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A Pharmaceutical Care Plan for the management of chronic obstructive pulmonary disease (COPD): development and validation for use in the community

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List of abbreviations

AAT	Alpha-1 antitrypsin
ACE	Angiotensin-converting enzyme
ADR	Adverse Drug reaction
BMI	Body Mass Index
BNF	British National Formulary
BODE	BMI, airflow obstruction, dyspnoea and exercise capacity
BP	Blood Pressure
CHI	Community Health Index
CI	Critical Incident
CMS	Chronic Medication Service
CO	Carbon monoxide
COPD	Chronic Obstructive Pulmonary Disease
CT	Computerised Tomography
CVD	Cardiovascular Diseases
DADS	Direct Access DXA Service
DoB	date of birth
DXA	dual energy X-ray absorptiometry
ECG	Electrocardiography
ePMS	ePharmacy Message Store
ERS	European Respiratory Society
FEV_1	forced expiratory volume in one second
FEV	forced vital capacity
FRAX	fracture risk
GFR	glomerular filtration rate
GGC	Greater Glasgow and Clyde
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GP	General medical practitioners
GPASS	General Practice Administration System for Scotland
HADS	Hospital Anxiety and Depression Scale
HbA_{1C}	Glycated hemoglobin
IC	inhaled corticosteroid
LABA	long acting $beta_2$ agonist
LAMA	long-acting muscarinic antagonist
LFT	liver function test

LTOT	long term oxygen therapy
MRC	Medical Research Council
MSR1	Macrophage scavenger receptor 1
n/a	not applicable
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NRT	Nicotine Replacement Therapy
PaO_2	partial pressure of oxygen in the arterial blood
PEFR	peak expiratory flow rate
PPSU	Pharmacy prescribing support unit
PSP	Prescribing Support Pharmacist
SABA	Short-acting $beta_2$ agonist
SAMA	Short-acting muscarinic antagonist
SaO_2	arterial oxygen saturation
SHOW	Scotland's Health on the Web
SIGN	Scottish Intercollegiate Guidelines Network
TDM	Therapeutic Drug Monitoring
T_LCO	Transfer factor for carbon monoxide
TNFα	tumor necrosis factor-alpha
UK	United Kingdom
X-ray	RadiographList of tables

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1 INTRODUCTION

1.1 Pharmaceutical care

Pharmaceutical care has been defined as 'the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life' [1]. It can be seen as a systematic approach that ensures that the patient gets the right medicines, for the right reasons, at the right time and in the right dose, so the patient's drug therapy is as safe and effective as possible. Therefore medicine-related problems such as drug interactions, receiving of wrong doses, adverse drug effects that could be avoided, and drug administration problems need to be identified, resolved and prevented. Within that concept the patient needs to be educated so they understand and get the desired outcome for each medical condition [2, 3]. 'Of all the healthcare professions, pharmacists have the widest knowledge in the science and use of medicines', but this should not lead to the false conclusion that pharmaceutical care is exclusively provided by the pharmacist [2]. 'Pharmaceutical care can be delivered in different clinical settings in different clinical cultures by different teams of pharmacists, technicians, doctors and nurses. Pharmaceutical care can therefore be understood as a quality assurance system based on improved teamwork and improved systems for providing drug treatment' [3].

Hudson et al. [3] identified current threats to the quality of medication and proposed a systematic approach in pharmaceutical care to improve it:

- 'Patients' needs for drug therapy are not always formally assessed or agreed with the patient. Medication gets prescribed to solve one problem after another. One clinician needs to take an overview, sometimes needing to rationalise certain combinations.
- The goals of medication (for example, target blood pressures) need to be made more clear to patients and all members of the health care team.

- Patient monitoring needs to be improved according to written plans.
- Documentation needs to be improved in the monitoring of long term medication and pharmacists can help to document successful achievement of target goals as they become more patient oriented.‘ [3]

Mehuys et al [4] identified four main issues of patients with COPD in primary care that could be improved: (1) Drug adherence, (2) inhalation technique, (3) smoking cessation and (4) influenza vaccination in patients younger than 65 years.

1.1.1. Pharmaceutical care planning

A pharmaceutical care plan is a tool to identify and record problems with a patient’s medicines [3] and to assure that a patient’s therapy is conform as far as possible with guidelines. It is a systematic documentation of patients’ pharmaceutical care needs and care issues, the desired outcomes and the required actions that need to be undertaken to fulfil these outcomes. *Pharmaceutical care needs* can be product or service specific. A product specific need is for example the requirement of additional medication, or another formulation of the drug. Service specific needs include the requirement for additional monitoring or counselling. Potential and actual *pharmaceutical care issues* are generated from a patient’s pharmaceutical care needs and the consideration of risk factors such as age, medical history, reduced renal clearance, polypharmacy or potential drug toxicity.

The pharmacist can identify and review both, pharmaceutical care needs and pharmaceutical care issues, by face to face dialogue with the patient and by obtaining information from previous patient records. The next step is to define the desired *outcomes* and consider *actions* that need to be taken to achieve those outcomes. The outcomes and actions have to be agreed with the patient and communicated to other involved healthcare professionals. A care plan facilitates continuity of care, enables the pharmacist to respond to changes in a patient’s needs and allows a comparison of actual outcomes

with desired outcomes. It is used as a basis for ongoing review and monitoring linked to the patient's dispense of repeat or serial prescription. An end of care treatment summary is generated from the care plan and can be used to communicate with the patient's GP about considered actions to be taken. Furthermore each patient receives a tailored action plan, containing specific advice for self management of their disease and actions they need to undertake themselves [5].

In chapter '1.2 Background information on COPD (page five)', potential care issues for patients with COPD have been identified and are summarised in a box at the end of each section.

1.1.2. Community pharmacists and pharmaceutical care

In Scotland community pharmacists are often a patients' first point of contact, or sometimes even their only regular contact with a healthcare professional [2]. The National Institute for Clinical Excellence's (NICE) COPD guidelines propose that management of COPD should be provided by a multidisciplinary team [6]. Currently, in advance of a formal role for community pharmacists, local schemes are using Prescribing Support Pharmacists (PSPs) to undertake medication review.

1.1.3. Medication review clinics

In Greater Glasgow and Clyde (GGC) the Pharmacy prescribing support Unit (PPSU) encompasses all of the staff and work in relation to medicines in a single system function. The role of NHS Greater Glasgow and Clyde PPSU is to ensure that patients derive maximum benefit and minimum harm from their pharmaceuticals and that medicines are purchased, stored and prescribed as cost effectively as possible. As members of PPSU, PSPs are running medication review services in community health centres for patients with

chronic conditions such as COPD [5]. Patients are targeted with the General Practice Administration System for Scotland (GPASS) [7].

The PSP performs a full medication review and as part of it, they arrange an appointment for a face-to-face dialogue with the patient. Once the GP approved the PSP's suggestions, submitted by referral, it is the pharmacist's responsibility to ensure that they are carried out. It has been shown by the pharmacy team at County Durham and Darlington NHS Foundation Trust that PSPs can improve clinical outcomes and quality of life outcomes for patients with COPD [8]. Also it has been demonstrated that significant cost savings can be made in this patient group [5].

1.2 Background information on COPD

1.2.1 Definition

NHS guidelines [6] define COPD as a progressive, not fully reversible airflow obstruction. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines [9] moreover associates the disease with an abnormal inflammatory response of the lungs to noxious particles or gases, predominantly tobacco smoke. Airflow limitation can be detected through measurement of the forced expiratory volume in one second (FEV_1) and the FEV_1/FEV (forced vital capacity) ratio, which both are decreased [10].

1.2.2 Epidemiology and economic impact

In 2000 more than 2.7 million people died of COPD worldwide, about 70% of them in China and India, and approximately 300,000 in Europe, North America and Australia [11]. In industrialised countries smoking of tobacco is the major risk factor for developing COPD [10]. In UK 3.7 million people are thought to be living with COPD and they are responsible for more than one million hospital bed days every year [12, 13]. A remarkable percentage of young adults (aged 20-44) already suffer from COPD, the prevalence in this age group in UK is 3.3% which is around the average of high income countries [14]. Almost 2% of the Scottish population have been diagnosed with COPD and 4500 deaths are associated with the disease each year. The incidence of COPD is expected to increase by 33% in the next 20 years [12].

1.2.3 Pathology, pathogenesis and pathophysiology

A healthy lung has reached its maximum FEV_1 value (about 3.5-5 litres/second) at the age of 20-25, thereafter a natural slow irreversible decline in lung function occurs of around 25ml/second per year in asymptomatic non-smokers. In smokers accelerated losses of 50ml/second per year or more are observed [15].

The pathological impairment of lung function is a result of different pathological mechanisms that accompany each other and occur combined in most patients, such as narrowing of small airways, emphysematous destruction of lung parenchyma, tissue remodelling, loss of lung elasticity, enlargement of mucus glands and mucus hypersecretion [16, 17]. They are caused by both innate and adaptive immune responses [10].

The physical barrier between airspace and tissue is made up with tight junctions between lung epithelial cells. The junctions are disrupted by chronic exposure to cigarette smoke and the innate immune response is activated. The response leads to phagocytosis procured by different kinds of inflammatory cells like polymorphonuclear cells, eosinophils, macrophages, natural killer cells and mast cells as well as B- and T- lymphocytes [10].

The ***innate immune response*** mechanisms include sputum, mucociliary escalator activity and cough. These mechanisms work co-operatively with the cells of the immune system to transport particles out of the lungs and maintain mucociliary clearance. Furthermore the normal host response to immigration of micro-organisms from the upper airways to the usually sterile lung is suppressed by chronic cigarette smoke exposure. Smoke exposure therefore allows microbes to invade tissue and cause infections [10].

The ***adaptive immune response*** takes place inside the lung, either after the antigen has been transported through the intact epithelium by specialised, so called M-cells or after penetration through injured epithelium. Dendritic cells transport antigens into bronchial associated lymphatic tissue and regional lymph nodes, where antigen presentation takes place. T- and B-lymphocytes are involved and as a result, antibody-producing cells as well as memory cells are built. Cytokines like e.g. tumor necrosis factor-alpha (TNFα) and interleukin 1β regulate innate and adaptive immune responses and play a major role in fever induction [10].

Infections of the lower respiratory tract

Through chronic exposure to particles and gases the immune response manifests, the chronic inflammation of central airway's epithelium results in increased cough and sputum production and finally leads to the disruption of the epithelial barrier which causes loss of bacterial sterility. Smoking is known to increase the amount of leucocytes in lung capillaries due to different mechanisms, like stimulation of bone marrow or capillary compression [10].

Lower respiratory illness occurs more frequently, and the FEV_1 loss is significantly greater, in COPD patients who are smokers compared to quitters [18]. This outcome is supported by reports that have shown that the presence of B- and T- Lymphocytes in the airways tissue (especially in the bronchial associated lymphatic tissue) results in a decrease in FEV_1 [10].

The bronchial associated lymphatic tissue seems to play a major role. In smokers and COPD patients its size is depending on the disease's severity, on the contrary in healthy non-smoker almost none of this tissue can be found [10].

Small airways obstruction

Airways lumen calibre is decreased by accumulation of mucus in the small, peripheral airways, swelling of airway walls due to immigration of cells into the sub epithelial bronchial associated lymphatic tissue and smooth-muscle contraction. Furthermore lumen volume and enlargement during lung inflation are restricted by peribronchiolar fibrosis, which is a deposition of connective tissue in the adventitial compartment. Additionally number and strength of alveoli attachment to the airway's outer walls declines, which leads to a higher FEV_1 loss [10].

Emphysema

Emphysema is a progression of COPD from the over-distension of the lung's air cells with partial destruction of their walls. The rupture and fusion of contiguous air-vesicles results in the formation of large sacs and subsequent reduced maximum expiratory flow due to limitation of the elastic recoil force

that is used for driving the air out of the lungs and holds the airways open in expiration [19]. The centrilobular form of emphysema is mostly found in the upper lobes of the lung while the panacinar form affects mainly the lower lobes. The centrilobular form goes along with more severe small-airway obstruction and its appearance correlates with the total overall exposure in pack-years to cigarette smoking, although only 40% of even heavy smokers develop substantial lung destruction [10].

In many cases a high amount of lung capacity has been lost decades before symptoms like breathlessness appear. The detailed correlation between FEV_1 and occurrence of symptoms in natural history remains unclear [15].

1.2.4 Risk factors

1.2.4.1 Toxic gases and particles

The total burden of toxic gases and particles that individuals inhale during their lifetime correlates with the diagnosis of COPD. In tobacco smokers the number of pack years is closely related to a decline in FEV_1 [20]. Pack years are defined as the number of cigarette smoked per day, divided by 20, multiplied by the years of consumption [6].

In industrialised countries smoking of tobacco is the major risk factor for developing COPD [10]. The smoking rate in Scotland was 27.2% in 2007 [21]. Prevalence rates of COPD in USA population aged >45 are about 35% in smokers and 22% in former smokers compared to 8% in non-smokers [22]. A study from Sweden reported that approximately fifty percent of elderly smokers develop COPD [23]. Around 25-45% of patients with COPD have never been smokers [24].

In cannabis consumers smoking of one joint has the equal effect on airflow obstruction as 2.5-5 tobacco cigarettes. While in the study by Aldington et al. microemphysema was diagnosed in 18.9% of users of combined cannabis

and tobacco but only in 1.3% of users of cannabis alone. Decreased lung density was found in high-resolution computer tomography scans of cannabis smokers [25].

Non smoking causes may be prevalent in some developing countries where there is higher exposure to smoke from coal and biomass fuel, which is generated through cooking and home heating. Some 4-5% of worldwide mortality (1.5 million - 2 million deaths in 2000) can be attributed to indoor air pollution. Approximately half of these deaths are caused by acute lower respiratory infections in childhood and a dominant part of the rest is associated with COPD, followed by lung cancer in adult women [26].

Outdoor pollution is known to cause a range of health problems, including a raise in cardiopulmonary deaths and higher incidence of different pulmonary diseases. Urban ambient air has been associated with increased prevalence of COPD and worsening of existing COPD. Children growing up close to a motorway have a lower rate of growth in FEV_1, resulting in impaired lung function as adults [27]. One study showed that the prevalence of COPD in UK postmen from higher polluted areas was higher than those in cities with lower pollution. There is a range of other occupations containing an elevated risk for developing COPD through exposure to toxic gases, dust or fumes in workplaces like farms, factories, mines and construction sites. Some 318 000 deaths worldwide from COPD were associated to occupational exposure in 2000 [24].

Pharmaceutical care issues:

- Record smoking status
- Ask patient about dust or fume exposure
- Calculate pack years

1.2.4.2 Prenatal and childhood events

Premature birth is related with respiratory illness in childhood and birth weight correlates with lung function [28]. Smoking during pregnancy, maternal hypertension and a family history of asthma lead to reduced respiratory function in offspring directly after birth, which is related to wheezing illness and asthma, but the potential association with the development of COPD remains unclear [29]. The occurrence of chronic bronchitis or pneumonia in young children results in a reduced maximal attained lung function in adulthood [30] but childhood respiratory illness does not increase the decline in FEV_1 and FVC later in life [31].

Maternal smoking during pregnancy and in childhood affects the offspring in several different ways: It lowers their lung volume independently from own smoking and if children of smoking mothers take up smoking themselves in adulthood their smoking intensity is higher and they are more unlikely to quit smoking. Personal and maternal smoking increase airflow limitation [32].

1.2.4.3 Genetic factors

Alpha-1 antitrypsin (AAT) deficiency

Severe alpha-1 antitrypsin (AAT) deficiency is a well known genetic predisposition for COPD, although only about 1-2% of COPD patients inherit the mutation in the PI Z allele which is the most common deficient variant and accountable for the majority of AAT deficiencies [33]. The SZ and ZZ genotype in the α1-antitrypsin gene are early disease markers for COPD and could be used as biomarkers [34]. AAT is synthesised in the liver and belongs to the serine protease inhibitor superfamily. It protects the lungs against the elastolytic damage which is mediated by neutrophile elastase. Prevalence of neutrophile elastase leads to increased proteolytic activity and therefore to emphysema. Moreover AAT deficiency is associated with further disorders

such as liver and skin diseases or Wegener's granulomatosis. The disorder is autosomal co-dominant inherited and occurs in 1 of 2000-5000 humans [35].

Most likely there are further genetic determinants, like e.g. variations in the Macrophage scavenger receptor 1 (MSR1) gene [36] that influence the susceptibility to develop COPD but further studies need to be performed to support these hypotheses.

Pharmaceutical care issues:

- Record if patient has a diagnosis of AAT-deficiency
- Patients with a family history of AAT-deficiency or with young onset (aged <40 years) of COPD should be referred to a specialist

1.2.4.4 Socioeconomic status

A low socioeconomic status is an independent risk factor for COPD. Reasons therefore might be housing conditions, intra-uterine growth retardation and poor nutrition [24].

1.2.5 Impact of gender

In the EU in average 35% of man smoke compared to 22% of women, and two to three times more males die of COPD than females [37]. On the other hand it has been proven that female smokers have a faster decrease of FEV_1 [38] and their level of dyspnoea is higher than in males [39]. Especially the field of pharmaceutical care is affected by gender related differences: Female patients have a lower health related quality of life score [40], one of the reasons therefore is that anxiety and depressive symptoms appear more often in them [39] and moreover it has been shown that male COPD patients have a significantly higher benefit from exercise therapy on health-related quality of life [41]. In one comparison of patients women performed poorer in walking

distance, even though they had the same FEV_1, better oxygenation, better $PaCO_2$ and fewer co-morbidities [42]. Gender related differences regarding both the burden of disease and the response to its therapy should be kept in mind when designing treatment strategies for COPD patients.

Pharmaceutical care issues:

- Record patient's sex

1.2.6 Diagnosing

The rate of undiagnosed COPD is rarely measured, but it could be as high as 12% [43]. Approximately 20% of smokers over the age of 40 have undiagnosed COPD, and every third patient older than 40 years diagnosed with asthma actually has COPD instead [44].

1.2.6.1 Symptomatic diagnosis

Patients often accept their symptoms as a consequence of smoking or a part of ageing, which makes them less likely to report their symptoms [45]. In the UK NICE guidelines recommend that in patients older than 35 who show symptoms like breathlessness, cough, wheeze, frequent respiratory tract infections or regular sputum production and have risk factors like smoking, spirometry should be performed to substantiate a potential diagnosis of COPD. Weight loss, effort intolerance, waking at night, ankle swelling, fatigue or existing occupational hazards can support the suspicion. While if chest pain or haemoptysis occur another diagnosis should be considered [6].

NICE guidelines recommend the use of the Medical Research Council (MRC) dyspnoea scale to assess the breathlessness.

Table 1: MRC dyspnoea scale [6]

Grade	*Degree of breathlessness related to activities*
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying or walking up a slight hill
3	Walks slower than contemporaries on level ground because of breathlessness, or has to stop for breath when walking at own place
4	Stops for breath after walking about 100m or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing or undressing

In most cases these symptoms appear many years after the presence of the structural and functional changes described in chapter 1.2.3 (page five) [15].

Pharmaceutical care issues:

- Assess MRC grade
- If unexpected clinical worsening occurs, the patient should be referred to a specialist

1.2.6.2 Spirometry and classification of severity

Spirometry is a safe, uncomplicated, economical and non-invasive method to scan reliably for airflow obstruction. In UK it can be performed by any trained health care worker. The most important obtained values for diagnosing COPD are FVC and FEV_1 [6, 44].

Forced vital capacity (FVC) is defined as the volume of gas that can be exhaled during a forced expiration starting from maximal inspiration and ending at complete expiration. A loss of 500ml or more within 5 years is defined as rapid progress of the disease. These patients should be referred to a specialist. The timed forced expiratory volume (FEV_1) is defined as the

volume of gas that can be exhaled within the first second of the forced vital capacity manoeuvre. The European Respiratory Societies (ERS) reference values for FEV_1 are used to calculate the grade of severity of airflow obstruction. Spirometry is performed after application of a bronchodilator [6, 46].

Table 2: ERS equations for predicting FEV_1 [46]

Gender	*Predicted FEV_1*
Male	4.30 · height (m) - 0.029 · age (years) - 2.49
Female	3.95 · height (m) - 0.025 · age (years) - 2.60

Table 3: NICE classification of severity of airflow obstruction [6]

Severity	
mild	$FEV_1/FVC < 0.70$ $FEV_1 \geq 80\%$ predicted
moderate	$FEV_1/FVC < 0.70$ $50\% \leq FEV_1 < 80\%$ predicted
severe	$FEV_1/FVC < 0.70$ $30\% \leq FEV_1 < 50\%$ predicted
very severe	$FEV_1/FVC < 0.70$ $FEV_1 < 30\%$ predicted or $FEV_1 < 50\%$ predicted plus respiratory failure

As there is a high rate of under diagnosed and misdiagnosed COPD some study authors suggest that spirometry screening should broadly be performed in high-risk populations. Spirometry allows an early detection, even of preclinical conditions and enables an efficient disease management and early smoking cessation and consequently a possible reduction of accelerated losses in FEV_1 [44, 43, 45]. It has been shown that by confronting smokers with the results of spirometry in form of their ‘lung age’ (the average age of a healthy lung with the same performance in spirometry) they are more likely to quit smoking [47].

Peak expiratory flow rate

Another approach for detecting COPD is by using the peak expiratory flow rate (PEFR). PEFR is defined as the maximal flow during a forced expiratory vital capacity manoeuvre starting from full inspiration. It is widely used and most general practitioners are more familiar with this measurement than with the more complex spirometry tests. In an analyses of data from the third national health and nutrition survey 90% of patients with COPD could be identified by having a PEFR smaller than 80% [46, 48].

Reversibility testing

The measurement of changes in FEV_1 after application of an inhaled bronchodilator used to be a common method for diagnosing COPD and distinguish it from asthma. But the results of such an assessment are not reproducible in one patient and hardly comparable between patients [49]. The previous belief that airways obstruction in COPD is largely irreversible has been challenged due to new study results. In the UPLIFT trial a majority of patients showed significant improvement in FEV_1 in response to bronchodilator application [50]. Furthermore there is evidence that a single dose of a bronchodilator cannot predict the response to long term treatment, as it was primarily thought [49]. However reversibility testing is recommended by NICE and GGC guidelines to distinguish COPD from asthma as described in chapter 1.2.6.4 (page 17).

Pharmaceutical care issues:

- Record spirometry results
- Classify severity by spirometry results according to NICE
- Record reversibility testing results

1.2.6.3 Further investigations

Disability in COPD can not only be assessed by airway obstruction, also factors like frequency of exacerbations, general health status and exercise capacity are important factors. Additional investigations recommended by NICE guidelines [6] include a chest radiograph (chest X-ray), a full blood count and the calculation of body mass index (BMI) in addition to spirometry for every patient. If there is an early onset, a minimal smoking history or a family history, scanning for AAT deficiency should be performed. If symptoms disproportionate to the spirometric impairment occur, a computerised tomography (CT) scan of the thorax should be performed and the transfer factor for carbon monoxide (T_LCO) should be investigated.

Electrocardiography (ECG), pulse oximetry and echocardiogram should be performed to assess cardiac status in patients with cor pulmonale. If purulent sputum is persistently present a sputum sample should be cultured [6]. In patients who are considered for oxygen therapy pulse oximetry is a non-invasive method to measure the arterial oxygen saturation (SaO_2) without taking a blood sample by measuring the characteristic light absorption of saturated haemoglobin. An arterial blood gas analysis is used to determine amongst others the partial pressure of oxygen in the arterial blood (PaO_2) [6, 51]. The BMI, airflow obstruction, dyspnoea and exercise capacity (BODE) index can be calculated by summing up achieved points for BMI, FEV_1, degree of breathlessness according to MRC dyspnoea scale and covered meters in a 6-minute walk test. The BODE index allows an assessment of the prognosis: the higher the BODE score, the higher the COPD mortality [6, 52].

Pharmaceutical care issues:

- Record chest X-ray results
- Record weight, height and BMI
- Record CT scan
- Calculate BODE index

1.2.6.4 Differential diagnosis

In young people with symptoms of COPD and a FEV_1/FVC ratio greater than 0.7 or older people without symptoms of COPD but a FEV_1/FVC ratio smaller than 0.7 an alternative diagnosis should be considered [6]. One very common misdiagnosis is asthma [44]. In many cases asthma can be distinguished from COPD by clinical features and history. Many COPD patients are smokers or ex-smokers. COPD is associated with chronic productive cough and persistent and progressive breathlessness while in asthma cough is uncommon and breathlessness varies and is often present during night time. In asthma symptoms occur frequently under the age of 35 and show significant diurnal or day to day variability, while in COPD there is a later onset and variability is uncommon. If uncertainty remains, performance of reversibility testing, imaging and serial domiciliary peak measurements as well as the investigation of the transfer factor for carbon monoxide can help to resolve cases [6]. According to Glasgow NHS (GGC) Guidelines a response in FEV_1 greater than 15% to inhaled corticosteroids or bronchodilators suggests asthma [7], NICE guidelines define a greater than 400ml response to a bronchodilator as identification criteria for asthma [6].

Pharmaceutical care issues:

- If respiratory diagnosis is unclear patient should be referred for clarification

1.2.7 Management of stable COPD

According to NICE guidelines management of stable COPD should be provided by a multidisciplinary team [6].

1.2.7.1 Smoking cessation

Both, NICE and GOLD guidelines strongly recommend the reduction of risk factors, and thus smoking cessation, as the first intervention. Help to stop

smoking should be offered by health care professional at every opportunity. Stopping smoking slows down the progression of symptoms and the rate of decline in FEV_1 [6, 9]. Community pharmacies on the NHS run a smoking cessation programme within they provide patients with advice and Nicotine Replacement Therapy (NRT) supplies [2]. NHS Health Scotland and the Scottish Government published a booklet for smokers who are thinking about stopping smoking. '*How to stop smoking and stay stopped*' recommends a careful preparation before the actual Stopping. Preparation starts with making a list of reasons for stopping, and only if the person is sure that they really want to quit, they should continue with making an action plan. The first point of this plan is to set a stopping date. Smoking should be stopped completely instead of a gradually reduction. As part of the action plan, the patient decides weather they want to use stop smoking medication and if a support programme (e.g. from a NHS Board specialist or the NHS Health Scotland's telephone service 'smokeline' or its website 'www.canstopsmoking.com') should be used, which both are highly recommended because they increase the success rate. Furthermore the booklet contains hints on how to cope with withdrawal symptoms and stress, informs about problems that can occur during the first months and explains how to avoid weight gain. Also an overview about pharmacological treatment is provided. [53]

According to NICE guidelines the smoking history should be documented for every patient with COPD [6]. After an unsuccessful attempt to quit smoking, no further attempts should be made within 3 months. It is important to be supportive and help the patient understand the reasons for the rebound [37].

Carbon monoxide (CO) measurements and spirometry

The CO concentration in a smoker's breath is about 10 times higher than in a non-smoker. Within 1-2 days after the last cigarette the CO level returns to normal, which is very rewarding for the person to see. Confronting a subject with the results of spirometry demonstrating their impaired lung function can increase their motivation to quit [37, 47].

Psychological and behavioural interventions

All three Individual, group and telephone counselling are more effective than no intervention. The success rate can be increased by arranging scheduled visits after the quit day with a health care provider. Up to eight follow-up meetings after 1, 2, 4 and 8 weeks and 3, 6 and 12 months are recommended [37].

Pharmacological treatment

The odds ratio for smoking cessation under NRT was 1.8 compared to placebo. The combination of a patch combined with another NRT formulation is more effective than monotherapy. The antidepressant bupropion is effective in people who are motivated to stop and who smoke more than 10 cigarettes per day [37]. More than twice as much patients stop smoking when following bupropion therapy than with placebo. NICE guidelines recommend bupropion, varenicline or NRT combined with a support programme for COPD patients [6].

The new drug varenicline is a partial agonist of the α4β2 subtype of the neuronal nicotinic receptors. It reduces the withdrawal symptoms, the urge to smoke and also the satisfaction from smoking, but there might be psychiatric adverse effects. In Phase III studies around 50% of patients following varenicline therapy were continuously abstinent for the 12-week period of the trial, compared to around 30% of patients who received bupropion [54]. The weight-loss drug rimonabant is another new promising approach. It may influence the effects of nicotine on neural pathways within the brain. In animal experiments it has been shown that the self-administration of nicotine was decreased by blockade of the cannabinoid CB_1 receptor with rimonabant [37].

Another interesting approach is the development of nicotine vaccination. The active immunisation with a conjugated nicotine derivative results in an increased production of antibodies against nicotine. In animal experiments the brain nicotine concentration was reduced by 36%, while the plasma concentration rose 3- to 6-fold, when nicotine was administered in vaccinated

rats [55]. Studies in humans showed that not all smokers achieve high antibody levels, but in those who do, significantly higher continuous abstinence is found, but further studies need to be done [56].

Pharmaceutical care issues:

- Record number of previous smoking quit attempts
- Offer entry to cessation program to smokers

1.2.7.2 Pharmacotherapy of COPD

Guidelines recommend inhaled bronchodilators, theophylline and corticosteroids. Antitussive therapy should not be used while mucolytic therapy should be considered in patients with chronic sputum production. Prophylactic antibiotic therapy is not recommended. Pneumococcal and annual influenza vaccination reduce hospitalization rate and pneumonia vaccination reduces all cause mortality and are therefore recommended [6]. Existing medications can reduce symptoms and the severity and frequency of exacerbations but none of them can slow down the diseases progress expressed by the decline in lung function [9].

Delivery systems

Bronchodilator therapy is best administered using a hand-held inhaler device. Patient training and assessment of satisfactory technique is necessary and if appropriate a spacer device can be used. Spacers should not be cleaned more often than once a month because of static that can be built up and affects the performance. Nebulisers are meant for patients on maximal therapy who are still breathless. Its effectiveness and the patient's ability to use it should be assessed and servicing needs to be provided [6].

1.2.7.2.1 Inhaled bronchodilators

Inhaled agents are preferred to oral because they cause less systemic side effects. Two classes of drugs, beta$_2$-agonists and muscarinic antagonists are available. They can be sub-divided into short- and long- acting. Also combinations of different drug classes are used. Beta$_2$-agonists cause bronchodilatation and reduce static and dynamic hyperinflation by acting directly on bronchial smooth muscle, while muscarinic antagonists achieve these effects by inhibiting bronchoconstrictor effects. Their application does not necessarily result in an elevated FEV_1, even though clinical benefits like improvement in symptoms, elevated exercise capacity, faster symptom relief or improved activities of daily living can be seen. [6].

Short-acting bronchodilators

Short-acting bronchodilators are recommended for initial use in mild cases and as rescue medication. They can reduce breathlessness and exercise limitation. *Short-acting beta$_2$ agonists* (SABAs) like fenoterol, salbutamol and terbutaline last for about 6 hours. The duration of action of *short-acting* muscarinic antagonists (SAMAs) ipatropium bromide and oxitropium bromide is up to 9 hours. As mucus secretion is mediated by muscarinic receptors as well, muscarinic antagonist might have further beneficial effects [6, 9].

Long-acting bronchodilators

The long acting beta$_2$ agonists (LABAs) formoterol and salmeterol act for around 12 hours. Tiotropium is currently the only long-acting muscarinic antagonist (LAMA) with duration of action of more than 24 hours, so it only needs to be given once daily [6, 9].

Beta$_2$ agonists have to be used with caution in patients with cardiac problems or diabetes (see chapter 1.2.10, page 30). Hyperkalaemia may be caused by

beta$_2$ agonist, therefore plasma-potassium concentrations should be monitored [57].

Pharmaceutical care issues:

- Monitor blood glucose level
- Monitor plasma-electrolyte concentrations

1.2.7.2.2 Theophylline

A slow-release formulation of theophylline can be prescribed in patients who are unable to inhale bronchodilators, after a trial of short- and long-acting bronchodilators or in addition to bronchodilators if the patient is still symptomatic. Plasma levels must be monitored and interactions with some drugs, like e.g. fluroquinolone or macrolide antibiotics are known. Especially in elderly patients theophylline is associated with a higher risk because of the increased likelihood of co-mobidities and different pharmacokinetics [6].

Pharmaceutical care issues:

- Use of theophylline should be verified and patient should be on therapeutic drug monitoring (TDM)

1.2.7.2.3 Corticosteroids

The aim of corticosteroid therapy is to reduce exacerbation rates rather than improving lung function [6, 58], but their effect has been considered as controversial as the COPD inflammation might be resistant to the anti-inflammatory effects of corticosteroids due to increased acetylation of the glucocorticoid receptor [59]. Patients on high-dose inhaled corticosteroids or long term oral corticosteroid therapy have an increased risk of developing osteoporosis [6]. The NHS GGC's 'Direct Access DXA Service' (DADS) provides assessment of fracture risk (FRAX) including assessment for osteoporosis and performance of a dual energy X-ray absorptiometry (DXA

scan) to measure bone mineral density [7]. Further adverse events associated with corticosteroids are non-fatal pneumonia, cataracts, ocular hypertension and open-angle glaucoma [60].

Inhaled corticosteroids (ICs)

The use of inhaled corticosteroids alone is not licensed for the treatment of COPD in UK [6]. Beclomethasone, budesonide, fluticasone and triamcinolone are commonly used inhaled corticosteroids [9]. The combination with a long-acting $beta_2$ agonist in one inhaler is recommended [6, 58]. Formoterol plus budesonide and salmeterol plus fluticasone are available as a combination in one inhaler [9]. As corticosteroid treatment is a risk factor for osteoporosis, patients who receive 1000mcg beclomethasone (or equivalent) and have further risk factors should be considered for osteoporosis screening by DADS [7].

Oral corticosteroids

Maintenance use of oral corticosteroid therapy in stable COPD is not normally recommended, but might be required in patients in the severe stage of the disease when it can not be withdrawn after an exacerbation [6]. Commonly used drugs are prednisone and methylprenisolone [9]. The dose should be kept as low as possible. Patients on oral steroids should be monitored for the development of osteoporosis and given prophylaxis. Patients on 5mg/day prednisolone (or equivalent) for longer than three months should be referred to DADS. Patients older than 65 years should be on prophylactic osteoporosis treatment without monitoring. [6]

1.2.7.2.4 Combined therapy

NICE guidelines [6] recommend a combined therapy in patients who remain symptomatic on short acting bronchodilator. If FEV_1 is greater than 50% predicted, either LAMA or LABA should be added, if FEV_1 is smaller than 50% predicted either a combined inhaler of LABA and IC (‘{LABA+IC}’) or LABA

and LAMA should be added, in case IC are n/a. In patients on regular SAMA four times a day SAMA should be replaced with LAMA. In patients who remain breathlessness or have exacerbations with an FEV_1 greater than 50% {LABA+IC}, or LAMA in addition to LABA where IC is not applicable, should be considered. In all patients who still remain symptomatic a combination of {LABA+IC} and LAMA should be prescribed.

Table 4: Medication scheme generated from NICE Guidelines [6]:

<table>
<tr><th colspan="4">SABA or SAMA</th></tr>
<tr><th colspan="2">$FEV_1 \geq 50\%$</th><th colspan="2">$FEV_1 < 50\%$</th></tr>
<tr><td>LABA</td><td>LAMA</td><td>• {LABA+IC} or
• LABA+LAMA (if IC n/a)</td><td>LAMA</td></tr>
<tr><td>• {LABA+IC} or
• LABA+LAMA (if IC n/a)</td><td rowspan="2">LAMA + {LABA+IC}</td><td rowspan="2">LAMA + {LABA+IC}</td><td rowspan="2">LAMA + {LABA+IC}</td></tr>
<tr><td>LAMA + {LABA+IC}</td></tr>
<tr><td colspan="4">Additional:
• Oral Steroid
• Theophylline
• Mucolytic (carbocistein)</td></tr>
</table>

Pharmaceutical care issues:

- Check if NICE therapy schema applies, and if it doesn't record reasons for exclusion of certain drugs
- If patient's symptom control is inadequate, more medication should be added
- Patients on regular SAMA ≥ 4/d should be switched to LAMA
- Verify choice of delivery system
- Assess if nebuliser therapy or spacer is applicable
- Assess patient's inhaler and/or nebuliser technique
- Patients with chronic sputum production should be on carbocistein

- Record pneumonia and influenza vaccination status
- Record DXA scans
- Discuss possible adverse effects from steroids with the patient
- Patients on high dose inhaled steroids (≥1000 mcg beclometasone or equivalent) and have further risk factors for osteoporosis should be referred to DADS
- Patients on ≥ 5mg/day prednisolone (or equivalent) for longer than three months should be referred to DADS.
- Patients older than 65 on oral Steroids should be on prophylactic osteoporosis treatment, without monitoring
- Check for unmet preventive medication (CV risk, osteoporosis, vaccinations)

1.2.7.3 Oxygen therapy

Long term oxygen therapy (LTOT)

The need for LTOT should be assessed by blood gas analyses and pulse oximetry in COPD patients with moderate and severe airflow obstruction (FEV_1 < 49%), polycythaemia, a raised jugular venous pressure, cyanosis, oxygen saturation less than 92% breathing air or peripheral oedema. LTOT is indicated in stable COPD patients with PaO_2 less than 7.3 kPa or less than 8 kPa if there is nocturnal hypoxemia (SaO_2 < 90% for more than 30% of time), peripheral oedema, secondary polycythaemia or pulmonary hypertension. Inappropriate use of oxygen therapy can cause respiratory depression. Patients should be warned about the risks of fire and explosion if they continue smoking. Patients who apply for LTOT should breathe the supplemental oxygen as much as possible, 20 hours per day showed greater benefits than 15 hours [6].

Pharmaceutical care issues:

- Record LTOT assessments (including PaO_2 and SaO_2)

- Assess if patients not on LTOT should be referred for LTOT assessment
- Assess if LTOT is used a sufficient amount of hours (>15) per day

1.2.7.4 Further interventions

Physiotherapy

Patients with excessive sputum production should be taught the use of positive expiratory pressure masks and active cycle of breathing techniques [6]. Pulmonary rehabilitation is an individually tailored care programme for COPD patients to optimize the patient's autonomy and social and physical performance delivered by a multidisciplinary team. The programme contains physical training, disease education and nutritional, behavioural and psychological intervention. All patients with a MRC grade greater than two should attend pulmonary rehabilitation, however if the patient is unable to walk or has unstable angina or has had a recent myocardial infarction the programme is not suitable. [6, 7]

Nutritional factors

The normal range of BMI is between 20 and 25. As COPD patients with a low body mass index have poorer prognosis and higher mortality, referral to dietetic advice and nutritional supplements combined with exercise encouragement might be necessary [6, 61].

Lung surgery

In patients with a single large bulla a bullectomy, in patients with upper lobe predominant emphysema a lunge volume reduction should be considered. Patients with homogeneously distributed emphysema can benefit from lung transplantation [6].

Patient education

NICE guidelines [6] recommend a comprehensive education for each patient, including topics like:

- Smoking cessation
- Education about COPD (anatomy, pathology and pharmacology, oxygen therapy and vaccinations)
- Anxiety management
- Symptom and dyspnoea management, including relaxation and chest clearance techniques
- Exacerbation management (including when to seek help, self-management and decision making, coping with setbacks and relapses)
- Nutritional advice
- Identifying and changing beliefs about exercise and health related behaviours
- List of local support groups
- Information about social services like home care support

Palliative care

In patients with end-stage COPD which is unresponsive to medical therapy opioids, benzodiazepines, major tranquillisers, tricyclic antidepressants and oxygen can be used to palliate breathlessness [6].

Social services

The need for occupational therapy should be assessed by asking the patient about their ability to undertake activities of daily living. Patients disabled by COPD should be referred to home care support service [6].

Pharmaceutical care issues:

- Record if patient is pregnant
- Record previous attendance in pulmonary rehabilitation or any other secondary care services
- Patients with MRC≥3 should be referred for pulmonary rehabilitation
- Patients with abnormal BMI should be referred for dietetic

advice/nutrition support; If BMI is low give nutritional supplements

- Record if patient had lung surgery
- Find out about patient knowledge about COPD and educate if necessary
- Patients with clinical failure after all treatment options should be referred to a specialist to assess the need for palliative care
- Record patient's social circumstances (patient: Lives alone, is housebound, has professional carer, is in family care)
- Patients who are not coping at home should be referred for home care support

1.2.8 Management of exacerbations

An exacerbation is defined as a sustained worsening of the patient's symptoms from their usual stable state which is beyond normal day-to-day variations, sustains for at least a day, and is acute in onset. Cough, worsening breathlessness, increased sputum production and change in sputum colour are commonly reported symptoms. The diagnosis of an exacerbation is made clinically and does not depend on the results of investigations [6]. Treatment includes the step up of current SABA and adding of 30mg/day prednisolone for 7-14 days. In case of purulent sputum the antibiotics amoxicillin or clarithromycin are initiated [7]. In severe cases additional intravenous theophylline and oxygen therapy are necessary. In patient requiring frequent courses of oral corticosteroids osteoporosis prophylaxis should be considered [6].

Self management

Patients at risk of exacerbations should be given a course of oral corticosteroids and antibiotics to response promptly to symptoms of an exacerbation by self-initiation. A self management plan should be tailored for these patients [6].

Pharmaceutical care issues:

- Record if patient is on disease self-management plan
- Assess if patient on self-management plan requires support or revision
- Record number of exacerbations requiring antibiotics or oral corticosteroids in past year

1.2.9 Emerging therapy

Improvement of long acting inhaled bronchodilators

Researchers are currently working on the improvement of long acting inhaled bronchodilators. The new β_2-agonists carmoterol and indacaterol and the long-acting inhaled muscarinic antagonists aclidinium bromide and glycopyrrolate have to be applicated once daily only. New combinations of β_2 agonists and muscarinic antagonists are in development, as well as single molecules that link a beta agonist with a muscarinic antagonist. [59]

Antibodies and inhibitors

While trials with blocking of inflammation mediators like leukotrien or TNFα have not been very promising, antibodies against chemokines involved in the inflammation process like CXC ligand 8 as well as blocking of their receptors have shown inhibition of lung inflammation. Another new promising approach is anti-inflammatory treatment with inhibitors of the enzymes Nuclear Factor κB, phosphodiesterase 4, phosphoinositide-3-kinase-γ and p38 mitogenactivated protein kinase but their clinical practice might be limited by side effects. [59]

Vitamin D and respiratory health

In a recent UK study it has been observed recently that the vitamin D status in winter of patients with COPD is below the average. It has been shown that vitamin D can inhibit TNF-α and enhance IL-10 in immune cells from healthy

individuals, the potentially beneficial effects of 1, 25$(OH)_2D_3$ on the function of airway epithelial cells are currently explored. [62]

Reversing corticosteroid resistance

As the inflammation in COPD patient's lungs might be corticosteroid resistant, the probably most promising finding is the reversing of this resistance by increasing histone deacetylase-2 activity through theophylline-like drugs, nonantibiotic macrolide agents and more effective antioxidants. [59]

1.2.10 Co-morbidities

The diagnosis of COPD is associated with multiple co-morbidities and almost 70% of patients report the appearance of at least one [27]. According to data from the UK General Practice Research Database the most common within the first year after COPD diagnosis are angina occurring in 4% of incident COPD patients followed by cataracts, bone fractures, osteoporosis, pneumonia and respiratory infections. There is vastly increased risk for the occurrence of various illnesses compared to non COPD patients. Relative risk values are: 16.0 for pneumonia, 3.1 for osteoporosis, 2.2 for respiratory infection, 1.7 for myocardial infarction, 1.7 for angina, 1.6 for fractures and 1.3 for glaucoma [63]. Beside respiratory failure the two major causes of death of patients with end-stage COPD are lung cancer and cardiovascular diseases. The mechanisms for developing each of these conditions seem to be linked with each other and might be attributed to the presence of abnormal inflammations in COPD. Furthermore smoking is clearly associated with all three of them [64] and osteoporosis, glaucoma and cataracts might be caused by the corticosteroid therapy of COPD [60].

COPD and asthma

In UK 43% of patients with COPD also have a reported history of asthma [63], but this high prevalence might be caused by a prior misdiagnosis of the patient, because a study shows that one third of patients over the age of 40

diagnosed with asthma actually has COPD instead [44]. The clinical features differentiating COPD and asthma are described in chapter 1.2.6.4 (page 17).

COPD and cardiovascular diseases (CVD)

British National Formulary (BNF) recommends avoiding β-Adrenoreceptor blockers in patients with heart failure, angina pectoris, myocardial infarction, cardiac arrhythmia and hypertension if there is a history of asthma or bronchospasm because although some of the β-blockers are cardio selective, none of them is cardio specific and lung's β_2-receptors blockade can lead to bronchospasm as a side effect. However a cardio selective β-Adrenoreceptor blocker can be used under specialist supervision if there is no alternative [57]. Since in a meta-analysis in 2002 no significant pulmonary adverse effects in patients with mild to moderate COPD secondary to a cardiovascular disease were found, the use of cardio selective β-blockers or β1-blockers is strongly suggested by the study authors [65].

In Scotland almost one fourth of heart failure patients also have COPD, 18% of them receive β-blockers, compared to 41% of heart failure patients without COPD. It was found that heart failure patients who also had COPD are more frequently treated with loop diuretics and calcium channel blockers in Scotland [66]. The use of digoxin in those patients may reduce lung function whereas angiotensin-converting enzyme (ACE) inhibitors, Angiotensin-II receptor blockers and spironolactone might have beneficial effects on pulmonary inflammation, obstruction and gas diffusion [67].

β_2-adrenoreceptor agonists, which are the most commonly used COPD treatment, are not completely selective, so myocardial β_1-adrenoreceptors may also be stimulated which leads to increased mortality in patients with left ventricular dysfunction [67]. BNF recommends the use of β_2-adrenoreceptor agonists in patients with CVD, hypertension or arrhythmias with caution [57]. Inhaled β_2-adrenoreceptor agonists are prescribed to 57% of patients with heart failure and COPD in Scotland [66].

In patients with severe COPD (oxygen or steroid dependent or dyspnoea at rest) warfarin dose has to be decreased by 33% [68].

Pharmaceutical care issues:

- Record co-morbidities
- Record Blood Pressure (BP)
- Measure BP
- Record blood lipids
- COPD patients on β-blocker should be under specialist supervision
- Patients with CVD, hypertension or arrhythmias who receive β-agonists should be under specialist supervision
- Patients on warfarin need special precaution

Pulmonary hypertension and cor pulmonale

NICE guidelines highlight the possibility of development of pulmonary hypertension secondary to COPD because of hypoxic vasoconstriction and structural changes. Years of presence of pulmonary hypertension can lead to changes in the rights heart ventricle's function and structure which is defined as the clinical syndrome of cor pulmonale. It is characterized by raised venous pressure, peripheral oedema and fluid retention. As this condition is caused by hypoxia LTOT is recommended for these patients. Oedema should be treated with diuretic therapy. ACE inhibitors, alpha-blockers, calcium channel blockers and Digoxin are not recommended since there are not enough studies to support their benefit [6].

Pharmaceutical care issues:

- Patients with presence of peripheral oedema (ankle swelling) should be on diuretics

Anxiety and depression are widespread among COPD patients. In stable COPD prevalence rates up to 19% for anxiety and 42% for depression were found. The incidence of depression in patients who depend on oxygen therapy is even 62%. Two thirds of depressive COPD patients suffer from moderate-severe depression. A quarter of COPD patients are assumed to

have unrecognized subclinical depression, and less than one third of patients receive appropriate treatment. Incomplete treatment is associated with increased frequency and prolonged length of hospitalisation, impaired treatment adherence, poor quality of life and premature death [69]. Hypoxic patients, patients with severe dyspnoea or patients who have been to hospital due to an exacerbation have increased risk for anxiety or depression, and their mental wellbeing should therefore be assessed by a validated assessment tool [6].

The Hospital Anxiety and Depression Scale (HADS) is a self rating questionnaire designed to measure the severity of states of depression and anxiety in patients under medical treatment. The first half of the items (HADS-D) measures mostly depression, the second half (HADS-A) measures anxiety. Scores range from 0 to 21 for each subscale, scores greater than seven imply 'possible' depression/anxiety, scores greater than ten imply 'probable' depression/anxiety disorder. The HADS-D can identify patients who may benefit from antidepressant drugs [70]. Pharmacotherapy should be offered and explained to anxious or depressed patients [6].

Pharmaceutical care issues:

- Record previous HADS scores
- Assess HADS score
- Discuss management of anxiety and depression in patients with HADS-D or HADS-A ≥8

2 AIM, OBJECTIVES and SETTING

2.1. Aim

To design the documentation of a patient profile that includes the identification and assessment of pharmaceutical care issues in patients with COPD.

2.2. Objectives

1. To review the literature in order to define the pharmaceutical care issues of patients with COPD and to define a model of pharmaceutical care provision within a multidisciplinary team setting.

2. Identify necessary fields of data for inclusion in a pharmaceutical care plan for COPD patients and design the documentation based on a previous template of a care plan.

3. Field test the design formats for the care plan by conducting a survey of a case series.

4. Present findings to clinical pharmacist practitioners to obtain feedback from which a final design will be validated.

5. Propose future research to help introduce systematic care provision and documentation into the delivery of pharmaceutical care to COPD patients.

2.3. Setting

The work would fit into a programme of service developments involving community pharmacists in services in primary care which aim to reduce hospital admission rates.

In Greater Glasgow and Clyde Prescribing Support Pharmacists (PSPs) and COPD Support Pharmacists are running medication review services in community health centres for patients with COPD. Patients with moderate

airflow obstruction (according to NICE classification) and patients who are prescribed bronchodilator therapy are targeted by their GPASS read codes. A full medication review is performed and as part of it, an appointment for a face-to-face dialogue with the patient, either in the clinic or for a house visit in patients with a further progressed stage of disease is arranged. Around six patients per day are seen by the pharmacist. Approximately two hours are required in the morning to prepare for the patients before the first appointment. GPASS is used to obtain patient records.

One patient's face-to-face dialogue lasts on average half an hour and includes assessment of inhaler technique, smoking status and MRC grade as well as a measurement of BP. Each patient is asked to bring all of their medicines with them and explain when and how often they take it. Smokers are given a brief advice to stop smoking. In patients with suspicion of anxiety or depression HADSs are assessed and in case of a positive result, pharmacotherapy is discussed with the patient. Patients are asked about their knowledge about their condition and are educated if necessary. The presence of oedema is checked by asking the patient about ankle swelling. The obtained information also covers the annual review the NICE guideline [6] demands in patients with COPD, which includes recording of smoking and immunisation status, assessment of MRC grade and identification of psychological and social co-morbidity.

After the patient's appointment a summarised report is inputted into GPASS and a referral for the GP containing the PSP's recommendations is written. Once the GP has approved all changes to the treatment plan, the pharmacist then prints off prescriptions, sends off referrals and sends a letter or phones the patient informing them about actions. It is up to the PSP to ensure that all recommendations are carried out and followed up as necessary.

3. METHODS

3.1. Literature review and identification of pharmaceutical care issues

Literature review was performed to provide background information on pharmaceutical care, to define a model of pharmaceutical care provision within a multidisciplinary team setting for patients with COPD, to provide background information on COPD and to identify potential pharmaceutical care issues in patients with COPD.

The sources include reports on pharmaceutical care by the Scottish Government [2, 5], NICE guidelines on COPD [6], guidelines by the Global Initiative for COPD (GOLD) [9], the NHS Greater Glasgow and Clyde's 'Primary care COPD Guideline' [7] and the British National Formulary (BNF) [57] as well as systematic reviews, reports and papers.

Therefore the database Pubmed was browsed with the following terms:

- Chronic obstructive pulmonary disease
- Co-morbidities in chronic obstructive pulmonary disease
- Depression and Anxiety and chronic obstructive pulmonary disease
- Detecting markers of chronic obstructive pulmonary disease
- Diagnosis of chronic obstructive pulmonary disease
- Emerging therapy in chronic obstructive pulmonary disease
- Epidemiology of chronic obstructive pulmonary disease
- Gender in chronic obstructive pulmonary disease
- Genetic factors in chronic obstructive pulmonary disease
- Hospital Anxiety and Depression Scale
- Management of chronic obstructive pulmonary disease
- Natural history of chronic obstructive pulmonary disease
- Non-smoking causes for chronic obstructive pulmonary disease
- Pharmaceutical care
- Pharmaceutical care planning

- Pharmaceutical care in patients with chronic obstructive pulmonary disease
- Risk factors for chronic obstructive pulmonary disease
- Smoking cessation
- Therapy of chronic obstructive pulmonary disease
- Vitamin D and respiratory health

Articles in English language written within the last 35 years have been considered. Information on health care services were obtained by web pages of the Scottish government (section: Health and Community Care), of the NHS and Scotland's Health On the Web (SHOW). During literature research and compiling of the introduction on background information on COPD, 57 pharmaceutical care issues were identified and summarised in a box at the end of each section. In June 2010 new NICE guidelines for COPD were issued. Subsequent the introduction of this report as well as the identified care issues were revised and new care issues were identified.

3.2. Identification of necessary fields of data for inclusion in a care plan

All pharmaceutical care issues that had been identified during literature research were regarded as necessary for inclusion in a pharmaceutical care plan. A transformation of identified pharmaceutical care issues into fields of data for a pharmaceutical care plan was performed. The majority of data fields of an existing respiratory review form for patients with COPD (F-RR) obtained from the first visit in a COPD medication review clinic, and some of the data fields contained in an existing care plan for patients with long term conditions (CP-LTC) were considered as necessary fields of data for inclusion in a pharmaceutical care plan. A list of suggestions for improvement of F-RR by COPD Support Pharmacist Joanna Johnson was taken into consideration. Anyway data fields from different sources were partly overlapping. F-RR, the list of suggestions and CP-LTC can be found in Appendix I.

3.3. Designing and revising the pharmaceutical care plan

An existing pharmaceutical care plan for patients with long term conditions (CP-LTC) created with Microsoft word by Ejim Chukwuka Ejim [71] was revised and several data fields were replaced. The CP-LTC was expanded to be more specifically focussed on COPD. The Microsoft Word template of CP-LTC was maintained. All identified fields of data for inclusion in a pharmaceutical care plan were added to CP-LTC in green font colour to obtain a care plan for patients with COPD, CP-COPD-1. CP-COPD-1 was field tested by the researcher in a medication review clinic and then revised. During field testing new care issues have been identified, and moreover in June 2010 new NICE guidelines for COPD were issued. Identified improvements, newly identified care issues and new guidelines were implemented into CP-COPD-1 in green font colour to obtain a second version of the care plan CP-COPD-2. Changes were discussed with the research group and then another survey of case series was conducted by the researcher with CP-COPD-2. As no more improvements were found, CP-COPD-2 was sent to two Pharmacists to obtain feedback. Their feedback and suggested changes were discussed with Dr. Julienne Johnson and agreed changes were implemented to obtain the third version of a care plan, CP-COPD-3. All versions of the pharmaceutical care plan can be found in Appendix I.

3.4. Clinic sit-ins and home visit

A full police clearance certificate about the researcher stating that there are no adverse records was provided to enable access to NHS facilities and patients. Dr. Julienne Johnson assisted the researcher by contacting COPD Support Pharmacist Joanna Johnson. Initially a request was sent to Richard Lowrie, the clinical services lead of the community pharmacy development team in NHS Greater Glasgow and Clyde. Richard Lowrie identified COPD Support Pharmacist Joanna Johnson as collaborator. A first appointment with Joanna Johnson was made by the researcher.

The first sit-in on 24.05.2010 at Govan Health Centre with Joanna Johnson was used to obtain general knowledge about how COPD clinics are run, and

to receive a copy of documentation (F-RR), which is currently used by pharmacists for COPD medication reviews as well as a list of suggestions for improvement.

Joanna Johnson then arranged an opportunity for the researcher to shadow home visits of patients with PSP Lynn Alexander on 22.06.2010, starting from Carolside Medical Centre. This second visit was used to field test CP-COPD-1 on five patients with COPD.

The third sit-in visit on 12.07.2010 at Govan Health Centre with Joanna Johnson was used to field test CP-COPD-2 on four patients with COPD. No more improvements for CP-COPD-2 were found.

3.5. Feedback by PSPs

A pdf file of CP-COPD-2 in black and white colour was created and sent to the pharmacists Lynn Alexander and Joanna Johnson on 17.07.2010 by email (Appendix II). Both agreed to try out the care plan at the medication review clinics for patients with COPD they were running in their surgeries, Lynn Alexander on 23.07.2010, Joanna Johnson on 26.07.2010. On 28.07.2010 the pharmacists sent an email containing their feedback to the researcher (see Appendix II). The suggested changes were discussed with the research group on 03.08.2010. The feedback by both pharmacists was summarised and commented in a table.

3.6. Final design

Suggestions found useful by the researcher and the research group were implemented into CP-COPD-2 to obtain the final design of the pharmaceutical care plan for patients with COPD, CP-COPD-3.

4. RESULTS

All drafts of pharmaceutical care plans, CP-COPD-1, CP-COPD-2 as well as the final version of the pharmaceutical care plan for COPD, CP-COPD-3 can be found in Appendix I.

4.1. Analysis of CP-LTC

The design of a care plan for long term conditions, CP-LTC was maintained for the development of the COPD care plan. The template was categorised in eight sections:

1. Personal data

Personal data include name, reference number, address, date of birth (DoB), sex, body weight, height, BMI, smoking status and social circumstances.

2. Monitoring data

This section contains fields of data for the record of basic lab parameters such as blood preasure (BP), glomerular filtration rate (GFR), cholesterol and peak expiratory flow rate (PEFR).

3. Medication

Relevant Medical History, Relevant Past Medication and Current medication are to be recorded in this section.

4. Disease specific monitoring data

CP-LTC focuses on monitoring of relevant patient data for cardiovascular disease (CVD), diabetes and pulmonary diseases. Therefore CVD Risk, lipid profile, HbA1c and MRC dyspnoea score are to be recorded in this section.

5. Standard checks

The standard check section can be described as a list of possible pharmaceutical care issues that need to be ruled out in each patient. If an

actual care issue is identified a check box is ticked. The standard checks in CP-LTC are sub divided into CVD prevention, hypertension, diabetes and lung disease.

6. Monitoring notes

Monitoring notes consist of a blank box for additional notes the PSP might want to take and a data fields to fill in the next 12-months review date.

7. Standard treatment verifications

In this section the PSP needs to verify weather the choice of medication and dose and the clinical/laboratory monitoring meet the guideline recommendations. Also there are check boxes for the identification of unmet preventive medication needs (CVD risk and osteoporosis) and the assessment of patient comprehension and ability to administer medication.

8. Individualised care issues

In the final section of the pharmaceutical care plan all identified care issues are to be summarised. Actions to be taken such as treatment plan changes, patient education or additional checks and an output need to be defined.

4.2. Transformation of identified care issues into fields of data

All pharmaceutical care issues, identified during literature research have been transformed into fields of data suitable for implementation into a pharmaceutical care plan by rephrasing, categorising and sorting by section, as shown in Table 5. A medication algorithm for pharmacotherapy of COPD (therapy scheme) has been generated from NICE guidelines, although it, among others, had to be revised completely, after new NICE guidelines were issued in June 2010.

Table 5: Transformation of identified care issues for patients with COPD into fields of data for implementation into CP-COPD-1

Pharmaceutical care issue identified during literature research	***Implementation into a pharmaceutical care plan (CP-COPD-1)***
Personal data	
Record smoking status	❑Smoker, ❑Cannabis smoker, ❑Past smoker, ❑Never smoked, ❑Under cessation, ❑Motivated to quit
Record number of previous smoking quit attempts	❑ Previous quit attempts:
Calculate pack years	Pack years:
Record patient's sex	❑Male ❑ Female
Record weight, height and BMI	Weight:, ❑Unintentional weight loss, Height:, BMI:
Record previous attendance in pulmonary rehabilitation or any other secondary care services	❑ Seen by secondary care respiratory services:
Record if patient had lung surgery	❑ Attended surgery
Find out about patient knowledge about COPD and educate if necessary	Knowledge of COPD? ❑ yes ❑ no
Record patient's social circumstances (patient: Lives alone, is housebound, has professional carer, is in family care)	Was already covered by CP-LTC: Social Circumstances: ❑Lives alone ❑Housebound ❑Professional carer ❑Family care
Patients who are not coping at home should be referred for home care support	Specialist advice: ❑social service
Record if patient is on disease self-management plan	Already covered by CP-LTC: ❑ On disease self management plan
Monitoring data	
Record pneumonia and influenza vaccination status	Vaccinations (up to date?): ❑Pneumonia ❑Influenza
Monitor blood glucose level	HbA_{1C}:
Monitor plasma-electrolyte concentrations	**Urea and Electrolytes** ❑ normal ❑impaired:
Record Blood Pressure (BP)	Blood Pressure: four columns, each consisting of date and mm Hg
Measure BP	Blood Pressure: four columns, each consisting of date and mm Hg
Record blood lipids	Was already covered by CP-LTC: ❑TC≥4mmol/L ❑HDL<1mmol/L ❑LDL≥2mmol/L and Cholesterol: four columns, each consisting of date and a blank box to fill in the Cholesterol value in mmol/L
Disease specific monitoring data	
Assess MRC grade	MRC GRADE 1❑ 2❑ 3❑ 4❑ 5❑
Record spirometry results	Spirometry: Three columns, each consisting of date, FEV_1/FVC and FEV_1
Classify severity by spirometry results according to NICE	***COPD profile** ❑Mild ❑Moderate ❑Severe
Record reversibility testing results	**Reversibility with Salbutamol ❑ no ❑ yes** [more than 15% response in FEV_1 suggests asthma]
Record chest X-ray results	Chest X-Ray:
Record CT scan	CT-scan:
Record DXA scans	DXA scan (DADS):
Record number of exacerbations requiring antibiotics or oral corticosteroids in past year	**Number of exacerbations** requiring Antibiotics and /or oral corticosteroids **in past year:**

Check if NICE therapy schema applies, and if it doesn't record reasons for exclusion of certain drugs	***Current COPD therapy:** ❑ SABA ❑ +Tiotropium ❑ +LABA ❑ +Inhaled Steroid ❑ +LTOT ❑ Oral Steroid ❑ Theophylline ❑ Mucolytic (carbocistein) ❑ Other:
Medication	
Record co-morbidities	Covered by 'Relevant Medical History', moreover an extra check box, ❑coexisting asthma, was introduced
Record if patient has a diagnosis of AAT-deficiency	Covered by 'Relevant Medical History'
Standard checks	
Record if patient is pregnant	**Pregnancy**
Patients with a family history of AAT-deficiency or with young onset (aged <40 years) of COPD should be referred to a specialist	**Young onset or non-smoker:** AAT-deficiency?
If unexpected clinical worsening occurs, the patient should be referred to a specialist	Unexpected **change in symptoms or MRC grade**: referral to ❑ Spirometry ❑Chest X-ray
Use of theophylline should be verified and patient should be on therapeutic drug monitoring (TDM)	**Theophylline:** ❑ Use verified, ❑ Plasmalevel monitored
If respiratory diagnosis is unclear patient should be referred for clarification	Respiratory **diagnosis unclear:** refer patient
Offer entry to cessation program to smokers	Was already covered by CP-LTC: **Smoker** offered entry to cessation programme
Patients on ≥ 5mg/day prednisolone (or equivalent) for longer than three months should be referred to DADS	Was already covered by CP-LTC: **Oral steroid**/6mths annual diabetes, BP & DADS
Patients on high dose inhaled steroids (≥1000 mcg beclometasone or equivalent) and have further risk factors for osteoporosis should be referred to DADS	**1000 mcg beclometasone + risk factors**: DADS referral
Patients older than 65 on oral Steroids should be on prophylactic osteoporosis treatment, without monitoring	>65 yrs + oral steroids: Osteoporosis prophylaxis
Assess if patients not on LTOT should be referred for LTOT assessment	**LTOT**/ ambulatory OT assessment required
Patients with MRC≥3 should be referred for pulmonary rehabilitation	**MRC>2**: referral to pulmonary rehabilitation
Patients with abnormal BMI should be referred for dietetic advice/nutrition support; If BMI is low give nutritional supplements	**BMI<20**: dietitian/ **BMI>25**: encourage weight control
Patients with clinical failure after all treatment options should be referred to a specialist to assess the need for palliative care	On maximum doses +OT: if dyspnoeic: **palliative care**
Assess if patient on self-management plan requires support or revision	**Exacerbations & self management** issues discussed
Patients with presence of peripheral oedema (ankle swelling) should be on diuretics	**Ankle swelling**: cor pulmonale?
Ask patient about dust or fume exposure	Asked about **occupational dust or fume exposure**

Discuss management of anxiety and depression	**Anxiety/Depression** management
Check if NICE therapy schema applies, and if it doesn't record reasons for exclusion of certain drugs	***>1 exacerbation/year + FEV_1 < 50%:** LABA + inhaled Steroid (not > 2x daily)
Standard treatment verifications	
If patient's symptom control is inadequate, more medication should be added	Already covered by CP-LTC, Standard treatment verifications - care issue 1: Choice of medication/dose ❑Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution
verify choice of delivery system	Standard treatment verifications - care issue 1: Choice of inhaler type ❑Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution
Assess if nebuliser therapy or spacer is applicable	Already covered by CP-LTC, Standard treatment verifications - care issue 4: Assess patient's comprehension and ability to administer medication (SPACER?) Inhaler Technique: Poor 0 1 2 3 Satisfactory
Assess patient's inhaler and/or nebuliser technique	Already covered by CP-LTC, Standard treatment verifications - care issue 4: Assess patient's comprehension and ability to administer medication (SPACER?) Inhaler Technique: Poor 0 1 2 3 Satisfactory
Patients with chronic sputum production should be on carbocistein	Already covered by CP-LTC, Standard treatment verifications - care issue 1: Choice of medication/dose
Check for unmet preventive medication (CV risk, osteoporosis, vaccinations)	Already covered by CP-LTC, Standard treatment verifications - care issue 3: Check for unmet preventive medication needs: CV Risk ❑ Osteoporosis ❑ Candidate for ❑ statin ❑ aspirin ❑ ACEI ❑ ß Blocker ❑Oral Biphosphonate ❑Ca & Vit D
COPD patients on β-blocker should be under specialist supervision	Already covered by CP-LTC, Standard treatment verifications - care issue 1: Choice of medication/dose, ❑ Identified special precaution
Patients with CVD, hypertension or arrhythmias who receive β-agonists should be under specialist supervision	Already covered by CP-LTC, care issue 1: Choice of medication/dose ❑ Identified special precaution
Patients on warfarin need special precaution	Already covered by CP-LTC: - Standard treatment verifications - care issue 1: Choice of medication/dose ❑ Identified special precaution - and 'High risk medication user: ❑ Warfarin'

*as according to NICE guidelines 2004; Has been subject of revision due to changes in NICE guidelines (see Table 10).

4.3. CP-COPD-1

The starting point for designing a care plan for patients with COPD was CP-LTC. To develop CP-COPD-1 mainly the sections ‘personal data’, ‘disease specific monitoring data - pulmonary function’ and ‘standard checks - lung disease’ of CP-LTC were expanded by the fields of data described in Table 5, while other sections such as ‘disease specific monitoring data - diabetes profile’ and some of the standard checks were replaced. All added data fields were included into CP-LTC with green font colour. The medication section was modified and moved from page one to page two due to shortage of space. The ‘Relevant Medical History’ and its ‘Past Medication’ subsection was expanded with the fields ‘Past medication trials without clear benefit’, ‘Excluded medication’ and ‘Reason for Exclusion’.

In the ‘Current Medication’ subsection one column to note the actual dose the patient takes, one column for comments on compliance, efficacy, adverse drug reactions (ADRs), critical incidences (CIs) and cost effectiveness and one column containing a check box to tick weather the drug showed clear benefit after one month or not was added next to each medication. At the bottom a field for recording of concordance issues and a box for the number of medications on repeat were inserted. The space for individualised care issues was reduced from 16 fields to ten, so that the third page of the care plan consists of ‘Individual care issues’ only and the care plan contains no more than three pages; If required the third page can be printed more than once. A complete list of removed fields of data and reasons for removing can be found in Table 6. In Table 7 all added fields of data and their sources are listed.

Table 6: Fields removed from CP-LTC to develop CP-COPD-1

Field	Comment
Medication *(section was moved from page one to page two)*	
Disease Specific Monitoring Data	
Past MI dates	Recording of previous MIs is covered by the section 'Relevant Medical History'
Diabetes complications	Recording of Diabetes and its Complications is covered by the section Relevant Medical History
COPD prognosis index, Mortality, Hospitalisations	Do not influence the management of COPD
Obesity Profile – Target weight	BMI, weight and height alone are sufficient to decide about dietetic advice and nutritional support
Combined medication scheme for COPD and asthma	Was replaced with a medication scheme for COPD alone
Standard Checks *(all standard checks except in the section 'lung disease' were maintained)*	
Lung disease	The headline 'lung disease' was replaced with 'COPD'
Suitability of multiple inhaler prescribing; on>2 inhalers has response confirmed	Does not reflect the guideline recommendation, was replaced by the check box 'clear benefit after 1 month' in the 'Current Medication' section
On inhaled steroid not > twice daily	Care issue is already covered by the section 'Standard treatment verifications' – Choice of medication/dose
Oral steroid/6mths annual diabetes, BP & FRAX	Was replaced with '**Oral steroid/6mths** annual diabetes, BP & DADS', as FRAX is assessed as part of osteoporosis scanning by DADS
FRAX assessment (if>800 mcg/day)	Was replaced with '**1000 mcg beclomethasone + risk factors** DADS referral' (according to latest guideline recommendation)
COPD/asthma candidate for LABA	Care issue is already covered by the medication scheme for COPD
Oral steroid/6mths is also on inhaled high dose	Care issue is already covered by the section 'Current Medication' and the medication scheme for COPD
Individualised care issues *(number of fields was reduced from 16 to 10)*	

Table 7: Fields added to CP-LTC to develop CP-COPD-1

Field	Source		
	Identified during literature research	Contained in F-RR	Suggested by Pharmacist
Personal data			
Tel No.		X	
Age	X	X	
GP		X	
Specialist advice: social service	X		
Knowledge of COPD	X	X	
Attended surgery		X	
Seen by secondary care respiratory services	X		X
Smoking status: Motivated to quit	X	X	
Smoking status: Previous quit attempts	X	X	
Smoking status: Cannabis smoker	X		
Smoking status: Never smoked	X	X	
Monitoring data			
Urea and electrolytes	X		X
Disease specific monitoring data			
Spirometry performed in practice or outreach			X
Spirometry record FEV1/FVC, FEV1	X		
Chest X-Ray	X	X	
MRC grade assessed by pharmacist, patient			X
Number of exacerbations requiring antibiotics and /or oral corticosteroids in past year	X		X
Reversibility with Salbutamol	X		X
Coexisting asthma	X		
COPD therapy algorithm	X		
Standard Checks			
Pregnancy	X		
Anxiety/Depression	X	X	
BMI<20: dietitian/ **BMI>25**: encourage weight control	X		X
Asked about **occupational dust or fume exposure**	X		
Young onset or non-smoker: AAT-deficiency?	X		
Exacerbations & self management issues discussed	X	X	
>1 exacerbation/year + FEV1 < 50%: LABA+inhaled Steroid	X		
Theophylline: use verified, plasmalevel monitored	X		
>65 yrs + oral steroids: Osteoporosis prophylaxis	X		
1000mcg beclometasone+risk factors:DADS referral	X		
Encourage **physical activity**, exercise referral	X		
Unexpected **change in symptoms or MRC** grade: referral to ❑ spirometry ❑ Chest X-ray	X		
LTOT/ ambulatory OT assessment required	X	X	
Ankle swelling: cor pulmonale?	X		
MRC>2: referral to pulmonary rehabilitation	X	X	
On maximum doses+OT: if dyspnoeic: **palliative care**	X		
Medication			
Past medication trials without clear benefit	X		
Excluded medication	X		
Reason for exclusion of medication	X		
Number of medications on repeat, [• medication on repeat]		X	
Actual dose		X	
Concordance issues		X	

Clear benefit (after 1 month)			
Compliance, efficacy, ADRs, CIs, cost effectiveness			
Standard treatment verification			
Choice of inhaler type			
Necessity for spacer			
Monitoring notes			
Date of review			
Ie Read code: Asthma, COPD, Other			
Exception coded from COPD review			
House visit, phone review			
Follow up, phone review required			
Time taken for review			
Costs saved or incurred			

4.4. CP-COPD-2

CP-COPD-1 was improved in form and content. More pharmaceutical care issues could be identified and also new NICE guidelines for COPD have been issued after CP-COPD-1 had been field tested and while CP-COPD-2 was developed in June 2010.

4.4.1. Structural improvements

During the first field testing it was found that a more structured and simplified design might be useful. This was obtained by different moves:

4.4.1.1. Division of data fields into two groups

Data field were divided into (1) data that can be filled out before the patient is seen, and (2) data which have to be assessed with the patient during a face to face dialogue or afterwards the meeting. This is reflected by white (1) and grey (2) shading of the data field. Therefore the fields social circumstances, smoking status, latest BP, latest MRC grade, latest HADS scores, most of the monitoring notes, and several standard checks were shaded grey.

4.4.1.2. Sorting of data fields

Another approach to obtain a more structured plan was to sort data fields, both spatially and with regard to contents. A new section ‘COPD profile’ was introduced. The section ‘disease specific monitoring data’ was abrogated and its data fields were embedded either into the ‘monitoring data’ or into the ‘COPD profile’ section. All monitoring data were arranged next to each other on the left side of page one. The ‘COPD profile’ section, located in the middle part of page one, contains NICE classification of severity, BODE index, patient’s age at initial diagnosis, numbers of exacerbations, LTOT assessment parameters, a list of co-morbidities and the NICE therapy schema. A list of the most prevalent co-morbidities was included. Multiple checks for one care issue were reduced and some fields were identified as unnecessary and removed.

4.4.1.3. Revision of ‘standard checks’

The subdivisions were removed and the standard checks were sorted by incidence and priority rather than by disease. A consistent format was introduced by rephrasing the standard checks: The possible care issue was formatted in bold font, and the consequent action in normal font, like for example: **‘Hypertensive patient** on treatment’. The pharmacist checks whether any of the possible care issues (bold font) apply to the patient, and if so, they check if the consequent action (normal font) has been taken. In case it has not, an actual care issue has been identified, which is indicated by ticking the associated check box ‘care issue’. A second check box, ‘action’, next to each standard check has been introduced in CP-COPD-2. It is ticked to signalise that the consequent action has been taken, in case of the previous example, the action is to put the hypertensive patient on treatment.

A complete list of structural improvements can be found in Table 8.

Table 8: Structural improvements in CP-COPD-1 to develop CP-COPD-2

Field	Comment
Personal data	
Specialist Advice (Diet, Exercise, Smoking, social service)	Removed, as covered by the standard checks: , '**BMI abnormal** nutritional supplements, refer to dietician', '**Smoker** offered entry to cessation programme' and '**Not coping at home** refer for home care support'
Attended pulmonary rehabilitation	Added. Was previously covered by 'seen by secondary care respiratory services', but was found to be more convenient as a separate option
No. Cigs./day	This additional field allows a quick overview over the patient's smoking habits, while the calculation of pack years is more time consuming
❑ Dust/fumes exposure	Added, replaces standard check 'Asked about **occupational dust or fume exposure**'
❑ Cannabis smoker	Removed, as during field testing none of the patients admitted to be cannabis smoker.
❑ Desire to quit	Added, replaces '❑ Motivated to quit'
Monitoring Data	
Unintentional weight loss	Removed as covered by standard check: '**BMI abnormal** nutritional supplements, refer to dietician'
Glucose (❑<6, ❑6-7, ❑>7)	Added. Replaces the field 'HbA_{1c}'
Diabetes risk	Removed, as calculation is time consuming and not supported by GPASS and result does not influence therapy
Fracture risk	Removed, as calculation is time consuming and not supported by GPASS, already covered by 'DXA scan'
CVD risk	Replaced with CVD risk (assign) Assign is the cardiovascular risk score chosen for use by Scottish Intercollegiate Guidelines Network (SIGN) and Scottish Government Health Directorates [72] and is supported by GPASS
Reversibility with Salbutamol (❑yes, ❑no)	Check boxes (yes, no) were replaced with blank boxes for percentage of reversibility, attached to each spirometry result
PEFR	Removed as not state of the art of science
Cholesterol	Row with four columns for last four records of cholesterol was replaced by one check box '❑ Chol ≥ 6' next to lipids
MRC grade	More columns were added to record latest three MRC assessments
COPD profile	
Knowledge of COPD? (❑yes, ❑no)	Replaced with standard check '**Patient knowledge inadequate** provide education'
Coexisting asthma	Included into the section with a list of co-morbidities
Comorbidities (AAT-Deficiency, Asthma, Cor pulmonale, CVD, Depression, Diabetes, Glaucoma, Hypertension, Osteoporosis, Other)	Added to give an overview over the most prevalent co-morbidities, as this is essential information for choosing treatment.
Patient's age at initial COPD diagnosis	Added, as this gives information about possible early onset and duration of disease
Standard Checks	
Pregnancy	Rephrased: **Pregnancy confirmed** refer to specialist

BMI<20: dietitian/ **BMI>25**: encourage weight control	Rephrased: **BMI abnormal** nutritional supplements, refer to dietician
CHD – '0n aspirin achieved a BP ≤ 150/90mm/Hg'	Removed, as already covered by '**Hypertensive patient** on treatment'
Aspirin C/I, on Clopidogrel 75mg	Removed, as already covered by Standard treatment verifications - care issue 3: Check for unmet preventive medication needs: CV Risk ❑
Stroke or TIA history on dipyridamole 200mg BD	Removed, as already covered by Standard treatment verifications - care issue 3: Check for unmet preventive medication needs: CV Risk ❑
TC≥4mmol/L on Statin unless C/I	Removed as already covered by Standard treatment verifications - care issue 3: Check for unmet preventive medication needs: CV Risk ❑**,** Candidate for ❑ statin
Not prescribed combination of thiazide & b/blocker	Removed as already covered by Standard treatment verifications - care issue 1: Choice of medication - ❑Meets guideline recommendations ❑Identified exception ❑Identified special precaution
Diabetes/CVD /Chronic Renal Failure blood pressure optimised (≤130/≤80)	Rephrased: **Diabetes/CVD /Chronic Renal Failure** BP ≤130/≤80
Diabetes – 'All antagonist ❑ indicated **/** ❑ use verified'	Removed as already covered by Standard treatment verifications - care issue 1: Choice of medication - ❑Meets guideline recommendations ❑Identified exception ❑Identified special precaution
Diabetes – 'BMI> 26(F)/27(M) kg/m^2 on metformin'	Rephrased: **Diabetes + BMI> 26(F)/27(M) kg/m^2** on metformin
+ BP Controlled, CVD≥20% on aspirin 75mg	Removed as covered by: Standard check '**10yr CVD risk ≥20% , Age>40** on aspirin 75mg'
Asked about **occupational dust or fume exposure**	Removed, replaced with check box in personal data: ❑ Dust/fumes exposure
Young onset or non-smoker: AAT-deficiency?	Rephrased: **COPD onset<40yr, FH AAT-Deficiency** refer to specialist
Exacerbations & self management issues discussed	Rephrased: **On self management** but requires revision/support
Theophylline: ❑ use verified, ❑plasmalevel monitored	Rephrased: **On theophylline** ❑use verified, ❑on TDM
Oral steroid/6mths annual diabetes, BP & DADS	Rephrased: **≥5mg prednisolone/3mths** annual diabetes, BP + DADS
>65 yrs + oral steroids: Osteoporosis prophylaxis	Rephrased: >**65 yrs + oral steroids** osteoporosis prophylaxis
1000 mcg beclometasone + risk factors: DADS referral	Rephrased: **≥1000 mcg beclometasone+ risk factors** refer to DADS
Respiratory **diagnosis unclear:** refer patient	Rephrased: **Respiratory diagnosis unclear** refer for clarification
Unexpected **change in symptoms or MRC** grade: referral to ❑ spirometry ❑ Chest X-ray	Rephrased: **Unexpected clinical worsening** refer to specialist
LTOT/ ambulatory OT assessment required	Rephrased: **On maximum medication** refer for LTOT assessment
Ankle swelling: cor pulmonale?	Rephrased: **Oedema presence (ankle swelling)** on diuretics
MRC>2: referral to pulmonary rehabilitation	Rephrased: **MRC≥3** refer to pulmonary rehabilitation
On maximum doses +OT: if dyspnoeic: **palliative care**	Rephrased: **Clinical failure after all treatment options** refer to specialist (palliative care)
Patient knowledge inadequate provide education	Added, replaces COPD profile: 'Knowledge of COPD ❑yes, ❑no'
Symptom control inadequate adding of medication	Added, was previously covered by COPD Profile – medication schema, but found to be useful as an additional standard check
Not coping at home refer for home care support	Added, replaces Specialist Advice (Diet, Exercise, Smoking, social service)

Chronic sputum production on carbocisteine	Added, was previously covered by COPD Profile – medication schema, but found to be useful as an additional standard check
Warfarin + severe COPD decrease dose by 33%	Added, was previously covered by Standard treatment verifications - care issue 1: Choice of medication/dose ❑ Identified special precaution and 'High risk medication user: ❑ Warfarin' but found to be useful as an additional standard check
Medication *(more rows for medical history and current medicines were added)*	
Current medication – 'compliance, efficacy, ADRs, CIs, cost effectiveness'	Replaced by 'column Comment'
Current medication – 'Concordance issues'	Removed, as now covered by 'comment'
Relevant Medical History/ Relevant Past Medication Excluded medications – 'Trial: from – to'	Added, as a field for date was lacking
Standard treatment verifications	
Choice of inhaler type	Replaced by 'choice of delivery system', as the term delivery system is more general
Check for unmet preventive medication needs ❑Vaccinations	Added, was previously covered by 'COPD-Profile Vaccinations'
❑Nebuliser use verified	Added, was previously covered by 'Choice of inhaler type', but found to be useful as an additional check box
Candidate for ❑ Spacer ❑ Nebuliser	Added, replaces 'SPACER?'
Monitoring notes	
Exception coded from COPD review	Removed as identified as irrelevant
Review: clinic	The data field with the options 'House visit' and 'Phone review' was changed to 'Review: House visit, Phone, Clinic'

4.4.2. Editing of content

4.4.2.1. New care issues and data fields

Eight new pharmaceutical care issues in patients with COPD regarding depression and anxiety management, LTOT and medication precaution were identified during field testing of CP-COPD-1. After performing a literature review on them, they were included into the introduction of this report. Then they were transformed into fields of data for inclusion in a care plan and implemented as shown in Table 9.

Table 9: Transformation of identified care issues for patients with COPD into fields of data for implementation into CP-COPD-2

Monitoring data	
Record previous HADS scores	HADS-D & HADS-A: date:
Assess HADS score	HADS-D & HADS-A: date:
COPD profile	
Record LTOT assessments (including PaO_2 and SaO_2)	❑ **LTOT assessment** date: PaO_2:, SaO_2:
Standard checks	
Discuss possible adverse effects from steroids with the patient	**On steroids** educate about adverse effects
Assess if LTOT is used a sufficient amount of hours (>15) per day	**Patient on LTOT** on >15 hours/day
COPD patients on β-blocker should be under specialist supervision	**Beta blocker + COPD** under specialist supervision
Patients with CVD, hypertension or arrhythmias who receive β-agonists should be under specialist supervision	**CVD/↑BP/arrhythmia + β-agonist** specialist supervision
Discuss management of anxiety and depression in patients with HADS-D or HADS-A ≥8	**HADS-D or HADS-A≥8** Anxiety/Depression management (replaces standard check '**Anxiety/Depression** management')

4.4.2.2. Implementation of changes in NICE guidelines

New NICE guidelines for COPD have been issued between CP-COPD-1 and CP-COPD-2 in June 2010 and the introduction of this report was revised. Changes in guidelines include a new classification of severity, introduction of

a very specific medication algorithm, and assessment of BODE index. A clear benefit from pharmacologic treatment after a one month trial is no longer required. All changes to CP-COPD-1 due to the new issue of the NICE guidelines are summarised in Table 10.

Table 10: Changes from CP-COPD-1 to develop CP-COPD-2 due to new NICE guidelines

<table>
<tr><th>CP-COPD-1</th><th>CP-COPD-2</th></tr>
<tr><td colspan="2">COPD Profile</td></tr>
<tr><td>NICE classification of severity:
❑Mild ❑ Moderate ❑ Severe</td><td>Replaced by:
NICE:
❑ Mild [FEV_1 ≥80%] ❑ Severe [30-49%]
❑ Moderate [50-79%] ❑ Very Severe
[<30 or <50 + RF]</td></tr>
<tr><td>Medication scheme:

Current COPD therapy:
❑ SABA
❑ +Tiotropium
❑ +LABA
❑ +Inhaled Steroid
❑ +LTOT
❑ Oral Steroid
❑ Theophylline
❑ Mucolytic (carbocistein)
❑ other:</td><td>Replaced by:
Medication:
❑ SABA or ❑ SAMA
❑ FEV_1 ≥ 50% | ❑ FEV_1 < 50%
❑LABA | ❑LAMA | ❑{LABA+IC} ❑LABA+ LAMA (if IC n/a) | ❑LAMA
❑{LABA+IC} ❑LABA+ LAMA (if IC n/a) | ❑LAMA + {LABA+IC} | ❑LAMA + {LABA+IC} | ❑LAMA + {LABA+IC}
❑LAMA + {LABA+IC} | ❑LAMA + {LABA+IC}
❑ Oral Steroid ❑ Mucolytic (carbocistein)
❑ Theophylline ❑ Other:</td></tr>
<tr><td>Calculate BODE index</td><td>Added</td></tr>
<tr><td colspan="2">Standard checks</td></tr>
<tr><td>>1 exacerbation/year + FEV1 < 50%:
LABA+inhaled Steroid (not > 2x daily)</td><td>Removed</td></tr>
<tr><td>On SAMA+LAMA switch to SABA</td><td>Added</td></tr>
<tr><td colspan="2">Medication</td></tr>
<tr><td>clear benefit after 1 month</td><td>Removed</td></tr>
<tr><td>Relevant Medical History/ Relevant Past Medication – Past medication trials without clear benefit</td><td>Removed</td></tr>
</table>

4.5. CP-COPD-3

4.5.1. Division of pages

The main improvement of CP-COPD-2 was to split the pages of the care plan into one page for ‘recording data’ (data that can be obtained from the patient file e.g GPASS) and four ‘review’ sheets.

4.5.1.1. ‘Recording data’ sheet (page one)

The section ‘Standard checks’ and all fields for data that need to be assessed by the pharmacists were moved from page one to other pages and so page one now is for recording of data only: The fields patient data, monitoring data and COPD related recording data (Co-morbidities, Vaccination, LTOT assessment, BODE index, ‘Patient’s age at initial COPD diagnosis’ and ‘No. of exacerbations’) were maintained on page one and a row to fill in the date was attached to them.The previous introduced concept of shading data fields that have to be assessed with the patient during the face-to-face dialogue grey, was not considered as applicable on the ‘recording data sheet’ and was therefore disintegrated on the ‘recording data sheet’.

4.5.1.2. ‘Review’ sheets (pages two - five)

All fields for the actual medication review were placed on the pages two to five. The second page is now entirely occupied by the ‘medication’ section. The field ‘High risk medication’, formerly part of personal data, is now included in the ‘medication’ section and located on bottom of page two. Page three now consists of: monitoring notes; standard treatment verifications; assessment of risk factors (including smoking status), and the COPD medication scheme. The section ‘standard checks’ is now placed on page four and page five contains the table for individualised care issues.

4.5.2. Creating more space

The number of pages was expanded from three to five. This made a scaling up of the font size from eight to twelve possible, and enabled the creating of more space for multiple records of data on page one (for example the number of columns for BP and Spirometry values were expanded from three to five).

A summary of feedback by the pharmacists and the description of its implementation are listed in Table 11.

Table 11: Summary of feedback by pharmacists and description of implementation

Feedback by pharmacists	**Description of implementation**
The font on the first page is too small to be easily workable.	The font size was scaled up from 8 to 12 after more space was obtained by moving sections and expanding the care plan from three to five pages.
Personal data	
Two separate boxes to record CHI and DOB are needed	A seperate box for CHI was introduced.
The Ref number at thetop, what's that for?	Ref. number was removed
I am not convinced that surgery is necessary to have on.	'Attended surgery' was removed
The fields about self management should be changed to look something like: COPD self management plan YES/NO Attended Pulmonary Rehabilitation YES/NO (If yes, when?) Appropriate for referral to Pulm RehabYES/NO Other secondary care services YES/NO (If yes, details) Maybe dates would be useful here instead of a tickbox?	The fields were changed to: On COPD self management plan ❑no ❑yes–date: Attended pulmonary rehabilitation ❑no ❑yes-date: Other secondary care services: date: The suggestion 'Appropriate for referral to Pulm Rehab YES/NO' was not realized at this location as this section is for recording of patient data only and moreover the care issue is already covered by standard check '**MRC≥3** refer to pulmonary rehabilitation'.
The box about self management plans should be moved to after the recording of MRC grade	The box was not moved, as moving to after the recording of MRC grade would only make sense if the field 'Appropriate for referral to Pulmonary Rehabilitation YES/NO' had been implemented at this location.

<table>
<tr><td>Smoking:
The third box I would change to:

Pack Years:
Currently using NRT ❑
Ready to quit ❑
Unwilling to quit ❑
No of quit attempts:
Products used in failed attempts:</td><td>The Assessment of smoking status was redesigned and moved from page one to page three and implemented into the section ‘Pharmaceutical care review – Assessment of risk factors’:

Assessment of risk factors:
<table><tr><td>❑Smoker</td><td>❑Past Smoker</td><td>❑Never smoked</td></tr><tr><td>❑Under cessation</td><td colspan="2">❑Occupational dust/fumes exposure:</td></tr><tr><td colspan="3"></td></tr><tr><td>Pack years
No. Cigs./day</td><td></td><td>Currently using NRT
❑no ❑yes:</td></tr><tr><td colspan="3"></td></tr><tr><td colspan="2">❑Ready to quit</td><td>❑Unwilling to quit</td></tr><tr><td colspan="3"></td></tr><tr><td colspan="2">Previous quit attempts</td><td></td></tr><tr><td colspan="2">Products used in failed attempts</td><td></td></tr></table></td></tr>
<tr><td colspan="2">Monitoring data</td></tr>
<tr><td>GFR, Glucose, Lipids: I would just leave the boxes blank for the pharmacist to write the level in themselves.</td><td>check boxes for values were replaced with:
‘❑ normal ❑ impaired: ‘</td></tr>
<tr><td>Liver function tests (LFTs) need to be included in the investigations part.</td><td>‘LFTs date: ❑ normal ❑ impaired: ’
was included</td></tr>
<tr><td colspan="2">COPD Profile</td></tr>
<tr><td>The severity scale needs to go immediately underneath the spirometry details.</td><td>The NICE severity scale was moved underneath the spirometry details</td></tr>
<tr><td>There needs to be much more space to enter details of co-morbidities and I think this needs to go further up the page as this is an essential piece of information to get.

Also under "co-morbidities" can there be a box for "none"</td><td>The Co-morbidities section was expanded significantly and moved into an own section on the ‘Recording data sheet’.

A check box for ‘none’ was included

Allergies were removed from the personal data section and included into the Co-morbidities.</td></tr>
<tr><td colspan="2">Standard checks</td></tr>
<tr><td>The Standard Checks might not be necessary to have. My recommendation would be to have a ‘reminder page’ at the back containing this information that people can use if they want or else just not print it off. This list would help pharmacists very new to running clinics.</td><td>Standard checks were moved to a seperate sheet on page four.</td></tr>
</table>

The line '**On SAMA+LAMA** switch to SABA' is not correct.	The pharmaceutical care issue • Patients on SAMA and LAMA should be switch to SABA had been identified incorrect. The correct care issue is: • Patients on regular SAMA ≥ 4/d should be switched to LAMA The data field '**On SAMA+LAMA** switch to SABA' was replaced by '**On regular SAMA ≥ 4/d** switch to LAMA'
Medication	
High risk medications: I think that if you are going to include this box it should be on the second page. Can the "high risk medication user" be changed to "High risk Medications" and add a box for "none" as an empty box could sometimes be an oversight so adding a "none" rules that out.	'High risk medication user' was renamed to 'High risk medication', and placed in the section 'Medication' on the second page. A check box for 'none' was included.

5. DISCUSSION

5.1. Developing a pharmaceutical care plan

The aim of this research was to develop a pharmaceutical care plan specifically for patients with COPD. The resulting work (CP-COPD-3) should be understood as one of many parts of a comprehensive care plan which will be developed to be used in every patient with any chronic disease, rather than as a self-contained project.

Pharmaceutical care issues for patients with COPD have been identified via a comprehensive literature review. To ensure consideration of all relevant topics, the content of this literature review was carefully compared with the latest guidelines. Following this phase, a pharmaceutical care plan for patients with COPD was developed in the following stages: 1) Starting with an existing pharmaceutical care plan, several fields were removed and replaced with fields identified as important for patients with COPD. 2) This first design was then field tested and identified improvements were implemented. 3) This process was then repeated until no further improvements were found. 4) The design was then field tested by experienced pharmacists running medication review clinics. 5) Their professional feedback was then incorporated into the final version of the care plan.

5.1.1. Selecting of care issues and level of detail

The problem of identifying care issues and implementing them (as data-fields) into the care plan at a sufficient level of detail was a particularly difficult task. Some of the identified care issues were found to be too detailed and some too broad, while others might not have been identified at all. While generally recognized care needs were covered by general wording such as the standard treatment verifications “Choice of medicine/dose/delivery system” and ‘Check for unmet preventive medication needs’, more specific care issues were implemented as detailed standard checks like ‘**Patient on LTOT** on >15 hours/day’ or ‘**≥5mg prednisolone/3mths** annual diabetes, BP + DADS’.

However, the identification, selection and prioritisation of care issues into a care plan remains an individualised and subjective process within the context of intuitive clinical work; thus extensive field-testing on a larger sample of patients is essential to ensure that care issues are incorporated into the plan at the correct level of detail.

A particularly important point in this regard is that some standard checks are very specific and might only apply in a minority of patients, while a very broad formulation runs the risk of pharmacists forgetting to check for important issues. For example the very broad, generally recognized, care issue, 'The patient needs to receive the right medicines' can be formulated in the very general phrase: 'Choice of medicine/dose/delivery system ❑ Meets guideline recommendations, ❑ Identified exception, ❑ Identified special precaution' or it can be broken down into several very detailed standard checks: '**Hypertensive patient** on treatment', '**On regular SAMA ≥ 4/d** switch to LAMA', '**Patient with CVD** prescribed aspirin & statin' and many more. And even most of the already very detailed standard check such as '**Hypertensive patient** on treatment' can be in-depth more: '↑**BP, ≤ 55yr, non-black** on ACE inhibitor', '↑**BP, >55yr, black** on thiazide diuretics/ Ca Blocker' and so on.

In this care plan both general treatment verifications and detailed standard checks were implemented. One of the pharmacists who field-tested the design gave the following feedback about the detailed standard checks: "*I am undecided about whether the Standard Checks are necessary to have. My recommendation would be that you have a 'reminder page' at the back containing this information that people can use if they want or else just not print it off. This list would really only be necessary to pharmacists very new to running clinics so I do think a reminder sheet would be helpful for them.*"

5.1.2. Structuring the care plan

It has been found that a well-structured design is essential. This was obtained by different approaches:

5.1.2.1. Division of data fields

In the very early stages of developing the care plan it became clear that division of data fields into different categories is useful, and a categorial difference (reflected by different shading of the boxes) was made between those fields that can be filled out before the patient is seen and those that have to be assessed during a face-to-face dialogue with the patient. Later, the care plan was further sub-divided into fields that can be completed using data from the patient's existing record and data that are the object of the actual medication review:

The '***Recording data sheet'*** on page one of the care plan is for the recording of existing data obtained from the patient file before the patient is seen, such as personal data, monitoring data (lab results) and COPD-related data (for example, co-morbidities, vaccinations and LTOT assessment). Page one is independent of the 'review' section and in case of any further medication reviews, it can remain as the first page of a patient folder/computer record and need only be updated with the latest values.

The '***Review sheets'*** (pages two - five) contain all fields of data for the actual medication review. These can be understood as work sheets for the pharmacist.

5.1.2.2. Sorting of data fields

To obtain a structured care plan, data fields were sorted to group similar fields spatially. For example all monitoring data were arranged next to each other on the left side of page one, all COPD related recording data on the right side of

page one and the entire medication section was placed on the second page. Multiple checks for one care issue were avoided, with the exceptions of:

- A list of most prevalent co-morbidities was included on page one although this care issue was already covered in the 'medication' section. The summary on the first page allows an overview, as co-morbidities are essential information for choosing the right treatment.
- The additional field 'high risk medication' with check boxes for medications such as digoxin, high dose inhaled corticosteroids and warfarin represents a safety net to make sure risk medication is identified as such and considered when choosing or changing the treatment.

5.1.2.3. Unambiguous labelling

Exact and specific expressions were used to prevent misunderstandings about the kinds of data requested in each field. As dates are attached to all monitoring data values, it can easily be recognized if the latest assessment (for example of BP or MRC grade) is out of date, and the health care professional can carry out the assessment and fill-in the obtained value.

A data field without any ticked check boxes might give the impression that it has not been filled out. To ensure that every data field is considered by the person who fills out the care plan, fields of data containing lists such as 'high risk medications' and 'co-morbidities' were amended with check boxes for 'none'.

5.1.2.4. Font size

A major criticism from the pharmacists was that the font size of eight point was too small in the earlier versions of the care plan (CP-COPD-1, CP-COPD-2) was. Font size point twelve was found to be workable.

5.1.2.5. Automatic highlighting of impaired values by using check boxes

In the earlier versions of the care plan (CP-COPD-1, CP-COPD-2) the recording of lab parameters such as glucose, GFR or blood lipids was via check boxes. The pharmacist simply indicates fixed values as for example: '**GFR** [ml/min]: ❑ >50, ❑ 50-30, ❑<30', while other data fields, such as BP and cholesterol, gave a blank space into which the pharmacist would write the exact value. Check boxes allow a quick overview, as it can be seen more easily if a value is impaired. The pharmacists preferred the second option, however: empty boxes to fill-in values. A compromise was arrived at in the final version of the care plan, where data fields give check boxes for 'normal' and 'impaired,' and a blank box next to it to write down the impaired value.

5.1.3. Tools for designing

The care plan was designed using an existing pharmaceutical care plan template in Microsoft Word, which was found to be cumbersome and led to frequent formatting issues. The use of more flexible design tools, or the introduction of an electronic system as suggested in section 5.5.2. below would allow the researcher to focus on the content, rather than the design, of the care plan in its formative stages.

5.2. Pharmaceutical care provision in Scotland

In 2009 the Scottish Government published a report about the establishment of therapeutic partnerships between community pharmacists, general medical practitioners (GP) and patients, on which the currently negotiated Chronic Medication Service (CMS) element of the Community Pharmacy Contract within NHS (National Health Service) Scotland is built. The CMS is a new approach to involving community pharmacists in the management of patients with long term conditions, such as COPD, and is based on the collaboration and communication between different healthcare professionals.

Patients with long term conditions within this new contract are envisaged to be able voluntarily to register for the CMS in their local community pharmacy. Once the patient has done so, the patient's electronic record gets flagged as 'CMS registered', which enables the GP to generate electronic serial prescriptions of medicines, and gives the pharmacist the opportunity to provide care to the patient [5].

Currently, in advance of a formal role for community pharmacists, local schemes are using pharmacists to undertake medication reviews. In the community health centres visited during this research COPD Support Pharmacists and PSPs are performing full medication reviews for patients with COPD. As part of this process, an appointment for a face-to-face dialogue with the patient is arranged. In this setting, the patient's GP has to approve the recommended changes in the treatment plan by the pharmacist. If the pharmacist is an independent prescriber (PSP) they can sign the new prescriptions, otherwise they are given to the GP to sign.

5.2.1. Limitations of the current services

- Within the current medication reviews provided to patients with COPD, the pharmacists who specialise in COPD may not give adequate attention to co-morbidities by limiting the focus to COPD alone.
- By expanding the existing services to community pharmacies, a larger number of patients can benefit from systematic care provision. Through implementation of CMS a big step in the right direction will be achieved.
- Finite resources need to be best distributed, and this requirement needs to be balanced with the ideal wish to most fully improve each patient's quality of life by providing the best available treatment and a yearly medication review [6].

5.2.2. Limitation of the current clinical documentation

Patients are targeted for a medication review in a community health centre by their read codes in GPASS. The GP's system is also used to obtain patient's records and to input a summarised report after the appointment. Obtaining patient data from GPASS is time-consuming and cumbersome, as much data does not exist in the form of data fields, but is buried within free text or scanned patient documents.

Some of the pharmacists shadowed for this research are currently using the 'respiratory review form' (F-RR) as a work sheet and for documentation of the services they provide. This form focuses on COPD and asthma only and does not contain the following data fields:

- Complete list of current medication
- Lab results such as blood lipids, cholesterol, glucose and GFR
- Assessments such as BODE index, BP HAD scores and CVD risk
- Checklist for unmet preventive medication needs (osteoporosis, cardiovascular risk)
- Detailed medication scheme
- Comprehensive and detailed standard checks
- Comprehensive smoking status assessment form
- List of co-morbidities, date of diagnosis and associated clinical data
- Recording of medication history and excluded medication
- Highlighting of high-risk medication

5.3. Advantages of the new care plan

The care plan for patients with COPD that has been developed is detailed, comprehensive and summarises all relevant data. If the documentation is filled out accurately and in full, it ensures consideration of all potential care issues covered by the care plan. Its design, especially that of the standard checks, the medication scheme and the assessment of the smoking status,

are intuitive and do not require lengthy instruction. The care plan allows efficient task sharing between different health care professionals.

5.3.1. Task sharing

The division of the care plan into a 'recording sheet' and 'review sheets' resulted in a page containing mainly lab results and previous diagnoses, which could be collected and filled out by a technician, followed by worksheets for the actual medication review which is carried out by a pharmacist. This is supported by Hudson et. al., who further argue that the initial documentation, patients' education and administration of medicines (especially inhaler technique) might be carried out by a technician before referral to the pharmacist [3]. This suggests a possible time-saving measure, for while in the medication reviews run by the community health centres shadowed during this research, the entire assessment, including preparation work (for example obtaining relevant information from patient files) was carried out by a PSP.

5.3.2. Other functions of clinical documentation:

- Peer review sharing of experience and obtaining colleagues views and therefore a way of reviewing the service
- Sharing information with other healthcare professionals
- Enables discussion of individual cases with other colleagues
- Medico-legal function
- Evidence of service being provided and therefore evidence to support payment for the service
- A way of training pre-registration pharmacists

5.4. Limitations of the pharmaceutical care plan

The limitations of a very detailed care plan, such as developed during this research, might be that pharmacists are tempted to stop using their skills and knowledge and trust only in the care plan. This could lead to pharmacists forgetting their knowledge and diminution of feelings of responsibility, as the

care plan might give the false impression of covering all possible circumstances and conditions. The use of a computer based system might further exacerbate these risks. Another problem might be that Pharmacists are focusing on the documentation more than talking to the patient. Both classroom education and practical implementation with experienced role models would be necessary to minimise the risk of making these mistakes.

5.5. Future prospects

5.5.1. Introduction of systematic care provision and documentation

CMS is a promising approach for involving community pharmacists in systematic care provision for patients with chronic conditions such as COPD. Its introduction enables pharmacists to provide systematic care to a large number of patients by performing regular medication reviews. As suggested by the Scottish government, areas of inter-professional working, communications, and education and continuing professional development need to be improved to support the successful implementation of CMS [5], so that systematic care can be provided to patients not only in community health centres with pharmacists running medication review clinics, but in every community pharmacy.

5.5.2. Electronic solution

Anecdotal evidence suggests that some pharmacists favour the introduction of a computer application for care planning. The advantages of an electronic version of a care plan would be:

- Design problems as discussed in section 5.1.3 above could be circumvented
- Automatic identification of pharmaceutical care issues
- Automatic recommendation of actions to be taken to resolve an identified care issue
- It might be possible to integrate an electronic care plan application into the Patient Medication Record (PMR) system which is currently used in community pharmacies in the UK [5], and connect it with the GP's IT systems

- In that case, necessary patient data like lab results or the patient's current medication could be collected and summarised automatically, and then printed off. Similar interactions between the pharmacy's and the GP's IT systems are already in use, as for example in the patient registration process for CMS [5].
- Automatic highlighting of instances where data is lacking
- Simplification of audit procedures (for example that of adherence to guidelines)

Current limitations to the realisation of an electronic care plan are:

- As described in section 5.2.2 above, many of the GP's patients' results are not in the form of data fields and can therefore not be transferred easily into fields of data, as would be necessary for an electronic care plan.
- The future implementation might reveal the collection of data which the pharmacists can collect but which are not routinely collected by the doctor.
- There are obvious data protection issues: the electronic transfer of information is the subject of great concern about privacy and in certain countries the legal right to privacy may be a serious barrier.

5.5.3. Guidelines

The development of a pharmaceutical care plan such as has been the focus of this study would be eased by the creation of guidelines, which would provide care plan developers with a common structural framework and define categories of data for inclusion. Another potential approach would be the direct integration of a draft of a care plan into every guideline issued by clinical practice guideline developers such as NICE and SIGN. In developing recommendations for the care of patients, they undertake reviews of the best available evidence and are therefore highly qualified to identify and prioritise pharmaceutical care issues and develop pharmaceutical care plans. This is partially happening already: see, for example, the appendix of the latest COPD guidelines [6], which contains a detailed algorithm for inhaled therapies, generated from guideline recommendations.

5.5.4. Future research about COPD

So far no cure for COPD has been found. Improvement of long acting inhaled bronchodilators, further investigation of the connection between vitamin D and respiratory health and the revision of corticosteroid resistance are promising approaches in COPD therapy and more research is going on. The impact of risk factors, gender and genetic factors needs to be researched further. Smoking cessation and prevention programmes need to be improved. The NICE guidelines [6] suggest the following other areas for future research into treatment of COPD:

- Research the benefits of pulmonary rehabilitation during hospital admission
- Finding a simple multidimensional assessment of outcomes, as the BODE index assessment is impractical
- Research whether triple therapy improves outcomes compared to single or double therapy, including health economic evaluation.
- Investigate whether mucolytic therapy prevents exacerbations.

6. CONCLUSIONS

- A very detailed pharmaceutical care plan for patients with COPD has been developed. It should be understood as one of many parts of a comprehensive care plan which will be developed to be used in every patient with any chronic disease, rather than as a self-contained project.
- The developed care plan allows efficient task sharing and enables sharing of information between different health care professionals.
- The Identification, selection and prioritisation of care issues is an individualised and subjective process. Extensive field-testing on a larger sample of patients is essential to ensure that care issues are incorporated into the plan at the correct level of detail.
- There is a need for more research on treatment of COPD
- The development of guidelines could ease the process of care plan development.
- Theoretical and practical training are necessary to train involved health care professionals in the correct use of the care plan
- The care plan needs to be reviewed periodically to be kept up to date
- The development and introduction of an electronic application for care planning would have many benefits. Paper versions of care plans such as developed during this research can be used for training and implemented in pilot schemes for electronic solutions.
- The success of this pharmaceutical care plan will be judged by whether pharmacists extend their services and take on more responsibility.
- The introduction of CMS will involve community pharmacists in Scotland to provide systematic care to a large number of patients

Scotland provides a great example to the rest of Europe of the generation of efficient pharmaceutical care through the provision of a range of pharmaceutical care services which are backed up by constant research and development. Austria and other European countries could introduce a model similar to the Scottish one, and harness the particular skills and knowledge of pharmacists, as part of multidisciplinary teams, to provide pharmaceutical care to patients and thus make significant cost savings in times of a deficit national health insurance fund.

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APPENDICES

APPENDIX I: Pharmaceutical care plans

APPENDIX II: Feedback by PSPs

APPENDIX III: Curriculum vitae

APPENDIX I

CP-LTC

F-RR

List of suggestions for improvement of F-RR by Joanna Johnson

CP-COPD-1

CP-COPD-2

CP-COPD-3

Applicable version of CP-COPD-3 (black and white)

CP-LTC

Pharmaceutical Care of Patients with Long Term Conditions: Structured Assessment

Name

Number√
CHI (DoB)

Address √

On disease self management plan√ ❑

Smoker√ ❑
Past Smoker √ ❑

Pack Years: √
Under cessation√❑

Specialist Advice √ ❑ Diet ❑Exercise ❑ Smoking

Male ■ Female ❑

Body Weight:

Height:

BMI

Blood Pressure √
mm Hg

Dates
Sys/ Dia

PEFR Litres/hr √

Dates
Value

GFR ml/min √ ❑ >50 ❑ 30-50 ❑ <30

Cholesterol mmol/L
Dates
Value

DEXA scan√

Known Allergies√

High risk Medication user√
❑ Corticosteroids ❑ High dose inhaled steroids
❑ Warfarin ❑Digoxin ❑ MTX Others:

Social Circumstances√

❑ Lives alone ❑ Housebound ❑ Professional carer ❑Family carer

	Relevant Medical History	Relevant Past Medication	Date
1			
2			
3			
4			
5			
6			
7			
8			

Current Medication

1		7	
2		8	
3		9	
4		10	
5		11	
6		12	

Disease Specific Monitoring Data

Past MI Date(s) √
CVD Risk: √ %/10yr

Lipid profile √

TC ≥4 mmol/L √ ■
HDL <1 mmol/L √ ❑
LDL ≥ 2mmol/L √ ❑

Diabetes Profile √
Diabetes Risk: %/10yr

HbA1c mmol/L: 9.9 date 11/10/09
[Target <7mmol/L]

Diabetes Complications √
Neuropathic pain√ ■
Microalbuminuria √ ❑
Last check dates: Eye 11/09 : Foot

Pulmonary Function
COPD Prognosis index:
Predicted 3yrs
Mortality:
Hospitalisations:
Exacerbations:

MRC DYPSNOEA SCORE /yr
1❑ 2 ❑ 3 ❑ 4 ❑ 5❑

❑ Mild ❑ Moderate ❑ Severe
FEV_1 ≥80% 50-79% 30-49%

Stage	COPD / Asthma
1❑	SABA
2❑	+ Anticholinergic / + Inhaled steroid
3❑	+ LABA
4❑	+ Inhaled steroid / minus LABA + Add on
5❑	+ Add on / + Oral steroid

Exacerbations: in past yr
[LABA indicated if >1]

Vaccination√
√ Pneumonia √ ❑ Influenza

Obesity Profile
Target Wt: √ 68kg

Fracture Risk √ %/10yr
FRAX:

Standard Checks

		√	Care issue
CHD Prevention	**Smoker** offered entry to cessation programme	√	❑
	10yr CHD risk ≥20% , Age>40 on aspirin 75mg	√	❑
	As above plus Diabetes & FH on Statin (MTD)	√	❑
	0n aspirin achieved a BP ≤ 150/90mm/Hg	√	❑
	Aspirin C/I, on Clopidogrel 75mg	√	❑
	Stroke or TIA history on dipyridamole 200mg BD	√	❑
	TC≥4mmol/L on Statin unless C/I	√	❑
	Patients with CHD Prescribed aspirin & statin	√	❑
			❑
Hypertension	**Hypertensive patient** on treatment	√	❑
	Not prescribed combination of thiazide & b/blocker	√	❑
	↑BP, ≤55yr, non-black on ACE inhibitor	√	❑
	↑BP, >55yr, black on thiazide diuretics/ Ca Blocker	√	❑
	Heart failure patient on ACE inhibitor -target dose	√	❑
	Diabetes + Angina, Hypertension on ACE inhibitor	√	❑
	Diabetes/CVD /Chronic Renal Failure blood pressure optimised (≤130/≤80)	√	❑
Diabetes	**AII antagonist** indicated ❑/use verified ❑	√	❑
	BMI> 26(F)/27(M) kg/m² on metformin	√	❑
	+ BP Controlled, CVD≥20% on aspirin 75mg	√	❑
	+ CVD, TC<5, HDL<1 started on gemfibrozil	√	❑
Lung Disease	**Suitability of multiple inhaler prescribing ; on >2 inhalers** has response confirmed	√	❑
	On inhaled steroid ❑ not > twice daily	√	❑
	Oral steroid/6mths annual diabetes, BP & FRAX	√	❑
	FRAX assessment (if >800 mcg/day)	√	❑
	COPD/asthma candidate for LABA	√	❑
	Oral steroid/6mths is also on inhaled high dose	√	❑

Monitoring Notes

Next 12 month review date:

Care Issue	STANDARD TREATMENT VERIFICATIONS		Output (Initial)
1	Choice of medication/dose	❑ Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
2	Clinical/Laboratory monitoring	❑ Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
3	Check for unmet preventive medication needs CV Risk ❑ Osteoporosis ❑	Candidate for ❑ statin ❑ aspirin ❑ ACEI ❑ ß Blocker ❑Oral Biphosphonate ❑Ca & Vit D ❑	
4	Assess patient comprehension and ability to administer medication	Inhaler Technique Poor 0 1 2 3 Satisfactory	

INDIVIDUALISED CARE ISSUES

	Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)	Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
Specify *Action* *Output (Initial)*	**1**			**4**		
Specify *Action* *Output (Initial)*	**2**			**5**		
Specify *Action* *Output (Initial)*	**3**			**6**		

INDIVIDUALISED CARE ISSUES						
	Week No + Date	**Patient Education Documentation Additional Checks**	**Therapeutic Plan Changes** (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)	**Week No + Date**	**Patient Education Documentation Additional Checks**	**Therapeutic Plan Changes** (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
Specify	**7**			**12**		
Action						
Output (Initial)						
Specify	**8**			**13**		
Action						
Output (Initial)						
Specify	**9**			**14**		
Action						
Output (Initial)						
Specify	**10**			**15**		
Action						
Output (Initial)						
Specify	**11**			**16**		
Action						
Output (Initial)						

F-RR

Respiratory Review

Date: patient's name: DOB: Age:

Address: GP:

Telephone number: Ref no:
ht: wt: BMI:

Attended surgery □ House visit □ Phone review □ Other……..

Exception coded from COPD review?: Yes □ No □

Diagnosis

Read code(s) recorded in records: Asthma □ COPD □ Other □
Date of spirometry _____ Results (FEV_1/FVC and FEV_1% predicted):

Mild (as per NICE guideline) □ Moderate □ Severe □

Recent chest x-ray Date and result_____ (For repeat CXR?)

Other medical history:

CHD		Others:
Diabetes		
PVD		
CVA/ TIA		

Previous year attendances for resp conditions only:

Attendance	**Number in previous year**
At hospital outpatient	
At hospital inpatient stay	
At A & E	
At GP appointment	
At practice nurse appointment	

Number of exacerbation(s) in previous 2 years?

1. Medication

Number of medications on repeat (for any indication):

Current respiratory prescription (Information from patient)

Inhalers/ respiratory medication	Actual dose	knowledge, compliance, efficacy, ADRs, CIs, cost effectiveness ?

Concordance issues
None known □ Yes □ Reason, if known? _____

Referral to LTMS?

2. COPD review

Date of review:

Knowledge of COPD?

Smoking status (information from patient)
Never smoked □ Ex smoker □ Smoker □ Motivated to quit ? Yes □ No □
Previous quit attempt(s) _____

Advice given Yes □ No □ Details……

MRC Grading (COPD)

	MRC Grade
Diagnosis of COPD but not restricted in usual daily activity	1
Copes with daily activity but some difficulty keeping up with peers – especially hills and stairs	2
Restricted activity out-of-doors – unable to keep up with peers on the level	3
Marked limitation in outdoor activity – stairs and inclines with great difficulty. Self caring indoors	4
Essentially housebound and requires some assistance in personal care	5

	Yes	No	Not applicable (give details)
Satisfactory inhaler technique			
Discussed exacerbations			
Up to date flu vaccination			
Up to date pneumococcal vaccination			

	Yes	No	Details
Pulmonary rehabilitation appropriate?			
LTOT/ ambulatory oxygen therapy assessment required?			
Depression?			
Onward referrals (pulmonary rehab, GP, LTMS)?			

Care issues (see attached referral):

Follow up required □ Planned date for follow up _____

Time taken for review:

Costs saved or incurred:

COPD review (follow up)

Date _____ Attended surgery □ House visit □ Phone review □ Cancelled □ DNA □

Changes to treatment:

COPD control

MRC Grading (COPD)

	MRC Grade
Diagnosis of COPD but not restricted in usual daily activity	1
Copes with daily activity but some difficulty keeping up with peers – especially hills and stairs	2
Restricted activity out-of-doors – unable to keep up with peers on the level	3
Marked limitation in outdoor activity – stairs and inclines with great difficulty. Self caring indoors	4
Essentially housebound and requires some assistance in personal care	5

Assessment of response to therapy change (after minimum 1 month trial)

	Yes	No
Has your treatment made a difference to you?		
Is your breathing easier in any way?		
Has your sleep improved?		
Can you do some thing now that you couldn't do before or do the same things faster?		
Can you do the same things as before but are now less breathless when you do them?		

COPD management

	Yes	No	Not applicable (give details)
Satisfactory inhaler technique			
Written self management plan			
Up to date flu vaccination			
Up to date pneumococcal vaccination			

List of suggestions for improvement of F-RR by Joanna Johnson

How would I change the respiratory review form?

Patient details

Then a box with Height, weight, BMI, Blood pressure (enough room for the last 3 reported), Latest cholesterol, Cardiovascular Risk,

U&E's normal – Yes/No with a line for comments next to this.
Urea and Electrolytes

Smoking Status (currently on Pg 2)

Other Medical History – just a box for details

COPD details Ie Read code: Asthma, COPD, Other

Knowledge of COPD?

Spirometry: Practice/Outreach Spirometry
Date:
Fev1% Predicted:
FEV1/FVC:
Reversibility with salbutamol?

Repeat spirometry needed? Referral sent?

Grade of COPD (as per NICE): Mild/Moderate/Severe

MRC Scale: Assessed by pharmacist/patient? – currently on page 2

Number of exacerbations requiring Antibiotics and /or oral corticosteroids in the last year:

Discussed exacerbations/self management issues _____

Seen by secondary care respiratory services? If so, which ones? Last seen?

Current respiratory therapy – leave table but add on a column for inhaler technique for each of the meds.

Concordance issues?

Pulmonary Rehab Approp?

Other issues ie Oxygen, Depression, further onward referrals: DEXA scan, smoking cessation, Live Active, Dietitic Advice, outreach spirometry etc

Care Issues: etc

Follow up, time taken etc – all ok to stay as is.

CP-COPD-1

Pharmaceutical Care of Patients with COPD: Structured Assessment

Date

Name

Ref. Number:

CHI (DoB) | **Age**

Tel No:

Address:

❑ House visit
❑ Phone review

GP:

Next 12 month review date:
❑ Follow up required:
❑ Phone review required:

Ie Read code: ❑Asthma ❑ COPD
❑ Other:
❑ Exception coded from COPD review

❑Smoker
❑ Cannabis smoker
❑ Past Smoker
❑ Never smoked

Pack Years:
❑ Under cessation
❑ Motivated to quit
❑ prev. quit attempts:

❑ On disease self management plan
❑ Attended surgery
❑ seen by secondary care respiratory services:

❑ Male ❑ Female	weight: ❑ unintentional wt loss	height:	BMI:

Social Circumstances: ❑ Lives alone ❑ Housebound ❑ Professional carer ❑ Family care

Knowledge of COPD? ❑ yes ❑ no | **Specialist Advice:** ❑ Diet ❑Exercise ❑ Smoking ❑ social service

GFR ml/min ❑>50 ❑30-50 ❑<30 | Urea and Electrolytes ❑ normal ❑ impaired:

Blood Pressure	dates				
	mm HG				
PEFR	dates				
	litres/hr				
Spirometry dates	❑ practice ❑ outreach	❑ practice ❑ outreach	❑ practice ❑ outreach		
FEV_1/FVC / FEV_1					
Cholesterol	dates				
	mmol/L				

DXA scan (DADS)		Chest X-Ray		CT-scan	

High risk Medication user ❑ MTX ❑ Corticosteroids ❑ High dose inhaled steroids ❑ Warfarin ❑Digoxin ❑Others:

Known Allergies

Monitoring notes:

Time taken for review:

Costs saved or incurred:

❑ TC ≥4 mmol/L
❑ HDL <1 mmol/L
❑ LDL ≥ 2mmol/L

HbA_{1c} mmol/L
Diabetes Risk: %/10yr

CVD Risk: %/10yr

Fracture Risk FRAX: %/10yr

Vaccinations (up to date?):
❑Pneumonia ❑Influenza

COPD profile
❑Mild ❑ Moderate ❑ Severe

MRC GRADE (assessed by ❑ pharmacist ❑ patient):
1❑ 2 ❑ 3❑ 4 ❑ 5❑

Number of exacerbations requiring Antibiotics and /or oral corticosteroids **in past year:**

Current COPD therapy:

❑ SABA
❑ +Tiotropium
❑ +LABA
❑ +Inhaled Steroid
❑ +LTOT

❑ Oral Steroid
❑ Theophylline
❑ Mucolytic (carbocistein)

❑ other:

Reversibility with Salbutamol
❑ no ❑ yes [more than 15% response in FEV_1 suggests asthma]

❑ coexisting asthma

Standard Checks

		Care issue
	Pregnancy	❑
	Smoker offered entry to cessation programme	❑
	Anxiety/Depression management	❑
	BMI<20: dietitian/ **BMI>25**: encourage weight control	❑
CHD Prevention	**10yr CHD risk ≥20% , Age>40** on aspirin 75mg	❑
	As above plus Diabetes & FH on Statin (MTD)	❑
	0n aspirin achieved a BP ≤ 150/90mm/Hg	❑
	Aspirin C/I, on Clopidogrel 75mg	❑
	Stroke or TIA history on dipyridamole 200mg BD	❑
	TC≥4mmol/L on Statin unless C/I	❑
	Patients with CHD Prescribed aspirin & statin	❑
Hypertension	**Hypertensive patient** on treatment	❑
	Not prescribed combination of thiazide & b/blocker	❑
	↑BP, ≤55yr, non-black on ACE inhibitor	❑
	↑BP, >55yr, black on thiazide diuretics/ Ca Blocker	❑
	Heart failure patient on ACE inhibitor -target dose	❑
	Diabetes + Angina, Hypertension on ACE inhibitor	❑
	Diabetes/CVD /Chronic Renal Failure blood pressure optimised (≤130/≤80)	❑
Diabetes	**AII antagonist** ❑ indicated / ❑ use verified	❑
	BMI> 26(F)/27(M) kg/m² on metformin	❑
	+ BP Controlled, CVD≥20% on aspirin 75mg	❑
	+ CVD, TC<5, HDL<1 started on gemfibrozil	❑
COPD	Asked about **occupational dust or fume exposure**	❑
	Young onset or non-smoker: AAT-deficiency?	❑
	Exacerbations & self management issues discussed	❑
	>1 exacerbation/year + FEV1 < 50%: LABA+inhaled Steroid (not > 2x daily)	❑
	Theophylline: ❑ use verified, ❑plasmalevel monitored	❑
	Oral steroid/6mths annual diabetes, BP & DADS	❑
	>65 yrs + oral steroids: Osteoporosis prophylaxis	❑
	1000 mcg beclometasone + risk factors: DADS referral	❑
	Respiratory **diagnosis unclear:** refer patient	❑
	Unexpected **change in symptoms or MRC** grade: referral to ❑ spirometry ❑ Chest X-ray	❑
	LTOT/ ambulatory OT assessment required	❑
	Ankle swelling: cor pulmonale?	❑
	MRC>2: referral to pulmonary rehabilitation	❑
	On maximum doses +OT: if dyspnoeic: **palliative care**	❑

MEDICATION

	Relevant Medical History	Relevant Past Medication	date		Current medication [• medication on repeat]	Actual dose	compliance, efficacy, ADRs, CIs, cost effectiveness	clear benefit (after 1 month) yes	clear benefit (after 1 month) no
1				1					
2				2					
3				3					
4				4					
5				5					
6				6					
7				7					
8				8					

Past medication trials without clear benefit	date	Number of medications on repeat:	Concordance issues:
Excluded medication:	Reason for exclusion:		

Care Issue	STANDARD TREATMENT VERIFICATIONS		Output (Initial)
1	Choice of medication/dose/ inhaler type	❑Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
2	Clinical/Laboratory monitoring	❑ Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
3	Check for unmet preventive medication needs CV Risk ❑ Osteoporosis ❑	Candidate for ❑ statin ❑ aspirin ❑ ACEI ❑ ß Blocker ❑Oral Biphosphonate ❑Ca & Vit D	
4	Assess patient comprehension and ability to administer medication (SPACER?)	Inhaler Technique Poor 0 1 2 3 Satisfactory	

INDIVIDUALISED CARE ISSUES						
	Week No + Date	**Patient Education Documentation Additional Checks**	**Therapeutic Plan Changes** (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)	**Week No + Date**	**Patient Education Documentation Additional Checks**	**Therapeutic Plan Changes** (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
Specify	**1**			**6**		
Action						
Output (Initial)						
Specify	**2**			**7**		
Action						
Output (Initial)						
Specify	**3**			**8**		
Action						
Output (Initial)						
Specify	**4**			**9**		
Action						
Output (Initial)						
Specify	**5**			**10**		
Action						
Output (Initial)						

CP-COPD-2

Pharmaceutical Care of Patients with COPD: Structured Assessment

Name		**Ref. Number:**	
		CHI (Dob)	**Age:**
Tel. No.			
Address:		**GP:**	
Ie Read code: ❑COPD ❑Asthma ❑Other:	**Review:** ❑House visit ❑Phone ❑Clinic	❑On disease self management plan ❑Attended surgery ❑Attended pulmonary rehabilitation ❑Other secondary care services:	
High risk Medication user: ❑Digoxin ❑MTX ❑High dose inhaled Corticosteroid ❑Warfarin ❑Corticosteroid ❑Others:		**Known Allergies:**	
❑Female ❑Male	**Social Circumstances:**	❑Smoker	❑Under cessation
weight	❑Lives alone	❑Past Smoker	❑Desire to quit
height	❑Housebound	❑Never smoked	No. Cigs./day:
BMI	❑Professional carer	❑Dust/fumes exposure	No. quit attempts:
	❑Family care		Pack years:

U&Es:	date:	❑normal	❑impaired:	
GFR [ml/min]	date:	❑>50	❑50-30	❑<30
Glucose [mmol/l]	date:	❑< 6	❑6-7	❑>7
Lipids [mmol/l]	date:	❑Chol ≥ 6	❑TC ≥4	❑HDL <1 ❑LDL ≥ 2
BP [Sys/Dia]				
dates				
Spirometry	❑practice ❑outreach		❑practice ❑outreach	❑practice ❑outreach
dates				
FEV_1/FVC / FEV_1				
Reversibility [%]				
MRC grade	1❑ 2❑ 3❑ 4❑ 5❑		1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑
assessed by	❑pharmacist ❑patient		❑pharmacist ❑patient	❑pharmacist ❑patient
dates				
Chest X-Ray		**CT-scan**		
date		date		
CVD risk (assign)		**HADS-D & HADS-A**		
date		dates		
DXA scan		**Vaccinations**	❑Pneumonia	
date		(up to date)	❑Influenza	

COPD profile

NICE:

❑ **Mild** [FEV_1 ≥80%] ❑ **Severe** [30-49%]
❑ **Moderate** [50-79%] ❑ **Very Severe** [<30 or <50 + RF]

BODE index

Patient's **age** at initial COPD **diagnosis**

Number of exacerbations requiring antibiotics or oral corticosteroids **in past year**

❑ **LTOT assessment** date:

PaO_2:	SaO_2:

Comorbidities:

❑ AAT-Deficiency	❑ Diabetes
❑ Asthma	❑ Glaucoma
❑ Cor pulmonale	❑ Hypertension
❑ CVD	❑ Osteoporosis
❑ Depression	❑ Other:

Medication:

❑ SABA or ❑ SAMA			
❑ FEV_1 ≥ 50%		❑ FEV_1 < 50%	
❑LABA	❑LAMA	❑{LABA+IC} ❑LABA+ LAMA (if IC n/a)	❑LAMA
❑{LABA+IC} ❑LABA+ LAMA (if IC n/a)	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}
❑LAMA + {LABA+IC}			
❑ Oral Steroid ❑ Theophylline		❑ Mucolytic (carbocistein) ❑ Other:	

Date

Standard Checks	action	care issue
MRC≥3 refer to pulmonary rehabilitation		
On SAMA+LAMA switch to SABA		
On theophylline ❑use verified, ❑on TDM		
≥1000 mcg beclometasone+ risk factors refer to DADS		
≥5mg prednisolone/3mths annual diabetes, BP + DADS		
>65 yrs + oral steroids osteoporosis prophylaxis		
Hypertensive patient on treatment		
↑BP, ≤ 55yr, non-black on ACE inhibitor		
↑BP, >55yr, black on thiazide diuretics/ Ca Blocker		
Diabetes/CVD /Chronic Renal Failure BP ≤130/≤80		
Beta blocker + COPD under specialist supervision		
CVD/↑BP/arrhythmia + β-agonist specialist supervision		
Heart failure on ACE inhibitor -target dose		
Patient with CVD prescribed aspirin & statin		
10yr CVD risk ≥20% , Age>40 on aspirin 75mg		
+ Diabetes & FH on Statin (MTD)		
Warfarin + severe COPD decrease dose by 33%		
Diabetes + Angina, Hypertension on ACE inhibitor		
Diabetes + BMI> 26(F)/27(M) kg/m² on metformin		
+ CVD, TC<5, HDL<1 started on gemfibrozil		
Respiratory diagnosis unclear refer for clarification		
COPD onset<40yr, FH AAT-Deficiency refer to specialist		
Smoker offered entry to cessation programme		
Patient knowledge inadequate provide education		
Symptom control inadequate adding of medication		
On maximum medication refer for LTOT assessment		
Clinical failure after all treatment options refer to specialist (palliative care)		
Not coping at home refer for home care support		
Chronic sputum production on carbocisteine		
HADS-D or HADS-A≥8 Anxiety/Depression management		
Oedema presence (ankle swelling) on diuretics		
On steroids educate about adverse effects		
BMI abnormal nutritional supplements, refer to dietician		
On self management but requires revision/support		
Patient on LTOT on >15 hours/day		
Unexpected clinical worsening refer to specialist		
Pregnancy confirmed refer to specialist		

Next 12 month review date:
❑ Follow up required:
❑ Phone review required:

Time taken for review:
Costs saved or incurred:

Monitoring notes

MEDICATION

	Relevant Medical History	Relevant Past Medication	Date		Current medication [• medication on repeat] Total number of medications on repeat:	Actual Dose	Comment
1				1			
2				2			
3				3			
4				4			
5				5			
6				6			
7				7			
8				8			
9				9			
10				10			
Excluded medications:		Trial: from - to	Reason for exclusion:	11			
				12			
				13			

Care Issue	STANDARD TREATMENT VERIFICATIONS			Output (Initial)
1	Choice of medication/dose/ delivery system		❑Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
2	Clinical/Laboratory monitoring		❑ Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
3	Check for unmet preventive medication needs ❑ CV Risk ❑ Osteoporosis ❑Vaccinations:		Candidate for ❑statin ❑aspirin ❑ACEI ❑ß Blocker ❑Ca & Vit D ❑Biphosphonate	
4	Assess patient comprehension and ability to administer medication ❑Nebuliser use verified		Inhaler Technique Poor 0 1 2 3 Satisfactory Candidate for ❑ Spacer ❑ Nebuliser	

INDIVIDUALISED CARE ISSUES

	Week No + Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)	Week No + Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
Specify	**1**			**6**		
Action						
Output (Initial)						
Specify	**2**			**7**		
Action						
Output (Initial)						
Specify	**3**			**8**		
Action						
Output (Initial)						
Specify	**4**			**9**		
Action						
Output (Initial)						
Specify	**5**			**10**		
Action						
Output (Initial)						

CP-COPD-3

PHARMACEUTICAL CARE PLAN FOR PATIENTS WITH COPD

Name **Tel. No.**	**CHI:** **Dob**	**Age:**		**GP:**				**Co-morbidities**	
Address:	❑Female ❑Male	weight		**Ie Read code:** ❑COPD ❑Asthma ❑Other:				❑ AAT-Deficiency date of diagnosis:	
		height						❑ Allergies date of diagnosis:	
		BMI						❑ Asthma date of diagnosis:	
Social Circumstances: ❑Lives alone ❑Housebound ❑Professional carer ❑Family care	On COPD self management plan ❑no ❑ yes – date: Attended pulmonary rehabilitation ❑no ❑ yes - date: Other secondary care services: date:							❑ Cor pulmonale date of diagnosis:	
U&Es	date:	❑normal	❑impaired:					❑ CVD date of diagnosis:	
LFTs	date:	❑normal	❑impaired:					❑ Depression date of diagnosis:	
Lipids & Chol	date:	❑normal	❑impaired:					❑ Diabetes date of diagnosis:	
GFR	date:	❑normal	❑impaired:					❑ Glaucoma date of diagnosis:	
Glucose	date:	❑normal	❑impaired:					❑ Hypertension date of diagnosis:	
BP [Sys/Dia]								❑ Osteoporosis date of diagnosis:	
dates								❑ None	
Spirometry	❑practice ❑outreach	❑practice ❑outreach	❑practice ❑outreach	❑practice ❑outreach	❑practice ❑outreach			❑ Others:	
dates									
FEV_1/FVC FEV_1									
Reversibility [%]									
NICE classification of severity	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe				
MRC grade	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑				
dates									
assessed by	❑pharmacist ❑patient	❑pharmacist ❑patient	❑pharmacist ❑patient	❑pharmacist ❑patient	❑pharmacist ❑patient				
CT-scan		**Chest X-Ray**		**BODE index**					
date		date		date					
LTOT assessm.	PaO_2:	SaO_2:	**DXA scan**						
date			dates						
CVD risk (assign)		**HADS-D**							
		HADS-A							
date		dates							

Vaccinations: Pneumonia ❑no ❑yes-date:
Influenza ❑no ❑yes-date:

Patient's age at initial COPD diagnosis

No. of exacerbations requiring ABs or oral corticosteroids in past year

MEDICATION

	Relevant Medical History	Relevant Past Medication	Date
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			

Excluded medications:	Trial: from - to	Reason for exclusion:

	Current medication [• medication on repeat] Total number of medications on repeat:	Actual Dose	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

High risk Medications: ❑Digoxin ❑MTX ❑High dose inhaled Corticosteroid ❑Warfarin ❑ Corticosteroid ❑ None ❑Others:

PHARMACEUTICAL CARE REVIEW

Date:

❑ House visit ❑ Phone ❑ Clinic

STANDARD TREATMENT VERIFICATIONS

Care Issue				Output (Initial)
1	Choice of medication/dose/ delivery system		❑Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
2	Clinical/Laboratory monitoring		❑ Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
3	Check for unmet preventive medication needs ❑CV Risk ❑ Osteoporosis ❑Vaccinations		Candidate for ❑statin ❑aspirin ❑ACEI ❑ß Blocker ❑Ca & Vit D ❑Biphosphonate	
4	Assess patient comprehension and ability to administer medication ❑Nebuliser use verified		Inhaler Technique Poor 0 1 2 3 Satisfactory Candidate for ❑ Spacer ❑Nebuliser	

Assessment of risk factors:

❑Smoker	❑Past Smoker	❑Never smoked
❑Under cessation	❑Occupational dust/fumes exposure:	
Pack years		Currently using NRT ❑no ❑yes:
No. Cigs./day		
❑Ready to quit	❑Unwilling to quit	
Previous quit attempts		
Products used in failed attempts		

Monitoring notes

COPD medication:

❑ SABA or ❑ SAMA			
❑ $FEV_1 \geq 50\%$		❑ $FEV_1 < 50\%$	
❑LABA	❑LAMA	❑{LABA+IC} ❑LABA+LAMA (if IC n/a)	❑LAMA
❑{LABA+IC} ❑LABA+LAMA (if IC n/a)	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}
❑LAMA + {LABA+IC}			
❑Oral Steroid ❑Others:	❑Theophylline	❑Mucolytic (carbocistein)	

Time taken for review:	Costs saved or incurred:	❑ Follow up required:	❑ Phone review required:	**Next 12 month review date:**

Standard Checks	action care issue	
MRC≥3 refer to pulmonary rehabilitation		
On regular SAMA ≥ 4/d switch to LAMA		
On theophylline ❑use verified, ❑on TDM		
≥1000 mcg beclometasone+ risk factors refer to DADS		
≥5mg prednisolone/3mths annual diabetes, BP + DADS		
>65 yrs + oral steroids osteoporosis prophylaxis		
Hypertensive patient on treatment		
↑BP, ≤ 55yr, non-black on ACE inhibitor		
↑BP, >55yr, black on thiazide diuretics/ Ca Blocker		
Diabetes/CVD /Chronic Renal Failure BP ≤130/≤80		
Beta blocker + COPD under specialist supervision		
CVD/↑BP/arrhythmia + β-agonist specialist supervision		
Heart failure on ACE inhibitor -target dose		
Patient with CVD prescribed aspirin & statin		
10yr CVD risk ≥20% , Age>40 on aspirin 75mg		
+ Diabetes & FH on Statin (MTD)		
Warfarin + severe COPD decrease dose by 33%		
Diabetes + Angina, Hypertension on ACE inhibitor		
Diabetes + BMI> 26(F)/27(M) kg/m² on metformin		
+ CVD, TC<5, HDL<1 started on gemfibrozil		
Respiratory diagnosis unclear refer for clarification		
COPD onset<40yr, FH AAT-Deficiency refer to specialist		
Smoker offered entry to cessation programme		
Patient knowledge inadequate provide education		
Symptom control inadequate adding of medication		
On maximum medication refer for LTOT assessment		
Clinical failure after all treatment options refer to specialist		
Not coping at home refer for home care support		
Chronic sputum production on carbocisteine		
HADS-D or HADS-A≥8 Anxiety/Depression management		
Oedema presence (ankle swelling) on diuretics		
On steroids educate about adverse effects		
BMI abnormal nutritional supplements, refer to dietician		
On self management but requires revision/support		
Patient on LTOT on >15 hours/day		
Unexpected clinical worsening refer to specialist		
Pregnancy confirmed refer to specialist		

INDIVIDUALISED CARE ISSUES

	Week No + Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)	Week No + Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
Specify	**1**			**6**		
Action						
Output (Initial)						
Specify	**2**			**7**		
Action						
Output (Initial)						
Specify	**3**			**8**		
Action						
Output (Initial)						
Specify	**4**			**9**		
Action						
Output (Initial)						
Specify	**5**			**10**		
Action						
Output (Initial)						

Applicable version of CP-COPD-3 (black and white)

PHARMACEUTICAL CARE PLAN FOR PATIENTS WITH COPD

Name	**CHI:**		**GP:**	**Co-morbidities**		
	Dob	**Age:**		❑ AAT-Deficiency date of diagnosis:		
Tel. No.						
Address:	❑Female ❑Male	weight	**Ie Read code:** ❑COPD ❑Asthma ❑Other:	❑ Allergies date of diagnosis:		
		height		❑ Asthma date of diagnosis:		
		BMI				
Social Circumstances: ❑Lives alone ❑Housebound ❑Professional carer ❑Family care	On COPD self management plan ❑no ❑ yes – date: Attended pulmonary rehabilitation ❑no ❑ yes - date: Other secondary care services: date:			❑ Cor pulmonale date of diagnosis:		

U&Es	date:	❑normal	❑impaired:			❑ CVD date of diagnosis:
LFTs	date:	❑normal	❑impaired:			
Lipids & Chol	date:	❑normal	❑impaired:			❑ Depression date of diagnosis:
GFR	date:	❑normal	❑impaired:			
Glucose	date:	❑normal	❑impaired:			❑ Diabetes date of diagnosis:
BP [Sys/Dia]						
dates						❑ Glaucoma date of diagnosis:
Spirometry	❑practice ❑outreach	❑practice ❑outreach	❑practice ❑outreach	❑practice ❑outreach	❑practice ❑outreach	
dates						❑ Hypertension date of diagnosis:
FEV_1/FVC / FEV_1						❑ Osteoporosis date of diagnosis:
Reversibility [%]						
NICE classification of severity	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑Mild ❑Moderate ❑Severe ❑Very Severe	❑ None
						❑ Others:
MRC grade	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	
dates						
assessed by	❑pharmacist ❑patient	❑pharmacist ❑patient	❑pharmacist ❑patient	❑pharmacist ❑patient	❑pharmacist ❑patient	
CT-scan		**Chest X-Ray**		**BODE index**		
date		date		date		**Vaccinations:** Pneumonia ❑no ❑yes-date: Influenza ❑no ❑yes-date:
LTOT assessm.	PaO_2:	SaO_2:	**DXA scan**			
date			dates			Patient's age at initial COPD diagnosis
CVD risk (assign)		**HADS-D**				
		HADS-A				**No. of exacerbations** requiring ABs or oral corticosteroids in past year
date		dates				

MEDICATION

	Relevant Medical History	Relevant Past Medication	Date
1			
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13			
14			
15			

Excluded medications:	Trial: from - to	Reason for exclusion:

	Current medication [• medication on repeat] Total number of medications on repeat: ……	Actual Dose	Comment
1			
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5			
6			
7			
8			
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High risk Medications: ❑Digoxin ❑MTX ❑High dose inhaled Corticosteroid ❑Warfarin ❑ Corticosteroid ❑ None ❑Others:

PHARMACEUTICAL CARE REVIEW

Date:

❑ House visit ❑ Phone ❑ Clinic

Care Issue	STANDARD TREATMENT VERIFICATIONS			Output (Initial)
1	Choice of medication/dose/ delivery system		❑Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
2	Clinical/Laboratory monitoring		❑ Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
3	Check for unmet preventive medication needs ❑CV Risk ❑ Osteoporosis ❑Vaccinations		Candidate for ❑statin ❑aspirin ❑ACEI ❑ß Blocker ❑Ca & Vit D ❑Biphosphonate	
4	Assess patient comprehension and ability to administer medication ❑Nebuliser use verified		Inhaler Technique Poor 0 1 2 3 Satisfactory Candidate for ❑ Spacer ❑Nebuliser	

Assessment of risk factors:

❑Smoker		❑Past Smoker	❑Never smoked
❑Under cessation		❑Occupational dust/fumes exposure:	
Pack years		Currently using NRT ❑no ❑yes:	
No. Cigs./day			
❑Ready to quit		❑Unwilling to quit	
Previous quit attempts			
Products used in failed attempts			

Monitoring notes

COPD medication:

❑ SABA or ❑ SAMA			
❑ $FEV_1 \geq 50\%$		❑ $FEV_1 < 50\%$	
❑LABA	❑LAMA	❑{LABA+IC} ❑LABA+LAMA (if IC n/a)	❑LAMA
❑{LABA+IC} ❑LABA+LAMA (if IC n/a)	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}
❑LAMA + {LABA+IC}			
❑Oral Steroid ❑Others:	❑Theophylline	❑Mucolytic (carbocistein)	

Time taken for review:	Costs saved or incurred:	❑ Follow up required:	❑ Phone review required:	**Next 12 month review date:**

Standard Checks	action	care issue
MRC≥3 refer to pulmonary rehabilitation		
On regular SAMA ≥ 4/d switch to LAMA		
On theophylline ❑use verified, ❑on TDM		
≥1000 mcg beclometasone+ risk factors refer to DADS		
≥5mg prednisolone/3mths annual diabetes, BP + DADS		
>65 yrs + oral steroids osteoporosis prophylaxis		
Hypertensive patient on treatment		
↑BP, ≤ 55yr, non-black on ACE inhibitor		
↑BP, >55yr, black on thiazide diuretics/ Ca Blocker		
Diabetes/CVD /Chronic Renal Failure BP ≤130/≤80		
Beta blocker + COPD under specialist supervision		
CVD/↑BP/arrhythmia + β-agonist specialist supervision		
Heart failure on ACE inhibitor -target dose		
Patient with CVD prescribed aspirin & statin		
10yr CVD risk ≥20% , Age>40 on aspirin 75mg		
+ Diabetes & FH on Statin (MTD)		
Warfarin + severe COPD decrease dose by 33%		
Diabetes + Angina, Hypertension on ACE inhibitor		
Diabetes + BMI> 26(F)/27(M) kg/m² on metformin		
+ **CVD, TC<5, HDL<1** started on gemfibrozil		
Respiratory diagnosis unclear refer for clarification		
COPD onset<40yr, FH AAT-Deficiency refer to specialist		
Smoker offered entry to cessation programme		
Patient knowledge inadequate provide education		
Symptom control inadequate adding of medication		
On maximum medication refer for LTOT assessment		
Clinical failure after all treatment options refer to specialist		
Not coping at home refer for home care support		
Chronic sputum production on carbocisteine		
HADS-D or HADS-A≥8 Anxiety/Depression management		
Oedema presence (ankle swelling) on diuretics		
On steroids educate about adverse effects		
BMI abnormal nutritional supplements, refer to dietician		
On self management but requires revision/support		
Patient on LTOT on >15 hours/day		
Unexpected clinical worsening refer to specialist		
Pregnancy confirmed refer to specialist		

INDIVIDUALISED CARE ISSUES						
	Week No + Date	**Patient Education Documentation Additional Checks**	**Therapeutic Plan Changes** (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)	**Week No + Date**	**Patient Education Documentation Additional Checks**	**Therapeutic Plan Changes** (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
Specify	**1**			**6**		
Action						
Output (Initial)						
Specify	**2**			**7**		
Action						
Output (Initial)						
Specify	**3**			**8**		
Action						
Output (Initial)						
Specify	**4**			**9**		
Action						
Output (Initial)						
Specify	**5**			**10**		
Action						
Output (Initial)						

APPENDIX II

Applicable version of CP-COPD-2, as submitted to Pharmacists
Email containing feedback by Joanna Johnson
Attachment of email by Joanna Johnson
Email containing feedback by Lynn Alexander

Applicable version of CP-COPD-2, as submitted to Pharmacists

Pharmaceutical Care of Patients with COPD: Structured Assessment

Name		**Ref. Number:**	
		CHI (Dob)	**Age:**
Tel. No.			
Address:		**GP:**	
Ie Read code: ❑COPD ❑Asthma ❑Other:	**Review:** ❑House visit ❑Phone ❑Clinic	❑On disease self management plan ❑Attended surgery ❑Attended pulmonary rehabilitation ❑Other secondary care services:	
High risk Medication user: ❑Digoxin ❑MTX ❑High dose inhaled Corticosteroid ❑Warfarin ❑Corticosteroid ❑Others:		**Known Allergies:**	
❑Female ❑Male weight height BMI	**Social Circumstances:** ❑Lives alone ❑Housebound ❑Professional carer ❑Family care	❑Smoker ❑Past Smoker ❑Never smoked ❑Dust/fumes exposure	❑Under cessation ❑Desire to quit No. Cigs./day: No. quit attempts: Pack years:

U&Es:	date:	❑normal	❑impaired:	
GFR [ml/min]	date:	❑>50	❑50-30	❑<30
Glucose [mmol/l]	date:	❑< 6	❑6-7	❑>7
Lipids [mmol/l]	date:	❑Chol ≥ 6	❑TC ≥4	❑HDL <1 ❑LDL ≥ 2
BP [Sys/Dia]				
dates				
Spirometry	❑practice ❑outreach	❑practice ❑outreach	❑practice ❑outreach	
dates				
FEV_1/FVC FEV_1				
Reversibility [%]				
MRC grade	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	1❑ 2❑ 3❑ 4❑ 5❑	
assessed by	❑pharmacist ❑patient	❑pharmacist ❑patient	❑pharmacist ❑patient	
dates				

Chest X-Ray		**CT-scan**	
date		date	
CVD risk (assign)		**HADS-D & HADS-A**	
date		dates	
DXA scan		**Vaccinations**	❑Pneumonia
date		(up to date)	❑Influenza

COPD profile

NICE:

❑ **Mild** [FEV_1 ≥80%] ❑ **Severe** [30-49%]
❑ **Moderate** [50-79%] ❑ **Very Severe** [<30 or <50 + RF]

BODE index

Patient's **age** at initial COPD **diagnosis**

Number of exacerbations requiring antibiotics or oral corticosteroids **in past year**

❑ **LTOT assessment** date:

PaO_2:	SaO_2:

Comorbidities:

❑ AAT-Deficiency	❑ Diabetes
❑ Asthma	❑ Glaucoma
❑ Cor pulmonale	❑ Hypertension
❑ CVD	❑ Osteoporosis
❑ Depression	❑ Other:

Medication:

❑ SABA or ❑ SAMA			
❑ FEV_1 ≥ 50%		❑ FEV_1 < 50%	
❑LABA	❑LAMA	❑{LABA+IC} ❑LABA+ LAMA (if IC n/a)	❑LAMA
❑{LABA+IC} ❑LABA+ LAMA (if IC n/a)	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}	❑LAMA + {LABA+IC}
❑LAMA + {LABA+IC}			
❑ Oral Steroid		❑ Mucolytic (carbocistein)	
❑ Theophylline		❑ Other:	

Date

Standard Checks	action	care issue
MRC≥3 refer to pulmonary rehabilitation		
On SAMA+LAMA switch to SABA		
On theophylline ❑use verified, ❑on TDM		
≥1000 mcg beclometasone+ risk factors refer to DADS		
≥5mg prednisolone/3mths annual diabetes, BP + DADS		
>65 yrs + oral steroids osteoporosis prophylaxis		
Hypertensive patient on treatment		
↑BP, ≤ 55yr, non-black on ACE inhibitor		
↑BP, >55yr, black on thiazide diuretics/ Ca Blocker		
Diabetes/CVD /Chronic Renal Failure BP ≤130/≤80		
Beta blocker + COPD under specialist supervision		
CVD/↑BP/arrhythmia + β-agonist specialist supervision		
Heart failure on ACE inhibitor -target dose		
Patient with CVD prescribed aspirin & statin		
10yr CVD risk ≥20% , Age>40 on aspirin 75mg		
+ Diabetes & FH on Statin (MTD)		
Warfarin + severe COPD decrease dose by 33%		
Diabetes + Angina, Hypertension on ACE inhibitor		
Diabetes + BMI> 26(F)/27(M) kg/m² on metformin		
+ CVD, TC<5, HDL<1 started on gemfibrozil		
Respiratory diagnosis unclear refer for clarification		
COPD onset<40yr, FH AAT-Deficiency refer to specialist		
Smoker offered entry to cessation programme		
Patient knowledge inadequate provide education		
Symptom control inadequate adding of medication		
On maximum medication refer for LTOT assessment		
Clinical failure after all treatment options refer to specialist (palliative care)		
Not coping at home refer for home care support		
Chronic sputum production on carbocisteine		
HADS-D or HADS-A≥8 Anxiety/Depression management		
Oedema presence (ankle swelling) on diuretics		
On steroids educate about adverse effects		
BMI abnormal nutritional supplements, refer to dietician		
On self management but requires revision/support		
Patient on LTOT on >15 hours/day		
Unexpected clinical worsening refer to specialist		
Pregnancy confirmed refer to specialist		

Monitoring notes

Next 12 month review date:
❑ Follow up required:
❑ Phone review required:

Time taken for review:
Costs saved or incurred:

MEDICATION

	Relevant Medical History	Relevant Past Medication	Date
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Excluded medications:	Trial: from - to	Reason for exclusion:

	Current medication [• medication on repeat] Total number of medications on repeat:	Actual Dose	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			

Care Issue	STANDARD TREATMENT VERIFICATIONS		Output (Initial)
1	Choice of medication/dose/ delivery system	❑Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
2	Clinical/Laboratory monitoring	❑ Meets guideline recommendations ❑ Identified exception ❑ Identified special precaution	
3	Check for unmet preventive medication needs ❑ CV Risk ❑ Osteoporosis ❑Vaccinations:	Candidate for ❑statin ❑aspirin ❑ACEI ❑ß Blocker ❑Ca & Vit D ❑Biphosphonate	
4	Assess patient comprehension and ability to administer medication ❑Nebuliser use verified	Inhaler Technique Poor 0 1 2 3 Satisfactory Candidate for ❑ Spacer ❑ Nebuliser	

INDIVIDUALISED CARE ISSUES

	Week No + Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)	Week No + Date	Patient Education Documentation Additional Checks	Therapeutic Plan Changes (Individualisations/ Dosage change/ Treatment interruption/ Management of co-morbidity)
Specify	**1**			**6**		
Action						
Output (Initial)						
Specify	**2**			**7**		
Action						
Output (Initial)						
Specify	**3**			**8**		
Action						
Output (Initial)						
Specify	**4**			**9**		
Action						
Output (Initial)						
Specify	**5**			**10**		
Action						
Output (Initial)						

Email containing feedback by Joanna Johnson

Hi there,

I have attached my comments re the care plan - reading my big long list looks like I have pulled it to pieces however I really think you have done a great job pulling all this information together. The changes I have suggested will make the process of care planning simpler and more logical as for most of us, this is done in a mad rush.

I have just written the list of comments in a mad rush so I hope they make sense - please let me know if you would like me to try using any ammended versions that you produce and if my comments aren't clear.

Jo

Joanna Johnson
COPD Support Pharmacist
Pharmacy & Prescribing Support Unit
NHS Greater Glasgow & Clyde
Queens Park House, Langside Road
Glasgow G42 9TY
0141 201 5333

Attachment of email by Joanna Johnson

Comments for Magdalena,

1. The font on the first page is just too small to be easily workable. I am undecided about whether the Standard Checks is necessary to have. My recommendation would be that you have a 'reminder page' at the back containing this information that people can use if they want or else just not print it off. This list would really only be necessary to pharmacists very new to running clinics so I do think a reminder sheet would be helpful for them. It also gives you a lot more space to increase the font size of the other information. I haven't had a chance to check this section for correctness but the line on SAMA & LAMA switch to SABA is not correct.
2. I think you need two separate boxes to record CHI and DOB.
3. The box where you ask about self management plans I would move to after you have recorded MRC grade and change it to look something like:

   COPD self management plan YES/NO
   Attended Pulmonary Rehabilitation YES/NO
   If yes, when?
   Appropriate for referral to Pulm Rehab YES/NO
   Other secondary care services YES/NO
   If yes, details

   I am not convinced that surgery is necessary to have on.
4. GFR, Glucose, Lipids: I would just leave the boxes blank for the pharmacist to write the level in themselves.
5. High risk medications: I think that if you are going to include this box it should be on the second page.
6. Smoking:
   a. The third box I would change

      Pack Years:
      Currently using NRT O
      Ready to quit O
      Unwilling to quit O
      No of quit attempts:
      Products used in failed attempts:
7. The severity scale needs to go immediately underneath the spirometry details.
8. There needs to be much more space to enter details of co-morbidities and I think this needs to go further up the page as this is an essential piece of information to get.

Email containing feedback by Lynn Alexander

Hi Magdelena,

Yes i did try this out, thanks for reminding me! (Friday seems like ages ago!)

I think it's really good. A couple of things that confused me - the Ref number at the top, what's that for? Is it for anonymising patients therefore leaving out the CHI number and name/address?

Can the "high risk medication user" be changed to "High risk Medications" and add a box for "none" as an empty box could sometimes be an oversight so adding a "none" rules that out.

Also the wee box that starts "on disease management plan" Think this is good stuff to have in but it did confuse me a little, why is attended surgery in there? Is it "Attended clinic in surgery" or "Attended yearly review in surgery"? Should the pulmonary rehab perhaps be expanded to: Referred to pulm rehab, Attended pulm rehab, Completed pulm rehab? Should there also be "Attends 2ndary care clinic" in there as well as "other secondary care services"? Maybe dates would be useeful here instead of a tickbox?

LFTs need to be included in the investigations part.

Also under "co-morbidities" can there be a box for "none" as unusually I did have one patient with no co-morbidities on Friday!

Really useful to have so well done, Hope these suggestions help. Let me know if there's anything else I can do,

Lynn Alexander MRPharmS
Prescribing Support Pharmacist
East Renfrewshire CHCP
07810054227

APPENDIX III

Curriculum vitae (Lebenslauf) in German
Curriculum vitae in English

Curriculum vitae (Lebenslauf) in German

LEBENSLAUF

Magdalena Hellauer
03.02.1985
Michaelistr. 20
5280 Braunau
Austria

Schulbildung:

1991 - 1995 **Volksschule Braunau Neustadt**

1995 - 1999 **Bundesrealgymnasium Braunau**

1999 - 2004 **HTL Braunau, Austria**

- Programmiersprachen : Java, C++, Java Script, PHP, MySQL, HTML
- Digitale Bildbarbeitung und Videoschnitt
- Cisco Network Administrator Zertifikat
- Matura mit Auszeichnung

10/2004 **Ergänzungsmatura Biologie am BORG Ried**

- Spezialisierung: „Homöopathie kritisch betrachtet“

10/2004 **Beginn des Diplomstudiums Pharmazie an der Universität Wien**

01/2008- 06/2008 **Erasmus Auslandssemester an der Universität Helsinki, Finnland:**

- Spezialisierung auf Patientenorientierte Pharmazie
- Mitarbeit in einer Forschungsgruppe („Polymorphism screening of Betulin“)

03/2010- 09/2010 **Auslandssemester an der University of Strathclyde, Glasgow, Vereinigtes Königreich:**

- Durchführung der Forschungsarbeiten für die Diplomarbeit am Strathclyde Institute of Pharmacy and Biomedical Sciences

09/2010 **Diplomprüfung Pharmazie**

- Titel der Diplomarbeit: ‘A Pharmaceutical Care Plan for the management of chronic obstructive pulmonary disease (COPD): development and validation for use in the community’

Berufserfahrung:

01.10.2005 - 30.09.2010	Angestelle für administrative Tätigkeiten Dürr KG, Tribuswinkel
01.10.2007 - 28.02.2010	Tutorin für Mikrobiologie Labor Department für Pharmakologie und Toxikologie, Universität Wien
01.07.2007- 31.08.2007	Praktikum Baxter BioScience, LCM Coagulation, Wien
01.09.2006 - 30.09.2006	Praktikum Anstaltsapotheke Braunau
01.07.2004 - 30.09.2004	Praktikum Wacker Chemie, Burghausen, Deutschland
01.08.2002 - 31.08.2002 01.07.2001 - 31.07.2001	Praktikum Austrian Aerospace, Wien

Curriculum vitae in English

CURRICULUM VITAE

Magdalena Hellauer
03.02.1985
Michaelistr. 20
5280 Braunau
Austria

Education:

1991 - 1995 **Primary school Braunau Neustadt, Austria**

1995 - 1999 **Grammar school Braunau, Austria**

1999 - 2004 **HTL Braunau, Austria**
(College for Programming, Engineering and Mediadesign)

- Programming languages : Java, C++, Java Script, PHP, MySQL, HTML
- Digital image and video processing
- Cisco Network Administrator Certification
- 'Matura' with distinction

10/2004 **Additional 'Matura' for Biology at BORG Ried, Austria**
(Grammar school)

- Specialistation: 'A critical overview of Homoeopathy'

10/2004 **Beginning of Pharmacy studies at University of Vienna, Austria**

01/2008- 06/2008 **Exchange semester at University of Helsinki, Finland:**

- Specialiation in pharmaceutical care
- Laboratory experience within a research group (Polymorphism screening of Betulin)

03/2010- 09/2010 **Exchange semester at University of Strathclyde, Glasgow, UK:**

- Conduction of research for the master thesis at the Strathclyde Institute of Pharmacy and Biomedical Sciences

09/2010 **Graduation as MSc of Pharmacy at University of Vienna**

- Title of master thesis: 'A Pharmaceutical Care Plan for the management of chronic obstructive pulmonary disease (COPD): development and validation for use in the community'

Employment Experience:

01.10.2005 - 30.09.2010	Quality- and Process Management Administrator Dürr KG, Tribuswinkel, Austria
01.10.2007 - 28.02.2010	Tutor for Microbiology lab course University of Vienna, Austria
01.07.2007- 31.08.2007	Internship, Administration Baxter BioScience, LCM Coagulation, Vienna, Austria
01.09.2006 - 30.09.2006	Internship, Pharmacy Technician Hospital Pharmacy Braunau, Austria
01.07.2004 - 30.09.2004	Internship, Product Quality Assessor Wacker Chemie, Burghausen, Germany
01.08.2002 - 31.08.2002 01.07.2001 - 31.07.2001	Internship, Programmer Austrian Aerospace, Vienna, Austria