptive to it) or signposting to such a service if not provided in the pharmacy
- Referral letter to their GP to obtain a COPD rescue pack.

Where recommendations were identified, these were also communicated to the patient's GP. An action plan was agreed with each patient and monitored in follow-up patient visits that were arranged at the patient's convenience; usually this coincided with collection of regular prescriptions.

Data collection

Age, gender, height, weight, body mass index and smoking status (patient reported) were collated for each recruited patient. Activities undertaken within the initial consultation were recorded.

At baseline the following information was additionally obtained:

- EQ-5D (T) (quality of life)[23]
- Morisky assessment of adherence (8 = high adherence, 6 < 8 = moderate adherence, < 6 = low adherence).[24]

EQ-5D was chosen as the preferred measure of quality of life as it is recommended by the National Institute for Health and Care Excellence (NICE), which is the UK Government body for recommending which health interventions can be afforded.[25]

Participants were also asked at (1) baseline (recall period: previous 6 months) and (2) every subsequent visit (recall period: since their last visit) to report the number of the following items of resource use:

- routine GP visits for COPD;
- exacerbations treated by GP;
- hospital admissions for severe COPD exacerbations (and associated number of days per admission, if applicable);
- other hospital admissions (and associated number of days per admission, if applicable);
- A&E visits;
- rescue packs obtained; and
- days off sick.

Data analysis

To be included in the final analysis, each patient was required to have attended:

- an initial assessment where all baseline data were measured; and
- at least one follow-up visit at 6 months ± 30 days.

The demographics of those who were included in the final analysis were compared with those who were excluded (due to incomplete data) to assess for selection bias.

Service impact

For the main analysis, once mean values had been derived for each parameter before and after the pharmacy service intervention, mean differences and associated confidence intervals (CIs) were generated. The underlying assumption was that the sampling distributions of the mean estimates were normally distributed (though the distributions of many of the parameters were skewed). The assumption of a normal sampling distribution was made by applying the central limit theorem that requires that samples in question should have $n > 30$ patients. CIs associated with the estimate of mean change that did not cross zero were deemed to be statistically significant. The impact of potential confounding, bias and regression to the mean were not explored in the analysis.

Economic evaluation

Costs (see Table 1) were assigned to each of the aforementioned items of resource use, where these were estimated

Table 1 Unit costs attached to different items of resource use, with associated source

Item	Estimated unit cost
Pharmacist (non-patient contact time)*	£50.00
Pharmacist (patient contact time)*	£63.00
Health care assistant (cost per hour of employment)	£12.50
GP visit*	£43.00
Hospital admission (cost per day)†	£254.00
Day case (weighted average of all procedures)†	£680.70
A&E visit (not admitted cost)*	£112.00
Rescue pack#	£7.00
Day off work (excluding over time) ‡	£110.70

*Taken from Curtis.[34] †Taken from the National Schedule of Reference Costs.[35] #Estimate based on Schomberg *et al*.[36] ‡Based on the Office for National Statistics Annual Survey of Hours and Earnings.[37]

at 2011/2012 financial year levels. Total cost of the intervention was estimated by summing the cost of the consultations, training and equipment. Total other NHS costs were estimated by summing the costs associated with each of the self-report items of resource use, apart from days off sick. Total NHS costs were estimated by summing the intervention cost and total other NHS costs. Total societal costs were estimated by summing the lost productivity (estimated from days reported off sick) and total NHS costs. Mean costs over the 6-month pre-intervention period and the 6-month follow-up period were subsequently estimated for each of these total costs, and the mean difference was estimated by subtracting the mean 6-month pre-intervention cost from the mean 6-month follow-up cost. This difference provides an estimate of the change in cost associated with the intervention.

EQ-5D scores were converted into a utility score (death is equal to 0 and full health to 1).[23] The area under the curve method[26] was used to estimate the change in quality adjusted life year (QALY) score between the baseline and follow-up. This difference provides an estimate of the QALY change associated with the intervention.

The intervention would be estimated to dominate no intervention if the mean estimated change in cost associated with the intervention was negative and the mean estimated QALY change associated with the intervention was positive (i.e. the intervention was estimated to be less costly overall and more effective). Alternatively, the incremental cost-effectiveness ratio would be calculated (mean change in cost/mean QALY change)[25] and compared with the threshold (λ) of £20,000 per QALY.[25] Based on the cost-effectiveness acceptability curve (CEAC),[27] we also report the estimated probability of the intervention being cost-effective at the λ of £20,000 per QALY.

Results

Thirty-four community pharmacies from the Wirral area in England participated in the study. Three hundred six patients were registered for the service of which 156 (51.0%) patients were male and 117 (38.2%) were smokers.

One hundred seven (35.0%) patients dropped out during the 6-month service with the main following reasons provided: 23 (7.5%) did not want to bother again, 14 (4.6%) became housebound, nine (2.9%) did not have any time, nine (2.9%) died, eight (2.6%) unknown and eight (2.6%) were no longer customer at the pharmacy.

One hundred ninety eight (99.5%) of initial visits involved an inhaler check, 136 (68.3%) resulted in a change in inhaler technique, 72 (36.3%) resulted in smoking cessation advice, 181 (91.0%) in healthy lung advice, 197 (99.0%) flu advice and 194 (97.5%) were subsequently recorded as having had a flu vaccination. Fifty-eight (42.3%) patients received advice on physical activity, 53 (38.7%) received advice on diet and nutrition, 26 (19.0%) weight management and 20 (14.6%) on alcohol use. Twenty-five (18.2%) of patients were referred to the GP following pharmacist consultation.

Data were available for comparison at baseline and 6 months for 137 patients (within the ± 30 days timeframes). Previous levels of resource use were also reported at this point by the 137 patients. Follow-up EQ-5D scores were also available for the 137 patients, though only 92 patients reported the resource use and EQ-5D data at the same visit. The 47.5% of the final cohort for analysis were male compared with 54.2% in the sample not used. The mean (standard deviation) age of the final cohort was 69 (8.4) compared with 68 (10.9) in the sample not used.

Table 2 provides a comparison of patient characteristics and service outcomes at baseline and 6 months. It can be seen that the COPD assessment test score improved over the 6 months, as did patient reported adherence. In total, there was a 4.1% decrease in the percentage of patients smoking over the 6-month duration of the evaluation. In patients who were smoking at baseline, this represented a quit rate of 13.85%.

A description of the resource use associated with the component parts of the intervention is given in Table 3, where the mean intervention cost was estimated to be £63.62 per participant. Table 3 details that all 306 participants had an initial consultation and that there were a subsequent 742 monthly consultations and 423 quarterly consultations across all patients. The estimated length of each of these consultations is also given. The main purpose of these consultations was to reinforce what had previously been discussed and to answer any questions participants may have had.

The levels of resource use reported by the 137 patients are summarised in Table 4, where it can be seen that the mean levels of resource are all lower in the 6-month follow-up

Table 2 Comparison of outcome measures at baseline and six months

Parameter (n = 137)	n	Measure	Baseline	Follow-up	Difference (95% CI)	P
Proportion smokers	98	No. (%)	30 (30.6)	26 (26.5)	–4.1%	0.219#
CAT score	137	Mean	20.810	19.955	–0.869 (–0.099, 1.836)	0.078*
Medical Research Council dyspnoea	137	Mean	2.854	2.880	0.044 (–0.090, 0.186)	0.542*
Adherence	137	Mean	7.073	7.6369	0.564 (0.304, 0.824)	< 0.001*

#McNemar's test. *Paired samples *t*-test.

Table 3 Intervention costs

Component part	Resources cost (unit cost), participant costing	Mean cost (£ per participant)
Training (receipt)	Pre-course e-learning (16 pharmacist hours) plus training course (2 h for pharmacist trainer and 8 h for pharmacists trained) plus 1 h of cascade training (pharmacist and three healthcare assistants) (pharmacists £50 per hour*, healthcare assistant £12.50 per hour), divided across all n = 306 participants	3.23
Initial consultation	20-min patient contact time with pharmacist (£63 per hour*), n = 306 participants attended	21.00
Monthly review	7-min patient contact time with pharmacist (£63 per hour*) and 3 min of healthcare assistant time (£12.50 per hour†), n = 742 occurred.	19.34
Quarterly review	11-min patient contact time with pharmacist (£63 per hour*) and 4 min of healthcare assistant time (£12.50 per hour†), n = 423 occurred.	17.12
Equipment	In check (£49.55) and other services materials (£75.00), divided across all n = 306 participants	1.63
Total		63.62

†estimated within study costs; *Taken from Curtis.[34]

period compared with pre-intervention, with the exception of the rescue packs.

Overall, the mean (per patient) total other NHS costs pre-intervention were higher compared with that in the 6-month follow-up period (see Table 3), as was the mean total NHS and societal costs (when the intervention costs and lost productivity costs, respectively, were included). Thus, the mean cost of the intervention was estimated to be off-set by reductions in other items of resource use – the overall mean per participant estimated change in cost associated with the intervention was estimated to be a cost saving of £87.66 (95% CI £148.91 increase to £323.96 saving) (based on total NHS costs) and £94.12 (95% CI £140.21 increase to £331.88 saving) (based on total societal costs).

The mean baseline and follow-up EQ-5D scores were 0.615 and 0.644, respectively. This equates to a mean change in EQ-5D score of 0.029 (95% CI 0.005 to 0.052) and resulted in an estimated change in QALY of 0.008 (95% CI 0.000 to 0.017) at follow-up (mean time = 201 days).

As the intervention was estimated to be associated with a cost saving (from both an NHS and a societal perspective) and a QALY gain, the intervention was estimated to dominate no intervention. According the CEAC, the estimated probability of the intervention being cost-effective at the λ of £20,000 per QALY was 96.7% and 97.2%, respectively.

Discussion

COPD is a progressive degenerative disease, and consequently ongoing reductions in quality of life scores and measurements related to the management of the condition are expected over time. The significant improvement in quality of life and reduction in the COPD assessment test score suggests that the community pharmacy–led COPD service can provide positive patient outcomes. The improvement in patient-reported adherence may explain some of the effect seen, as may the increase in use of rescue packs and the reduction in the number of smokers. Interestingly, a reduction in overall NHS costs was also identified that suggests that the service is likely to represent good value for money and be considered to be cost-effective in relation to NICE criteria.[25]

These data however have to be viewed with some caution as they are based on a before-and-after study with no control group for comparison. Consequently, it is difficult to differentiate differences that may have occurred without the intervention from those which occurred as a result of the intervention. Knowledge of the nature of the intervention is used to enable the reader to determine the likelihood of resultant changes from the pharmacy service. Additionally it should be noted that participants received the initial intervention contact between September 18, 2012 and November 26, 2012. As such, the follow-up period was concentrated more in the winter months (when the condition would be expected to be worse) than the pre-intervention period (to which it was compared). Also, though resource use information was not always requested at precisely 6 months

Table 4 Per participant mean (range) levels of resource use and associated costs for $n = 137$

	Levels of resource use			Mean cost (£)		
Item	Pre-intervention	6-month follow-up	Difference	Pre-intervention	6-month follow-up	Difference
Routine GP visits for COPD	1.40	0.90	–0.50	£60.26	£38.61	–£21.66
Exacerbations treated by GP	1.12	1.10	–0.01	£48.02	£47.39	–£0.63
Hospital admissions: COPD exacerbations	0.12	0.07	–0.06			
Days per admission (average)	4.18	5.14				
Combined total (days in hospital)	0.04	0.02	–0.02	£177.39	£116.21	–£61.18
Hospital admissions: other	0.31	0.23	–0.07			
Days per admission (average)	3.08	2.72				
Combined total (days in hospital)	0.94	0.64	–0.31	£282.33	£201.64	–£80.68
A&E visits	0.09	0.05	–0.04	£10.63	£4.91	–£5.72
Rescue packs issued	0.42	0.66	0.24	£2.96	£4.65	£1.69
Lost productivity (based on days off)	0.25	0.19	–0.04	£27.47	£21.01	–£6.46
Total other NHS costs				£581.59	£413.41	–£168.19
Intervention costs					£80.53	£80.53
Total NHS costs				£581.59	£493.94	–£87.66
Total societal costs				£609.07	£514.95	–£94.12

post-intervention, the mean follow-up time (and time over which people would be asked to report levels of resource use) was longer than 6 months (mean time was 190 days post initial contact). A further potential weakness is that though a wide range of NHS services were asked about (see Table 4) information was not requested on all NHS and personal social service items. Though the methods used to collect resource use data are in line with many other economic studies,[28] it should also be noted that the self-report resource use data were not compared with resource use data in medical records.

Furthermore, although relatively large numbers of patients were recruited in a relatively short period of time, one-third did not complete the service. This attrition rate is higher than that reported in similar studies,[15] studies to improve self-management in COPD patients[29] and for interventions not designed to test new treatments.[30] Further in-depth exploration of patient withdrawal may help to improve service acceptability and perceived value. The recruitment rate of approximately one patient per pharmacy per week in its first 10 weeks of initiation (with a minimum rate of 0.4 and maximum rate of 1.9) is relatively high for a specific condition and detailed inclusion criteria,[18,31,32] suggesting that recruitment to the service would not be difficult if the service was extended.

Validated and nationally recognised tools were used for data collection purposes and therefore the available results can generally be trusted as accurate reflections of patient status. However, tools such as Morisky are known to have poor specificity[24] as they rely on patients responding honestly to surveys from healthcare professionals whom they may not wish to admit deviant behaviour to. Although a second measure of adherence would have improved validity, it is a process measure and was used as a possible explanation for changes in clinical outcomes. Statistical analyses did not explore the potential impact of confounding, bias, or regression to the mean. That said, pharmacy data were only available for a 6-month period; over a longer time horizon, greater cost savings and improvements in patient quality of life may be possible.

Even with a diminished sample size, significant changes in patient outcomes were seen. With a mean score nearing 8 on the Morisky scale, it can be seen that the majority of patients reported very high adherence at the end of the 6-month period. The proportion of patients who had low and medium adherence at beginning reduced, whereas patients reporting high adherence increased. Although this improvement could also be due to social desirability bias, i.e. patients knowing that the pharmacist expects their adherence to improve may rate it higher to please the researchers, it is unlikely to have a large effect as the same bias may have been present when the service was first introduced and the scores were originally obtained. The use of the In-Check Dial is known to improve inhaler selection for patients with COPD,[10] and therefore the improvement in adherence may partially result from receiving greater benefit from treatment. It may also be due to the pharmacist explaining the importance of the medicines and due to patient concerns regarding side effects being allayed.

Elements of the pharmacy service that were not directly measured included the provision of comprehensive advice on weight management, diet and alcohol. These additional interventions will provide some added value to the service that may not have been directly captured within the 6-month window of the evaluation.

A substantially higher proportion of patients within the analysis cohort received flu vaccinations (97.5%) compared with the reported general uptake rate of 75.4% in the Wirral area,[33] and again the benefit of this has not been extrapolated in either the measured impacts or estimated costs.

The signposting and referral to the GP resulted in the prescribing of rescue packs. With GPs responsible for the cost of acute hospital admissions, the proactive nature of this intervention, which is designed to reduce GP call out and hospitalisation, should have been well received. Unfortunately, data on GP opinions of the service were not collated.

This service represents a unique collaboration by the large companies that represent just under half of community pharmacies in the UK. The service was set up within 9 months of initial concept and demonstrates that collaborative working is possible and may be necessary if arguments are to be made to government for additional funding for more patient facing services. The fact that recruitment was undertaken efficiently and improvements in patient parameters were seen suggests that this service is being delivered effectively and to standard quality.

The service was estimated to be associated with a mean cost saving (from both NHS and societal perspectives) and a mean QALY gain. This suggests that the service was cost-effective, though due to the before-and-after nature of the analysis, these results should be treated with caution.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflicts of interest to disclose.

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Authors' contributions

DW led on the writing of the paper and outcome data analysis. DW will be responsible for responding to reviewer comments.

MT contributed to the writing of the paper, reviewing and commenting in detail on all versions.

GB undertook the economic analysis and contributed mainly to the writing of the economics elements of the paper.

TT managed the outcomes workstream of the project from inception through to delivery and commented on all versions of the paper.

CK supported the overall management and delivery of the project and data collection. CK also commented on final versions of the paper.

The authors were given all data in a format suitable for analysis as requested and have unrestricted access to the total dataset. All Authors state that they had complete access to the study data that support the publication.

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