A study of patient pharmaceutical care needs assessment in chronic obstructive pulmonary disease; as an example of a multidisciplinary intervention to reduce hospital re-admission in long term conditions

A partial fulfilment of the Norwegian degree
Master of Pharmacy
2009

Project Researcher: Stian Skogly,
University of Tromsø

Academic supervisors: Steve Hudson,
Institute of Pharmacy and Biomedical Sciences,
University of Strathclyde
and
Pauline Westwood,
NHS Lothian, Edinburgh

Co-supervisor: Moira Kinnear,
Institute of Pharmacy and Biomedical Sciences,
University of Strathclyde and
NHS Lothian, Edinburgh

Academic Co-supervisor: Thrina Loennechen,
Institute of Pharmacy, University of Tromsø

Collaborators: Karen Simpson, Alpana Mair,
Debbie Magee, Jenny Scott, and
Janet Connelly (All NHS Lothian)

University of Strathclyde

Acknowledgments

Abstract

Introduction — The aim of Edinburgh Improved Anticipatory Care and Treatment (IMPACT) service is to reduce admissions and re-admissions to hospital for people with LTCs. The service consists of nurse case managers co-ordinating patients' care, including reviewing medication. As a pilot project, an arrangement was made to refer such patients to a team of primary care pharmacists for clinical medication review. This project will examine the pharmaceutical care needs of this particular patient group and prepare an electronic system for reporting pharmaceutical care contributions in the evaluation of this service.

Methods — A model of care for COPD was generated to characterise the pharmaceutical care needs of patients recruited into the anticipatory care service from a pharmacy perspective. A generic database was designed for the purposes of characterising patients and for addressing their pharmaceutical care needs. Anonymous and categorised pharmaceutical care plans from the pharmacists conducting the medical reviews was used to populate the database. A pharmaceutical care plan for COPD was proposed to match the database. A qualitative research approach was used in order to design the potential clinical tools in response to specific feedback obtained from a nominal group. The nominal group consisted of pharmacists, three from the primary care pharmacists and one specialist pharmacist.

Results — There were 21 patients' pharmaceutical care plans included for analysis of care provided to 13 females (62%) and 8; males (38%). The mean age was 74 years (SD 10, range 51-88). COPD are present in 57% of the records (n=12), ischaemic heart failure in 43% (n=9), chronic heart failure in 33% (n=7), chronic kidney disease 33% (n=7), depression in 29% (n=6), myocardial infarction in 29% (n=6), hypertension in 29% (n=6), and diabetes type 2 in 24% (n=5). There were 127 pharmaceutical care issues identified, an mean of 6 care issues per person. C*hecks* accounted for 46 (36%), and there were 65 (51%) *changes in drug therapy*, and 16 (13%) *changes in drug therapy process*. The most common drug therapy problem was *inappropriate compliance* in 35% (n=23) out of all drug therapy problems identified (n=65). The database was face validated by the nominal group and is fit for purpose.

Discussion — The population of the database toolkit was done to demonstrate the functionality of reporting important outcomes from the pilot. For further work it is possible to link disease, medications, and pharmaceutical care issues, which will produce reports indicating the kind of medications or diseases / co-morbidities that are generating most problems. The database is fit for purpose and can be used for further evaluating the medication reviews conducted by pharmacists. It can also be a teaching tool for use during pharmacy education.

Abbreviations

BAI	-	Breath activated inhaler
BMI	-	Body Mass Index
BNF	-	British National Formulary
COPD	-	Chronic Obstructive Pulmonary Disease
CTB	-	Camilla Torset Berg
DPI	-	Dry powder inhaler
FEV$_1$	-	Forced Expiratory Volume in one second
FVC	-	Forced Vital Capacity
GOLD	-	The Global Initiative for Chronic Obstructive Lung Disease
GP	-	General practitioner
JC	-	Janet Connelly
LTC	-	Long Term Conditions
MDI	-	Metered Dose Inhaler
NHS	-	National Health Service
NICE	-	National Institute for Clinical Excellence
NRT	-	Nicotine Replacement Therapy
PW	-	Pauline Westwood
SH	-	Stephen Hudson
SIGN	-	Scottish intercollegiate guidelines network

List of figures

List of tables

Table of contents

1 Introduction

1.1 Background

The ageing of Scotland's population is a particular challenge for the National Health Service. People are getting older than before. In the next 25 years the proportion of the population over 65 is calculated to increase to over one in four. Old people are likely to have one or more long term condition, often in combinations, which increase the chance for hospital admission. In fact, people with long term conditions are twice as likely to be admitted to hospital than those with no chronic condition. One big increase of pressure on the National Health Service (NHS) over the last twenty years has been the rise in emergency hospital admissions. The Scottish government has now decided to make change to the existing system, and an increased focus on the delivery of proactive, locally responsive care is present.[1]

In the past few years there has been a move to shift the balance of care in Scotland. Shifting the balance is a term used to describe change in different levels; the focus, the location, and the responsibility.[1, 2] The focus has changed from services aimed towards acute medicine to preventative medicine, which mean; people with long term conditions and a strong emphasis on continuous care will be given preference to, rather than reactive care for people with acute medical issues. The idea behind this is to prevent adverse events by earlier interventions, which in turn will decrease institutional bed days.[1, 2] The location of the services is changed from hospital centred to services and support provided in community hospitals, other local facilities and at home, which will provide services and care which are more easily accessible for the patients.[1, 2] The responsibility has also changed. Patients are now partners and at the centre, not passive recipients as before. Support for self care and use of the most recent medical technology will help people to manage their conditions and stay longer in their own homes.[1, 2]

1.1.1 HEAT-targets

To continuously improve the health service given by the NHS Boards, there are local delivery plans which set out an agreement between the Scottish Government and each NHS Board. These local delivery plans are based on four key objectives which the health minister has generated. These key objectives are performance targets known as the HEAT-targets (Health, Efficiency, Access and Treatment) and include; health improvement for the people of Scotland, efficiency and governance improvements of the NHS, recognising the patients' needs for quicker access to NHS Services, and ensuring that patients receive appropriate services.[3]

Three of the targets related to admission rates are: To reduce the proportion of older people who are admitted as an emergency inpatient two or more times in a single year by 20% compared with 2004/05, and reduce by 10% emergency inpatient bed days for people aged 65 and over by 2008; to reduce the number of readmissions; and to achieve agreed reductions in the rates of hospital admissions and bed days of patients with primary diagnosis of chronic obstructive pulmonary disease (COPD), asthma, diabetes or chronic heart disease (CHD), from 2006/07 to 2010/11.[3]

There are also targets relevant to specific long term conditions such as COPD. For example 8% of each NHS board's smoking population should be supported in successfully quitting over the period 2008/09 – 2010/11.[3]

1.2 Long term conditions

A long-term condition is a "condition that requires ongoing medical care, limits what one can do, and is likely to last longer than one year". Other terms that are commonly used are "long-standing illness" and "chronic disease".[4]

Examples of long term conditions (LTCs) are coronary heart disease, hypertension, diabetes, COPD and asthma. COPD will be dealt with in more detail later in this thesis.

LTCs affect 1 in 5 of the population of Scotland and 1 in 3 households.[5] In the whole United Kingdom people with LTC account for 80% of all general practitioner consultations, but it is not known if all of the consultations were because of the actual LTC or other co-morbidities. Sixty percent of hospital bed days are for people with LTC or its complications.[4] People with a LTC are twice as likely to be admitted to hospital and they stay in the hospital for a longer time than those without LTCs. As time goes by the number of older people will increase, and it is to be expected that the people in Scotland will suffer from one or more LTCs in the future.[6] Therefore, it is important to support people in their homes which will prevent unnecessary hospital admissions and readmissions. Reducing the number of hospital admissions reduces the cost for the nation.

In the last years there has been a move to give people good service in their homes, to prevent hospital admissions, morbidity and mortality. Scottish Government's aim is to allow people to remain in their homes as long as possible. This primary care service in Edinburgh community health partnership is named IMPACT.

1.2.1 IMPACT

An anticipatory care model within primary care in Edinburgh was introduced last year to meet needs of people with LTC in keeping with local and national health policy and strategy.[1, 2, 5] This service is named IMPACT (IMProved Anticipatory Care and Treatment). The service targets people with LTCs at most risk of readmission to hospital to ensure the early initiation of care, treatment and support interventions to prevent escalation of health problems. Each patient will have a named case manager (usually a nurse) who will: liaise with other professionals and in partnership develop an anticipatory care plan; co-ordinate augmented care in the community by simplifying and streamlining patient pathways; educate on self care management techniques which include advising on falls prevention; improve clinical care, and carer

support. The model is delivered through general practice and co-ordinated by community nurses. Pharmacists have recently been included in the team to conduct medication reviews.[7] A medication review is defined as; *"a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste".*[7]

There are four different levels of medication reviews; level 0, level 1, level 2, and level 3. A level 0 review, also named ad-hoc review is an unstructured opportunistic review of a patient's medications. From a pharmacist point of view it could be a question of clarification about a dosage or formulation, but this would normally not be classified as a medication review. A level 1 review, or a prescription review, is a technical review of list of patient's medicines. The pharmacists normally don't have the patient's medical records. In a level 2 review, treatment review, the pharmacists have patient's full notes. Pharmacists who are based in GP practices have the opportunity to do this kind of review. Level 3 review is also named clinical medication review. This is face-to-face and a complete review of medications and conditions. The patient is a partner in the review, which means listening to the patient's views and beliefs abouttheir medicines and taking account of their preferences in any decisions about treatment.

People who will benefit from the IMPACT service are identified using a tool named SPARRA. People awaiting discharge from hospital and those with complex health and social care needs can also be referred to IMPACT.

1.2.2 SPARRA

Scottish People at Risk of Readmission or Admission (SPARRA) data or referral from health care professionals. SPARRA is a risk prediction tool that predicts an individual's risk of being admitted to hospital as an emergency within the next year. The risk for hospital admission is estimated using a

formula which includes; age, sex, deprivation, number of prior admissions, time since last admission, total bed days accumulated in three years, principal diagnosis, number of co-morbidities, and number of elective admissions. This formula will work out a percent score of risk.[8]

It is important to understand that this algorithm will only identify a pool of patients at most risk for hospital admission, but it does not define to which degree hospital admissions are preventable or to which degree these people will benefit from a service like the anticipatory care service.[8] Further screening and assessment is needed before the patient is recruited into the service. This is a two stage process; first, statistical risk prediction with SPARRA. Second, local screening and assessment identifying the people at high risk who would benefit from anticipatory care.[8]

1.2.3 The role of the pharmacist in the management of LTCs

A multidisciplinary team is a group of health professionals made up from different professions. There are many examples of multidisciplinary teams delivering specialist care, for example managing care for people with cancer, chronic obstructive pulmonary disease and diabetes. A multidisciplinary team rehabilitating patients with chronic obstructive pulmonary disease can for example include a physician, nurses, exercise specialists, social workers, and dieticians.[9] The team can also include occupational therapists, pharmacists and other health care professionals. The roles of the team members are complementing each other, which will provide the aim of the highest quality of care.

There is a need for evidence of the benefits of reviewing a patient's medications. Pharmacists are a potential source of assistance in reviewing medications, which is why pharmacists are a subject for research. In the UK there have been some studies on pharmacy led medication review, but the results vary.[10] A study done in elderly people in a general practice demonstrated the benefits of a pharmacist-led medication review. The review

resulted in significant changes in patients' drugs and saved more than the cost of the intervention without affecting the workload of general practitioners.[11]

A recent systematic review evaluated the effect of pharmacist care on patient outcomes in heart failure. Studies were included from all over the world, and the investigators concluded that pharmacist care in the treatment of patients with heart failure greatly reduces the risk of hospital admissions.[12]

Another UK study was done in elderly patients with chronic diseases using several medications. This one concludes that pharmacist-led medication review can reduce the number of pharmaceutical care issues, which will decrease the potential for medical related problems.[13]

On the other hand, a randomised control trial from 2007 shows the opposite. The study was done in UK, and the aim was to test whether a medication review by community pharmacists on home visits to patients could reduce hospital admissions or mortality in persons with heart failure. The conclusion showed that the pharmacist interventions did not lead to reductions in hospital admission.[14]

Another smaller study could not find a positive outcome for hospital admissions. One of the key points of the study was that home-based medication review by pharmacists does not appear to reduce hospital admissions. The authors wrote in the conclusion; "This is a relatively small study using one pharmacist in a single general practice setting, therefore the generalisation of these findings on their own are limited".[15]

A randomised controlled trial with the aim of determining whether home base medication review by a pharmacist affects hospital readmission rates was performed in UK. The researchers concluded that the intervention was associated with a significantly higher rate of hospital admissions and did not improve the life quality or reduce deaths.[16]

The belief persists that carefully targeted medication reviews do benefit some patients, despite the lack of supporting evidence in reducing unplanned hospital admissions.[17] The role of the pharmacist in the medication review in the UK needs more randomised studies to evaluate the pharmaceutical care.[11, 16, 17] Therefore, it is important that pharmacists document what they are doing and seek to standardise the pharmaceutical care process.

It can be problematic to extract useful conclusions when comparing articles because of variations in the nature of the review described, the populations studied, the outcomes measured, and the evaluation criteria used. A level 3 medication review, rather than level 0-2, will make it easier to get positive outcomes because of access to patients' full records. The pharmacists in the Edinburgh IMPACT service are conducting level 3 medication reviews.

1.3 Pharmaceutical care

1.3.1 Definition

Hepler and Strand defined pharmaceutical care as;

"The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or preventing a disease or symptomatology".[18]

Medication review, as defined above, contributes to the achievement of these outcomes.

As Hudson et. al. point out in a review article, the word 'pharmacist' does not appear in the definition of pharmaceutical care. This allows pharmaceutical care to be delivered in different ways and in different clinical settings. Pharmaceutical care can be delivered by any member of an anticipatory care team. Therefore, this is a description of what the patient should receive and not what the pharmacist does.[19] All the members of a multidisciplinary team play an important role in the delivery of pharmaceutical care.[20]

Use of medicines is the most common of all long term treatments. Of all the healthcare professions, pharmacists have the widest knowledge in the science and use of medicines. Therefore, the pharmacist has a key role wherever medicines are used.[20]

Pharmaceutical care consists of three components; the philosophy of pharmaceutical care, the patient-care process, and the practice management system to support the practice.[21]

The philosophy of pharmaceutical care is caring for a patient's drug-related needs by taking responsibility for the identification, resolution and prevention of drug therapy problems.[21] The patient-care process is everything that is happening between the patient and the health care professional when the pharmaceutical care is offered.[21]

To deliver pharmaceutical care, there should be an assessment of the patient and the patient's drug-related needs. A care plan should be developed to resolve existing, and to prevent future, drug therapy problems. The care plan will help achieve the therapeutic goals of the patient.[21]

After this there should be a follow-up evaluation, where the health care professional in planned intervals will look at the patient's current status. In the follow-up evaluation the patient's progress is compared towards the therapeutically goals, the health care professional finds out if previous drug therapy problems have been resolved and assesses whether new drug therapy problems have developed.[21]

The health care professional has to make sure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons.[20] It is also important that the patient is taking the medications properly.[21] It is also the person who is offering the pharmaceutical care responsibility to make sure that the patient's medicines are as effective as possible and as safe as possible.[20]

The practice management system includes the primary organisational structure. This may have to be adjusted if pharmaceutical care is to be supported. Practice management systems include the mission of the organization, the necessary financial, physical, and human resources, the evaluation system and the reward mechanisms.[21]

1.3.2 Pharmaceutical care needs

Needs for services such as medication reviews, new medication, monitoring or advice on medication are often named pharmaceutical needs. Pharmaceutical needs may be identified by the patient or by any member of the health care team, including the pharmacist. The pharmacist will review the patient's medicines and identify any pharmaceutical care issues during the assessment of the patient. Identifying pharmaceutical care issues is a part of the formulation of a pharmaceutical care plan, which outlines an individual patient's medication related problems, desired outputs and the actions planned to achieve them.[22]

To describe pharmaceutical care a categorisation system has been developed. By analysing the pharmaceutical care issues, each care issue is assigned into categories. This classification makes it possible to make a qualitative description of pharmacist's contribution to pharmaceutical care. This could in turn be used to report the pharmacist's contribution to the anticipatory care service. In 2008 a master project updated this categorisation system[23]. This project builds on the work that has been done at Strathclyde University.[19, 23] The categorisation system is briefly described below;

Each pharmaceutical care issue is categorised into two or three dimensions. The first dimension is; *Check, change in drug therapy*, or *change in drug therapy process*. When the pharmacist has identified a care issue, *checks* have to be performed to figure out if there's a need for a *change (e.g. measuring blood pressure to see if it is within limits)*[23]. If there is no need for a *change (e.g. increasing the dose of the blood pressure lowering agent)*, the care issue is categorised as a *check*. On the other hand, a *check* can lead to a *change* and in that case the care issue will only be categorised as a *change.* After a check by the pharmacist a change is recommended in a patient's drug therapy, but if the recommendation isn't followed up the care issue will still be categorised as a check.

The *check* is further categorised into four subcategories; *medication needs, effectiveness, safety* or *compliance.*[19, 23] *Change in drug therapy* is further divided into seven subcategories; *drug selection (starting new or changing drug), dose, route/dose form, dose interval/timing, duration, stop drug temporarily/permanently, patient or carer understanding/compliance.* These categories make changes to the patient's drug therapy. Often the pharmacist has to make recommendations to the GP, the recommendations are accepted and carried out. Pharmacists who are independent prescribers and can do all of this by themselves if within their own competence.[19, 23]

Change in drug therapy process is also divided into subcategories, but only five; *clinical (shared) record of patient characteristics, clinical (shared) record of drug history, continuity of information/care between clinical* settings, *level of patient monitoring, health care team member(s).* These categories describe the actions the pharmacist performs to prevent potential drug therapy problems and to identify actual drug therapy problems. Not all these actions results in a change in patient's drug therapy, but it is still important to quantify these actions, since this is a substantial part of the pharmacists' delivery of pharmaceutical care.[23] However, certainly all *changes* are results from *checks,* but these *checks* will not be categorised as *checks* since they are not a drug therapy problem endpoint.

Quality Assurance

In the second dimension, the care issue is further categorised into one or two different Quality Assurance Descriptors; *Time perspective* or/and *degree of change.* The *time perspective* indicates where the care issue is in the process of delivering pharmaceutical care. In the *change in drug therapy* category the care issues have to be categorised into both *change point* and *degree of change*, which describes the extent of the change.[23]

The research group has decided to use the wording from the original version of the categorisation system, so instead of *Degree of change*, the term *Type of change* is used. The *Time Perspective* is changed to *check point* and

change points. The subcategories of the check/change point are design (*verification*), delivery (*monitoring*), and *(evaluation) confirmation*.[19, 23]
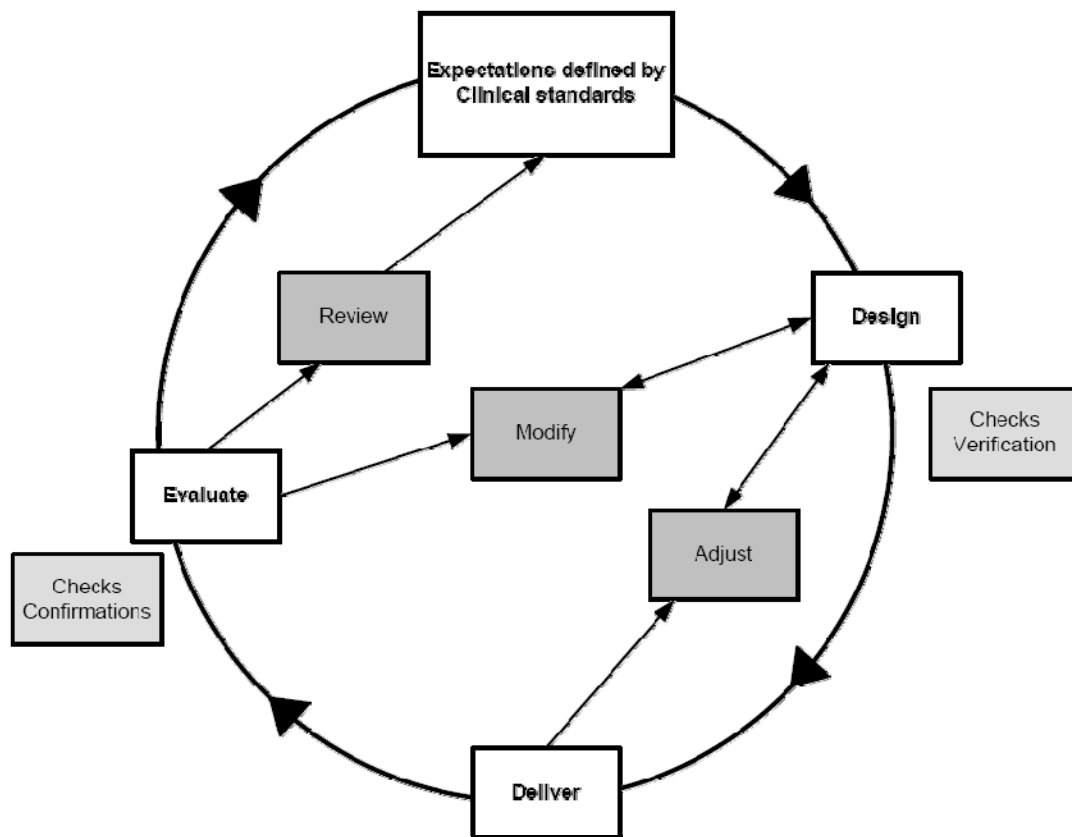
Figure 1: The quality assurance circle used in the categorisation system[19, 23]

The *verification* makes sure in the beginning of a new medicine, that the patient is on the right medicine, right dose, not using unnecessary medications, no need for new medication, no interactions, and understands how to use the medications properly. In other words, it is a check to make sure that the medications are appropriate for the patient.[19, 23] From the original version this category was named *design*. Both words describe where in the quality assurance circle the action is happening. The investigator has decided to use the original term *design* in the rest of this project. The *monitoring* makes sure as treatment continues, that the patient is receiving the medication as intended, continues to be on the most suitable dose, has no adverse drug reactions, and understands how to take the medications.[19, 23] This is also a part which has been updated in 2008, so from the original version this category was named *delivery*. As same as above both words

describe where in the quality assurance circle the action is happening. The investigator has decided to use the original term delivery in the rest of this project. The *confirmation* makes sure that the medications are producing positive outcomes. Documentation shows if the treatment is resulting in expected effects, not failing to control the condition, or not producing unwanted effects requiring a new clinical review.[19, 23] The original name of the confirmation category was *evaluation*. The investigator has decided to use the original word also here, namely evaluation.

The *Type of change* category is divided into three subcategories: *Adjustment*, *modification*, and *prompt a review*. These subcategories are describing the degree of change which is made. The *adjustment* and the *modification* may both take place in the beginning or during the treatment. *Adjustment* is defined as "a recommended change to patient behaviour, treatment regimen or process of continuity of care that individualises pharmaceutical care *within* the agreed treatment plan". These are in other words minor changes. A *modification* is a change to the patient treatment that is not anticipated and leads to a change of the patient's treatment plan. *Review,* or prompt *a review,* is a result of a failed treatment, which means that it only can happen after the treatment has lasted for a while often in an outpatient setting or in a pharmacy where the patient comes regularly.[23]

In the third dimension the care issues identified as a change in drug therapy can be categorised into the *Drug therapy problem* category[23]. These drug therapy problems are defined by Cipolle and Strand[21]. The *drug therapy problem* category is divided into eight subcategories; *Unnecessary drug therapy*, *need for additional drug therapy*, *ineffective drug*, *dosage too low*, *adverse drug reaction*, *dosage too high*, *inappropriate compliance*, and *unclassified i.e. NON-DTP.* One of the updates which were done in 2008 was the extra category named *unclassified, for care issues where change is not patient specific.* Each of these categories is divided into *common causes of drug therapy problems* ranging from *a-h* in each category. As mentioned above, a *change* isn't a *change* before it has been changed. If the pharmacist is recommending a *change* from a *check,* but the general practitioner doesn't

act on it or disagrees with the decision, it will still be a *check*. Below is a graphical summary over the categorisation of the pharmaceutical care issues.

Pharmaceutical Care Issue

Check
- Medication needed
- Effectiveness
- Safety
- Compliance

Change in Drug Therapy
- Drug selection (starting new or changing drug)
- Dose
- Route/dose form
- Dose interval/timing
- Duration
- Stop drug temporarily/permanently
- Patient or carer understanding/compliance

Change in Drug Therapy Process
- Clinical (shared) record of patient characteristics
- Clinical (shared) record of drug history
- Continuity of information/care between clinical settings
- Level of patient monitoring
- Health care team member(s) education/information

Check Point
- Design
- Delivery
- Evaluation

Change Point
- Design
- Delivery
- Evaluation

Change Point
- Design
- Delivery
- Evaluation

Type of Change
- Adjustment
- Modification
- Review

Drug Therapy Problem
- Unnecessary drug therapy
- Need for additional drug therapy
- Ineffective drug
- Dosage too low
- Adverse drug reaction
- Dosage too high
- Inappropriate compliance
- Unclassified i.e. Non-DTP

Figure 2: Graphical view of the classification of pharmaceutical care issues

1.4 Chronic obstructive pulmonary disease

1.4.1 Definition

In 2004 the National Institute for Clinical Excellence defined chronic obstructive pulmonary disease as:

"Chronic obstructive pulmonary disease is characterised by airflow obstruction. The airflow obstruction is usually progressive, not fully reversible and does not change markedly over several months. The disease is predominantly caused by smoking."[24]

Prior named diseases such as chronic bronchitis, emphysema, chronic obstructive airways disease and chronic obstructive lung disease are now changed to the preferred term chronic obstructive pulmonary disease or in short COPD. [24,25]

1.4.2 Epidemiology

"COPD is a leading cause of morbidity and mortality worldwide and results in an economic and social burden that is both substantial and increasing."[26] This disease is a major public health problem and it is increasing globally. COPD is more common in UK and in Eastern Europe than in most developed countries. In Western Europe COPD was known as the "English disease", since England was the first intensively industrialised country. This disease is the fourth leading cause of chronic morbidity and mortality. The overall prevalence of COPD in UK is about 4% in men aged about 50 years, 9% at 60 years, 12% at 80 years, but only 3% in women. As you can see, the prevalence increases with age, and the mean age of diagnosis in the UK is 67 years. The difference in gender is because of the difference in smoking habits. The change in smoking habits in the past 50 years will minimise the difference, since the numbers of young women smoking cigarettes has increased. COPD is more common in men and low socioeconomic groups.

Over the last decade the prevalence of COPD has increased in women, but has reached a plateau in men.[24, 27]

Approximately 26,000 people die of COPD each year in the United Kingdom. This is 5% of all deaths. The mortality rate due to COPD is difficult to quantify, as many people with COPD die *with* the disease rather than *because of* it. Mortality from COPD increases with age, how severe the disease is, and low socioeconomic status.[24, 27]

1.4.3 Pathophysiology

Processes which are causing an airway obstruction; Inflammation causing structural changes and narrowing of the small airways, destruction of small airways, airway collapse due to loss of elasticity, hyper-secretion of mucus and bronchial hyper-reactivity.

INFLAMMATION

Small airway disease
Airway inflammation
Airway remodeling

Small airway disease
Loss of alveolar attachments
Decrease of elastic recall

AIRFLOW LIMITATION
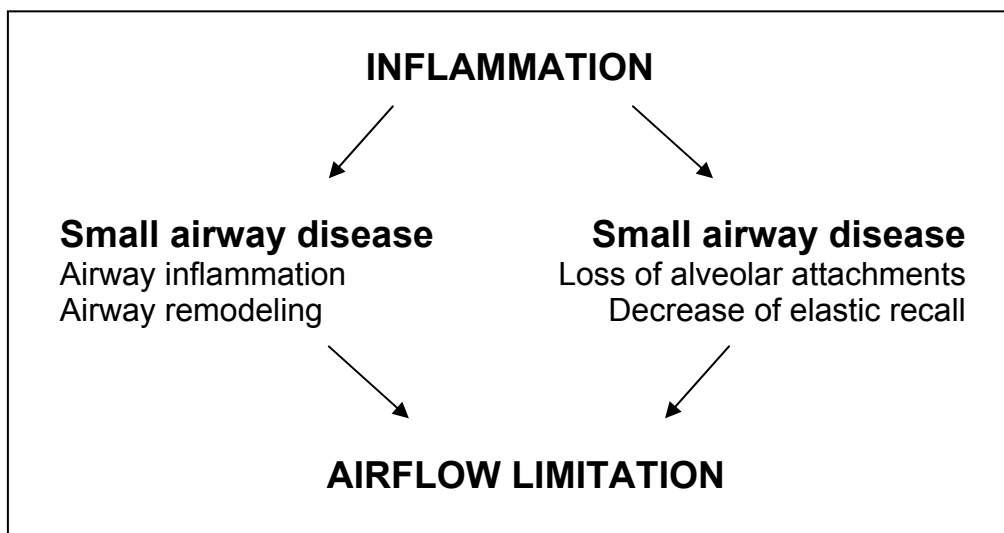
Figure 3: Mechanisms underlying airway limitation in COPD[26]

These factors will cause productive cough, wheeze and breathlessness. Unlike asthma, airflow limitation can never be returned to normal. Breathlessness leads to hypoxia which is lack of oxygen in the blood. This can further lead to "cor pulmonale". Cor pulmonale is right heart failure secondary to lung disease characterized by fluid retention, peripheral oedema, and raised venous pressure. Frequent respiratory infections are common in people

with COPD. Complications such as depression and anxiety, and respiratory failure are also seen in people suffering from this disease. The disease often results in a general disability and impairs a person's quality of life, which may develop reduced mobility and become more and more housebound.

1.4.4 Risk factors for development

Tobacco smoking is the largest risk factor for the development of COPD. Smoking cessation can help to slow down the progression of the disease, and this should be the primary focus in the management of COPD.

Non-smokers rarely develop COPD. The incidence is set to 5%. For smokers it is about 15%, but the higher the exposure, the higher is the risk of developing COPD. Tobacco exposure can be calculated in "pack-years" by using this formula.[25, 28]

$$\text{Total pack - years} = \frac{\text{(number of cigarettes smoked per day)}}{20} \times \text{number of years of smoking}$$

An up-to-date smoking history, including "pack-years" smoked, should be documented for everyone with COPD.[24] There is a large individual variation in susceptibility for tobacco. [25]

It is not only smoking which is a risk factor. As mentioned above; age, gender, occupation, socioeconomic status and air pollution are other risk factors in addition to genetic factors (i.e. homozygous alpha$_1$-antitrypsin deficiency), airway hyper-responsiveness and allergy.[25] In a case controlled study there was a trend towards increased risk for COPD with passive smoking[29]

1.4.5 Clinical guidelines for the management of COPD

In general, clinical guidelines are evidence based recommendations for the treatment of specific diseases. The aim of the guidelines is to improve the quality of life for people with these specific diseases and to ensure that all patients are receiving the best practice and treatment available.

The first British guidance for the management of COPD was published by the British Thoracic Society (BTS) in 1997. This one was used until 2004 when the National Institute for Clinical Excellence (NICE) improved and updated this guideline and then published the NICE-12 guideline for COPD. In this guideline the recommendations around diagnosis, management and prevention of COPD are evidence based.

Another guideline is The Global Initiative for Chronic Obstructive Lung Disease (GOLD). In 2001 the National Heart, Lung and Blood Institute, USA (NHLBI) and the World Health Organization (WHO) developed an international guideline for the management of COPD. The GOLD has recently been updated and republished.

The National Health Service in Scotland does not have a separate guideline for COPD yet, so the NICE-12 in addition to GOLD 2008 are mainly used.
By using these guidelines the practice in Scotland can be assessed and the level of adherence to the COPD clinical guidelines can be evaluated.

1.4.6 Diagnosis

It is a good reason for the GP to suspect COPD if a person is; over 35 years old, is a smoker or ex-smoker in addition to any of these symptoms; exertional breathlessness, chronic cough, regular sputum production, frequent winter bronchitis or wheeze. There should not be any clinical features of asthma.[24] If these symptoms are present, spirometry should be performed in addition to recording the signs and symptoms above. If the FEV_1 (Forced Expiratory

Volume in one second) is less than 80% of the predicted value and the ratio FEV_1/FVC (Forced Vital Capacity) is less than 0,7, COPD can be diagnosed.[24] The predicted values are normal values for the person's gender, age, and height.[26]

If the GP is in doubt about the diagnosis a spirometric reversibility test could be done. In this test you first measure the values of the patient with a following up test after using a bronchodilator[24]. The results from the two tests are then compared. This test is also referred to as a post bronchodilator test. This is an important part in diagnosing asthma versus COPD.

The diagnosis could be asthma; if there is more than 0.4 litres response to bronchodilators, or serial peak flow measurements show significant variability in one day or day-to-day. There can also be asthma if there is a response over 0.4 litres to 30 mg prednisolone daily for two weeks. The COPD diagnosis cannot be set if FEV_1 and FEV_1/FVC ratio return to normal value with drug therapy.[24]

If the GP still is in doubt about the diagnosis, the patient may be treated empirically, usually a short acting bronchodilator. The patient response to the treatment can aid the diagnosis.[24]

A trial of a high-dose inhaled corticosteroid *or* an oral corticosteroid is recommended for patients with moderate airflow obstruction to ensure that asthma has not been overlooked.[30] This is a reversibility test by using spirometry and inhaled steroid before and after measuring.
As shown above, there is no single test for diagnosing COPD.

According to the GOLD 2008 guidelines the spirometric classification of severity of COPD now includes four stages of severity. From older GOLD guidelines a fifth category named "at risk" was also included. The evidence of people moving from this category to the next was incomplete, so it was removed. As you can see by comparing the two tables below, the *mild* category in NICE-12 guideline is including both *mild* and *moderate* categories

in the GOLD 2008 guideline. So when categorising people with COPD after severity, it is important to be aware of these two categorisation systems. It has to be clarified which system is used, if the categories are used rather than the predicted value.

Table 1: Assessment of severity of airflow obstruction according to FEV$_1$ as a percentage of the predicted value according to the NICE-12 guideline[24]

Severity	FEV$_1$
Mild airflow obstruction	50–80% predicted
Moderate airflow obstruction	30–49% predicted
Severe airflow obstruction	<30% predicted

Table 2: Assessment of severity of airflow obstruction according to FEV$_1$ as a percentage of the predicted value according to the GOLD 2008 guideline[26]

Severity	FEV$_1$
Mild	>80% predicted
Moderate	50–80% predicted
Severe	30–49% predicted
Very severe	<30% predicted

The Medical Research Council has developed a dyspnoea scale which looks at the grade of breathlessness related to activities. This guide, shown below, is often used to characterise a patient's physical health.

Table 3: Medical Research Council dyspnoea scale[31]

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 pace
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

1.4.7 Pharmaceutical care for patients with COPD

This project identifies pharmaceutical care issues for people with long term conditions such as COPD. Some of these care issues are drug therapy problems. This could potentially give pharmacists and other health care professionals a better view of how to help people suffering from this chronic disease and may reduce the hospital admission rate. Previous studies have shown interventions that decrease the risk of hospitalisation in COPD patients. These include vaccinations for influenza[32], smoking cessation[33] and pulmonary rehabilitation[34]. A study by Dahlén and Janson showed that anxiety and depression were related to a higher risk of relapse in patients with asthma and COPD who were admitted for emergency treatment.[35, 36]

1.5 Management of stable COPD

No medication can modify the long term progression of COPD, but symptomatic treatment is available. The aims that should be worked towards are; to reduce the disability of the patient, prevent further worsening of the disease, preserve the lifestyle and maintain the independence of the patient. As in other chronic diseases, life quality is very important.

To achieve the aims above, the first and most important thing to do is to help the patient with smoking cessation. This will be managed by offering a support programme in combination with nicotine replacement therapy (NRT).[37]

According to the NICE-12 guidelines, COPD care should be delivered by a multidisciplinary team.[24] The objectives are to prevent and control the symptoms, decrease the frequency and severity of exacerbations and to improve health status, exercise tolerance and quality of life.[25, 38]

1.5.1 Pharmacological treatment

The medications for COPD are divided into two main groups; symptom relievers and preventers. The relievers which are available are short-acting beta$_2$-agonists, anticholinergics (also known as antimuscarinic agents), and methylxanthines.

Preventers which are used in the treatment of the disease are corticosteroids and long-acting beta$_2$-agonists. No currently licensed treatments reduce the underlying inflammation of COPD.

1.5.2 Devices and inhaler technique

Today there are three different main groups of inhalers on the market. One of them is the *metered dose inhalers* (MDI), which are filled with a gas-drug emulsion/suspension under pressure. The operator has to release a metered dose by pushing a button simultaneously as breathing in. The second group of inhalers are named *dry powder inhalers* (DPI). As the name says, these are inhalers filled with dry drug powder. The dose is inside the device until the operator inhales it. The third group is *breath activated inhalers* (BAI). These inhalers are drug emulsions doses which are released by the operator's inhalation.

There are several potential inhalation problems with these inhalers for the people who are using them. One of them is; the inhalers are made by different pharmaceutical industry companies, which mean that the devices are slightly different from brand to brand. Correct use and inhaler technique is very important. Wrong use and a non satisfactory inhalation technique will cause no effect or even an unwanted effect (e.g. fungal infections while using corticosteroids). The pharmacist has a responsibility to teach the patient how to use the inhaler properly, especially when changing drugs or devices. The correct delivery system is as important as the drug.[39]

The users' common problems with inhalers are: the device isn't loaded before use, or inspiratory flow rate is too weak or too strong. Each group of devices have their own problems, for example the trouble of co-ordinating breath and release of dose with a MDI. Another issue for some of these devices is that they have to be shaken before use, since they are suspensions.

Pharmaceutical care issues like this have to be identified by the pharmacist, which can be done in the community pharmacy during dispensing, in the education part of the pulmonary rehabilitation, and in primary care during a medication review. The effectiveness of inhaler therapy depends not only on compliance, but also on the inhaler technique. If not the inhaler technique is correct, the amount of drug delivered to the lungs may be reduced.[40]

In the Scottish intercollegiate guidelines network (SIGN) for asthma there is mentioned that there is a lack of non-standardised scores of inhalation technique, which makes comparison between different studies difficult.[41] In a review article from UK they were measuring the impact of teaching users of inhalers the correct technique, and they concluded that correct usage of different inhalers was improved from a mean of 60% to 79%.[42]

1.5.3 Non-pharmacological management

COPD care should be delivered by a multidisciplinary team[24]. Evidence is increasing that a chronic disease management program for COPD patients that incorporates a variety of interventions, such as pulmonary rehabilitation benefits the patients.[26] Programs like this are often implemented by primary care, and one study shows that this could reduce hospital admissions and bed days in hospitals.[43]

Persons, who consider themselves functionally disabled by COPD, should be made aware of the benefits of pulmonary rehabilitation.[24] These programs should be customised to the individual patient's needs, are held at times that suit the patient, and in buildings that are easy to get to and have good access

for people with disabilities.[24] This will improve the concordance and effectiveness of these rehabilitation programs.[24] The goals of rehabilitation are to reduce the symptoms, disability, and handicap and to improve functional independence in people with COPD. The rehabilitation process should incorporate a programme of physical training, disease education, nutritional, psychological and behavioural intervention.[24]

Physical training is, maybe not a surprise, an essential part of a healthy life. It is important that the heart and the breathing muscles are in shape so they can work with less oxygen, which means that the patient can do more before feeling tired. The training will not reverse the COPD, but it is helpful to improve the functional independence and everyday quality of life.

Disease education is a part of the pulmonary rehabilitation programme. This leads to a better understanding of the changes that happen with a chronic illness. Patients will become more skilled at management of the disease and hopefully have improved compliance.

Lifestyle advice is another important topic in the pulmonary rehabilitation programme. People with COPD prior divided into "blue bloaters" and "pink puffers", where the first one suffer from chronic bronchitis and are often over weight. The last group suffers from lung emphysema and malnutrition. These patients often have a higher use of energy because of more struggles with breathing, infections and medical care. Today both these diseases are named COPD. Disease complications such as breathlessness can make eating difficult, in addition to that cooking of food in general can be hard work for a COPD patient.

Body mass index (BMI) should be calculated in patients with COPD.[24] A normal BMI is between 18.5 and 24.9. If the BMI is abnormal, underweight (BMI: <18.5), overweight (BMI: 25-29.9), or obesity (BMI of 30 or greater), the patient should be referred to a dietician. This is calculated by dividing adults weight in kilograms by their height in metres squared.

Psychological and behavioural intervention is a part of the programme. Many people struggle with anxiety and depression after getting the diagnosis, so psychological support is important.

Smokers must be advised to stop smoking, since it is the most important factor in the development of the disease. But the smoker must be motivated to quit smoking, so smoking cessation nurses or other health personal should support and help those who want to stop. Often it is a good idea to set a date when the cessation should be complete.[24, 25] Medical aids to stopping smoking include nicotine replacement therapy, bupropion and varenicline.[24, 30] Stopping smoking is a cost-effective way to prevent COPD. This will in the next step reduce poor health and prolong life in the population[30].

People with the diagnosis COPD will have a self management plan. This is a verbal or written plan with advice on how to respond in the right way to symptoms of an exacerbation. Information on how and when to contact health care professionals is also a part of this plan.[24]

A Cochrane review concludes that pulmonary rehabilitation relieves dyspnoea and fatigue, improves emotional function and enhances patients' sense of control over their condition. Rehabilitation forms an important component of the management of COPD.[24, 34]

1.5.4 Stepwise management of the disease

There are guidelines for when which treatment should be used in the stepwise management of the disease. First of all it is important to make the person understand that smoking is a risk factor. Smoking cessation will reduce the progressive decline in the lung function. The person should be offered help to stop smoking. This should be a combination of drug therapy and support from a multidisciplinary team.[24, 30] Two articles written by Anthonisen et. al. concluded that: "*Smoking cessation is the single most effective and cost effective way to reduce exposure to COPD risk factors. Quitting smoking can prevent or delay the development of airflow limitation, or reduce*

progression."[26, 44, 45] Nicotine replacement therapy increases the success rate of quitting smoking by 50-70%.[37]

Below is a figure which demonstrates how lung function falls with age and the importance of stopping smoking if patients with COPD are to avoid disability.
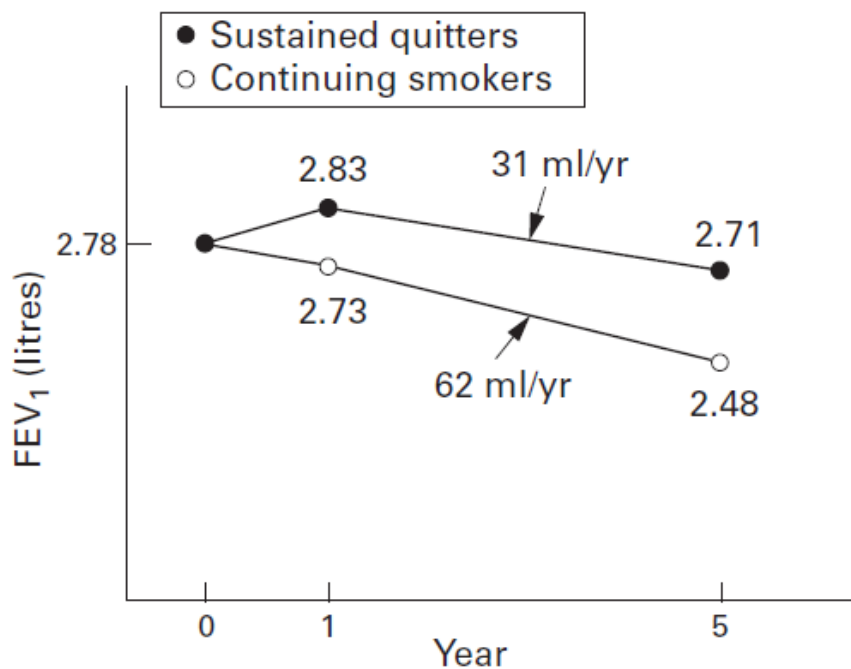
Figure 4: Lung function related to smoking cessation[46, 47]

Infections complicate the disease. This can be prevented by regular vaccination. The pneumococcal vaccine and the influenza vaccine are the most important ones.[24, 30] Initially a short-acting beta$_2$-agonist or a short-acting antimuscarinic bronchodilator should be used as required to treat the symptoms of the disease.[24, 30]

If the symptoms are still present, another short-acting bronchodilator (either a beta$_2$-agonist or an anticholinergic) given regularly should be added to the drug regimen.[24, 30]

In those who still are symptomatic or have two or more exacerbations in a year, there should be added a long-acting bronchodilator given regularly. If a long-acting anticholinergic agent is added, the short-acting bronchodilator from the previous stage should be discontinued.[24, 30]

If the patient has an airway obstruction FEV_1: ≤ 50% predicted and having two or more exacerbations requiring treatment with antibiotics or oral corticosteroids in a year, a combination of a long-acting beta$_2$-agonist and an inhaled corticosteroid can be used.[24, 30] The effectiveness of combined treatments should be assessed by looking at symptoms, activities of daily living, exercise capacity and lung function. Combination treatment should be discontinued if there is no benefit after 4 weeks.[24] If the patient still has symptoms, addition of slow release formulations of oral theophylline should be considered.[24, 30] If some of the stages listed above are ineffective, the therapy should be stopped.[24]

In addition to these drugs, a patient with a chronic productive cough may have benefits from a mucolytic drug. These drugs make the sputum less viscous, and thereby easier to cough up. Mucolytic therapy should be continued if there is symptomatic improvement.[24] However, mucolytics are not indicated for use in COPD in the joint formulary of NHS Lothian. The Lothian Joint Formulary is guidance on first choice and second choice drugs provided to all prescribers. A group of hospital specialists, GPs and pharmacists in Lothian decide which drugs should be included in the list. Evidence of clinical effectiveness, safety and cost-effectiveness are taken into account when making the recommendations. Prescribers can use non-formulary medications, but an explanation is then required. If a mucolytic is prescribed they should be reassessed after one month for any benefits.[39]

Oxygen should be regarded as a drug, and is prescribed to hypoxaemic patients to increase the alveolar tensions and decrease the work of breathing.[30] Some COPD patients need help to provide oxygen to the issues in the body. It is important to have a satisfactory oxygen delivery with the

blood, which will maintain the normal organ function in the body.[26] The NICE-14 guideline says the need for oxygen therapy should be assessed in; *all patients with a FEV₁ less than 30% predicted value, people with cyanosis, patients with polycythaemia, patients with peripheral oedema, patients with a raised jugular venous pressure, and patients with oxygen saturations less than or equal to 92% breath air.* People with a FEV_1 30-49% predicted value should also be considered to be assessed for oxygen therapy start up.[24]

Oxygen therapy can be administrated in three ways; long term oxygen continuous therapy (LTOT), during exercise, and to relieve acute dyspnea. The goal of using this treatment is to increase the baseline PaO_2 to at least 8.0 kPa (60mm Hg) and/or produce an SaO_2 at least 90%. (The values are set at sea level. The measurements should be done when resting.)[26] People with chronic respiratory failure using the long term oxygen administration more than 15 hours per day have shown increased survival.[48, 49] Greater benefits are seen in patients receiving oxygen for 20 hours per day.[24] Treatment should be initiated in hospital because several blood gas measurements are required to set the correct oxygen concentration.[30]

Oxygen should only be prescribed for use at home after close evaluation by respiratory experts.[30] It is important that the patients receiving LTOT are reviewed at least once a year by a practitioner who is familiar with LTOT. Another important thing is to make sure that the patients understand the risk of fire and explosion when using oxygen.[24] In Scotland prescriptions for oxygen cylinders and accessories can be dispensed by pharmacists contracted to provide domiciliary oxygen services.[30]

1.6 Management of exacerbations of COPD

When a person with COPD is getting worsening cough, increased breathlessness, increased sputum volume, and change in sputum colour it is probably an exacerbation of COPD. People with COPD are at increased risk of infections than healthy people. When using corticosteroids the immune system is reduced, this allows infections to settle down easier. The increased volume of sputum also contributes to this.

In case of an exacerbation the medical regimen is altered. The initial management of an exacerbation is an increased frequency of the inhaled bronchodilator. It may be necessary to give this via a nebuliser. If the sputum is purulent, an oral antibiotic should be given. If the breathlessness is largely increased an oral corticosteroid should be given. All patients admitted to hospital should get this, unless it is contraindicated. Further down the line it has to be decided where the exacerbation should be managed; either in the hospital or at home.[24]

If it is decided to manage the patient at home, appropriate review of the patient has to be arranged. Optimal medical therapy has to be established. A multidisciplinary assessment should be carried out if necessary.[24] Many patients with an exacerbation can be managed successfully at home, but there should be a low threshold for hospital admission – especially for those with evidence of a severe exacerbation and for those who do not respond to initial treatments. The decision of where the exacerbation should be managed depends on the severity of the underlying disease, the presence of other diseases, and their social situation. To avoid the need for hospital admission some hospitals (for example Royal Infirmary of Edinburgh and Western General Hospital, Edinburgh) have a rapid access clinic which can treat the exacerbation before it gets to a severe stage.[39]

If it is decided to manage the exacerbation in the hospital, more investigations are done; chest X-ray, arterial blood gasses, ECG to exclude other co-

morbidities, full blood count and urea and electrolytes are measured. A sputum sample has to be sent for analysis if the sputum is purulent. Oxygen should be given to hold the (SaO$_2$) oxygen saturation in arterial blood over 90%.

If the patient does not respond to increased nebulised bronchodilator frequency, intravenous theophylline should be used in addition to the management of the exacerbation. It is important to know that prophylactic use of antibiotics have no place in the management of COPD.[25]

1.6.1 Risk of hospitalisation of people with COPD

NHS Scotland (HEAT target) has the interest to reduce the rate of hospital admissions and re-admissions of people with long term conditions especially people with COPD. There are a number of studies identifying the risk factors for hospitalisations of COPD patients. These studies have showed that low lung function[50-52], increased age[52], poor quality of life[53-55], low physical function[50, 54], history of frequent past exacerbations[53], history of previous admissions[50, 51], under-prescription of long-term oxygen therapy[51], hypercapnoea, and pulmonary hypertension[56] are risk factors for hospital admissions and readmissions.

Interventions that decrease the risk of hospital admissions and re-admissions because of COPD include vaccinations for influenza [32], smoking cessation[33], and pulmonary rehabilitation[32]. Co-morbidity in older people, especially those managed in the community, is a factor for readmission because of adverse drug reactions (ADRs) in hospital. Some of these older people will benefit from closer monitoring.[57]

Another risk factor for admission to hospital for COPD patients is cold weather. Cold air can worsen the symptoms by making airways narrower, which will make it harder to breathe. A Finnish company came up with an idea; to combine weather forecast with the latest telecommunication technology to alert people at risk of poor respiratory health to oncoming bad

weather. In practice this is an automated telephone alert system to warn people with COPD about forthcoming bad weather, which aims to cut the emergency hospital admissions. The Met Office are not only looking at the weather forecast, but also checking health information such as what respiratory viruses are circulating. A gathering of this information will decide when the warning may be sent out. If these factors generate an alert, patients will receive an automated phone call. This phone call will tell the patients what to do during the cold weather period, for example; advise them to go shopping beforehand; or contact their GP to get an appointment; or to get their prescription early so they have enough medications, and are not exposed to the low temperatures. COPD health forecasting, a service jointly developed by the UK MetOffice and Medixine, has proved to have a significant effect on hospital admissions of COPD patients in England. After a successful pilot in Cornwall in 2006-07 the service has now entered production in the UK with over 10.000 patients enrolled.[58]

The aim of the Edinburgh IMPACT service is to reduce admissions and re-admissions of people with LTCs to hospital. The funded service consists of nurses co-ordinating patients' care, including reviewing medication. In terms of COPD management, nurses are trained in assessment of inhaler technique and are familiar with national guidelines. However there can be a range of medication problems associated with COPD and other co-morbidities which may be identified and addressed by pharmacists. As a pilot project, an arrangement was made to refer such patients to a team of primary care pharmacists for clinical medication review. This project will examine the pharmaceutical needs of this particular patient group and prepare an electronic system for reporting pharmaceutical care contributions in the evaluation of this service.

2 Aims and objectives

2.1 Research Question

1. How can the pharmaceutical care needs of patients recruited into an anticipatory care service be profiled in a database design?

2. How can a theoretical model of care be used to generate a list of potential pharmaceutical care needs for people with long term conditions?

2.2 Aims

- To define the pharmaceutical care needs of patients with COPD recruited to an anticipatory care service from a pharmacy perspective.

- To demonstrate and validate a database design as a method of recording the contribution of the pharmacist to this patient group.

(Appendix 1)

2.3 Objectives

1. To generate a model of care for pharmacists using COPD as an example.

2. To characterise the pharmaceutical care needs of patients recruited into the anticipatory care service from a pharmacy perspective.

3   Design a prototype database for the purposes of characterising patients and for addressing their pharmaceutical care needs.

4. Validate a version of the database that is seen to be fit for purpose by pharmacists.

5. Propose a care plan that has been redesigned to match the database.

6. To make recommendations for implementation of method for systematic reporting of multidisciplinary pharmaceutical care.

2.4 Subjects and settings

2.4.1 Study design

The study comprises semi-structured interviews of health care professionals and a retrospective survey of pharmaceutical care needs using pharmacists' records to develop a database which will produce reports for audit purposes

2.4.2 Subjects and Settings

Four pharmacists from the anticipatory care service and hospitals with an interest in chronic diseases, especially COPD gave feedback on the model of care with linked table, database, and pharmaceutical care plan.

Inclusion criteria: Pharmaceutical care plans for 21 patients with long term conditions recruited into the anticipatory care service who have had a medication review carried out by a pharmacist, were analysed.

The research team comprised the researcher Stian Skogly, fellow investigator Camilla Torset Berg, Professor Stephen Hudson and co-supervisor Pauline Westwood.

A nominal group is a group of specialists in a specific subject. The nominal group for the model of care consisted of two pharmacists delivering anticipatory care and one specialist pharmacist, and for the database feedback was given from two of the pharmacists delivering anticipatory care. For the pharmaceutical care plan the nominal group was only one pharmacist from the anticipatory care service.

2.4.3 Ethics approval

The project involved analysis of data which pharmacists were collecting from their work in the anticipatory care service. The project protocol for this project was sent to the R.E.C (Research Ethics Committee) scientific officer. It was confirmed that this was service evaluation and R.E.C. review was not required. (Appendix 2) The project was also discussed within the Edinburgh IMPACT team and they agreed that the research was conducted. A summary of the project was approved by the University of Tromsø.

3 Methods

3.1 Generating a model of care

Literature reviews in databases such as Medline and Embase were conducted to locate literature detailing the current status on documenting pharmaceutical care within COPD and LTC in general. Free text and MeSH terms were used in Medline. A search in Embase was also done using similar terms as in Medline. Examples of terms used are: *COPD, chronic obstructive pulmonary disease, pharmaceutical care model, multidisciplinary teams, anticipatory care, medication review, and pharmacist.* Combinations of these search terms were sometimes used to narrow number of hits. Searches in the respiratory field in the online The Pharmaceutical Journal and British Medical Journal were also performed. Some of the articles were also found by review of relevant articles reference list. National guidelines such as the "National Institute of Clinical Excellence" (NICE) and the "The Global Initiative for Chronic Obstructive Lung Disease" (GOLD) were also used to identify processes of care, methods of targeting care and methods of communication and referral.

A meeting with an experienced nurse case manager working in this service was the beginning of this work. A modified model of care, adopted from a previous project, was used as a starting point for this conversation (Appendix 3)[59]. An explanation of the model from her point of view was made. A draft of a model of care for COPD was designed using a previous template (applied to diabetes) as an example[59]. This model was redesigned by the investigator to satisfy the need to make it more understandable to the practitioners in this project. Information collected from meetings with an experienced nurse case manager, pharmacists conducting the service, literature reviews in databases such as Medline and Embase, and national guidelines (NICE-14 and GOLD 2008) were used to identify processes of care, methods of targeting care and methods of communication and referral. This draft was used as the basis for the first meeting with the research group.

Improvements were made during and after the first meeting with the research group already defined. A prototype of the model of care was the starting point for the first meeting with the nominal group. The idea was to gather experienced pharmacists working in the anticipatory care service together with specialist hospital pharmacists. A form with possible meeting dates and times was sent to some chosen pharmacists in the local area by e-mail. This was returned to the researcher, who chose the most suitable day for the meeting. Because of impossibility to gather all the pharmacists at one meeting in the middle of their normal working hours, only two pharmacists confirmed that they would attend the meeting – one specialist pharmacist and one working in the anticipatory care service.

Only the anticipatory care pharmacist actually attended the meeting. CTB and PW also attended the meeting. Because of lack of attending participants in this meeting a backup plan was made. Comments were sought by interview with one of the pharmacists conducting the anticipatory care (Appendix 4) service and by e-mail from two pharmacists – one conducting the anticipatory care service and one specialist pharmacist. A few prompt questions were asked to all of them: Can you explain your first impression of the model? Do you understand the model? Can you explain your view/understanding of each step in the cycle? The nominal group reviewed and commented on the model of care during an interview or by e-mail. The care model was revised accordingly - see the results sections. The first draft and final model of care is attached in (Appendix 5 and 6)

3.2 Characterising the pharmaceutical care needs of patients

Pharmaceutical care needs of patients recruited into the anticipatory care were identified by using the model of care from objective 1. For each step of the model, processes of care identified from the evidence base for managing COPD were detailed to generate a list of activities that may be carried out by a health care professional. These are presented in a linked table (Appendix 5 and 6). This linked table was sent to the pharmacist together with the model

of care from objective 1. Feedback from the pharmacists in the nominal group was the basis for final improvements. A list of pharmaceutical actions was also developed.

3.3 Design a database

Information from prior projects references, information from meetings with pharmacists, pharmaceutical needs identified from the model of care, and the pharmaceutical care plan designed by fellow investigator CTB were used. This generic database was developed by using Microsoft Access 2003, a soft ware the investigator had to become familiar with before the designing could begin.

The first draft was made using data fields from the pharmaceutical care plan used by the pharmacists conducting this anticipatory care service. Printable reports with normal tables, cross tables, and charts showing different results, for example number of drug therapy problems were generated automatically (Appendix 7). The most recent version of categorisation, used in this project, is based on a master project done at Strathclyde University in 2008. This builds on the work that has been done through PhDs and master projects at Strathclyde University .[19, 23]

The second draft of the database was updated to use the most recent categorisation system for pharmaceutical care issues. Additional data fields were also added to the demographic part of the database, such as height, body weight, body mass index (BMI), smoking status, alcohol consumption. This was done by looking at data fields used in previous databases and pharmaceutical care plans from other projects, data fields were selected to be used in the new database to produce reports which can be useful to evaluate this anticipatory care service. Another improvement from the first draft was putting everything in one screen picture instead of several pages. When adding disease, medication or care issue to the patient a dialog window pops

up. Lists which got updated after every change to medical or drug history were added.

Structured Query Language (SQL) - a specialised programming language for sending queries to databases was also used in the database. The investigator wasn't familiar with use of these codes/language, neither the use of Visual Basic® and its codes/language was familiar to the investigator. However, some of the codes were copied from free forums on the World Wide Web to get the database running properly.

The research group had a meeting discussing this database and which outcomes from the reports which were desired to be useful in the evaluation of the service. A few fictitious patient details were typed onto the database to test the database, and some test automatically updated reports were printed. After the meeting some agreed improvements to the database, such as adding further and improved reports.

3.4 Validate a version of the database to be fit for purpose

The investigator arranged a meeting with the nominal group to discuss the database. Two of the three pharmacists conducting the medication reviews in the anticipatory care service attended the meeting. Since they had used a self modified categorisation system (Appendix 8) for drug therapy problems, they were informed about the system of categorising pharmaceutical care issues which was set to be used in the latest version of the database. Some examples from their patient samples were used to demonstrate the database. Since two different categorisation systems were used, discussions between the participants were used to categorise in a proper way. Because of using more time than expected on the re-categorisation, a new meeting date was set to populate the database. A few more reports were made for the next meeting as agreed with the nominal group.

In collaboration with the nominal group the database was populated with 21 anonymous patients recruited into the Edinburgh IMPACT anticipatory care service. This was done to demonstrate and produce reports to be used in the evaluation of the service. The database and its reports were face validated by the nominal group, and it is now fit for purpose.

3.5 Propose a care plan

The validation of the database will lead to redesign of the pharmaceutical care plan which is used within the anticipatory care service (Appendix 9). The fields in the plans will be matched with the database and the models of care in chronic heart failure and COPD. According to the categorisation system mentioned in the introduction a list of possible checks and changes done by the pharmacist was developed by the investigator. The list was revised during a research group meeting. The points of most importance, from the research group's point of view were transferred into a pharmaceutical care plan. A prototype of a pharmaceutical care plan was made. Further comments from the research group were followed up with updates in the care plan. The care plan was not field tested or commented on by professional health carers, but is a template for further work. (Appendix 10) One of the pharmacists in the nominal group commented on the pharmaceutical care plan. These comments will be for further work.

3.6 Recommendations for implementation

Before the meeting with the IMPACT Nurse Case Managers Team and the Long Term Conditions Implementation Group information from the database was sent to the pharmacist who was presenting the results from the Edinburgh IMPACT pilot. The investigator and one of the pharmacists conducting the medication reviews attended the meeting where the results were presented. The results will also be presented in a conference in Glasgow in June 2009.

4 Results

4.1 Model of care and linked table

The meeting with the experienced nurse case manager was the start of the production of the model of care. The main cycle from the primary project was the main discussion point of the meeting[59]. The outer boxes in the figure below are summary of the nurse case manager views on the anticipatory care service.
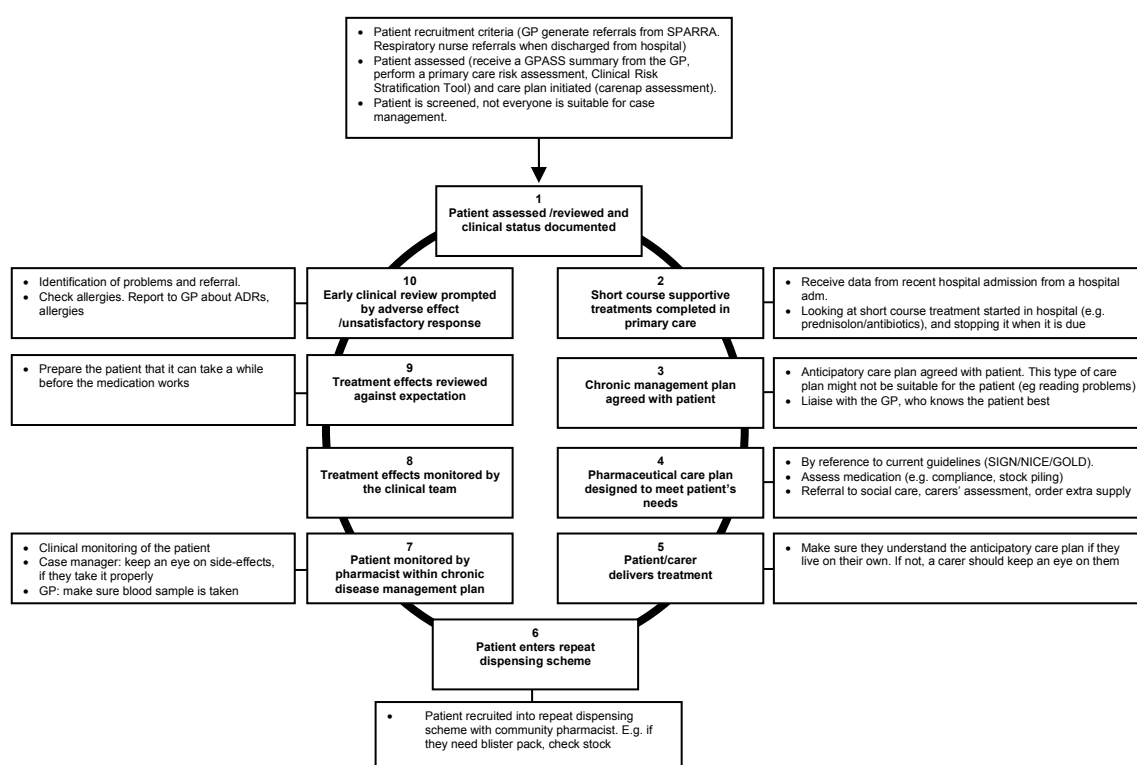

Figure 5: Summary of a nurse case manager's views of the anticipatory care service

The first draft of the model of care and the linked table was sent to four different pharmacists for feedback, but only three of them replied. The investigator met two of them. The pharmacists' comments to each circle in the model of care and the correlated linked table are summarised below.

	Definition		Activity

A	**Patient assessed / reviewed and clinical status documented**	Patient assessed routinely or during exacerbation. Hospital admission if necessary	• **Assessment of severity of airflow obstruction according to FEV_1 as a percentage of a predicted value.[1]**
			• **Mild/moderate patients; reviewed at least annual. Severe patients; at least twice per year.[1]**
			• **Full clinical assessment:[1]**
			  – **Clinical laboratory tests: T_{LCO}, BMI, SaO2, PaO2.**
			  – **Spirometric tests: PEF, FEV_1, FEV_1/FVC.**
			• **In an emergency situation: Steroids, heparin, oxygen, nebulisers, and antibiotics should be given.[3]**
			• **Patients with an exacerbation referred to hospital:[1]**
			  – **Chest radiograph**
			  – **Arterial blood gas tensions**
			  – **Inspired oxygen concentration**
			  – **ECG (to exclude co morbidities)**
			  – **Full blood count**
			  – **Urea and electrolyte concentrations**
			  – **Theophylline level should be measured in patients on theophylline therapy at admission**
			  – **If sputum is purulent, a sample should be sent for microscopy**
			  – **Blood cultures should be taken if the patient is pyrexial**
			• **Patients with α_1-antitrypsin deficiency should be referred to a specialist.[1]**
			• **Individualised targets that have been agreed with the patient are transferred via a pharmaceutical care plan (a list of pharmaceutical care issues arising from the clinical management plan) to the GP, the primary care pharmacist, and the case manager.**

	Short-course supportive treatments completed in primary care	Treatment to re-establish control of disease delivered by multidisciplinary clinical team	• **Short-courses of supportive treatments, such as oral corticosteroids and antibiotics, have to be completed in primary care. [1, 4]**
		Pharmaceutical care plan shared to maintain continuity of care	• **Details of course length are transferred via a pharmaceutical care plan to the GP, the primary care pharmacist, and the case manager.**

(Left vertical label: PATIENT CLINICAL ASSESSMENT)

Figure 6: Part A of the model of care and the correlated linked table

P1: It was commented during the meeting and by e-mail; "*I understand these and they seem appropriate*" about circle A.

P2: When talking about the model of care it was said; "'*Patients assessed routinely or during exacerbation is OK*'" The pharmacist also thought that the rest of the circle A was fine. When the pharmacist was talking about the table it was said; "*I do agree that they should be reviewed at least annually. I think that if you make any changes that should lead to a review appointment with the patient. I don't disagree with that at all*". The pharmacist explained further that some of these parameters are not so easy to do in primary care, because of lack of time and equipment. "*The practice has one now, we do all the*

spirometry tests, so that is not an issue". "*I think maybe, if you're going to make a tool for people, then dividing this box into primary and secondary care would be a possibility.*"

Since this pharmacist works in primary care, the comments were on aspects that were specific for primary care, and the points which were specific for secondary care were not commented on.

"*Patients with alpha anti-trypsin deficiency should be referred to a specialist, but I presume that gonna be happening at the point of diagnosis*". The pharmacist explained that as a primary care pharmacist you wouldn't get information from other people managing patients. It was more likely and useful if the community pharmacist got the information. The nurse case manager will get the information which is important.

P3: "*About the model: My understanding from reading is that hospital pharmacist shares care plan with primary care? Who in primary care? Some hospital care issues may be irrelevant after inpatient stay. The turnover is so rapid that the patient may not be seen by hospital pharmacist - can expand if required*"

There was confusion around the linked table. It wasn't clear enough where this would happen. "*I wouldn't check spirometry during an acute exacerbation. I don't know how often patients are reviewed? And by whom? T_LCO? Peak flow not used for hospital assessment of COPD. This can be inaccurate in COPD.*" The treatments to be used in an emergency situation are pretty vague. "*Not all these drugs are necessarily administered in every patient. Should this treatment plan be under bullet point 5?*"

Samples of sputum are not always sent to be analysed, though empirical treatment are often used. "*It will be hard enough to transfer the care plan to one person, but 3…? Sending a pharmaceutical care plan to three people for every patient discharge from respiratory would be a tall order.*"

The flowchart shows:

Clinical management plan agreed with patient → **Specialist referral to outpatient clinic or for rehabilitation if necessary**

Pharmaceutical care plan designed to meet patient's needs

B

Patient educated on treatment options and management plan individualised accordingly

Pharmaceutical care issues identified and shared among primary care team

B TREATMENT PLANNING	Clinical management plan agreed with patient	Specialist referral to outpatient clinic or for rehabilitation if necessary	• **Patient attends hospital respiratory department or GP clinic for initiation of multidisciplinary team care and medications for COPD.**
			• **Pulmonary rehabilitation offered to all patients who consider themselves functionally disabled by COPD.[1, 5]**
			• **Smoking cessation.[1, 4, 5]**
			• **Medications:[1, 4]**
			  − Bronchodilators **(first line: short-acting beta$_2$ agonist or antimuscarinic drug. More severe: Given regularly. Remain symptomatic or two or more exacerbations in a year: Use long-acting agents)**
			  − Corticosteroids **(Moderate to severe: Inhaled steroid + long-acting agent. Short-course of oral if increased breathlessness interferes with daily activities)**
			  − Theophylline
			  − Antibiotics **(If sputum becomes purulent or other signs of infections)**
			  − Mucolytic **(May be considered for patients with a chronic productive cough)**
			  − Oxygen **(Hypoxemic patients)**
			• **Prevention of complications**
			  − **Cor pulmonale (antihypertensive)**
			  − **Pneumonia, influenza (Vaccinations, antibiotics)**

	Pharmaceutical care plan designed to meet patient's needs	Patient educated on treatment options and management plan individualised accordingly	• **Education on using the medication correctly**
			  − **Different devises, spacers, nebulisers**
			  − **Compliance**
			• **Dietary and exercise advice**
			• **Individualised treatment targets made (smoking cessation, etc)**

		Pharmaceutical care issues identified and shared among primary care team	• **Regimen, pharmaceutical care issues, and agreed individualised targets documented in a pharmaceutical care plan which are given to the patient, the GP, the primary care pharmacist, and the case manager.**

Figure 7: Part B of the model of care and the correlated linked table

P1: "*I understand these and they seem appropriate*"

P2: "*I think B is fine as well.*" "*OK, clinical management plan agreed with the patient. I think that is good. All the issues you're trying to target and deal with, I think that's fine. Pharmaceutical care plan designed to meet patient's needs, I think that's fine.*" The pharmacist also commented on the table; "*Pulmonary rehab offered to all patients who consider themselves functionally disabled by COPD, I think that's a really good point. I think it should definitely be there.*" The pharmacist explained that smoking cessation is available through community pharmacies as well as group smoking cessation classes. "*In terms of the treatment, I think it is fine. You may give a bit more*

information around corticosteroids, in terms of what the guidelines says. And also mucolytic, some areas think that they are OK, some others don't. At the moment they are not in the joint formulary here in Lothian, but it is on the MCN guidelines"

P3: "*Currently no pharmacist in clinic seeing COPD patients. All 8 consultants see COPD patients, and there is no dedicated COPD clinic.*"

Mucolytics are not in the formulary. It may be necessary to use antihypertensive agents as prophylaxis and to reduce symptoms of cor pulmonale.

C	Patient/ carer delivers treatment	Support of patient self management provided by primary care team	• **Education on self-monitoring** - **PEF measurement and exercising tolerance**
(TREATMENT ADMINISTRATION)		Medication personalised to meet patient's needs	• **Discussion of individualised agreed targets** • **Adjustments to pharmaceutical care plan**
		Patient / carer educated on personalised treatment	• **Patients and carers should be educated in how to limit lung damage (Smoking cessation and exercising)** • **Ensure that patients and carers know how to respond to symptoms of a COPD exacerbation:**[1, 5] - **Oral steroid therapy start up if increased breathlessness.** - **Antibiotic therapy start up if their sputum is purulent** - **Bronchodilator therapy adjustment to control their symptoms.** • **Carers or patients at risk of having an exacerbation of COPD should be given a course of antibiotic and corticosteroid tablets to keep at home for use as a part of an anticipatory care strategy.** • **Patients / carers given a clinical management plan should be advised to contact the case manager if they do not improve.**[1]

Figure 8: Part C of the model of care and the correlated linked table

P1: "*Cycle C - It seems to me the main part of this cycle is the support of the patient with regards managing their illness and taking their medication. I don't really understand the bit in this cycle about 'medication personalised to meet patient's needs.' In cycle B they have been started on treatment, and then I think treatment would be monitored before making changes to personalise it.*"

P2: "*I think it is a bit overlap here between B and C in terms of the education plan and agreeing the plan with the patient.*" "*To me C is more about reinforcing the advice that you already have given in B. I guess B to me is maybe try to establish your care plan, and then C is about putting it into action. You got 'pulmonary rehab is offered to all patients who consider themselves functionally disabled by COPD', so if you put something in about reassessing patients needs for pulmonary rehab, and due to changes in the severity of disease, because you would do that. Patients might be alright when you first see them, but maybe later down the line things have worsened for them and actually they could then become candidate for pulmonary rehab.*" It was also given an explanation of the importance of regularly review of the patient's understanding of the plan that are set up, so they know what they are doing when they get an infective exacerbation of COPD.

"*Patient/carers given a clinical management plan should be advised to contact the case manager if they do not improve*". "*Well, in first instance if you were the prescriber and making a change, surely, you should be following that up. If you are not following it up, you should then pass that back to the case manager who will then following it up routinely. It is like an overlap here.*"

P3: "*Is C done by community pharmacist?*"

	Patient enters repeat dispensing scheme	Routine clinical verification at each dispensing	• Pharmacist conducts opportunistic checks of patient-held records and pharmacy patient medication records at each dispensing.[2]
D PATIENT TREATMENT MONITORING		Prescription verified against best practice/ clinical management plan	• Pharmacist conducts opportunistic check of individualised agreed targets set with the patient. (Smoking cessation, fewer infections, fewer exacerbations and hospitalisations, etc.) • Prescription checked for adherence to current NICE, GOLD and BNF and patient's clinical management plan.
		Patient educational needs addressed	• The pharmacist ensures that patients understand how to take the medications correctly and checks that the inhaler technique is correct.

Figure 9: Part D of the model of care and the correlated linked table

P1: "*Cycle D - this part seems fine*"

P2: "*Doing the 'opportunistic checks about smoking cessation', asking about things like that. I think that is all very good." "'Ensure that the patients understand how to take the medications' I think that is really good.*" "*Prescription checked for adherence to current NICE, GOLD and BNF*". It was explained that this should be done in an earlier stage, when making the management plan. The medication part in circle B should be according to the guidelines and has to be right in the beginning, when prescribing is happening. There also need to be a feedback to the GP practice. "*At the moment there is no electronic links between the GP practice and the community pharmacy*". "*I'm assuming that when the chronic medication service is set up, there will be an electronic link which is sending information back. If it's not electronic I am assuming there will be another system in place. Everywhere else you put pharmaceutical care issues are shared among the primary care team, so goes to the pharmacy, you need to make sure that any changes in treatment and recommendations are shared within the primary care team as well. You need to just put that in there as well.*"

P3: "*This is clear*".

Figure 10: Part E of the model of care and the correlated linked table

P1: "*Cycle E - this cycle seems fine, however I think that monitoring comes earlier in the management as well. In order to get the patients onto a stable medication regime* (when repeat dispensing is initiated) *treatment is monitored closely at the beginning and then once their medication is more stable monitoring is carried out, but usually less frequently than at the beginning.*"

P2: "*I think you're going to make sure you've reviewed them earlier on in B. You're not going to give them a clinical management plan if you think they are receiving a too high dose of or too low dose in a drug interaction, you gonna have dealt with all of that stuff in circle B.*"

The investigator asked if the circle E was unnecessary, then the answer was: "*I would say that it should be a review of the treatment. Some of the parameters that you have put into here* (care issue categories) *should already have been identified in A and B.*" "*Circle E could be review of treatment plan discussed in B, for example. I think E should be a review of what you have done with the patient*". "*I think in the E circle you need to put a review of treatment planned, to ensure ongoing monitoring for drug problems, so that is relevant*"

P3: "*This is clear*"

Figure 11: Part F of the model of care and the correlated linked table

P1: "*Cycle F - I'm not sure about this one! In terms of evaluating outcomes I feel that this is done to a certain extent before the patient enters the repeat dispensing scheme cycle. If the outcomes are successful then the patients will be maintained on this medication regime. Outcomes will however be evaluated when periodic monitoring is carried out and if continued treatment proves no longer to be successful management would then go back to cycle B?*"

P2: "*'Treatment outcomes evaluated as success or failure'. I think that's important. 'Documentation of outcomes within the clinical management plan'. I think that is important as well.*"

The investigator asked if it would be an alternative to make one circle out of E and F. The answer was; "*Yes*". "*There are two things that are joined not necessarily completely separate.*"

P3: "*This is clear*"

4.1.1 Actions after the feedback from the nominal group

The pharmacists thought the overall first impression was a bit confusing, so a simplification was needed. The investigator made a new layout to the first draft of the model, which made it more uncluttered compared with the original model. In the final version the circles were put into boxes, which made it in order and easy reading.

According to the feedback from the pharmacists a few things have been moved from the first circle C to the new circle B, because there was an overlap between these circles in the first draft. The information around the medications is improved with more details from the guidelines.

When the word "case manager" was mentioned in the model of care it was not clear for the pharmacists. Two of the pharmacists asked what it meant, so the wording was changed to "nurse case manager".

The full version of both the draft and the final simplified version are attached to the appendix 5 and 6.

4.2 Database

Since submitting a database would not be suitable, some screenshots from the final version of the designed database will follow below. When starting the database a "password required" field will appear. This element is added to protect the data, so non authorised people can't access it. The password is held by the investigator only.
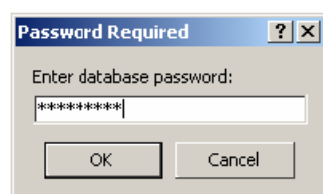
Figure 12: Password box which will appear when opening the database

If the password is accepted the front page below will appear. The front page is presenting the database, the collaborator, and universities with logos. Two command buttons are added to the page, these are shortcuts for adding a new record and to the results page.
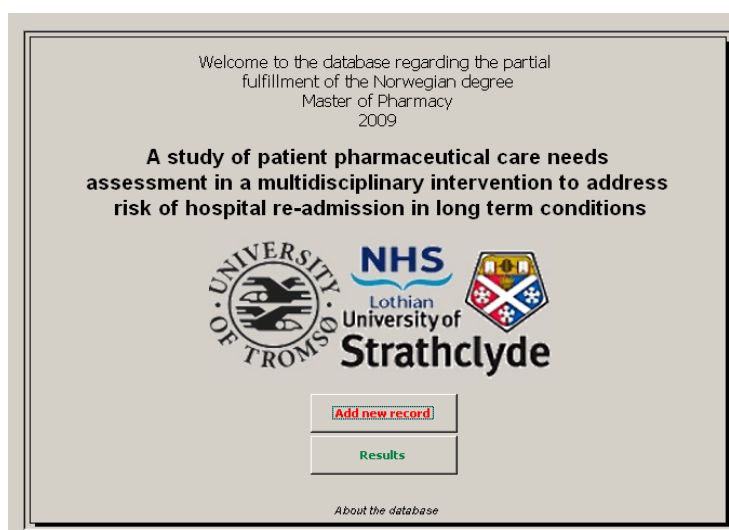
Figure 13: Front page of the database developed by the investigator

When clicking the "add new record" button a new screen will appear - the main form. Below is a screenshot of the main form of the database before entering any data.

Figure 14: Main form of the database developed by the investigator

The column on the left hand side is filled with command buttons for a new record, a shortcut to the automatically created reports of entered data. The button below the reports button is a binocular, which can be used to search in the database. The searching is formatted to search in the ID field, but can be set to search every field of the database. The *About* button is information about the database and who the developer is. The very last one in this column is an ordinary close button.

In addition to the entry password, all persons added to the database have a unique three digit identification number (ID). The ID number was used instead of patient name for data protection reasons. Name and personal information, such as community health index (CHI), could easily be added to this database, if people see the value of and want to use this database for systematic reporting of multidisciplinary pharmaceutical care in future. By pressing the tab key on the keyboard the focus from one text box to another,

and also between different command buttons. The order of the tabbing is set as the investigator thinks is most time saving.

The long form of date of birth was not fully used in the project, since this will make it easier to identify persons in the database – again an ethical reason. The date of birth was set to first of January on all the persons. The year of birth was recorded. From the date of birth a calculated field shows the age of the person.

The height and weight was not recorded, since the pharmacists hadn't recorded this information. However, a field was included, calculating the BMI from these values using the standard formula. The calculated value will generate a colour, which easily could be used to read out whether the person is underweight, normal weight, overweight, or obese.

The next step is around smoking status. There are two options; *smoker* and *ex-smoker.* If you check one of them, the other one will be disabled. In addition to the disabling, another dropdown menu is appearing; for smokers and ex-smokers respectively number of cigarettes per day and years since smoking cessation.

The next step is alcohol consumption. If the patient is drinking alcohol the checkbox is checked. A new dropdown list is appearing; within or excess limit. An information box is which is explaining the governments limits are appearing simultaneously as the drop down list.

When clicking the *Add Disease* button, a small form will pop up in the middle of the screen, as shown below. Instead of using the pointer when clicking the command button, *Alt + D* could be used from the keyboard, which is timesaving. This is the reason why the Disease is underlined. The ID number of the person which is going to be added a disease will automatically be entered into this form. A null value is not accepted in this field. The date of the diagnosis could be entered, but it is optional. The disease could be found in a

drop down list or writing manually. This list is interactive and manually typing generates the most suitable choice during typing, as shown in the screenshot.
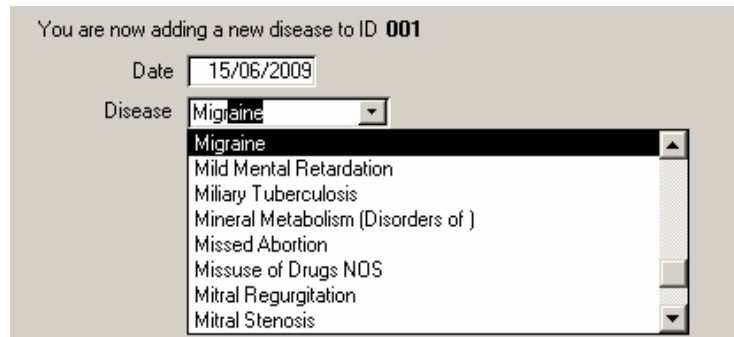
Figure 15: Disease form in the database

When the disease is selected either two easy hits of the *enter* key or clicking *add to list* button will close the window and add it into the disease list in the main form.
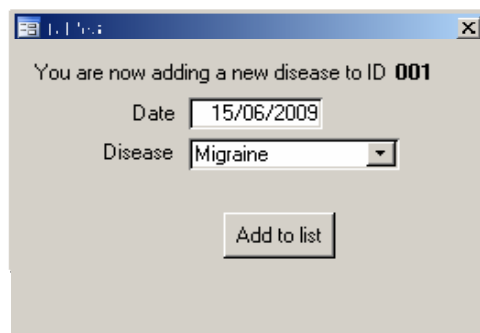
Figure 16: Completed disease form in the database

The drug form is quite similar to the disease form; with an automatically filled in ID number for the patient, an interactive list of drugs, and an *add to list* button in the bottom. To open it, a click on the *Add Medication* button will do the work. The short keys for this action is *Alt + M*.
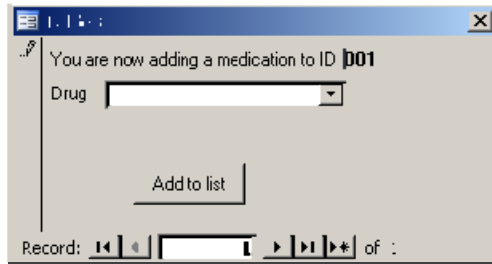
Figure 17: Completed medication form in the database

The short keys for adding a care issue are *Alt* + C, or simply just click the command button which is named *Add Care issue.* In the care issue form the same ID number as in the main form is added automatically. You also have three different kind of pharmaceutical care issue choices; *check*, *change in drug therapy*, *change in drug therapy process.* When checking one of these, different choices are appearing below the checkbox. The other checkboxes are disabled, since a care issue can't be both a check and a change, as mentioned in the introduction of this thesis.

With the categorisation system in mind, screenshots from the database is shown below:
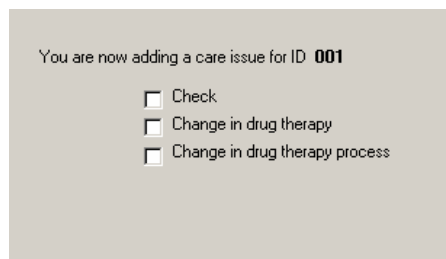
Figure 18: Care issue form with three different choices
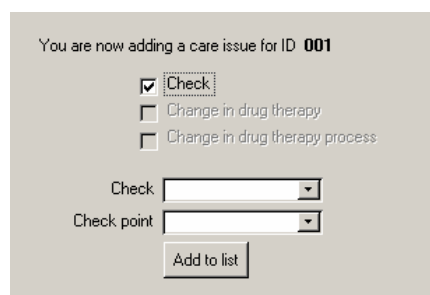
Figure 19: Care issue form and the different choices when a check is identified

Figure 20: Care issue form and the choices when a change in drug therapy is identified

Figure 21: Care issue form and the choices when a change in drug therapy process is identified

When the person is finally typed into the database, the main form may look like the screenshot below. When a new person should be added, simply press the *New record* button.

Figure 22: The mainframe may look like this after typing one record into the database

If the green button is pressed the report menu appears. Because of the large number of reports, they are grouped into four groups. Each group can be viewed by clicking the magnifier to the respective group, or click the print button and the reports are printed. The *Print all* button is self explanatory. All the different reports are attached into the appendices part in the end of this thesis.

Figure 23: Reports menu in the database

4.3 Validation of the database

4.3.1 Comments and changes on the database

The pharmacists conducting the medication reviews in the Edinburgh IMPACT service thought the overall first impression of the categorisation system was hard to understand, particularly around the *check point*, *change points*, and degree of change. Everyone agreed the idea of using one system instead of many different systems.

Another two chart reports were added to the database to show the number of change in drug therapy process and the number of checks, as requested by the pharmacists.

4.3.2 Results from the population of the database

All records were fitted smoothly into the database. The automatically created reports were printed after the meeting (Appendix 7). A summary of the findings is presented below:

There were conducted 21 home based medication reviews during the time of the pilot, which means the number of patients included into the pilot were 21 (n=21). There were 62% females (n=13) and 38% (n=8) males in the case load. The mean age of the females was 74 years (SD 10, range 51-87). For the males the mean was 75 years (SD 12, range 51-88). For the total case load the mean age was 74 years (SD 10, range 51-88). There were 33.3% smokers (n=7), 23.8% ex-smokers (n=5), and 42.9% non-smokers (n=9). 57.1% of the smokers were females (n=4).

Two of the reports produced from the database were around diseases. The most common diseases in the case load are COPD, Ischemic heart disease, chronic heart failure, chronic kidney disease, depression, myocardial

infarction, hypertension and diabetes in descending order. COPD are present in 57.1% of the records (n=12), ischemic heart failure in 42.9% (n=9), chronic heart failure in 33.3% (n=7), chronic kidney disease 33.3% (n=7), depression in 28.6% (n=6), myocardial infarction in 28.6% (n=6), hypertension in 28.6% (n=6), and diabetes type 2 in 23.8% (n=5). People with 2-3 diseases accounted for 28.6% (n=6) of the records, 4-5 diseases 19.1% (n=4), 6-7 diseases 23.8% (n=5), 8-9 diseases 23.8% (n=5), and for 12 diseases 4.8% (n=1).

Another report from the database was counting the number of medications in each record. People with 9 different medications counted for 4.8% (n=1), for 10 medications 14.3% (n=3), for 11 medications 14.3% (n=3), for 12 medications 19.1% (n=4), for 13 medications 4,8% (n=1), for 14 medications 14.3% (n=3), for 15 medications 9.5% (n=2), 18 medications 9.5% (n=2), and for 22 medications 9.5% (n=2) records.

The pharmacists had identified 150 pharmaceutical care issues, but after re-classification the numbers of care issues were reduced to 127, due to merging and splitting of care issues, in example checks which leads to changes are only categorised as changes. This will give an average of approximately 6 pharmaceutical care issues per person in the case load. Out of these 127 care issues there were 46 *checks* (36.2%), 65 *changes in drug therapy* (51.2%), and 16 *changes in drug therapy process* (12.6%). Below are five tables are displayed to show the relationships between the different parts of the categorisation system.

Table 4: Types of checks in relation to check point (n=46)

	Design	Delivery	Evaluation	Total
Medication needed	8	0	0	8 (17.4%)
Safety	14	0	0	14 (30.4%)
Effectiveness	7	0	0	7 (15.2%)
Compliance	17	0	0	17 (37.0%)
Total	**46**	**0**	**0**	**46 (100%)**

Table 5: Change point on relation to type of change (n=65)

	Design	Delivery	Evaluation	Total
Drug selection	11	0	0	**11 (16.9%)**
Dose	10	0	0	**10 (15.4%)**
Route/dose form	3	0	0	**3 (4.6%)**
Dose interval/timing	7	0	0	**7 (10.8%)**
Duration	6	0	0	**6 (9.2%)**
Stop drug	5	0	0	**5 (7.7%)**
Compliance	23	0	0	**23 (35.4%)**
Total	**65**	**0**	**0**	**65 (100%)**

Table 6: Type of change in drug therapy in relation to change point (n=65)

	Design	Delivery	Evaluation	Total
Adjustment	50	0	0	**50 (76.9%)**
Modification	14	0	0	**14 (21.5%)**
Review	1	0	0	**1 (1.5%)**
Total	**65**	**0**	**0**	**65 (100%)**

Table 7: Type of change in drug therapy process in relation to change point (n=16)

	Design	Delivery	Evaluation	Total
Clinical record of patient characteristics	1	0	0	**1 (6.3%)**
Clinical record of drug history	6	0	0	**6 (37.5%)**
Continuity of information	2	0	0	**2 (12.5%)**
Level of patient monitoring	7	0	0	**7 (43.8%)**
Health care team member(s)	0	0	0	**0 (0%)**
Total	**0**	**0**	**0**	**16 (100%)**

Table 8: Change in drug therapy in relation to drug therapy problems (n=65)

	Unnecessary drug therapy	Need for additional drug therapy	Ineffective drug	Dosage too low	Adverse drug reaction	Dosage too high	Inappropriate compliance	Unclassified	Total
Drug selection	1	7	1		2				11 (16.9%)
Dose				4	2	4			10 (15.4%)
Route/dose form			1		1		1		3 (4.6%)
Dose interval			1		1	3	2		7 (10.8%)
Duration	4				1	1			6 (9.2%)
Stop drug	3		1		1				5 (7.7%)
Compliance					2	1	20		23 (35.4%)
Total	8 (12.3%)	7 (10.8%)	4 (6.2%)	4 (6.2%)	10 (15.4%)	9 (13.9%)	23 (35.4%)	0 (0%)	65 (100%)

There were 46 checks identified. *Compliance* counted for 37% (n=17) of all checks. *Safety* accounted for 30.4% (n=14), *Medication needed* 17.4% (n=8), and *effectiveness* 15.2% (n=7).

As shown above the most common drug therapy problem was *inappropriate compliance* 35.4% (n=23) out of all drug therapy problems identified (n=65). The other most common was *adverse drug reactions*, which accounted for 15.4% (n=10) of all drug therapy problems, *dosage too high* 13.9% (n=9), *unnecessary drug therapy* 12.3% (n=8), *need for additional drug therapy* 10.8% (n=7), and *ineffective drug* and *dosage to low* accounted for 6.2% each (each n=4).

There were 16 changes in drug therapy process. *Level of patient monitoring* counted for 43.8% (n=7) of all changes in drug therapy process. The other ones where *Clinical (shared) record of drug history* 37.5% (n=6), *Continuity of information/care between clinical settings* 12.5% (n=2), and *clinical (shared) record* of patient characteristics 6.3% (n=1).

The objective was; *design a prototype database for the purposes of characterising patients and for addressing their pharmaceutical care needs.* The database produces reports which show the patient characteristics and addresses the patients' pharmaceutical care needs. The nominal group thought some of the reports made from the database could be useful in the evaluation of the service and in the future.

4.4 Propose a care plan

According to the categorisation system mentioned in the introduction a list of possible checks and changes done by the pharmacist was developed by the investigator. See list below.

Table 9: Checks which has to be made during the assessment of the patient

	Checks
Medication need inquiry	Does the patient use the medication(s) according to the recent guideline?
	Does the patient have a short-acting bronchodilator to reduce symptoms?
	Does the patient who has documented history of two or more exacerbations in the past 12 months receive a long acting bronchodilator?
	Has the patient got the influenza and the pneumococcal vaccination?
	Does the patient need a theophylline?
	Has the patient been prescribed a course of antibiotics and corticosteroids to keep at home for use in their own initiative?
	Has the patient with a $FEV_1 \leq 50\%$ predicted and two or more exacerbations requiring treatment of antibiotics or oral corticosteroids within a 12-months period been prescribed an inhaled corticosteroid?
	Has the patient got enough supply of oxygen?
Effectiveness inquiry	Satisfactory inhalation technique?
	Decreased breathlessness?
	Decreased sputum production?
	Does the patient improve the symptoms after using theophylline?
	Decreased effect of theophylline/aminophylline because of smoker?
Safety inquiry	The patient is not prescribed prophylactic antibiotics or anti-tussive for COPD
	Has the patient received a self management plan to respond promptly to early symptoms?
	Has the patient been prescribed a course of antibiotics and corticosteroids to keep at home for use in their own initiative?
	Monitor theophylline/aminophylline in blood
	Blood samples of markers. (e.g. potassium levels when salbutamol used)
	Has the patient had a medication review once in the past 12 months if mild/moderate COPD, or twice in the past 12 months if severe COPD?
	Has the patient receiving high dose inhaled or long term oral corticosteroids got osteoporosis prophylaxis?
	Is smoking and LTOT a combination?
Compliance inquiry	Monitor blood samples to find drug in blood
	Is the daily dose taken? Check monitoring dosing systems (MDS) or compliance aids

Table 10: Change in drug therapy process

Change in drug therapy process	
Clinical (shared) record of patient characteristics	Detect errors in the characteristics of the patient. (i.e. If penicillin allergy and receive penicillin)
Clinical (shared) record of patient drug history	Detect errors in the medication list. Changes made because of this.
Continuity of information/care between clinical settings	Transferring patient to pulmonary rehab Transferring to smoking cessation Make new arrangement to physiotherapist, occupational therapist, etc
Level of patient monitoring	Initiate or give advice for monitoring smokers who are using theophylline Initiate or give advice to monitor interactions which increase/decrease level of drug in body. When receiving high dose corticosteroids, initiate or give advice for bone density screening (DEXA-scan)
Health care team member(s) education/information	Educate nurses to look after adverse drug reactions, how to use inhalers correct, etc

Table 11: Changes in drug therapy

Change in drug therapy	
Drug selection (starting new or changing drug)	Change drug because of adverse drug reaction Prescribed inhaled corticosteroid if $FEV_1 \leq 50\%$ predicted and two or more exacerbations requiring treatment of antibiotics or oral corticosteroids within a 12-months period. Need for additional drug therapy because of lack of effectiveness or a new indication Prescribed theophylline when past trial of short and long acting bronchodilators is documented or failure to use inhaler. Change drug because of difficulties using the inhaler
Dose	Increase dose because of lack of effect Decrease dose because of toxicity Increase dose bronchodilator in periods with breathlessness
Route/dose form	Change route because of difficulties with swallowing From intravenous route in hospital to per oral route at home From inhaled to oral corticosteroids Use nebuliser instead of inhalers Use spacer as inhalation aid
Dose interval/timing	Change to modified release formulation will cause longer dosing intervals
Duration	Use antibiotics according to guidelines and effect
Stop drug temporarily/permanent	Temporarily stop a medication regime because of interaction with short course treatment. Discontinue drug with no indication Discontinue ineffective drug Adverse drug reaction
Patient or carer level of education (understanding/ compliance)	Corticosteroids are not working immediately Corticosteroids have to be discontinued gradually Demonstrate correct inhaler technique LTOT and safety

Table 12: Other checks to do identified by the investigator

Other Checks	Monitor the patient's FEV_1 Severity/stage of COPD Smoking history. Estimate pack years Body mass index (BMI) MRC dyspnoea scale (1-5)

One of the aims for the care plan was to put all the information on one sheet of paper. One of the pharmacists conducting the medication reviews in the Edinburgh IMPACT service commented on the pharmaceutical care plan template. She said; "*Although normally the least number of pages required in a form the better, in this case the information that is there is perhaps condensed too much, some of the boxes would only be practical for very small handwriting.*"

The pharmacist also requested a link to suggest bone protection if steroids = equivalent of 7.5 mg prednisolone (inhaled or if repeated courses of oral prednisolone).

"I'm not sure if the 'pulmonary rehab offered / started / completed' could end up complicated. I agree it is obviously useful knowing if a patient has / is on a programme, but there may be issues with referral criteria. Some areas are quite strict as to whom is entitled to the programme. In some cases smokers and non-smokers are apparently being separated as there has been trouble if non-smokers find out a current smoker is on the same session, it sends out mixed messages."

Around the medications the pharmacist commented: "For antibiotic treatment, the Lothian COPD guidelines suggest clarithromycin as an alternative for penicillin-sensitivity". A box for this choice may be added to the care plan. In the same care plan box the pharmacists commented that there could have been added 'Haleraid' under compliance aid, which is useful in some arthritic / MS (multiple sclerosis) patients.

4.5 Implementations of use

The presentation of the results from the database in the meeting with Nurse Case Managers Team and the Long Term Conditions Implementation Group generated an impression that the nurses were impressed with the pharmacists contributions – even though the case load was small. The nurses expressed the importance of having the pharmacists in the team and were curious how they could best work together to improve the health in the patients they are visiting. It was also requested work shops or study days using the pharmacists' expertise to heighten the level of knowledge in specific topics, such as inhaling technique for respiratory patients. This would be followed up by the pharmacists in Edinburgh IMPACT and the lead nurse. Unfortunately, the investigator will not be able to participate in the next meeting due to examination in Tromsø, Norway.

5 Discussion

5.1 Model of care and linked table

The pharmacists thought the overall first impression was a bit confusing, but all of the pharmacists tried to be familiar with the model of care and linked table for COPD. Although the investigator specified that this piece of work was a model of the ideal situation and not a picture of how the real situation was at present, many of the pharmacists commented on how the situation was at the point of interview. Consequently, some of the comments were not taken action on.

The participating pharmacists had not heard about the previous project which this model was adopted from. Would they have commented on the model differently if they had read this study beforehand? The pharmacists may have had a better understanding of how this model has worked from the start if the actual article has been sent in advance. The interviews would have been less time consuming as well. On the other hand if the article has been attached to the invitation e-mail, they would perhaps not take the time to read it or even meet the investigator.

There are both strengths and weakness with all forms of feedback. Having a semi-structured meeting with all pharmacists around one table is probably the best way to do it, but the only way to get response from two of the pharmacists at the time of the project was by e-mail. One of the weaknesses with feedback by e-mail is that ideas from other participants, which could lead to generate other thoughts in other participants, will not be discussed.

The pharmacists have not seen the model of care after the improvements made by the investigator, which may have made the model clearer. The pharmacists struggled with the understanding of the model in the beginning, but their thinking around it may still continue. It would have been of value to let

them see the model again, and get hold of more feedback for further improvements.

For further work, the model of care still could be more simplified. A result of the original work on the pharmaceutical care model was to simplify it.[59] For the linked table there could be an opportunity to put the different checks and changes into the linked table for model of care. This will link the different pharmaceutical care issues to each part of the model of care, and could make it clearer what to look for in each step of the model. This could in turn make it easier to reach this ideal situation the investigator is trying to picture in the Model of care for COPD. Maybe this model could be a tool used for education and research purposes in the future, but the practical value of this model has to be highlighted. The previous model was intended to be used to help identify the education needs of community pharmacists in relation to the management of diabetes in primary and secondary care. Both primary care and secondary care are captured by this model, so there was a need for views from both parts. No community pharmacists were invited to participate in this project, which the investigator thinks is a weakness.

5.2 Database

5.2.1 Categorisation of pharmaceutical care issues

The pharmacists thought the categorisation system developed from University of Strathclyde was hard to understand. Some of the feedback was around the same problems as in prior projects[23] using the same categorisation system, so it is clear that the system has to be simplified. A system like this has to be simple to understand, so all the pharmacists around the world could easily start to use it. All systems need training to be used correctly, and a standard system ought to be included as a part of the education of pharmacists. It is important to check that all users are categorising in the same way. The pharmacists said they had to ask each other several times during the pilot to

make sure that they categorised correctly when using their own categorisation system. This shows that validation is an important part of a system for categorisation of pharmaceutical care issues. By using one standard system, a large amount of data could be collected in a short time, the analysis of which could be useful to demonstrate the value of the pharmacy profession. The research evidence of the impact of the pharmacist's role in primary care and in general is limited, so it is important to do more research within this area to increase the evolution of the pharmacist as a professional.

The reclassification and assigning the categories to the pharmaceutical care issues was found to be achievable, but some of the reclassifications were harder than others. Some of the issues that came up during the meetings will be described briefly below.

Some interventions done by the pharmacists could not be captured in one care issue. This resulted in a dividing of one care issue into several care issues. The guideline for the categorisation is not clear on this point, so in the future this has to be clarified in which situations when it is correct to divide and in which situations it is not.

Some of the care issues could not be categorised into a subcategory. Two examples are given here; adverse drug reaction is identified because of too high dose. An alternative is *The drug product causes an undesirable reaction that is not dose related*, but not one for dose related issues. The solution was to categorise it as *Dose is too high.* The pharmacists edited the subcategory of their own system from *The drug product causes an undesirable reaction that is not dose related* into *The drug product causes an undesirable reaction that is / is not dose related.*

The second example is due to inappropriate compliance. When a person is taking too much of a medication is not an issue in the inappropriate compliance category. A possibility is to add this as a new subcategory. On the other hand, the truth is if all care issues should fit smoothly into the categories, the categorisation system have to be less detailed or more

complex with more categories. Just a few numbers of categories did not fit smoothly when re-categorising, so just a few more categories may be enough.

An issue around the intention of categorising into these check point, change points, and type of change arose during the meeting with the nominal group.

As mentioned in the introduction, this service is a pilot of pharmacist led medication reviews in primary care. The pharmacists conducting the medications reviews in this particular service are only seeing the patients once. In the guideline a 'design' categorisation in 'check points' is either done at the start of a new patient treatment or when the pharmacist first assesses the patient and the medications. The guideline is not clear on this point, and the pharmacist has to decide if the focus should be on the patient's treatment or on when the pharmacist first reviewed the patient's medications. In this anticipatory care service, since it is in a pilot phase, the pharmacist often does not know the outcome for the patient. Often the pharmacist only gives a recommendation to the general practitioner to change something in the drug therapy. This is a dilemma, since it is essential to know the outcome of the pharmaceutical care issue. If not, the care issue is incomplete and can't fit into this categorisation system. The definition of pharmaceutical care is also built on outcomes. There are outcomes, we just don't know them, so it's not correct to say that these pharmacists don't deliver pharmaceutical care. In the future the outcomes may be collected the next visit and typed into the database, which then will fit better into the categorisation system.

Consequently, almost all the care issues are categorised as 'design' in the check point and the change points. If the evaluation of the pilot gives positive outcomes and the service will carry on, the pharmacists may follow up the patients in the future. Categorising into check point could show where the main part of the activity is done. The pharmacists in the nominal group did not see the value of the point, most likely because of the fact that the care issues mainly were identified in one part of the quality cycle

The categorisation of the 'Type of Change' also generated confusion. The definition in the guideline was not clear enough, and it would have made it easier to understand if some practical examples were attached. It was hard to consider which category the care issues should be assigned to, especially for issues around compliance and understanding. The value of categorising into this point was understood, but the grading system may have been easier if numbers with corresponding definitions have been used.

The pharmacists are only seeing the patient once. If the pharmacist is recommending a change in drug therapy, but the GP or the patient is doing nothing about it, it will still be categorised as a check. The same result is even if the change is done, but the pharmacist has not been updated on the action done. Since the GP and the nurse case manager have not updated the pharmacists on all the outcomes, the number of checks will be higher. So using this categorisation system in this particular pilot may give a wrong picture of the reality.

This is important for the pharmacists conducting the medication reviews, because they are feeling that they are just checking, not doing important changes to the patient's drug therapy and drug therapy process. On the other hand, many of the checks that the pharmacists are doing are not documented because the check seems to be too obvious for the pharmacist to document, i.e. checking that each medication is indicated. If things like this don't get documented no one will actually know that the pharmacist is doing this type of work. The pharmacists were not aware of the category for reporting errors in the shared clinical records. Errors in the summaries printed from GPASS were often occurring.

One of the pharmacists suggested a further description of the check in the same way as the change in drug therapy, to describe the checks more in detail if the care issues should be categorised into checks.

There is a need for more research to determine what the general system should look like. Maybe it is possible to use or modify an existing one. This is

an important step which has to be figured out soon, instead of categorising in all sorts of ways. The pharmacists have to play on the same team and use consistent methods.

5.2.2 The database in general

The height, weight, body mass index fields were not used during this project, because the pharmacists haven't recorded this information, but they may be of interest in another setting in the future. A test of the database should have been done before the population of it. This could have revealed errors on a previous stage. Some of the things are mentioned below:

There should have been added labels with *kg* and *metre* after the respective textboxes, since this could lead to confusion when this is not explained and inch, pounds or stones are regularly used units in a country like Scotland.

When recording the patient's smoking status the operator ticks checkboxes to indicate if the patient is a smoker or an ex-smoker. If this field is not recorded by the pharmacist nothing is ticked in the boxes, which means non-smoker. This will give false answers. A solution for this will be to make boxes for "unknown" and "non-smoker"? When you check for either smoker or ex-smoker the other checkbox will be disabled. The investgator's thought during the designing was that you couldn't be both an ex-smoker and a smoker at the same time. After discussion with fellow investigator CTB it was concluded that this is not correct. If a person has smoked for twenty years, quit the smoking for a year, and then start to smoke again – it will give a wrong image of the real situation if he is categorised as he has smoked for only one year. In the secondary drop down list after checking ex-smoker it is not clear whether it is years since smoking cessation or how many years of smoking.

For further work the investigator thinks it will be possible to link disease, medications, and pharmaceutical care issues. This could in turn produce

reports which indicate which kind of medications or diseases/ co-morbidities are generating most problems.

5.2.3 Results from the database

First of all, the case load is very small – only 21 persons were recruited into the pilot. This is a too small a number to make significant and valid conclusions from, so the generalisibility is low. The reason for the low number is that the pharmacists have other jobs beside this pilot, which causes lack of time. There were a lack of referrals from the nurses, nurse case manager, and GP. Referrals may increase as a result of this project and realisation of the pharmacists contributions. It was a small number of patients but high numbers of issues identified.

The pharmacists have done these medication reviews for each patient only once, so most of the care issues are categorised into *design* in the 'check point' and 'change points'.

Recalling the results, there are a lot care issues around *inappropriate compliance*. A lack of compliance could mean a lack of information given from the health care professionals. Although it is a small number of records, assumptions could be made around this. It is an interesting thought if the care issues would have been identified whether the pharmacists have conducted the medication review or not. Anyway, it is very important that these kind of care issues are identified.

A high number of *unnecessary medications* care issues may not come as a surprise when 9.5% of the case load was using 22 drugs. There is overall a big issue with poly pharmacy in the case load. If the case load has been larger, it may have been possible to see a relationship between number of drugs or diseases and number of care issues. COPD which is the most present disease in the case load, are lifting the cardio vascular diseases like myocardial infarction, hypertension, ischemic heart diseases, and chronic

eart disease higher up on the list of diseases, since these are frequent co-morbidities to COPD.

For further work it would have been better if the pilot had been a part of a randomised controlled trial. In this study there was no control group to compare the findings with, but if this service will carry on it would have been an interesting research to do. It could also have been interesting to make questionnaires to assess the quality of life before and after a pilot like this.[60] Changes in GP visits, hospital admissions, or quality of life are end points that may be of interest in a future study.

5.3 Pharmaceutical care plan

The list of possible checks, changes in drug therapy, and changes in drug therapy process were not reviewed by any respiratory pharmacists, which would have been of great value. The pharmaceutical care plan was neither commented on by respiratory pharmacists. It was hard to get any examples of care plans for COPD, maybe because COPD patients often have several co-morbidities, and a care plan for one specific disease would not cover all the patient's needs. Since the service was started when we arrived here and the pharmacists team had their own care plan, the care plan was not field tested, but the care plan will still be a template for further work.

5.4 Implementations of use

The investigator made an excel worksheet view of their identification with their categorisation system. They were not feeling that they were enough familiar with the categorisation system, so they would use their categorisation in the presentation for the Nurse Case Managers Team and the Long Term Conditions Implementation Group. Another reason for using a simpler system in the presentation was to make it more understandable for the viewers.

6 Conclusions

A model of care from a previous project in diabetes was adapted to make a model of care for COPD. This model was simplified according to feedback from experienced pharmacists working in primary and secondary care. The model of care was used to generate a list of potential pharmaceutical care needs for people with LTCs.

The patients recruited into the Edinburgh IMPACT service could easily be profiled into the database that the investigator has developed, and their pharmaceutical care needs could be addressed by automatically updated reports ready for printing and analysing at all times. A case load of 21 records was populated into the database, but the number is too small to make significant and valid conclusion from, so the generalisibility is low. The database was face validated by the nominal group and is fit for purpose.

A pharmaceutical care for COPD plan was designed. The care plan has been commented on only inside the research group and has not been field tested, so it is meant as a template for further work.

Recommendations for implementations of the method for systematic reporting of multidisciplinary pharmaceutical care were made at a meeting with the clinical network Nurse Case Managers Team and the Long Term Conditions Implementation Group.

7 References

1.   Scottish Executive Health Department (SEHD). Building a health service fit for the future. NHS Scotland, Edinburgh; 2005

2.   Scottish Executive Health Department (SEHD). Delivering for Health. NHS Scotland, Edinburgh; 2005

3.   The Scottish Government. Better health, better care: Action plan. Edinburgh; 2007

4.   Long-Term Conditions Action Team. National framework for service change, long term conditions action team report. NHS Scotland, Edinburgh; 2005

5.   Lothian NHS Board. Primary care modernisation strategy & management of long term conditions. Edinburgh; 2007

6.   Audit Scotland. Managing long-term conditions. Edinburgh; 2007

7.   Task Force on Medicines Partnership, The National Collaborative Medicines Management Services Programme. Room for review - A guide to medication review: the agenda for patients, practitioners and managers. London; 2002

8.   ISD Scotland. Scottish patients at risk of readmission and admission. NHS Scotland, Edinburgh; 2008

9.   Kuzma AM, Meli Y, Meldrum C, Jellen P, Butler-Lebair M, Koczen-Doyle D, et al. Multidisciplinary care of the patient with chronic obstructive pulmonary disease. Proc Am Thorac Soc 2008;5(4):567-71.

10.   Royal S, Smeaton L, Avery AJ, Hurwitz B, Sheikh A. Interventions in primary care to reduce medication related adverse events and hospital admissions: systematic review and meta-analysis. Qual Saf Health Care 2006;15:23-31.

11.   Zermansky AG, Petty DR, Raynor DK, Freemantle N, Vail A, Lowe CJ. Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. BMJ 2001;323:1340-3.

12. Koshman SL, Charrois TL, Simpson SH, McAlister FA, Tsuyuki RT. Pharmacist care of patients with heart failure: a systematic review of randomized trials. Arch Intern Med 2008;168:687-94.

13. Krska J, Cromarty JA, Arris F, Jamieson D, Hansford D, Duffus PR, et al. Pharmacist-led medication review in patients over 65: a randomized, controlled trial in primary care. Age Ageing 2001;30:205-11.

14. Holland R, Brooksby I, Lenaghan E, Ashton K, Hay L, Smith R, et al. Effectiveness of visits from community pharmacists for patients with heart failure: HeartMed randomised controlled trial. BMJ 2007;334:1098.

15. Lenaghan E, Holland R, Brooks A. Home-based medication review in a high risk elderly population in primary care--the POLYMED randomised controlled trial. Age Ageing 2007;36:292-7.

16. Holland R, Lenaghan E, Harvey I, Smith R, Shepstone L, Lipp A, et al. Does home based medication review keep older people out of hospital? The HOMER randomised controlled trial. BMJ 2005;330:293.

17. Petty D. Can medicines management services reduce hospital admissions? Pharm J 2008;280:123-6.

18. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990;47:533-43.

19. Hudson S, Mc Anaw J, Johnsen B. The changing roles of pharmacists in society. IeJSME 2007;1:22-34.

20. Scottish executive Health Department (SEHD). The right medicine - A strategy for pharmaceutical care in Scotland. Edinburgh; 2002

21. Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice. The clinician's guide. 2nd edition: McGraw-Hill; 2004.

22. Clinical Resource and Audit Group. Clinical pharmacy practice in primary care. Edinburgh: The Scottish Office - National Health Service in Scotland; 1999.

23. Husabø KJ. Clinical audit of structured pharmaceutical care plans recorded within a hospital pharmaceutical care service. Glasgow: University of Strathclyde; 2008.

24.   National institute for clinical excellence (NICE). Chronic obstructive pulmonary disease. London; 2004

25.   Walker R, Edwards C. Clinical pharmacy and therapeutics. 3rd edition: Churchill Livingstone; 2003.

26.   The global initiative for chronic obstructive lung disease (GOLD). Global strategy for diagnosis, management, and prevention of COPD. 2008

27.   Greene RJ, Harris ND. Pathology and therapeutics for pharmacists - A basis for clinical pharmacy practice 3rd edition: Pharmaceutical press; 2008.

28.   Lokke A, Lange P, Vestbo J, Fabricius PG. Developing COPD-25 years follow-up study of the general population. Ugeskr Laeger 2006;168:4422-4.

29.   Silverman EK, Speizer FE. Risk factors for the development of chronic obstructive pulmonary disease. Med Clin North Am 1996;80:501-22.

30.   British National Formulary. 56 edition: BMJ Group and RPS Publishing; 2008.

31.   Fletcher CM, Elmes PC, Fairbairn AS, Wood CH. The significance of respiratory symptoms and the diagnosis of chronic bronchitis in a working population. Br Med J 1959;2:257-66.

32.   Nichol KL, Baken L, Nelson A. Relation between influenza vaccination and outpatient visits, hospitalization, and mortality in elderly persons with chronic lung disease. Ann Intern Med 1999;130:397-403.

33.   Godtfredsen NS, Vestbo J, Osler M, Prescott E. Risk of hospital admission for COPD following smoking cessation and reduction: a Danish population study. Thorax 2002;57:967-72.

34.   Lacasse Y, Martin S, Lasserson TJ, Goldstein RS. Meta-analysis of respiratory rehabilitation in chronic obstructive pulmonary disease. A Cochrane systematic review. Eura Medicophys 2007;43:475-85.

35.   Dahlén I, Janson C. Anxiety and depression are related to the outcome of emergency treatment in patients with obstructive pulmonary disease. Chest 2002;122:1633-7.

36. Gudmundsson G, Gislason T, Janson C, Lindberg E, Hallin R, Ulrik CS, et al. Risk factors for rehospitalisation in COPD: role of health status, anxiety and depression. Eur Respir J 2005;26:414-9.

37. Stead LF, Perera R, Bullen C, Mant D, Lancaster T. Nicotine replacement therapy for smoking cessation. Cochrane Database Syst Rev 2008:CD000146.

38. Scott J. Asthma and chronic obstructive pulmonary disease. Respiratory preregistration pharmacist teaching; 23rd October 2008; Edinburgh2008.

39. Hewitt N. Lothian chronic obstructive pulmonary disease (COPD) guidelines. Edinburgh 2009.

40. Cochrane MG, Bala MV, Downs KE, Mauskopf J, Ben-Joseph RH. Inhaled corticosteroids for asthma therapy: patient compliance, devices, and inhalation technique. Chest 2000;117:542-50.

41. Scottish Intercollegiate Guidelines Network (SIGN). British guideline on the management of asthma. A national clinical guideline. Edinburgh; 2008

42. Brocklebank D, Ram F, Wright J, Barry P, Cates C, Davies L, et al. Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature. Health Technol Assess 2001;5:1-149.

43. Rea H, McAuley S, Stewart A, Lamont C, Roseman P, Didsbury P. A chronic disease management programme can reduce days in hospital for patients with chronic obstructive pulmonary disease. Intern Med J 2004;34:608-14.

44. Anthonisen NR, Connett JE, Kiley JP, Altose MD, Bailey WC, Buist AS, et al. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV1. The Lung Health Study. JAMA 1994;272:1497-505.

45. Anthonisen NR, Skeans MA, Wise RA, Manfreda J, Kanner RE, Connett JE. The effects of a smoking cessation intervention on 14.5-year mortality: a randomized clinical trial. Ann Intern Med 2005;142:233-9.

46. Scanlon PD, Connett JE, Waller LA, Altose MD, Bailey WC, Buist AS. Smoking cessation and lung function in mild-to-moderate chronic obstructive pulmonary disease. The Lung Health Study. Am J Respir Crit Care Med 2000;161:381-90.

47.   Pride NB. Smoking cessation: effects on symptoms, spirometry and future trends in COPD. Thorax 2001;56 Suppl 2:ii7-10.

48.   Report of the Medical Research Council Working Party. Long term domiciliary oxygen therapy in chronic hypoxic cor pulmonale complicating chronic bronchitis and emphysema. Lancet 1981;1(8222):681-6.

49.   Nocturnal Oxygen Therapy Trial Group. Continuous or nocturnal oxygen therapy in hypoxemic chronic obstructive lung disease: a clinical trial. Ann Intern Med 1980;93(3):391-8.

50.   Garcia-Aymerich J, Farrero E, Felez MA, Izquierdo J, Marrades RM, Anto JM. Risk factors of readmission to hospital for a COPD exacerbation: a prospective study. Thorax 2003;58:100-5.

51.   Garcia-Aymerich J, Monso E, Marrades RM, Escarrabill J, Felez MA, Sunyer J, et al. Risk factors for hospitalization for a chronic obstructive pulmonary disease exacerbation. EFRAM study. Am J Respir Crit Care Med 2001;164:1002-7.

52.   Miravitlles M, Guerrero T, Mayordomo C, Sanchez-Agudo L, Nicolau F, Segu JL. Factors associated with increased risk of exacerbation and hospital admission in a cohort of ambulatory COPD patients: a multiple logistic regression analysis. The EOLO Study Group. Respiration 2000;67:495-501.

53.   Seemungal TA, Donaldson GC, Paul EA, Bestall JC, Jeffries DJ, Wedzicha JA. Effect of exacerbation on quality of life in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1998;157:1418-22.

54.   Osman IM, Godden DJ, Friend JA, Legge JS, Douglas JG. Quality of life and hospital re-admission in patients with chronic obstructive pulmonary disease. Thorax 1997;52:67-71.

55.   Fan VS, Curtis JR, Tu SP, McDonell MB, Fihn SD. Using quality of life to predict hospitalization and mortality in patients with obstructive lung diseases. Chest 2002;122:429-36.

56.   Kessler R, Faller M, Fourgaut G, Mennecier B, Weitzenblum E. Predictive factors of hospitalization for acute exacerbation in a series of 64 patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1999;159:158-64.

57.   Zhang M, Holman CD, Price SD, Sanfilippo FM, Preen DB, Bulsara MK. Comorbidity and repeat admission to hospital for adverse drug reactions in older adults: retrospective cohort study. BMJ 2009;338:a2752.

58.   Anon (News feature). COPD weather warning system cuts hospital admissions. Pharm J 2008;281:531.

59.   Power A, Douglas E, Gregor AMM, Hudson S. Professional development of pharmaceutical care in type 2 diabetes mellitus: a multidisciplinary conceptual model. IJPP 2006;14:289-99.

60.   Ledger-Scott M, Tadros L, Bradley C, Oates C. Chronic obstructive pulmonary disease: Using patients perceptions to improve symptom control and quality of life outcomes. Pharm J, supplement 1 May 2009:S1-S2.

8 Appendices

Appendix 1

Project protocol

The validation of a pharmaceutical care database tool for people with long term conditions using a model of care for Chronic Obstructive Pulmonary Disease

A partial fulfilment of the Norwegian degree Master of Pharmacy

Project Researcher: Stian Skogly, University of Tromsø

Academic Supervisors: Moira Kinnear and Steve Hudson, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde and NHS Lothian, Edinburgh

Co-supervisor: Pauline Westwood, Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde and NHS Lothian, Edinburgh

Academic Co-supervisor: Thrina Loennechen, Institute of Pharmacy, University of Tromsø

Collaborators: Sandra McNaughton, Karen Simpson (Pharmacy NHS Lothian), Alpana Mair, Aileen Kenny, Janet Connelly (Edinburgh Community Health Partnership, NHS Lothian)

Introduction

A long term condition (LTC) is a condition that requires ongoing medical care, limits what one can do, and is likely to last longer than one year.[4] LTCs affect 1 in 5 of the population of Scotland and 1 in 3 households.[5] In the whole United Kingdom people with LTCs account for 80% of all general practitioner consultations, but it is not known whether the consultations were because of the LTC or other co-morbidities.[4] Sixty percent of hospital bed days are for people with LTCs or its complications.[4] People with an LTC are twice as likely to be admitted to hospital and stay in hospital for a longer time.[1] As time goes by the number of older people will increase, and it is to be expected that around a third of the Scottish people will suffer from one or more LTC in the future.[1] Therefore, it is important to support people in their homes which will prevent unnecessary hospital admissions and readmissions. Reducing the number of hospital admissions reduces the cost to the NHS.

To continuously improve the health service given by the NHS Boards, there are local delivery plans which set out an agreement between the Scottish Health Executive Department (SEHD) and each NHS Board. These local delivery plans are based on four key objectives which the health minister has generated. These key objectives are also known as the HEAT-targets (Health, Efficiency, Access and Treatment) and include; health improvement for the people of Scotland, efficiency and governance improvements of the NHS, recognising the patients' needs for quicker access to NHS Services, and ensuring that patients receive appropriate services.

Three of the targets related to admission rates are: to reduce the proportion of older people who are admitted as an emergency inpatient two or more times in a single year by 20% compared with 2004/05 and reduce, by 10% emergency inpatient bed days for people aged 65 and over by 2008; to reduce the number of readmissions; and to achieve agreed reductions in the rates of hospital admissions and bed days of patients with primary diagnosis of COPD, asthma, diabetes or chronic heart disease (CHD), from 2006/07 to 2010/11. There are also targets relevant to specific long term conditions such

as chronic obstructive pulmonary disease (COPD). For example 8% of each NHS Board's smoking population should be supported in successfully quitting over the period 2008/09 – 2010/11.[3]

An anticipatory care model within primary care in Edinburgh was introduced last year to meet needs of people with LTC in keeping with local and national health policy and strategy.[1, 2, 5] This service is named IMPACT (IMProved Anticipatory Care and Treatment). The service targets people with LTCs at most risk of readmission to hospital to ensure the early initiation of care, treatment and support interventions to prevent escalation of health problems. People who will benefit from the IMPACT service are identified using SPARRA (Scottish People at Risk of Readmission or Admission) data or referral from health care professionals. SPARRA is a risk prediction tool that predicts an individual's risk of being admitted to hospital as an emergency within the next year.

The risk for hospital admission is estimated using a formula which includes; age, sex, deprivation, number of prior admissions, time since last admission, total bed days accumulated in three years, principal diagnosis, number of co-morbidities, and number of elective admissions. This formula will work out a percent score of risk.[8] People awaiting discharge from hospital and those with complex health and social care needs can also be referred to IMPACT. Each patient will have a named case manager who will: liaise with other professionals and in partnership develop an anticipatory care plan; co-ordinate augmented care in the community by simplifying and streamlining patient pathways; educate on self care management techniques which include advising on falls prevention; improve clinical care, and carer support. The model is delivered through general practice and co-ordinated by community nurses. Pharmacists have recently been included in the team to conduct medication reviews. A medication review is defined as; "a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste".[7]

Needs for services such as medication reviews, new medication, monitoring or advice on medication are often named pharmaceutical needs. Pharmaceutical needs may be identified by the patient or by any member of the health care team, including the pharmacist. The pharmacist will review the patient's medicines and identify any pharmaceutical care issues during the assessment of the patient. Identifying pharmaceutical care issues is a part of the formulation of a pharmaceutical care plan, which outlines an individual patient's medication-related problems, desired outputs and the actions planned to achieve them.[22] Pharmaceutical care can be delivered by any member of an anticipatory care team. Hepler and Strand defined pharmaceutical care as *"the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life".* These outcomes are cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or preventing a disease or symptomatology".[18] Medication review, as defined above, contributes to the achievement of these outcomes.

In the UK there have been some studies on pharmacy led medication review, but the results vary.[10] A study done in elderly people in a general practice demonstrated the benefits of a pharmacist-led medication review. The review resulted in significant changes in patients' drugs and saved more than the cost of the intervention without affecting the workload of general practitioners.[11]

Another study in people over 80 years concluded that domiciliary medication review carried out by community pharmacists was associated with a significantly higher rate of hospital admissions, did not improve quality of life and did not reduce deaths.[16] In this study, the pharmacists had no access to clinical records and the extent of training and standardisation of the medication review have been criticised.[16] Because of the lack of a specific focus on unplanned hospital admissions as an outcome measure, it could be that the results merely show that emergency hospital admissions records are not sufficiently sensitive to show the benefits of pharmacist medication

reviews.[14] On the other hand, a recent systematic review evaluated the effect of pharmacist care on patient outcomes in heart failure.   Studies were included from all over the world, and the investigators concluded that pharmacist care in the treatment of patients with heart failure greatly reduces the risk of hospital admissions.[12] The belief persists that carefully targeted medication reviews do benefit some patients, despite the lack of supporting evidence in reducing unplanned hospital admissions records.[17]The role of the pharmacist in the medication review in the UK needs more research to evaluate the pharmaceutical care delivered.[11, 16, 17] Therefore, it is important that pharmacists document what they are doing and seek to standardise the pharmaceutical care process.

Research Question

1. How can the pharmaceutical care needs of patients recruited into an anticipatory care service be profiled in a database design?

2. How can a theoretical model of care be used to generate a list of potential pharmaceutical care needs for people with long term conditions?

Aims

- To define the pharmaceutical care needs of patients with COPD recruited to an anticipatory care service from a pharmacy perspective.

- To demonstrate and validate a database design as a method of recording the contribution of the pharmacist to this patient group.

Objectives

1. To generate a model of care for pharmacists using COPD as an example.

2. To characterise the pharmaceutical care needs of patients recruited into the anticipatory care service from a pharmacy perspective.

3. Design a prototype database for the purposes of characterising patients and for addressing their pharmaceutical care needs.

4. Validate a version of the database that is seen to be fit for purpose by pharmacists.

5. Propose a care plan that has been redesigned to match the database

6. To make recommendations for implementation of method for systematic reporting of multidisciplinary pharmaceutical care.

Study design

The study is a semi-structured interview of health care professionals and a retrospective survey of pharmaceutical care needs using pharmacists' records to develop a database which will produce reports for audit purposes

Subjects and Setting

Health care professionals with an interest in COPD working in anticipatory care and secondary care.

People with COPD recruited into an anticipatory care service or admitted to hospital and under the care of specialist respiratory clinical pharmacists.

Inclusion criteria: patients recruited into the anticipatory care service who have had a medication review carried out by the pharmacist, or who are under the care of specialist respiratory clinical pharmacists in hospital.

Local approval sought from Long Term Conditions Implementation group and advice will be sought in terms of need for ethics and R&D management approval.

Methods

1. A model of care will be generated (Appendix 1)[59] using COPD as an example. The information collected in meetings with an experienced nurse case manager, pharmacists, literature reviews in databases such as Medline and Embase, and national guidelines will be used to identify processes of care, methods of targeting care and methods of communication and referral. A research group will have a meeting to redraft the model.

2. Pharmaceutical care needs of patients recruited into the anticipatory care will be identified by using the model of care from objective 1. For each step of the model, processes of care identified from the evidence base for managing COPD will be detailed to generate a list of activities that may be carried out by a health care professional. These will be presented in a linked table. Pharmacists who are interested in COPD will be invited to participate in a nominal group. The nominal group will review and comment on the model of care. The nominal group will give feedback to improve the model.

3. The investigator will design a database in Microsoft Access. Information from prior projects references; information from meetings with pharmacists; the pharmaceutical needs identified from the model of care and the pharmaceutical care plan designed by fellow investigator CTB will be used.

4. The investigator will test the database to demonstrate and produce reports using anonymous patient data from a sample of approximately 25 patients seen by the pharmacists as part of the anticipatory care service. No patient identifiable data will be recorded. The identifiable data of the patient will be coded. The decipher code will be securely held by the pharmacist responsible for the patients which are included to the survey. The investigator has no access to this information.

Feedback pharmacists will be used to improve the database. This testing and its reports will be face validated by the nominal group.

5. The validation of the database will lead to redesign of the pharmaceutical care plan which is used within the anticipatory care service. The fields in the plans will be matched with the database and the model of care.

6. The results and recommendations will be presented to the clinical pharmacists on the managed clinical networks Nurse Case Managers Team and the Long Term Conditions Implementation Group.

References:

1. Long-Term Conditions Action Team. National framework for service change, long term conditions action team report. NHS Scotland, Edinburgh; 2005

2. Lothian NHS Board. Primary care modernisation strategy & management of long term conditions. Edinburgh; 2007

3. Scottish Executive Health Department (SEHD). Building a health service fit for the future. NHS Scotland, Edinburgh; 2005

4. The Scottish Government. Better health, better care: Action plan. Edinburgh; 2007

5. Scottish Executive Health Department (SEHD). Delivering for Health. NHS Scotland, Edinburgh; 2005

6. ISD Scotland. Scottish patients at risk of readmission and admission. NHS Scotland, Edinburgh; 2008

7. Task Force on Medicines Partnership, The National Collaborative Medicines Management Services Programme. Room for review - A guide to medication review: the agenda for patients, practitioners and managers. London; 2002

8. Clinical Resource and Audit Group. Clinical pharmacy practice in primary care. Edinburgh: The Scottish Office - National Health Service in Scotland; 1999.

9. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990;47:533-43.

10. Royal S, Smeaton L, Avery AJ, Hurwitz B, Sheikh A. Interventions in primary care to reduce medication related adverse events and hospital admissions: systematic review and meta-analysis. Qual Saf Health Care 2006;15:23-31.

11. Zermansky AG, Petty DR, Raynor DK, Freemantle N, Vail A, Lowe CJ. Randomised controlled trial of clinical medication review by a pharmacist of elderly patients receiving repeat prescriptions in general practice. BMJ 2001;323:1340-3.

12. Holland R, Lenaghan E, Harvey I, Smith R, Shepstone L, Lipp A, et al. Does home based medication review keep older people out of hospital? The HOMER randomised controlled trial. BMJ 2005;330:293.

13. Koshman SL, Charrois TL, Simpson SH, McAlister FA, Tsuyuki RT. Pharmacist care of patients with heart failure: a systematic review of randomized trials. Arch Intern Med 2008;168:687-94.

14. Petty D. Can medicines management services reduce hospital admissions? Pharm J 2008;280:123-6.

15. Power A, Douglas E, Gregor AMM, Hudson S. Professional development of pharmaceutical care in type 2 diabetes mellitus: a multidisciplinary conceptual model. IJPP 2006;14:289-99.

Patient diagnosed with chronic disease by GP

Specialist referral if necessary for acute treatment intervention in secondary care

Acute treatment delivered by secondary care

Patient assessed /reviewed and clinical status documented

Hospital pharmacist patient profile/care plan communicated to GP/community pharmacist

Pharmacist documents treatment outcomes within management plan

Early clinical review prompted by adverse effect /unsatisfactory response

Short course supportive treatments completed in primary care

Pharmacist investigates and documents adverse treatment effects

Treatment effects reviewed against expectation

Chronic management plan agreed with patient

Specialist referral if necessary for management plan of chronic illness/shared care arrangements

Patient profile and care plan maintained and shared with the clinical team

Treatment effects monitored by the clinical team

Patient educated on treatment options

Pharmaceutical care plan designed to meet patient's needs

Individualised changes made by pharmacist within management plan

Patient monitored by pharmacist within chronic disease management plan

Patient/carer delivers treatment

Patient educated on medicines related care issues

Patient educational needs addressed

Patient enters repeat dispensing scheme

Patient/carer educated on self- management

Pharmacist changes care plan to individualise medicines treatment to meet patient's needs

Prescription verified against best practice /management plan

Routine clinical verifications at each dispensing

104

Appendix 2

Letter from R.E.C – ethical approval

South East Scotland Research Ethics Service

Name: : Pauline Westwood	Date: 17/02/2009
Address : Teaching and Research	Your Ref:
Lothian Pharmacy Practice Unit	Our Ref: NR/0209AB03
Western General Hospital	Enquiries to: Alex Bailey
Edinburgh	Extension:
EH4 2XU	Direct Line: 0131 536 9050
	Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Pauline,

Full title of project: The validation of a pharmaceutical care database tool for people with long term conditions using a model of care for Chronic Obstructive Pulmonary Disease

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer you are advised that, based on the submitted documentation (Protocol_versionSS7), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees in the UK. The advice is based on the following:.

- *The project is an audit using only data obtained as part of usual care but note the requirement for Caldicott Guardian approval to permit sharing or publication of patient-identifiable information.*

- *The project involves NHS staff and is an audit of current or past practice concerning a healthcare issue.*

If this project is being conducted within NHS Lothian you should inform the relevant local Quality Improvement Team(s).

Please note that this advice is issued on behalf of the Research Ethics Service and does not constitute a favourable opinion or an endorsement from a Research Ethics Committee. It may be provided to journal editors, conference organisers or others who require evidence of consideration of the need for ethical review prior to publication or presentation of your results. If you wish you may still decide to apply to a REC, but note that a retrospective ethical opinion cannot be given.

You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Alex Bailey
Scientific Officer
South East Scotland Research Ethics Service

Enclosure: NRES leaflet - "Defining Research"

1

Appendix 3

Original Model of care[59]

Patient diagnosed with chronic disease by GP

Specialist referral if necessary for acute treatment intervention in secondary care[19]

Acute treatment delivered by secondary care[19]

Hospital pharmacist patient profile/care plan shared[19]

1 Patient assessed / reviewed and clinical status documented[17–19]

2 Short-course supportive treatments completed in primary care[19]

Pharmacist documents treatment outcomes within management plan[13,20]

Pharmacist investigates and documents adverse treatment effects[12,13,20,23,27,28]

10 Early clinical review prompted by adverse effect / unsatisfactory response[12,13,19,20,25,26]

9 Treatment effects reviewed against expectation[13,19,25,26]

3 Chronic management plan agreed with patient[13,18,19,20]

Specialist referral if necessary for management plan of chronic illness/shared care[13,19]

Patient educated on treatment options[12,13,17,18,21–25]

Patient profile and care plan maintained and shared with the clinical team[13,19,20]

8 Treatment effects monitored by the clinical team[13,19,20,25,27,28]

4 Pharmaceutical care plan designed to meet patient's needs[13,18,19,20]

Patient profile/care plan communicated to GP/community pharmacist

Individualised changes made by pharmacist within management plan[13,19,20,27]

7 Patient monitored by pharmacist within chronic disease management plan[12,13,17,18,20]

5 Patient / carer delivers treatment[13]

Patient educated on medicines-related care issues[12,13,17–20,22,23]

Patient educational needs addressed[12,13,17,21,22,24]

6 Patient enters repeat dispensing scheme

Patient / carer educated on self-management[12,13,17–19,22,24]

Pharmacist changes care plan to individualise medicines treatment to meet patient's needs[12,13,20,22,26]

Prescription verified against best practice/management plan[13,20,24]

Routine clinical verifications at each dispensing[12,13,20,24,26]

108

Appendix 4

**Transcript of conversation with pharmacist commenting
on the Model of care and linked table**

Transcript of the conversation with one of the primary care pharmacists who are conducting medication reviews in the anticipatory care service

P2:   Normal font
Stian: Bold font

(The meeting starts with general information about the model, the background, which project it is based on, and the aim of making a model of care for COPD.)

I mean, I review all patients that I task having COPD. I review them at least annually. From a GP practice point of view, they get a list of people who they have to review for the "GMS action" point, so they will identify people who need to be reviewed. Ehhm, now the trigger for them will be the QOF point, the actions for the QOF being done, so it may be they're asking somebody to come and see me and I may have seen them. I may have seen them a few months ago, but they may say that I didn't necessarily do all the measurements that they required for the "GMS action", so I mean if someone comes to see me, I usually will do, if we do the spirometry. And usually it is not enough time to do spirometry and plus then draw up a clinical….. A full clinical management plan….Do everything, so usually you end up doing this over a couple of appointments. But, I do agree that they should be reviewed at least annually. I think that if you make any changes that you should....always.... have a review appointment with the patient, I don't disagree with that at all (point to review part in circle A).

Full clinical assessment: Some of these parameters are not so easy to do in primary   care
These are taken from the national guidelines, NICE and GOLD, but do you do all these, or?
BMI, yes, you can do the generally things like pulse oximetry and things like that. They get done in patients. You can do them, ehhm... But not all practices have pulse oximetry, so you need to make sure that if you are going to suggest that... I've got a pulse oximeter now we have to-you know-we didn't have one at the practice when I first started. The practice has one now, we do all the spirometry tests, so that is not an issue.

Ehhm, I mean I don't. Again... (Pause). I suppose, in terms of the assessment here. Are you talking about assessment by the pharmacist here? or are you talking about....? This bit here because you've got...The patient is diagnosed with COPD here, then they go down here (pointing at the model of care) **This is either an emergency/exacerbation or a routinely check, so if there are exacerbations they may be hospitalised (pointing at the model of care).**

So if there are exacerbations, then... Ehhm... at that point people might do pulse oximetry, but I wouldn't say that everybody will. I know they are assessed, but I just telling what happen in the practice. I am not saying it don't think it should not be there. Ehhm, but things like. Are these meant to be things that will be get done in hospital? Is that what you mean by that?

Ehhm... This one? (Pointing at the model of care)
Yes
Yes, I think so. In an ideal situation. Hehe. Maybe not in practice?
I think in the first instance, it depends what you mean by an exacerbation. Is it when someone gets an infection and... And...
Yes, and increased breathlessness...
Yes, is it something that could be managed in primary care or does it need an admission? Because if it doesn't need any admission they're not going to go through this. The rest of this... (Points at the model of care)
The arterial blood gas tension they're not gonna happen in primary care.
Do you think we could divide this box into one acute and one.....?
Primary care and secondary care. Yeah Yeah, maybe!
Primary and secondary...Or...Acute or routinely, maybe?
I think maybe, if you are going to make a tool for people, then that would be a possibility.
Yeah!
Patients with alpha antitrypsin deficiency should be referred to a specialist, but I presume that gonna be happening at the point of diagnosis.
OK
That would be established, if you know, if somebody shows signs of that they've presented, you know, at an early age or whatever that would happen.

Ehhm, "Individualised targets have been agreed with the patient are transferred through pharmaceutical care plan to the GP, the primary care pharmacist and the case manager."
Hmm, well It depends how the clinical management plan is set up, because if you set (pause) your clinical management plan to address your care issue, then all you really have to do is to make sure that you scan that in, and also if you're working with data collection processes that are already in the practice, so say: I have a clinical management plan, on my clinical management plan I would record things like MRC scale, what the patient is on, what they're going to do. Ehhm, but I also use the SPICE-screen to log things like hospital admissions, out of… You know, non- routine consultations, inhaler technique, all of that   gets documented on there. And then you have a note in the encounter, so I think that is important that that happens, so it gets transferred to the GP.
So, the primary care pharmacist. I don't know what… As a primary care pharmacist I will need to. Is that what you meant?
YES
I would not. I wouldn't want to know the…so if somebody else was managing the patient, I can't see that they would let me know what they were doing.
What about the community pharmacist?
Yeah, I think they should let the community pharmacist. They may want to let the community pharmacy know what they are doing generally with patients. If you get to a stage where you then are going to transfer patients over to the community pharmacist to manage then it is important I think to let the pharmacist know what you are doing. The case manager, I am not sure what you mean by a case manager?
Nurse case manager. What is her name again? (Name deleted for anonymous)?

Right, so, yes, yes, we will let them know what you're doing as well.

"Short-course of supportive treatments such as oral corticosteroids and antibiotics, have to be completed in primary care"
That's about the anticipatory care plan I presume you are talking about there? So the plan that they've got in place….and that should fit in with your treatment plan. So there should be some sort of recognition when you are drawing your management plan up for that patient that that's happening.
So you are not using the same management plans for all patients? You have a personalised management plan? You don't have a standard plan?
I got a standard one I use for COPD, so when I am doing the clinics at (delete this for anonymity). I've got standard one I use for patients with COPD. The trouble is when I go out to do the reviews for these patients it's not just COPD that they've got – they've got a lot of co-morbidities, you know, some of them have had heart attacks, they've got high blood pressure, they've got heart failure, they've got osteoporosis, so to use that template – I follow all the same protocols if I am dealing with COPD, but ehhm, we're using a different template on which we can record all the care issues which (name deleted for anonymity) or whoever the case manager will see will use that as the basis to inform the GP as well of any changes, but I do think that even you have a set of protocols at the end of the day, there will be elements that I've taken into that patients depending on that patient's needs. You know, cause… Ehhm… Ehhm, you know… Say for example your normal thing would be if someone was on ipratropium regularly taking it four times a day, it may be more convenient for the patient to take tiotropium, you know you just to take that once a day, you know, but actually it may be that the patient doesn't want to switch - that they want to stay. We had one patient like that actually. She didn't like the once day capsule, she preferred the other one. So that's… Out with so you are following the standard plan etc, but you're making it specific to that patient.
Yes, OK
I think the reviews are not disease specific. So it's not just y'know... The people that we are seeing have got lots of other co-morbidities that you also have to try and make sure… Or address
Do you have a pharmaceutical care plan?
Form
Ok, a pharmaceutical care form. Do you share this with the GPs?
Yes
Just the GPs. Any other?
Well, the GP and the nurse case managers. They get sight of it, and if it has been issue I have spoken with the pharmacist. The communication has been generally verbally with the community pharmacist.
Ok, can we take a look at this circle?
Aha
Do you think the boxes are appropriate (pointing at circle A)?
"Patient assessed routinely or during exacerbation", OK. Ehhm, what I am not clear about seeing this, is if you are trying to apply this generally for the management of patients with COPD, or are you thinking about specific to this project?

This was meant to be a generic cycle.
Right, OK. Not the project
This linked table is disease specific. If we need to make the circle specific, we can do that.
No, no, no… That's fine! I meant project specific
So, you're talking about this as a tool to apply for COPD patients generally, yeah?
Yes, this table is for COPD, just COPD, but this model is generic.
I think that's self explanatory…I think that's fine (point at circle A)
Mhm, good. So maybe we can divide this into one primary and secondary care in the table.
Yes,
Yepp

OK, "clinical management plan agreed with the patient" and "pharmaceutical care plan designed to meet patient's needs"
I think B is fine as well, ehhm
What about the table?
(Long pause)
"Pulmonary rehab offered to all patients who consider themselves functionally disabled by COPD" I think that's a really good point, but I know that even while I started to work with people with COPD locally that that has changed from when I first started working to now, because before when I first started working it wasn't available to everybody. Now it is and I am not sure if…You know, if this is a tool you want to apply sort of across Scotland, maybe you need to sort of… Ehhm, pulmonary rehab, ehhm, directing people to look at local guidelines and procedures, y'know…it may be that people have got cut offs. A lot of places are going on the breathless score. They are assessing people who feel they are functionally disabled from their COPD. So their FEV_1 might be fine, but actually they are not coping, so they are assessing themselves as not being able to manage it, so those patients can then access pulmonary rehab, and if you got the facilities, but not everywhere has the same level of access. I think it should definitely be there. But it's just really, y'know...

Smoking cessation.
Is smoking cessation included in the pulmonary rehab or is it two different things?
I think it is two different things. I don't know if it is within access through… I mean, here you got it available through community pharmacies as well, so it is something the community pharmacist could do with them, but it is not necessary the…ehhm
You don't need to go to this classes…?
Yes
You can just go to a community pharmacy…..
Yes, and get that as well, so there's lot of different ways.

In terms of the treatment, I think it is fine. You know, the only thing is… Will be ehhm… (Pause)

You may could give a bit more information around corticosteroids in terms of what the guidelines says, about which, you know, what the thresholds are. The treatment with, ehhm, corticosteroids and also mucolytics. Ehhm, some areas think that they are OK, some others don't. At the moment it is not on the joint formulary here in Lothian, but it is on the MCN guidelines, but they are looking to put a proposal to ehhm... The formulary committee about getting it included…

What about aminophylline/theophylline?
Theophylline, ehhm, I don't see it much, but I think it worth putting it in, you know, people do use it. It is on the list, but it is not in use very – I can't say I have seen it with anybody.

Maybe it is more usual in hospitals?
Ehhm, I suppose they may see it more, because they may use it for patients who are more difficult to ehhm... But… it's something that I used to see prescribed more often, but you don't see it as much any more so. Ehhm… Oxygen, you know, in primary care you're not really, you don't initiate oxygen that tends to get initiated by a specialist consultant in secondary care, so you, ehhm, might talk to the patient about how they are managing with their oxygen and that, but that, ehhm, it certainly something that you need a referral to a specialist to get that done.

So you don't meet people who are using oxygen?
Yeah, I do, you see you will talk to them, but I would never start them on the oxygen, so you will talk to them about how they're using it and you know making sure that they're not smoking, and.. Ehhm… But... Ehhm… But it wouldn't be initiated in primary care.

OK, I see…
Ehhm and, I think "pharmaceutical care plan designed to meet patient's needs", I think that's good. All the issues you're trying to target and deal with, I think that's fine. The fact that you share the so that when they meet other practitioners the message is reinforced.

What did you say?
So, if you… I think that's fine. I think that's good to share that, so that particularly with patients that are…If they're accessing a multidisciplinary team, if everybody knows what everybody is doing, you can reinforce messages rather than give the patient conflicting messages…I think this is fine as well

OK

And then C. Ehhm. (Long pause). I think in terms of… Ehhm… Education plan ehhm… It is a bit of overlap there in terms of the… you know, you are agreeing the plan with the patient, I mean to me there's an overlap here between here between B and C. Ehhm

So, ehhm… I suppose it is checking patient's understanding of the plan so after a period of time making sure that they understand it, you know one of the issues that came up with some of the patients been giving an emergency courses of antibiotics particularly if they are elderly and confused they would take them straight away. So they didn't understand , you know, some of the patients I went to visit with Janet, they were rather than waiting for an exacerbation because the prescription then arrived for steroids and antibiotics, they just took it, because that's what they thought they had to do. They didn't get this concept. So, I guess if you setting plans like that in place, you need to

regularly review patient's understanding. Ehhm, of the plan the plan you set up, so they know what they are doing. Ehhm, pulmonary rehabs, you know, I don't know if they... You've mentioned pulmonary rehab before, but I think it's quite important as well.

Do you think we should put it into circle C as well?

Well, I don't necessarily…. I just think there is a big overlap between what you are trying to do in B and C, and ehhm, I don't know whether… Ehhm… I guess B to me is maybe you try to establish your care plan and then C is about putting it into action. You've got "pulmonary rehab is offered to all patients who consider themselves functionally disabled by COPD", so I mean, if you put something in about, ehhm, reassessing patient's need to have pulmonary rehab, ehhm, due to changes in circumstances or deterioration in severity of disease, cause you would do that. Patients might be alright when you first see them, but maybe later down the line things have worsened for them and actually they could then become candidates for pulmonary rehab. Ehhm, ok... Is that enough?

I think we will come back to this monitoring point in circle E. Debbie Magee commented that she will have this monitoring earlier in the circle or several times.

(Long Pause)

I mean if I ever make a change to a patients treatment or add a treatment, I think it is appropriate to review that patient soon. You know, I would… To make sure that they have understood

Yeah

I wouldn't leave them to the next review, so I tend to see them within a month or so, just to make sure they've got a new inhaler device or you change a treatment that that's OK.

So, "Patient enters repeat…"Hey, actually go back to C. "Patient/carers given a clinical management plan should be advised to contact these case manager if they do not improve", ehhm, well, in first instance if you were the prescriber and making a change, surely, you should be following that up. Once you feel that the patient is managing you should then pass that back to the case manager who will then following them up routinely. It is like an overlap here, because, I guess,

Do you think we can smash them together B and C? The circles..

Ehhm

To simplify it?

I do think you got an overlap, cause you got patients educated on treatment options and management, but you could probably put y'know patient and carer educated. You could put some of the two things together.

M'hm…

Because, ehhm… Having an individual… You've got antibiotics in the medication in the individual treatment plan as well, haven't you?

Yes, I think so

Yes, so I think you've got a lot of overlap. I mean, see for example you've got "Ensure that patients and carers know how to respond to symptoms of a COPD exacerbation". Under medications you can put that information, or you can put…

I think this is more around the plan. The self management plan.

Right

But, yeah, maybe we can put it into the medications. The clinical management plan.

To me C is more about... B is more about making sure all the procedures are in place, making sure everything is in place, for the patient to basically go. And C, to me, if I look at this, this chart as opposed to your table, If I look at the chart it would be about reinforcing that message to making, so C to me, is to reinforcing the advice that you've already have given in B, cause it is about support a patient's self management plan provided by the team, you're not setting that up at the point. You almost reinforcing that what you set up in B is happening.

Yeah, OK

That's how I read it. And I could…And if we get on to D (Pause)

This is…. Are you making an assumption when the patient goes to chronic medication services? "Patient enters repeat dispensing scheme". What do you mean by that?

Ehhm, I think this is in the community pharmacy. So when the patient is coming with his…

Slips

Yeah, slips.. Isn't it called the repeat dispensing scheme? Or maybe not?

Ehhm

When you're stable…

Yeah, yes, I mean. At the moment, once, a patient could go to a pharmacy with a repeat prescription for an inhaler. Is that what you mean?

Yes.

So you just go and pick it out. OK

Ehhh…

Is it any other alternatives?

No, all I was only wondering, because you know how the new community pharmacy contract gonna to come in, and with that the chronic medication service, and with that what will happen is that from the GP practice maybe, you know, eventually what will happen the twelve months prescription will go to the community pharmacy they will do the interim assessment go through the … that's what you were referring to…

Yeah, **but maybe we should put that into this table?**

Cause that's sort of relevant.

(Telephone call and change tape)

OK. You see this bit about, in D, "prescription checked for adherence to current NICE, GOLD and BNF". Ehhm, I think that when you are doing your clinical management plan that, ehhm, maybe you ought to put something in there that… Ehhm… Because of this bit .. I was saying to you when you were saying with the corticosteroids you might want to put into before the medication. Ehhm, you know, the treatment is in line with GOLD, NICE or SIGN guidelines or locally approved guidelines, so that …. This bit here (pointing at the medications), you have to get that bit right here right in the beginning rather than waiting until the patient… I think that's important that the pharmacist thinks about that here, but I also think that whoever is deciding to prescribe it needs to make sure…that whatever they're prescribing… Ehhm… Doing the "opportunistic checks about smoking cessation", asking

about things like that. I think that is all really good. "Ensure that the patients understand how to take the medications" I think that is really good. And then I supposed to…then how. You know, One of the things you need to think about is, how are you then going to feed back to the GP practice and that, if they have dialog with the patient. **Is there some communication the other way? Or both ways? How is the information flow between the community pharmacy and the GP practice?**

At the moment there is no electronic links, so it would be a case of a…ehhm you know… They could… Ehhm… I think it eventually when chronic medication service comes, there will be something formalised, so if the pharmacist is working with a patient, they'll send something back. I don't know, because nobody has seen what this chronic medication service is like, but if you look at the current, you know the assessments that…. Have you seen the form that NES produces for patients with asthma, patients for COPD, you seen all of them?

Ehhm, I don't think so

You seen them? (Show these NES forms) The review forms that are.

I haven't seen them

These are like pharmaceutical care plans for, you know, you might review, for people with diabetes and if you then going to do any interventions you might use that as a list and send information back

Is it something similar for COPD?

I think there is something similar for COPD, actually

What do you call this?

It's a NES – National Education Scotland. That's where Ailsa Power….

OK, I see… Do you think something like this could be used to increase the information flow between the….

Well, I'm assuming that when the chronic medication service gets set up, there will be an electronic link you may be able to send, information back. If it's not electronic I'm assuming there will be a system in place. I guess in terms of here, if you are talking about something, cause here ehhh… everywhere else you put pharmaceutical care issues are shared among the primary care team, so once it goes to the pharmacy, you need to make sure that any changes in treatment and recommendations are shared within the primary care team as well. You need to just put that in there as well.

This new contract. Is there something in the future that each patient has his own pharmacist? So each time the patient is coming to the pharmacy, he will see the same pharmacist.

Not necessarily the same pharmacist. You will see the same… You will be going to the same pharmacy.

OK

Just like the GP practice. You go to the same GP practice; you don't necessarily see the same GP.

OK

It's a patient's choice to decide where they register, just like with E-MAS right now. If you now with the minor ailment scheme, where they choose to register with a pharmacist that would be the same thing.

E-MAS?

E-MAS, yes, Minor Ailment Scheme it stands for. It is the same sort of thing

that they register with a pharmacy where they get their regular prescriptions from.

OK

E…. "Treatment monitored for drug therapy problems". I don't see there a problem there. Again, I feel that some of these things I think you're going to make sure you've reviewed them earlier on in B, before…You know, things like you're not going to give them a clinical management plan if you think they are receiving a too high dose of or too low dose in a drug interaction, you gonna have dealt with all of that stuff here (pointing at circle B).

OK

Ehhm… I think you would do ongoing monitoring…

All the time or?

Ehhm, well, you know after a period of time, so, like I said, if you make a change of the treatment, you're going to review the treatment. At that point you might pick up things like if they got an adverse drug reaction, you might pick things like that up. Ehhm, again if you review them you might review and find that they didn't need a medication the last time you saw them, but actually this time their symptoms are such that actually it would be worth adding in another agent. See for example. Ehhm... So… Some of these… Ehhm… If you were on the wrong medication to meet the needs, you gonna pick that up at the initial - in this bit here (pointing at circle B) in the initial assessment. Because, part of the thing will be other experiences and symptoms, because they are not getting treated adequately. If that's the case, then your clinical management plan should reflect the treatment they should be getting.

M'm..

And then, F…

So do you think circle E is unnecessary, or?

Ehhm, I would say a review. I would say that that should be a review of the treatment, ehhm, some of the parameters that you have put into here (care issue categories) should already have been identified in A and B.

Ohyeah! So maybe we could….

E could be review of treatment plan discussed in B for example. Yeahh.

Yeah, maybe ☺

Yeah☺

Because I think E should be a review of what you have done with the patient, so if you put something into place that if you review that, It's at the review you might find that you need a new medicine, or they are not getting on with what you you've given them, or that they are not complying.

But when are you identifying the care issues or the drug therapy problems?

When you have that initial consultation with them. Because, you know, they tell you what inhalers they're on and not on. They tell you what the symptoms are. So you know, you've got the spirometry results, so from that you can work out where the gaps are.

M'hm…

You can also check... You'll be able to check inhaler technique with them, you will check compliance with them. So you got a huge picture of what is going on. Ehhm... Are you OK? Is it enough?

Yes! Just wondered if these points (care issue classification) should be added in earlier into the circle? Maybe A or B?

Yes, that's what I'm saying. I think you almost need to transfer this (care issue categorisation) out to here (medications circle B). That should have happen here.

So I can transfer the E circle into B?

Yes, I think here (E circle) you need to put a review of treatment planned to ensure ongoing monitoring for drug problems, so that bit is relevant. But a lot of these things here, to me are what you would do right at the beginning. Ehhm,   F. "Treatment outcomes evaluated as success or failure". I think that's important if you start a treatment you give it long enough if it's not working for the patient you review it and assess it, if it is then obviously it can get added to the patient's medication. Ehhm. Documentation of outcomes within the clinical management plan. I think that is important as well.

M'hm… Is it something you will add to this, or skip?

Again, I always think that would be amalgamated between E and F in terms of review of treatment, because, ehhm, when you're reviewing it, it's inherent that you will evaluate whether the treatment is being successful or not. You're not going to do it as two separate things.

I think F, you would do that… Ehhm, when you add something into a patient's treatment, you are going to assess whether it is effective or not, whether it is doing the job that you want, and then you'll add it to a repeat prescription. And I think this is a review appointment, so when you are doing E, when you are doing a review of the patient in terms of the treatment, how they're getting on, and if they still understand how to take the inhaler, all of that. You will also at that point be talking to them about if them got any problems with the medications, pick up adverse drug effects, if inhalers are working for them, if they feel so much better on them, if they don't, if they are having problems, if they're not getting any benefit out of them,

I think you sort of pick that up there. Because that's going to influence how you plan out your clinical management plan whether something's worked or not.

Y'know the two things are joined, not necessarily completely separate.

Do you think we can make one circle of E and F?

Yeh yeh

Ok, it is great to have another view of things, and to see things from different point of views.

Yes. Is that enough information?

Yes, thank you!

Appendix 5

**First draft of the model of care for COPD
and a linked table**

A process map of the treatment cycle for disease management in primary care

Patient diagnosed by the GP

Patient assessed/reviewed and clinical status documented

Patient assessed routinely or during exacerbation. Hospital admission if necessary

Short-course supportive treatments completed in primary care

Treatment to re-establish control of disease delivered by multidisciplinary clinical team

Pharmaceutical care plan shared to maintain continuity of care

A

Clinical management plan agreed with patient

Specialist referral to outpatient clinic or for rehabilitation if necessary

Pharmaceutical care plan designed to meet patient's needs

Patient educated on treatment options and management plan individualised accordingly

Pharmaceutical care issues identified and shared among primary care team

B

Patient/ carer delivers treatment

Support of patient self management provided by primary care team

Patient/carer educated on personalised treatment

Medication personalised to meet patient's needs

C

Patient enters repeat dispensing scheme

Patient educational needs addressed

Prescription verified against best practice/ clinical management plan

Routine clinical verification at each dispensing

D

Treatment monitored for drug therapy problems

Patient records are maintained and shared within the clinical team

Treatment individualised within clinical management plan

Individualised changes recommended or implemented by the pharmacist

E

Clinical referral prompted by unwanted effects / unsatisfactory response

Pharmacist investigates and documents any suspected adverse effects of treatment

Treatment outcomes evaluated as success or failure

Pharmacist documents treatment outcomes within clinical management plan

F

121

	Definition		Activity

A
 	
P A T I E N T   C L I N I C A L   A S S E S S M E N T
		Patient assessed routinely or during exacerbation. Hospital admission if necessary	• Assessment of severity of airflow obstruction according to FEV_1 as a percentage of a predicted value.[1]
			• Mild/moderate patients; reviewed at least annual. Severe patients; at least twice per year.[1]
			• Full clinical assessment:[1]
			  - Clinical laboratory tests: T_LCO, BMI, SaO2, PaO2.
			  - Spirometric tests: PEF, FEV_1, FEV_1/FVC.
			• In an emergency situation: Steroids, heparin, oxygen, nebulisers, and antibiotics should be given.[3]
			• Patients with an exacerbation referred to hospital:[1]
			  - Chest radiograph
			  - Arterial blood gas tensions
			  - Inspired oxygen concentration
			  - ECG (to exclude co morbidities)
			  - Full blood count
			  - Urea and electrolyte concentrations
			  - Theophylline level should be measured in patients on theophylline therapy at admission
			  - If sputum is purulent, a sample should be sent for microscopy
			  - Blood cultures should be taken if the patient is pyrexial
			• Patients with α_1-antitrypsin deficiency should be referred to a specialist.[1]
			• Individualised targets that have been agreed with the patient are transferred via a pharmaceutical care plan (a list of pharmaceutical care issues arising from the clinical management plan) to the GP, the primary care pharmacist, and the case manager.

	Patient assessed / reviewed and clinical status documented		
	Short-course supportive treatments completed in primary care	Treatment to re-establish control of disease delivered by multidisciplinary clinical team Pharmaceutical care plan shared to maintain continuity of care	• Short-courses of supportive treatments, such as oral corticosteroids and antibiotics, have to be completed in primary care. [1, 4] • Details of course length are transferred via a pharmaceutical care plan to the GP, the primary care pharmacist, and the case manager.

B
 	
T R E A T M E N T   P L A N N I N G
	Clinical management plan agreed with patient	Specialist referral to outpatient clinic or for rehabilitation if necessary	• Patient attends hospital respiratory department or GP clinic for initiation of multidisciplinary team care and medications for COPD.
			• Pulmonary rehabilitation offered to all patients who consider themselves functionally disabled by COPD.[1, 5]
			• Smoking cessation.[1, 4, 5]
			• Medications:[1, 4]
			  - **Bronchodilators** (first line: short-acting beta$_2$ agonist or antimuscarinic drug. More severe: Given regularly. Remain symptomatic or two or more exacerbations in a year: Use long-acting agents)
			  - **Corticosteroids** (Moderate to severe: Inhaled steroid + long-acting agent. Short-course of oral if increased breathlessness interferes with daily activities)
			  - **Theophylline**
			  - **Antibiotics** (If sputum becomes purulent or other signs of infections)
			  - **Mucolytic** (May be considered for patients with a chronic productive cough)
			  - **Oxygen** (Hypoxemic patients)
			• Prevention of complications
			  - Cor pulmonale (antihypertensive)
			  - Pneumonia, influenza (Vaccinations, antibiotics)

	Pharmaceutical care plan designed to meet patient's needs	Patient educated on treatment options and management plan individualised accordingly	• Education on using the medication correctly
			  - Different devises, spacers, nebulisers
			  - Compliance
			• Dietary and exercise advice
			• Individualised treatment targets made (smoking cessation, etc)

		Pharmaceutical care issues identified and shared among primary care team	• Regimen, pharmaceutical care issues, and agreed individualised targets documented in a pharmaceutical care plan which are given to the patient, the GP, the primary care pharmacist, and the case manager.

C TREATMENT ADMINISTRATION	Patient/ carer delivers treatment	**Support of patient self management provided by primary care team**	• Education on self-monitoring - PEF measurement and exercising tolerance
		Medication personalised to meet patient's needs	• Discussion of individualised agreed targets • Adjustments to pharmaceutical care plan

		Patient / carer educated on personalised treatment	• Patients and carers should be educated in how to limit lung damage (Smoking cessation and exercising)
			• Ensure that patients and carers know how to respond to symptoms of a COPD exacerbation:[1, 5]
			  - Oral steroid therapy start up if increased breathlessness.
			  - Antibiotic therapy start up if their sputum is purulent
			  - Bronchodilator therapy adjustment to control their symptoms.
			• Carers or patients at risk of having an exacerbation of COPD should be given a course of antibiotic and corticosteroid tablets to keep at home for use as a part of an anticipatory care strategy.
			• Patients / carers given a clinical management plan should be advised to contact the case manager if they do not improve.[1]

D PATIENT TREATMENT MONITORING	**Patient enters repeat dispensing scheme**	Routine clinical verification at each dispensing	• Pharmacist conducts opportunistic checks of patient-held records and pharmacy patient medication records at each dispensing.[2]
		Prescription verified against best practice/ clinical management plan	• Pharmacist conducts opportunistic check of individualised agreed targets set with the patient. (Smoking cessation, fewer infections, fewer exacerbations and hospitalisations, etc.) • Prescription checked for adherence to current NICE, GOLD and BNF and patient's clinical management plan.
		Patient educational needs addressed	• The pharmacist ensures that patients understand how to take the medications correctly and checks that the inhaler technique is correct.

E
 	
PATIENT CLINICAL MONITORING
	Treatment individualised within clinical management plan	Individualised changes recommended or implemented by the pharmacist	• Treatment changed because of drug therapy problems. These care issues may be categorised as:[6]
			  - Need new medicine
			  - Receiving medication that they do not need
			  - On the wrong medicine to meet their needs
			  - Showing symptoms of an adverse drug reaction
			  - Receiving a dose too high
			  - Receiving a dose too low
			  - Receiving medicines with a drug interaction
			  - Not receiving the medicine as intended (error in medicines administration due to compliance problem or administration error)

	Treatment monitored for drug therapy problems	Patient records are maintained and shared within the clinical team	• Patient's self-management records and self-reporting of symptoms routinely monitored. This is documented in the pharmaceutical care plan and shared with the multidisciplinary team.
F TREATMENT EVALUATION	**Treatment outcomes evaluated as success or failure**	Pharmacist documents treatment outcomes within clinical management plan	• Clinical laboratory tests and spirometric test to optimise the drug therapy.
	Clinical referral prompted by unwanted effects / unsatisfactory response	Pharmacist investigates and documents any suspected adverse effects of treatment	• Documentation of outcomes within the clinical management plan. Failure to reach targets addressed by referral for clinical review.

Appendix 6

Final version of model of care for COPD and linked table

Patient diagnosed by the GP

TREATMENT EVALUATION

- Treatment outcomes evaluated as success or failure
- Documented in clinical management plan, pharmaceutical care plan, and shared

PATIENT CLINICAL ASSESSMENT

- Routinely or during exacerbation
- Hospital admission if necessary
- Short course supportive treatments completed in primary care
- Treatment and clinical status documented. Sharing of pharmaceutical care plan

PATIENT CLINICAL MONITORING

- Individualised changes recommended or implemented by the pharmacist
- Treatment monitored for drug therapy problems.
- Documented in pharmaceutical care plan and shared

TREATMENT PLANNING

- Specialist referral to outpatient clinic or for rehabilitation if necessary
- Patient educated on treatment options and personalised treatment management. Clinical management plan individualised and agreed by the patient.
- Pharmaceutical care issues identified
- Documented in pharmaceutical care plan designed to meet patient's needs. This one is shared.

PATIENT TREATMENT MONITORING

- Patient enters repeat dispensing scheme. Routine clinical verification at each dispensing
- Prescription verified against best practice/ clinical management plan
- Patient educational needs addressed

TREATMENT ADMINISTRATION

- Review the patient
- Monitor for drug therapy problems
- Reassess patient's needs
- Document in pharmaceutical care plan and share

125

	Definition	Activity	
		Primary care	**Secondary care**

A *PATIENT CLINICAL ASSESSMENT*	Patient assessed routinely or during exacerbation
	
	Hospital admission if necessary
		Mild/moderate patients; reviewed at least annual. Severe patients; at least twice a year.[1]
		Full clinical assessment:[1]
		  - Clinical laboratory tests:
		    BMI, SaO2, PaO2.
		  - Spirometric tests:
		    PEF, FEV_1, FEV_1/FVC
		If any changes are done in drug therapy, a review appointment should be made
			- Oral steroid, oxygen, nebuliser, antibiotics
			- Chest X-ray[1]
			- Arterial blood gas tensions[1]
			- Inspired oxygen concentration[1]
			- ECG (to exclude co-morbidities)[1]
			- Full blood count and U&E[1]
			- If on Theophylline at admission, level measured[1]
			- If sputum is purulent, a sample should be sent for microscopy[1]
			- Blood cultures if the patient is pyrexial[1]

	Short-course supportive treatments completed in primary care	Short-courses of supportive treatments, such as oral corticosteroids and antibiotics, have to be completed in primary care. [1, 4] Details of course length are transferred via a pharmaceutical care plan to the GP, the community pharmacy, and the nurse case manager.	
	Treatment and clinical status documented. Sharing of pharmaceutical care plan	Individualised targets that have been agreed with the patient are transferred via a pharmaceutical care plan (a list of pharmaceutical care issues arising from the clinical management plan) to the GP, the primary care pharmacist, and the nurse case manager.	

B *TREATMENT PLANNING*	Specialist referral to outpatient clinic or for rehabilitation if necessary	Patient attends hospital respiratory department or GP clinic for initiation of multidisciplinary team care and medications for COPD.
		Pulmonary rehabilitation offered to all patients who consider themselves functionally disabled by COPD.[1, 5] This also includes dietary and exercise advice.
		Smoking cessation[1, 4, 5]
		Medications:[1, 4] (Stop therapy if ineffective)
		  - **Bronchodilators** (first line: short-acting beta$_2$ agonist or antimuscarinic drug. More severe: Given regularly. Remain symptomatic or two or more exacerbations in a year: Use long-acting agents)
		  - **Corticosteroids** (Inhaled corticosteroids should be prescribed for patients with an FEV_1 less than or equal to 50% predicted, who are having two or more exacerbations requiring treatment with antibiotics or oral corticosteroids in a 12-month period. Short-course of oral if increased breathlessness interferes with daily activities)[1]
		  - **Theophylline** (if still symptomatic after using bronchodilators and corticosteroids)[1]
		  - **Antibiotics** (If sputum becomes purulent or other signs of infections)
		  - **Oxygen** (Hypoxemic patients)
		  - **Mucolytic** (May be considered for patients with a chronic productive cough). COPD is not an indication for mucolytics on the joint formulary in Lothian.
		Carers or patients at risk of having an exacerbation of COPD should be given a course of antibiotic and corticosteroid tablets to keep at home for use as a part of an anticipatory care strategy[1]
		Ensure that patients and carers know how to respond to symptoms of a COPD exacerbation:[1, 5]
		  - Oral steroid therapy start up if increased breathlessness.
		  - Antibiotic therapy start up if their sputum is purulent
		  - Bronchodilator therapy adjustment to control their symptoms.
		Prevention of complications
		  - Cor pulmonale (antihypertensive)
		  - Pneumonia, influenza (Vaccinations, antibiotics)
		  - Osteoporosis (Patients treated with long-term oral corticosteroid therapy should be monitored for the development of osteoporosis and given appropriate prophylaxis. Patients over the age of 65 should be started on prophylactic treatment, without monitoring)[1]	

	Patient/carer educated on treatment options and personalised treatment management.
	Clinical management plan individualised and agreed by the patient/carer.
		Education on using the medication correctly
		  - Different devises, spacers, nebulisers
		  - Compliance
		Educated in how to limit lung damage
		Individualised treatment targets made (smoking cessation, etc)	

	Pharmaceutical care issues identified
	
	Documented in pharmaceutical care plan designed to meet patient's needs. This is shared.
		These care issues may be categorised as:[6]
		  - Need new medicine
		  - Receiving medication that they do not need
		  - On the wrong medicine to meet their needs
		  - Showing symptoms of an adverse drug reaction
		  - Receiving a dose too high
		  - Receiving a dose too low
		  - Receiving medicines with a drug interaction
		  - Not receiving the medicine as intended
		Regimen, pharmaceutical care issues, and agreed individualised targets documented in a pharmaceutical care plan which are given to the patient, the GP, the primary care pharmacist, and the case manager.	

|		
C TREATMENT ADMINISTRATION	**Review of the patient**	- Changes in the severity of disease - Patient's understanding of the self management plan that are set up
	Monitor for drug therapy problems	- Patient's self-management records and self-reporting of symptoms routinely monitored. This is documented in the pharmaceutical care plan and shared with the multidisciplinary team. - The pharmacist ensures that patients understand how to take the medications correctly and checks that the inhaler technique is correct.
	Reassess patient's needs	- Patients / carers given a clinical management plan should be advised to contact the case manager if they do not improve.[1] - Discussion of individualised agreed targets - Adjustments to pharmaceutical care plan
	Document in pharmaceutical care plan and share	- Document results and changes in pharmaceutical care plan and share with the primary care team
D PATIENT TREATMENT MONITORING	Patient enters repeat dispensing scheme. Routine clinical verification at each dispensing.	- Pharmacist conducts opportunistic checks of patient-held records and pharmacy patient medication records at each dispensing.[2]
	Prescription verified against best practice/ clinical management plan	- Pharmacist conducts opportunistic check of individualised agreed targets set with the patient. (Smoking cessation, fewer infections, fewer exacerbations and hospitalisations, etc.)
	Patient educational needs addressed	- The pharmacist ensures that patients understand how to take the medications correctly and checks that the inhaler technique is correct.
	Documented in pharmaceutical care plan and shared	- Changes in treatment and recommendations are shared within the primary care team

E
 	
PATIENT CLINICAL MONITORING
	Individualised changes recommended or implemented by the pharmacist	- Treatment changed because of drug therapy problems. These care issues may be categorised as:[6]
		- These care issues may be categorised as:[6]
		  - Need new medicine
		  - Receiving medication that they do not need
		  - On the wrong medicine to meet their needs
		  - Showing symptoms of an adverse drug reaction
		  - Receiving a dose too high
		  - Receiving a dose too low
		  - Receiving medicines with a drug interaction
		  - Not receiving the medicine as intended

	Treatment monitored for drug therapy problems.	- Patient's self-management records and self-reporting of symptoms routinely monitored. This is documented in the pharmaceutical care plan and shared with the multidisciplinary team
	Documented in pharmaceutical care plan and shared	- Patient records are maintained and shared within the clinical team
F TREATMENT EVALUATION	Treatment outcomes evaluated as success or failure	- Clinical laboratory tests and spirometric test to optimise the drug therapy - Pharmacist investigates and documents any suspected adverse effects of treatment - Clinical referral prompted by unwanted effects / unsatisfactory response
	Documented in clinical management plan, pharmaceutical care plan, and shared	- Pharmacist documents treatment outcomes within clinical management plan, pharmaceutical care plan, and share with rest of primary care team.

1. National institute for clinical excellence (NICE). Chronic obstructive pulmonary disease. London; 2004

2. British National Formulary. 56 edition: BMJ Group and RPS Publishing; 2008.

3. The global initiative for chronic obstructive lung disease (GOLD). Global strategy for diagnosis, management, and prevention of COPD. 2008

4. Cipolle RJ, Strand LM, Morley PC. Pharmaceutical care practice: McGraw-Hill; 1998.

5. Power A, Douglas E, Gregor AMM, Hudson S. Professional development of pharmaceutical care in type 2 diabetes mellitus: a multidisciplinary conceptual model. IJPP 2006;14:289-99.

NB: These references do not match with the rest of the thesis

Appendix 7

Reports produced from the database

Distribution of Gender
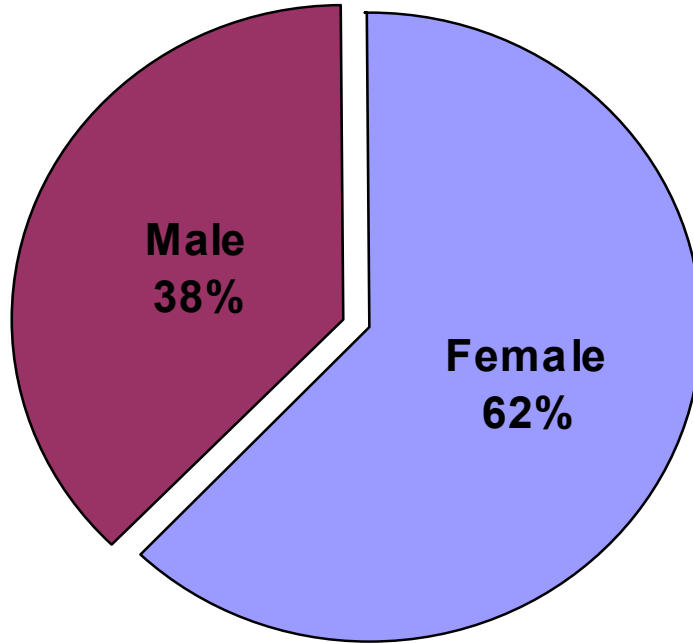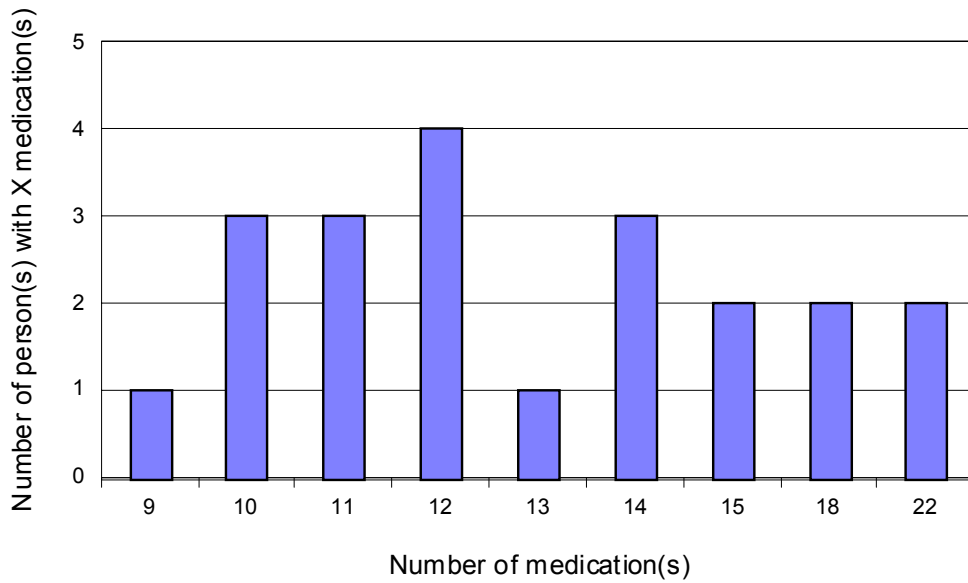

Female	13
Male	8

Age

Total

Average age	74.428
Standard Deviation	10.332
Highest age	88
Lowest age	51

Females

Average age	74.230
Standard deviation	9.8755
Highest age	87
Lowest age	51

Males

Average age	74.75
Standard deviation	11.732
Highest age	88
Lowest age	51

Number of drug(s) per person

Number of drug(s)	Number of person(s)
9	1
Number of drug(s)	Number of person(s)
10	3
Number of drug(s)	Number of person(s)
11	3
Number of drug(s)	Number of person(s)
12	4
Number of drug(s)	Number of person(s)
13	1
Number of drug(s)	Number of person(s)
14	3
Number of drug(s)	Number of person(s)
15	2
Number of drug(s)	Number of person(s)
18	2
Number of drug(s)	Number of person(s)
22	2

Most Frequent Diseases in Population

(Number of people with specific disease)

COPD	**12**
Ischemic Heart Disease	**9**
Chronic Heart Failure	**7**
Chronic Kidney Disease	**7**
Depression	**6**
Myocardial Infarction	**6**
Hypertension	**6**
Diabetes Type 2	**5**

The rest of the list below:

Diverticulitis	3		Iron-deficient anaemia	1
Atrial Fibrillation	3		Transient Cerebral Ischaemia (TIA)	1
Osteoarthritis	3		Stroke / CVA Unspecified	1
Pain	2		Rheumatoid Arthritis	1
Chronic Pancreatitis	2		Pulmonary Haemorrhage	1
Osteoporosis	2		Pulmonary Embolism	1
Anxiety	2		Psoriasis	1
Allergy	2		Polymyalgia	1
Coronary stent	1		Pneumonitis	1
Diabetes Type 1	1		Osteopenia	1
Chrohn's disease	1		Oesophogeal haemorrhage	1
Cervical spondolysis	1		Duodenal ulcer	1
Cluster headaches	1		Leg cramps	1
Cerebral vascular aneurysm	1		Abdominal aortic	1
Cerebral Artery Occlusion	1		Intemitted claudidation	1
Candidiasis	1		Hyperlipidaemia	1
Epilepsy	1		Hypercholesterolaemia	1
Brain tumor	1		Hemiplegia	1
Blackouts	1		Gout	1
Baker's cyst rupture	1		Giant cell artieritis	1
Asthma	1		Gastric ulcer	1
Aneurysm	1		Fractures	1
Allergic rhinitis	1		Vitamin B12 deficiency	1
Above knee amputation	1		Enteritis	1
Cerebral abscess	1		Myeloproliferative disease	1

Number of diseases per person
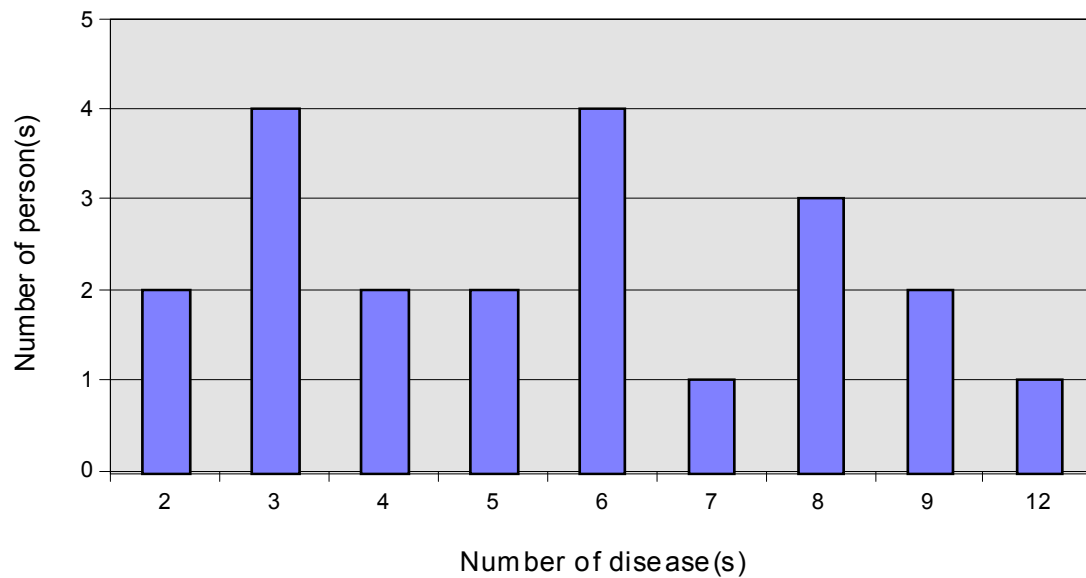
Number of disease(s)	Number of patient(s)
2	2
3	4
4	2
5	2
6	4
7	1
8	3
9	2
12	1

Checks
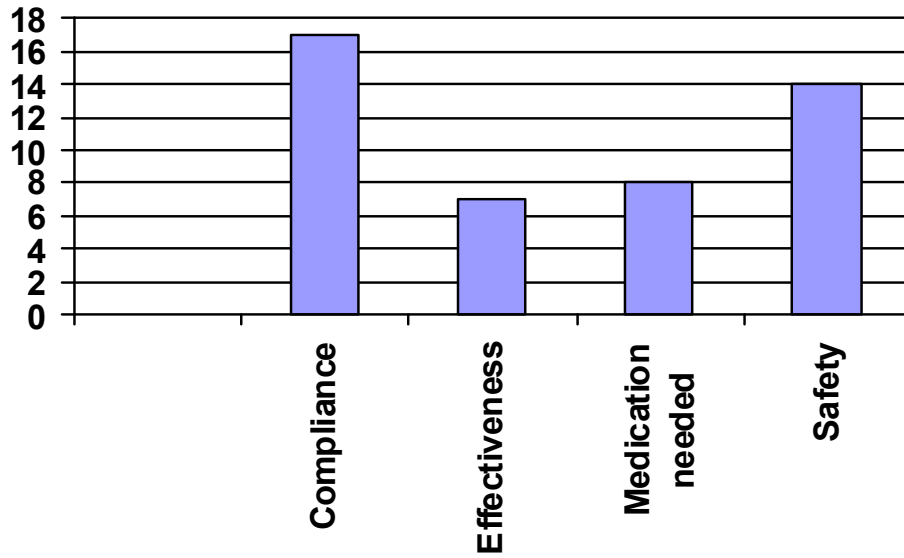
Compliance	17
Safety	14
Medication needed	8
Effectiveness	7
	0

Drug Therapy Problems

Distribution of drug therapy problems in the case load
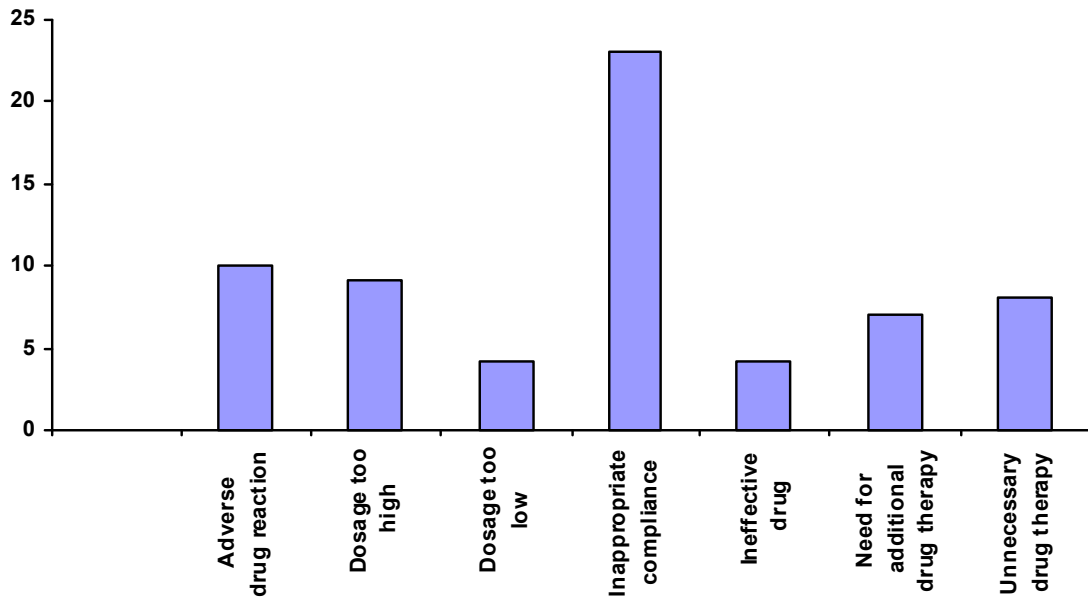
Inappropriate compliance	23
Adverse drug reaction	10
Dosage too high	9
Unnecessary drug therapy	8
Need for additional drug therapy	7
Ineffective drug	4
Dosage too low	4
	0

Changes in drug therapy process
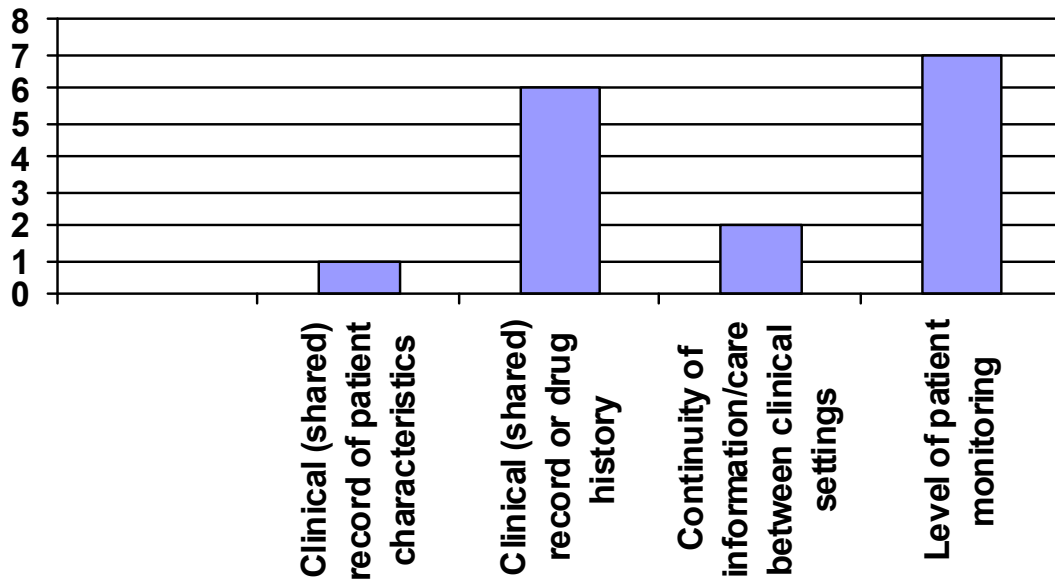
Level of patient monitoring	7
Clinical (shared) record or drug history	6
Continuity of information/care between clinical settings	2
Clinical (shared) record of patient characteristics	1
	0

Types of Checks in Relation to Check Point

	Check point ▾	
	Design	**Grand Total**
	+ −	+ −
Combo Check ▾	Count of Check	Count of Check
Compliance	17	17
Effectiveness	7	7
Medication needed	8	8
Safety	14	14
Grand Total	**46**	**46**

	Check point ▾	
	Design	**Grand Total**
	+ −	+ −
Combo Check ▾	Count of Check	Count of Check
Compliance	36.96%	**36.96%**
Effectiveness	15.22%	**15.22%**
Medication needed	17.39%	**17.39%**
Safety	30.43%	**30.43%**
Grand Total	**100.00%**	**100.00%**

Type of Change in Drug Therapy in Relation to Change Point

	Change point	
	Design	Grand Total
	+ −	+ −
Combo Change in drug therapy	Number of change(s)	Number of change(s)
Dose	10	**10**
Dose interval/timing	7	**7**
Drug selection (starting new or changing drug)	11	**11**
Duration	6	**6**
Patient or carer understanding/compliance	23	**23**
Route/dose form	3	**3**
Stop drug temporarily/permanently	5	**5**
Grand Total	**65**	65

	Change point	
	Design	Grand Total
	+ −	+ −
Combo Change in drug therapy	Percent change	Percent change
Dose	15.38%	**15.38%**
Dose interval/timing	10.77%	**10.77%**
Drug selection (starting new or changing drug)	16.92%	**16.92%**
Duration	9.23%	**9.23%**
Patient or carer understanding/compliance	35.38%	**35.38%**
Route/dose form	4.62%	**4.62%**
Stop drug temporarily/permanently	7.69%	**7.69%**
Grand Total	**100.00%**	**100.00%**

Drug therapy problems in relation to change in drug therapy

Combo Change in drug therapy	Adverse drug reaction Change	Dosage too high Change	Dosage too low Change	Inappropriate compliance Change	Ineffective drug Change	Need for additional drug therapy Change	Unnecessary drug therapy Change	Grand Total Change
Dose	2	4	4					10
Dose interval/timing	1	3		2	1			7
Drug selection (starting new or changing d	2				1	7	1	11
Duration	1	1					4	6
Patient or carer understanding/compliance	2	1		20				23
Route/dose form	1			1	1			3
Stop drug temporarily/permanently	1				1		3	5
Grand Total	10	9	4	23	4	7	8	65

Combo Change in drug therapy	Adverse drug reaction Change	Dosage too high Change	Dosage too low Change	Inappropriate compliance Change	Ineffective drug Change	Need for additional drug therapy Change	Unnecessary drug therapy Change	Grand Total Change
Dose	3.08%	6.15%	6.15%					15.38%
Dose interval/timing	1.54%	4.62%		3.08%	1.54%			10.77%
Drug selection (starting new or changing d	3.08%				1.54%	10.77%	1.54%	16.92%
Duration	1.54%	1.54%					6.15%	9.23%
Patient or carer understanding/compliance	3.08%	1.54%		30.77%				35.38%
Route/dose form	1.54%			1.54%	1.54%			4.62%
Stop drug temporarily/permanently	1.54%				1.54%		4.62%	7.69%
Grand Total	15.38%	13.85%	6.15%	35.38%	6.15%	10.77%	12.31%	100.00%

Type of change in drug therapy process in relation to type of change

	Change point ▾	
	Design	Grand Total
	+ –	+ –
Combo Change in drug therapy process ▾	Count of Change	Count of Change
Clinical (shared) record of patient characteristics	1	**1**
Clinical (shared) record or drug history	6	**6**
Continuity of information/care between clinical settings	2	**2**
Level of patient monitoring	7	**7**
Grand Total	**16**	**16**

	Change point ▾	
	Design	Grand Total
	+ –	+ –
Combo Change in drug therapy process ▾	Count of Change	Count of Change
Clinical (shared) record of patient characteristics	6.25%	**6.25%**
Clinical (shared) record or drug history	37.50%	**37.50%**
Continuity of information/care between clinical settings	12.50%	**12.50%**
Level of patient monitoring	43.75%	**43.75%**
Grand Total	**100.00%**	**100.00%**

Appendix 8

**Categorisation system used by the pharmacists
conducting the medication reviews**

Drug Therapy Problem		Common causes of drug therapy problems
1	**Unnecessary drug therapy**	a	There is no valid medical indication for the drug therapy at this time
		b	Multiple drug products are being used for a condition that requires fewer drug therapies
		c	The medical condition is more appropriately treated with non drug therapy
		d	Drug therapy is being taken to treat an avoidable adverse reaction associated with another medication
		e	Drug abuse, alcohol use, or smoking is causing the problem
		f	The duration of therapy is too long
2	**Need for additional drug therapy**	a	A medical condition requires the initiation of drug therapy
		b	Preventive drug therapy is required to reduce the risk of developing a new condition
		c	A medical condition requires additional pharmacotherapy to attain synergistic or additive effects
		d	The duration of drug therapy is too short to produce the desired response
3	**Ineffective drug**	a	The drug is not the most effective for the medical problem
		b	The medical condition is refractory to the drug product
		c	The dosage form of the drug product is inappropriate
		d	The drug product is not an effective product for the indication being treated
		e	The time of dosing or dosing interval is not the most effective
		f	Route of administration is not the most effective
4	**Dosage too low**	a	The dose is too low to produce the desired response
		b	The dosage interval is too infrequent to produce the desired response
5	**Adverse drug reaction**	a	The drug product causes an undesirable reaction that is / is not dose-related
		b	A safer drug product is required due to risk factors
		c	The dosage regimen was changed too rapidly
		d	The drug product causes an allergic reaction
		e	The drug product is contraindicated due to risk factors
		f	The time of dosing or the dosing interval is not the safest.

		g	Route of administration is not the most effective
6	**Dosage too high**	a	Dose is too high
		b	The dosing frequency is too short
		c	The dose of the drug was administered too rapidly
7	**Inappropriate compliance**	a	The patient prefers not to take the medication
		b	The patient forgets to take the medication
		c	The drug product is too expensive for the patient
		d	The patient cannot swallow or self-administer the drug product appropriately
		e	The drug product is not available for the patient
		f	The time of dosing or the dosing interval is decreasing compliance.
		g	Patient/carer not taking/giving medication as prescribed, due to confusion/misinterpretation of directions.
8	**Interactions**	a	A drug-drug/food/lab/disease interaction reduces the amount of active drug available
		b	A pharmacodynamic drug-drug/food/lab/disease interaction causes an undesirable reaction that is not dose-related
		c	A drug-drug/food/lab/disease interaction occurs resulting in a toxic reaction to the drug product
9	**Disposal of Medicines**	a	General disposal of medication
		b	Disposal of expired medication
		c	Patient at risk of accidental overdosing
10	**Monitoring**	a	Suggested monitoring
		b	Abnormal result identified
		c	Monitoring of patient compliance/understanding
11	**Unclassified i.e. Non-DTP**	a	Formulary adherence, e.g. generic switch

Appendix 9

**Pharmaceutical care plan
used by the pharmacist conducting the medication reviews in
Edinburgh IMPACT anticipatory care service**

PATIENT NAME:	DATE OF BIRTH

MEDICINE STORAGE INFORMATION: Are medicines being stored correctly? Y / N

MEDICINE DISPOSAL: Are there medicines requiring disposal?   Y / N   If Yes,

Relevant Medical History		Relevant Drug History	
Date	Current Problem	Date	Current drug therapy

CARE ISSUE	RATIONALE AND SUGGESTED ACTION

Abnormal Investigation Results (eg. U&Es, FBC, INR, lipid screen, glucose, etc)

Parameter / Date	Parameter /	Parameter	Parameter / Date

Further Information: (eg. relevant past medical history, relevant drug history, clinic attendance, hospital admissions)

Appendix 10

**Pharmaceutical care plan for COPD
(Not field tested)**

Surname	**First name**	**Date of birth**	**Age**	**Gender**	**Ethnic origin**

Gender: ♂ ☐ ♀ ☐

Ethnic origin: ☐White ☐Chinese ☐Black ☐Asian ☐Other ....

Social history
☐Living alone
☐Living with partner/family
☐Other: ....

Occupation
☐Retired

Weight (kg)

Height (metre)

BMI
☐Underweight
☐Normal
☐Overweight
☐Obesity

Smoking status
☐Smoker   Pack years
☐Ex-smoker   Years
☐Non-smoker

Comment

Comments on current attempts to stop smoking

COPD characterisation
☐FEV_1 ? 50% predicted
☐? 2 exacerbations/year
☐Respiratory failure
☐Cor pulmonale
☐Chronic productive cough
☐Anxiety
☐Depression
☐LTOT
☐Home nebuliser

Level of treatment
☐SA ß$_2$-agonist as required
☐SA anticholinergic and SA ß$_2$-agonist regularly
☐LA ß$_2$-agonist or LA anticholinergic regularly
☐LA ß$_2$-agonist and inhaled corticosteroid
☐Slow release oral theophylline regularly   ☐DTM

Dyspnoea (MRC-scale)   ☐1 ☐2 ☐3 ☐4 ☐5

Inhaler devices and inhaler technique

MDI ☐	DPI ☐	BAI ☐	Nebuliser ☐
Poor ... Good	Poor ... Good	Poor ... Good	Poor ... Good
0 1 2 3	0 1 2 3	0 1 2 3	0 1 2 3

Comments on inhalation technique

Medication	Start	Stop	Reason	Relevant med. history	Date	Relevant med. history	Date

---

Vaccinations ☐Influenza ☐Pneumococcal
Steroids (oral) ☐Prednisolone ☐Intermittent ....mg/day
Or ☐Long term ....mg/day
Antibiotics ☐Co-amoxiclav ☐Amoxicillin ☐Doxycycline
Smoking cess. ☐Offered ☐Started ☐Completed
Pulm. rehab. ☐Offered ☐Started ☐Completed
Compliance aid ☐MDS ☐Spacer
Sensitivities ☐Allergy Specify:.........

Date / Marker				
FEV_1/FVC				
Sputum				
Breathlessness				

Date	Care issue	Patient education / documentation changes and therapeutic plan checks	Therapeutic plan changes (Individualisations/dosage change/treatment interruption/management of co-morbidity)
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		
	Specify		
	Action		
	Output		