Medicines Optimisation Outreach Case Management Clinics for COPD Patients

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Abstract

Title
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Introduction
In line with the Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy and 'Transforming Your Care' (the restructuring of healthcare provision in Northern Ireland), this project brought specialist respiratory pharmacist case management medicines optimisation clinics to COPD patients in primary care.

Methods
Further to a process mapping event attended by stakeholders from both primary and secondary care, clinics were initiated within GP practices. After initially determining the patient's expectations of the consultation, the independent prescriber pharmacist determined disease classification (GOLD grade), assessed medication adherence, established COPD medication appropriateness, recorded and graded clinical interventions made using the Eadon criteria reflecting significant improvement in standard of patient care, prescribed COPD medications and smoking cessation support accompanied by education, determined whether antibiotic prescribing for infective exacerbations was according to guidelines and made appropriate referrals to other healthcare professionals in both primary and secondary care (respiratory specialist review, spirometry, pulmonary rehabilitation, smoking cessation). Patients were case managed for 30 days post baseline clinic with outcomes determined at six months post baseline clinic attendance. Net drug cost savings from the primary care drug budget were determined via reference to the NHS Dictionary of Medicines and Devices (dm+d).

Results
Patients seen over a six-month period (n=658) demonstrated statistically significant improvements in COPD medication appropriateness and adherence, and improvement in COPD symptoms at 30 day telephone follow-up. Primary care guideline-informed antibiotic prescribing improved whilst annual net drug cost savings from the primary care drug budget were £244k. Results at six months post review indicated reduced COPD exacerbations and reduced related unplanned hospital admissions with continued improvement in appropriate antibiotic prescribing in response to sputum sampling (78.7% versus 97.8% adherence to guidelines from baseline to six months post review).

Discussion and Conclusion
Providing specialist hospital pharmacist patient centred case management clinics for COPD patients in the GP practice setting resulted in safe and cost-effective medication use with improved patient outcomes and positive stakeholder feedback.

Keywords: Respiratory Pharmacist, COPD, case management, outreach clinics, medicines optimisation.

Introduction

Chronic Obstructive Pulmonary Disease (COPD) as defined by GOLD[1] (Global Initiative for Chronic Obstructive Lung Disease) is a common preventable and treatable disease characterised by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Exacerbations and comorbidities contribute to the overall severity in individual patients.

By 2002, COPD was the fifth leading cause of death in the world[2] with the economic burden being substantial and still increasing; by 2030 it is expected to rise to the third global leading cause of death.[3] Whilst exposure to tobacco smoke remains the most recognised risk factor for the development of COPD, other risk factors include exposure to indoor/outdoor/occupational air pollution,[4] increasing age,[5] genetics (a severe hereditary deficiency in alpha-1 antitrypsin),[6] and socioeconomic status.[7]

The relationship to increasing age is of concern within the Western Health and Social Care Trust (WHSCT), which serves a population of approximately 300,000 people with the number of people aged ≥65 accounting for 12% of these. Statistics relating to population projections show an overall increase of 34% in the number of people aged 65 and over and living in the Western area by 2017. This represents the largest single increase of any Health and Social Care Board area in Northern Ireland and is significantly above the projected average increase for Northern Ireland as a whole.[8]

Diagnosis and Management of the COPD Patient

In the 2016 update of the GOLD global strategy for the diagnosis, management and prevention of COPD, it was acknowledged that, in the past, COPD was viewed as a disease mainly characterised by the symptom of breathlessness. However, it is now recognised that COPD has multiple symptomatic effects and, for this reason, a combined assessment of symptoms [using the Medical Research Council (MRC) scale[9] and the COPD Assessment Test (CAT)[10]], exacerbation risk and comorbidities is recommended.[1]

Medicines Optimisation and Integrated Care of the COPD Patient

A report by the American Thoracic Society on the 'Integrated care of the COPD Patient' stated that optimal management of COPD patients requires a holistic approach encompassing three key elements:

1. Recognition and treatment of all aspects of the disease, its systemic effects and co-morbidities

2. Bringing together all the dimensions of COPD care in a continuum through the lifetime of the patient

3. The integration of medical care among healthcare professionals and across healthcare sectors using a patient-centred approach.

Additionally, they stated that optimal management requires provision of the *right treatment* at the *right time,* and in the *right place.*[11]

In June 2011, the Minister for the Department of Health, Social Services and Public Safety (DHSSPSNI) announced that a Review of the Provision of Health and Social Care Services in Northern Ireland would be undertaken; this review resulted in the publication later that year of The Compton Report 'Transforming Your Care (TYC).' Twelve major principles for change were identified including:

- placing the individual at the centre of any model by promoting a better outcome for the service user, carer and their family

- using outcomes and quality evidence to shape services

- providing the right care in the right place at the right time (as also previously recommended by the American Thoracic Society)[11]

- integrated care – working together

- promoting independence and personalisation of care.[12]

Further to the publication of the National Institute for Health and Care Excellence (NICE) definition of medicines optimisation[13] and the four guiding principles developed by the Royal Pharmaceutical Society Great Britain in 2013,[14] the DHSSPSNI launched a consultation on a Medicines Optimisation Quality Framework. This was officially launched in March 2016 and recognises that success in medicines optimisation is reliant on multidisciplinary teams with the correct skill mix working collaboratively.[15]

The holistic and patient-centred approach of these aforementioned recommendations and policies led the team to develop this project using an integrated approach to medicines optimisation at the primary/secondary care interface with seamless links being developed between the teams in these two settings.

Case Management

The term 'case management' originated in the USA where it was used interchangeably, often by healthcare researchers, with the term 'discharge planning'.[16] The King's Fund have reported that the lack of a single UK definition for case management has led to confusion about what it actually entails but, after reviewing the available literature, they concluded that the following core components are particularly important to case management programmes:

- case-finding

- assessment

- care planning

- care co-ordination.

This can include, but is not limited to:

- medication management

- self-care support

- advocacy and negotiation

- psychosocial support

- monitoring and review

- case closure (in time-limited interventions).

The King's Fund recognised that this categorisation might suggest that case management is a linear process with sequential elements, but in reality, it is a much more complex process.[17]

Previous work in the Trust where older patients were case managed by a consultant pharmacist in intermediate care demonstrated that this approach resulted in more appropriate medication prescribing, reduced healthcare resource usage and associated drug cost savings.[18] Therefore, it was decided that the case management approach would also be adopted in this project.

Method

Process Mapping and Development of a New COPD Patient Care Pathway

In order to visualise the existing Trust COPD patient care pathways between acute and secondary care, a process mapping event was held (July 2014). This event was attended by the Respiratory Consultant, Respiratory Registrar, Head of Pharmacy & Medicines Management, Advanced Specialist Respiratory Pharmacist, Consultant Pharmacist (older people), Research Pharmacist (Project Manager), Clinical Pharmacy Development Lead, Respiratory Ward Pharmacist, Respiratory Ward Technician, Early Supported Discharge Respiratory Nurses and the Directorate Support Manager (TYC).

It became apparent that placing the Trust pharmacist into primary care could potentially create access to those COPD patients most in need of review, education and intensive healthcare input. Following consultation with local GP practices on the feasibility of placing the specialist independent prescriber pharmacist within their surgeries, a new model of GP based care was developed; this integrated with care provided in primary care by GPs, practice nurses and the Community Respiratory Team (CRT) enabling more seamless access to secondary care. Figure 1 shows the new model, together with interventions made and outcomes measured, where patients were case managed for 30 days and followed up by telephone 30 days post review.

The Respiratory Pharmacist–led Clinics

A band 8a Specialist Pharmacist with an independent prescribing qualification was recruited to deliver the new service to all GP practices in the locality that were willing to engage. Eligible patients were identified using the GP COPD Quality and Outcomes Framework (QOF) register and invited to attend a 30 minute consultation and review service with the pharmacist. At the outset, the pharmacist set the scene, explained her role and established the patient expectations of this review. Patients were then comprehensively reviewed to ascertain the following:

- Confirmation of clinical diagnosis.
- Assessment of past and future exacerbation risk.
- COPD specific symptom scores.
- Appropriateness of COPD therapies.
- Medication adherence and reasons for unintentional/intentional omission of therapies.

The pharmacist educated the patient on their condition, explained their disease classification and the most appropriate medication changes to be made. With consent, these were implemented and reassessed at the 30 day telephone follow-up review.

Data Collection

Relevant baseline demographic and medical data were recorded for all patients seen by the pharmacist from December 1st 2014 to May 31st 2015. This was entered into the Statistical Package for the Social Sciences (SPSS) Version 22 for exploration and analysis. Clinical Interventions were recorded and self-graded by the pharmacist according to Eadon criteria;[19] a score from 1 to 6 where ≥4 indicates a significant improvement in standard of patient care. Net cost savings were calculated via referral to the most recent edition of the BNF and cross-referenced with dm&d[20] (NHS dictionary for medicines and medical devices). Follow-up data on COPD related unplanned hospital admissions, exacerbations, antibiotic prescribing and sputum sampling (where applicable) were obtained from computer-held records and directly from the patient.

Medication Adherence

Adherence to COPD treatments was quantitatively established at baseline via pharmacist questioning using the 4-item Morisky Medication Adherence Scale (MMAS-4).[21] This scale yields a score from 0-4, with 0 indicating non-adherence and 4 indicating full adherence to medicines prescribed. This was assessed by the pharmacist again 30 days post review. Repeat prescription fills on the GP system were also assessed in line with this. Open-ended probing questioning was employed to further explore reasons for intentional/unintentional non-adherence as indicated by the MMAS-4 score. A case management medicines optimisation care plan was developed to address any issues identified.

Medication Appropriateness

Appropriateness of COPD medication prescribing was determined using the Medication Appropriateness Index (MAI) at baseline and 30 days post review.[22] Caution was exercised when interpreting this as the scale was developed and validated in the older population (≥65 years). However, the 10-item questionnaire is highly reflective of those questions which should be asked by a pharmacist when conducting a medication review, encompassing ascertainment of clinical indication, appropriate dosing schedule and cost-effectiveness, amongst others. The resulting score ranges from 0 to 18 with a high MAI score indicating less appropriate prescribing.

Symptom Assessment

The MRC[9] and CAT[10] scores were measured at baseline and 30 days post review. The MRC is a score of 1 to 5 with 1 representing a patient who is not troubled by breathlessness except on strenuous exercise, whilst 5 is indicative of a patient who is too breathless to leave the house. The content of the CAT questionnaire comprises eight simple questions and has a scoring range of 0 to 40. The recommended cut point for CAT is a score of 10 with those patients scoring less than 10 experiencing less impact of COPD on their quality of life. A drop of two units is suggestive of a meaningful difference in symptoms.[23]

Spirometry

Spirometry reports were reviewed at baseline to assist with confirmation of clinical diagnosis and ascertainment of GOLD classification. Where reports were unavailable, or of questionable quality, repeat spirometry was undertaken.
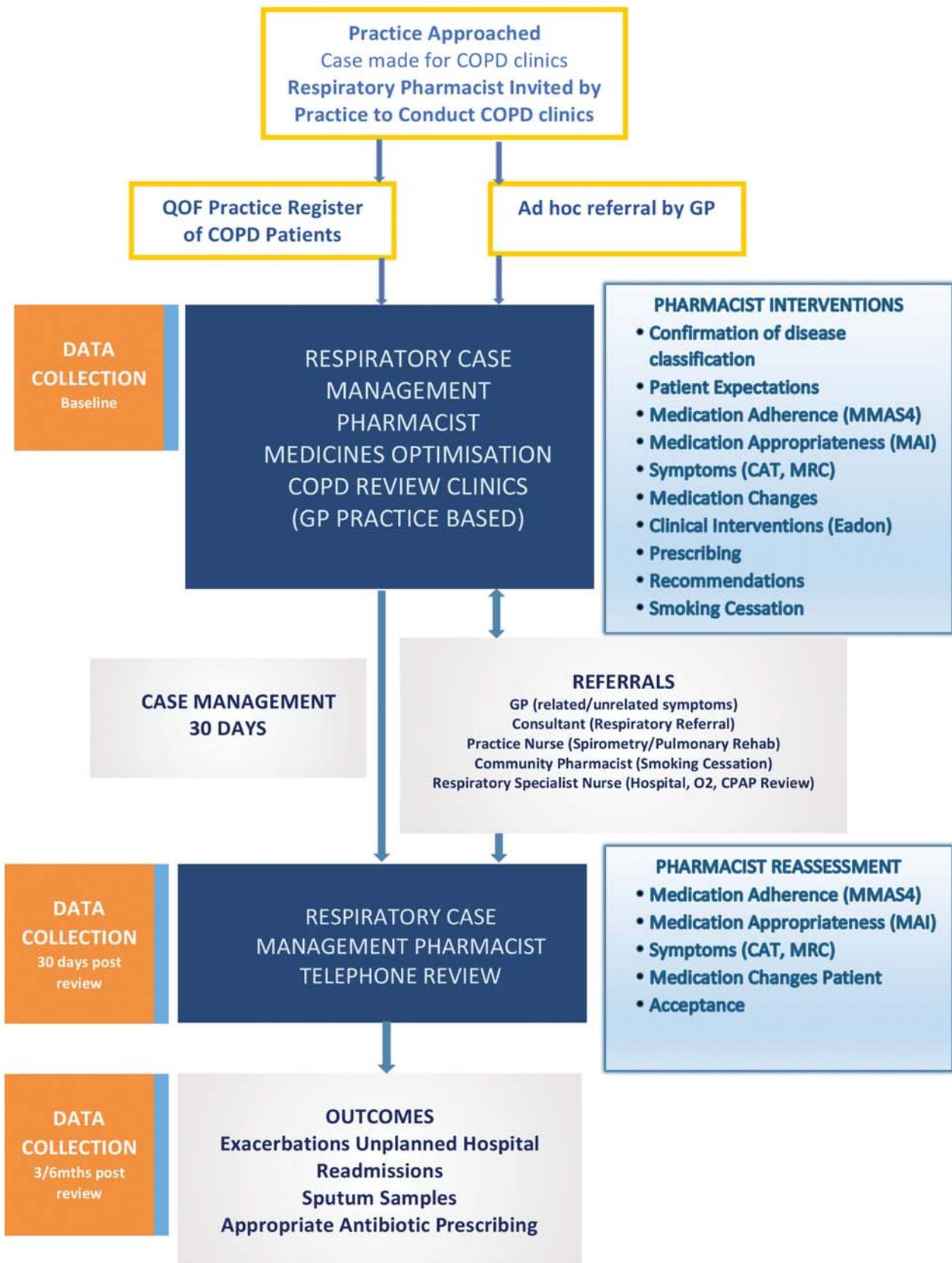
Practice Approached
Case made for COPD clinics
Respiratory Pharmacist Invited by
Practice to Conduct COPD clinics

QOF Practice Register of COPD Patients

Ad hoc referral by GP

DATA COLLECTION
Baseline

RESPIRATORY CASE MANAGEMENT PHARMACIST MEDICINES OPTIMISATION COPD REVIEW CLINICS (GP PRACTICE BASED)

PHARMACIST INTERVENTIONS
- Confirmation of disease classification
- Patient Expectations
- Medication Adherence (MMAS4)
- Medication Appropriateness (MAI)
- Symptoms (CAT, MRC)
- Medication Changes
- Clinical Interventions (Eadon)
- Prescribing
- Recommendations
- Smoking Cessation

CASE MANAGEMENT 30 DAYS

REFERRALS
GP (related/unrelated symptoms)
Consultant (Respiratory Referral)
Practice Nurse (Spirometry/Pulmonary Rehab)
Community Pharmacist (Smoking Cessation)
Respiratory Specialist Nurse (Hospital, O2, CPAP Review)

DATA COLLECTION
30 days post review

RESPIRATORY CASE MANAGEMENT PHARMACIST TELEPHONE REVIEW

PHARMACIST REASSESSMENT
- Medication Adherence (MMAS4)
- Medication Appropriateness (MAI)
- Symptoms (CAT, MRC)
- Medication Changes Patient
- Acceptance

DATA COLLECTION
3/6mths post review

OUTCOMES
Exacerbations Unplanned Hospital Readmissions
Sputum Samples
Appropriate Antibiotic Prescribing

Figure 1: New model of care for COPD patients attending a medicines optimisation GP-based clinic

Patient Experience Measurement

Evaluation of the patient experience was retrospectively considered by the team during this ongoing project. To enable measurement of this outcome, moving forward with the work, a Patient Experience Questionnaire (PEQ) was given to 30 patients not included in the original cohort between July and September 2015. This 18-item self-reported PEQ is a reliable, validated measure of patient experience suitable for measuring the outcomes from a one-to-one consultation. While it was developed for use by doctors, the questions are generic enough that it could be easily adapted to be used by other health professionals.[24]

Governance and Ethics

The proposed model and method of evaluation was assessed by the Trust research director who deemed this work to be service development and evaluation, not requiring research governance or ethical permissions.

Results

Over a period of six months, the respiratory pharmacist held clinics with 658 patients (326 male, 332 female, aged 66.1±11.0 years (range 30-92 years). Twelve patients were lost to follow-up, therefore outcome data is presented for 646 patients.

Disease Status: Gold Classification

Patients had their FEV1 recorded at baseline. Based on this, the GOLD classifications were established. Table 1 shows the results where 80.4% of patients were categorised as GOLD 1-2.

Patient History of COPD Exacerbations, Sputum Sampling and Unplanned Admissions

Almost two-thirds of patients (65.3%) had experienced one or more COPD exacerbations in the 12 months prior to clinic attendance (range 1-12).

The number of sputum samples taken over this time period ranged from 0-25 per patient (median = 1, n=95). Forty-seven patients were prescribed antibiotics in response to their sputum results with the most appropriate antibiotic being prescribed for

GOLD Classification	Number of Patients	% Patients
GOLD 1	147	22.3
GOLD 2	382	58.1
GOLD 3	109	16.6
GOLD 4	16	2.4
Not known	4	0.6
TOTAL	**658**	**100**

Table 1: GOLD classification of severity of airflow limitation at baseline of patients seen by the respiratory pharmacist
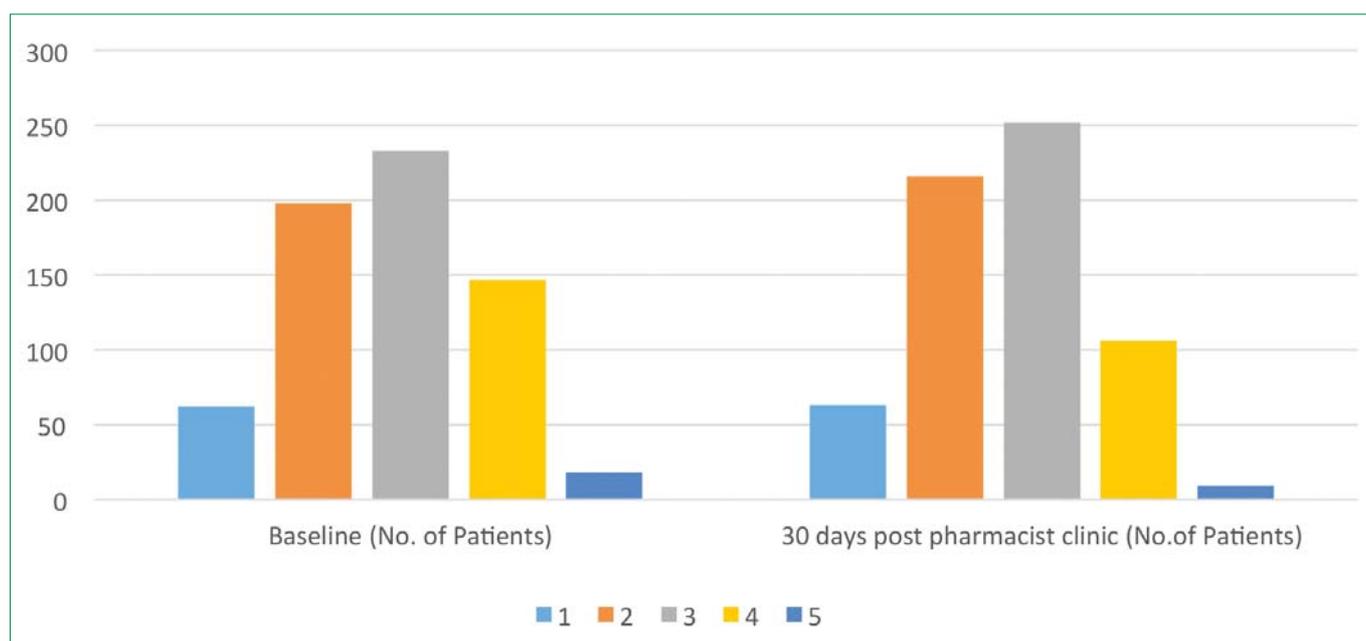
Figure 2: Change in the MRC breathlessness score at baseline and 30 days post review

78.7% of patients (n=47), thereby indicating less appropriate antibiotic prescribing for approximately one in five patients requiring treatment. Fifty-five patients (8.4%) had experienced an unplanned admission to hospital in the year prior to the clinic.

MRC Breathlessness Score

Figure 2 illustrates the statistically significant drop in MRC Breathlessness Score from baseline review, to 30 days post pharmacist review [2.8 ± 1.0 (n=658) versus 2.7 ± 0.9 (n=646), Wilcoxon Signed Rank Test, $p<0.001$)].

COPD Assessment Test (CAT score)

CAT scores at baseline were 11.0 ± 6.7 (n=658) versus 9.4 ± 5.6 (n=646) after 30 days representing a statistically significant drop (Paired sample t-test, $p<0.001$, n=646), with the average score dropping below the recommended cut point of 10. (Table 2)

Spirometry

Five patients were found to have a diagnosis of COPD with no spirometry having ever been performed. Sixty-six patients needed repeat spirometry with a further 28 requiring formal reversibility testing to confirm or rule out a concurrent diagnosis of asthma.

Smoking Status

Two hundred and sixty-nine patients (40.9%) were current smokers whilst just over half of the patients seen were former smokers (n=339); fifty patients had never smoked.

When appropriate, patients were given smoking cessation advice, with the long-term effects of continued smoking being clearly explained from a number of viewpoints (disease progression/daily symptoms/infection risk/Quality of Life). Nicotine Replacement Therapy (NRT) was prescribed by the pharmacist for patients willing to set a quit date. This was just eight patients, however all were still engaging with smoking cessation after 30 days.

Remaining patients were signposted to community pharmacy led cessation services and other community based established schemes.

Twenty-five patients explicitly declined cessation advice on the basis that they had no future intentions to stop, irrespective of all information provided.

CAT Score	Baseline (prior to pharmacist review and case management, n=658)	No. of patients (%) 30 days post pharmacist review (n=646) No. of patients (%)
<10	314 (47.7)	372 (57.6)
10 or more	344 (52.3)	274 (42.4)
Table 2: Baseline COPD Assessment Test (CAT) scores for medicines at baseline and 30 days post review and case management		

Total MAI Score for COPD medications		
Baseline (prior to pharmacist review)	Immediately post pharmacist review	30 days post review by pharmacist
7.8 ± 6 (n=658)	1.0 ± 1.9 (n=658)	0.44 ± 1.4 (n=646)
Table 3: Total MAI scores for patients prior to, immediately after and 30 days post review		

MMAS-4 Score	No. of Patients (Baseline prior to review & pharmacist interventions) (n=627)	No. of Patients (30 days post pharmacist review and case management) (n=622)
0	22	0
1	43	2
2	96	16
3	145	50
4	321	554
Table 4: Morisky Medication Adherence Scores (MMAS-4) for patients taking ≥1 COPD medications at baseline		

COPD Medicines

The number of medicines taken by patients to treat their COPD at baseline was 2.7±1.4 (range = 0-9). Immediately following review, this figure dropped to 2.5 ±1.3 (range = 0-9), a statistically significant reduction which was maintained when patients were reviewed 30 days later (p<0.001, paired samples t-test, n= 645).

Medication Appropriateness

Table 3 summarises the MAI scores for COPD medicines as determined by the pharmacist at: baseline prior to review; immediately after review; and 30 days post review and case management. Total MAI scores reduced immediately following review, with this improved upon even further 30 days post-review (Wilcoxon Signed Rank Test, p<0.001, n=646).

Medication Adherence

The move towards better adherence with COPD medicines was highly statistically significant (Wilcoxon Ranked Sign Test, p<0.001, n=622). (Table 4)

Clinical Interventions

An average of 2.85 clinical interventions was made per patient with the respiratory pharmacist self-grading 1600 interventions as Eadon grade 4 (85.3%) and 275 (17.7%) as grade 5. An example of a grade 4 and a grade 5 intervention are shown in Table 5.

Drug Cost Savings

The projected annual saving within the primary care drug budget after COPD medication review and case management by a respiratory specialist pharmacist was £244k pa, an approximate £4.14 return per £1 invested in the employment of a Band 8a pharmacist (based on an annual investment of £59k).The drug cost savings were achieved via more appropriate prescribing including a reduction in ICS/LABA dosing and general frequency, reduction and elimination of nebulised and oral bronchodilators, elimination of inhaled antimuscarinics and reduction/elimination of prophylactic antibiotics and oral steroids.

GP Referrals

Fifty-nine COPD patients were referred by the pharmacist to their GP. Thirty-four of these referrals were respiratory-related including referral to secondary care for Chest x-ray/6-min walk/overnight oximetry. The remainder had other relevant clinical issues including anxiety and pain management. Additionally, antibiotic prescribing was requested in response to pending sputum sensitivity results.

Other Referrals

Fifty-seven patients were referred to Specialist Oxygen nurses. Reasons for this included patient unsure about terms of use, therapy had originally been initiated in primary care (now restricted to specialist assessment only), not recently reviewed and uncertainty regarding genuine need. The Pulmonary Rehabilitation service was offered by the pharmacist to all eligible patients (15%). Other common referrals included those to the practice nurse for vaccines and up-to-date bloods (68 patients); these patients had originally been lost to follow-up and were now re-engaged appropriately in the healthcare system.

Patient Experience Questionnaire

All patients (n=30) surveyed reported an improved understanding of how to manage their breathing problems in the future. They felt that important decisions were made collaboratively and they had a chance to ask questions and discuss their condition and its treatment; they were now less worried, relieved and strengthened by the changes made to their treatment and the advice given to them by the respiratory pharmacist.

Six-month Outcome Data

During the six month follow-up period, 37.5% of patients had experienced an exacerbation (range = 1 to 4) with frequency of exacerbations also being reduced from the 12 months prior to review (range =1 to12). Sputum sampling was suitably ordered; in response to sensitivity results, antibiotic prescribing in line with current guidelines increased from 78.7% to 97.8%. Fifty-five patients (8.4%) had been admitted to hospital during the year prior to the review clinic. At six months follow-up, 3.2% of patients had been admitted non-electively to hospital with a COPD related diagnosis.

Stakeholder Feedback

GPs and Practice Managers from practices involved in the project have positively welcomed the pharmacist-led COPD clinics with many recommending the service to colleagues who then approached and requested the service from the Trust. Feedback received included:

Clinical Intervention	Eadon Grade
Discontinue theophylline No clinical indication: moderate breathlessness MRC 3 Not on maximal inhaled therapy and no significant inflammatory symptoms No Therapeutic Drug Monitoring (TDM) since commencing Possible drug-related side-effects: intermittent headache and nausea	4
Withdrawal of PPI and start bisphosphonate On high dose maintenance PPI for many years with no indication Frequent infective exacerbations – 7 antibiotics in past 12 months, therefore high risk of *C.difficile* 4 oral steroid courses in past 12 months, therefore risk of reduced Bone Mineral Density History of one mechanical fall with fracture	5
Table 5: Clinical intervention examples and Eadon grade	

"The GPs and practice nurses will be using your history taking and recording as an example for quite some time." (Practice Manager E-mail to pharmacist)

"…I think it has been very successful from a prescribing point of view" (GP E-mail to Respiratory Consultant)

"...patients offered very good feedback and she was an exceptionally professional lady who offered great support to our staff and nurses. Both our nurses had identified asthma and COPD as areas they would like to evolve and improve. They feel this was achieved. We look forward to improving our COPD register and improving the quality of care to our patients." (GP letter to Respiratory Consultant).

Discussion

In addition to establishing the impact of an intensive review and medicines optimisation service to COPD patients by a specialist respiratory pharmacist, with respect to many outcomes including improved medication adherence, improved appropriateness of prescribing and patient education, significant findings were also made in relation to the original disease diagnosis and subsequent treatment.

Five patients had a diagnosis of COPD without spirometry testing whilst the spirometry reports for a number of other patients had questionable interpretation; this has highlighted the issue of incorrect interpretation of spirometry tests and consequent misdiagnosis in primary care to the Trust, which is consistent with national findings.[25] A business case has therefore been established for a Respiratory Physiologist to be sent into primary care to both conduct spirometry and train practice staff to ensure enhanced quality of testing and more accurate test interpretation. Accurate spirometry testing would ultimately ensure correct diagnosis and suitable application of an appropriate level of treatment to prevent over-treatment.

The six-month follow-up data highlight significant learning by other healthcare professionals as demonstrated by the; improvement in sputum sampling and appropriate antibiotic prescribing according to primary care antimicrobial prescribing guidelines. Further learning was in relation to the correct interpretation of spirometry readings and responding to anomalies (in particular restrictive profiles), the importance of collaborative history taking to include a full review of childhood and family health status (in addition to past and present occupational risks) and application of the correct choice and level of treatment to maximise the potential for effective longer-term management and minimise associated drug-related spend. The project team originally set out to deliver a more holistic review service to COPD patients by integrating the secondary and primary care teams. In so doing, demonstrable patient and healthcare resource outcomes were achieved, thereby supporting the need to further develop, replicate and evaluate the case management approach as a future model of care.

Conclusion

The introduction of Trust outreach medicines optimisation case management clinics to GP practices has resulted in many positive outcomes, all of which sit neatly within the patient-centred ethos of integrated care and medicines optimisation, with benefits for both patients and healthcare staff working collaboratively across the healthcare delivery interfaces.

Funding

Acknowledgements

Declaration of interests

The authors of this paper have nothing to disclose.

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