



SIMPLE COPD Service (PILOT) Standard Operating Procedure & Protocol 4 December 2013

Background

COPD affects over 900,000 people in the UK and it is thought that a further 2 million cases could be currently undiagnosed. COPD generates a significant burden on healthcare systems in the UK.

The pharmacological management of people with COPD is clearly stated in a set of practice guidelines by the National Institute of Clinical Excellence (NICE). In spite of the development of these, several reports have shown that implementation of these guidelines is still poor, which may have an adverse effect on patient outcomes and health care costs. It is known that outcomes for people with COPD can be improved and considerable cost savings can be made by ensuring medicine treatment is optimised. Community pharmacists are ideally placed to improve the medicine usage of patients with COPD, as they are highly accessible members of the primary health care team, see patients frequently (e.g. on prescription refill) and have expertise on patient education and link with smoking cessation services.

Nationally, community pharmacists are undertaking services to review inhaler technique and provide advice and support to ensure that patients obtain the maximum clinical benefit from their inhaled medicines. However, inhaler technique, although fundamental to the care of a person with COPD, is only one component of the medicine optimisation agenda.

Community pharmacists can support the wider management of the person with COPD by encouraging smoking cessation and other lifestyle factors, medicine adherence, education and support long-term monitoring of their disease.

Purpose

To improve the overall management of people with COPD by promoting a system of care that integrates the community pharmacist into the healthcare team and improves medicine optimisation.

Scope

This project is an initiative aiming to improve the overall management of people with COPD by promoting a system of care that integrates the community pharmacist into the healthcare team and improves medicine optimisation.

The SIMPLE COPD Pilot Scheme will operate from 18th November 2013 for up to 12 months. If successful, it will be offered on a wider scale beyond that date.

Responsibilities

Suitably trained:

- Pharmacists
- Pre-registration Pharmacy Students
- Dispensers
- Dispensing Assistants and Counter Assistants

Objectives

The main objectives of The SIMPLE COPD Service are:

- To devise and implement a community pharmacy programme to support the local care pathway for people with COPD
- To foster closer working relationships between community pharmacists and healthcare professionals involved in the management of people with COPD (including GPs)
- To provide people with COPD greater choice and improved access to services
- To support the local and national medicine optimisation agenda
- To evaluate the efficacy of the community pharmacy COPD to support future commissioning of the service
- To ensure people with COPD gain maximum clinical benefit from the use of their respiratory medicines thereby improving clinical outcomes and reducing healthcare utilisation
- To ensure patients understand how and when to use all of their medicines
- To reduce unnecessary prescribing costs and prescribing waste
- To promote, support and encourage good prescribing practice (in line with local guidelines)

The SIMPLE COPD service will be undertaken in two phases. In phase one of the service community pharmacists will review patient with COPD within the pharmacy premises. The target for SIMPLE COPD consultations over the evaluation period is **10 patients per participating pharmacy**. Each patient will be monitored over a 6-month period.

Anticipated Benefits

- Improved understanding of the condition and its treatment amongst people with COPD, which may lead to increased adherence to medicines regimens
- Improved inhaler technique to optimise drug delivery to the lung, ensuring people with COPD gain the most benefit from their medicines. This may in turn lead to reduced hospitalisation costs
- Development of primary care capacity and expertise to provide enhanced care e.g. structured education using the SIMPLE framework
- A reduction of the burden of long-term conditions
- Improved cost-effectiveness of medicines usage. Many people with COPD are on multiple medicines. Pharmacist intervention could reduce wastage and over-use as well as identifying under usage (poor adherence)
- As pharmacists have access to other members of the family, the programme provides an opportunity to convey public health messages and influence positive behavior change across different generations
- Community pharmacies tend to employ staff from the varied ethnic backgrounds that they serve, enhancing communication and identifying problems for people with language difficulties

Fees

	Community Pharmacy SIMPLE review
Visit 1	£15.00 (plus £28.00 t-MUR fee)
Visit 2	£10.00
Visit 3	£10.00
Total	£35.00 / patient (plus £28.00 t-MUR fee)

Eligibility Criteria

Pharmacists

Pharmacy premises and pharmacist must be MUR accredited and have a recent history of delivering MURs (>100 MURs in 2012/13). Pharmacists providing the service should have attended the SIMPLE COPD training event and have a full understanding of the SLA, associated paperwork and protocols.

Patients

To support the diagnosis of COPD people will be asked the following three questions before formal recruitment into the service. If the person answers “yes” to all three questions the person can be invited into the service.

1. Are you 35 years old or over? **Yes / No**
2. Have you ever smoked or do you smoke or had exposure to dust in your job? **Yes / No**
3. Do you have one or more of the following: shortness of breath, wheeze, phlegm (sputum), cough ± recurrent chest infection? **Yes / No**

A patient is included in the service if he/she:

- ≥ 35 years of age
- has a self-reported diagnosis of COPD
- is able to speak and understand English or be supported in translation by the pharmacy team

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- is able to return for all follow-up visits (two over 6 months) or willing to have the pharmacist contact them by telephone for follow-up outcomes
- is registered with an NHS GP practice within a Leicestershire or Rutland CCG

Identifying patients for the service

Patients can be identified by any of the following routes:

- Patients identified at the point of dispensing
- Patient self-referral
- GP Referral
- Pharmacists actively searching the pharmacy patient database

Details of how the person was recruited will be documented as part of the evaluation. The number of people refusing the service will also be documented.

Process

Recruitment

Once a patient has been identified they will need to be recruited into the service. The pharmacist or pharmacy staff member will:

- Check patient eligibility for the service (see eligibility criteria above)
- Provide an overview of the SIMPLE COPD service
- Provide relevant patient information materials
- Ask the patient to complete and sign the consent form for the service

Pharmacist Consultation 1

Following recruitment of the patient into the service, the pharmacist should conduct the first consultation consisting of:

- A targeted MUR if the patient is eligible (see relevant MUR SP for details).
- A SIMPLE COPD consultation consisting of the following elements
 - Stop Smoking Support (refer/offer NRT if appropriate)
 - Inhaler technique - observe and optimise
 - Monitor - Record MRC dyspnoea score, COPD Assessment test (CAT) score and self-reported COPD exacerbation information
 - Pharmacotherapy - review and optimise medicines and give information to person on appropriate use
 - Lifestyle - consider factors (BMI, exercise, vaccinations, rehabilitation)
 - Education - provide self-management advice and information on COPD

Following the initial consultation, the pharmacist or pharmacy staff member will need to review and document patient adherence to respiratory medicines for a 6-month period immediately prior to their recruitment date.

Pharmacist Consultation 2

A follow up SIMPLE COPD consultation will need to be completed **2 months** after the initial Pharmacist Consultation 1

Pharmacist Consultation 3

This will be conducted 6 months after Pharmacist Consultation 1 and will consist of:

- Recording CAT score, MRC dyspnoea score and self reported exacerbation/hospital admission data
- Contacting the patients GP practice to confirm hospital admission data
- Documenting patient adherence to respiratory medicines over the last 6 months

Data Recording & Record Keeping

The pharmacy contractor must agree to the following IT requirements:

- To provide a suitable desktop or laptop computer for the recording of data
- To regularly check email for SIMPLE COPD Service notifications and updates
- To have availability of Adobe Reader software on the computer used for recording data
- To enter all patient data onto the IT Platform within 24 hours of collection

Initial intervention

The pharmacy must keep a written copy of each individual assessment using the relevant template provided with the SIMPLE tool kit. This document can be supplied, on request, in electronic format.

Subsequent interventions

The pharmacy must enter the data of each individual assessment into the bespoke SIMPLE COPD web-based reporting system.

At all times

All documents and data must be stored in a secure place that meets all local and national requirements regarding confidentiality and data protection.

No patient identifiable details can be stored on paper-based records. A reference number unique for each patient together with a unique code for the pharmacy contractor **must** be used.

Adverse Event Reporting

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All Adverse Experiences and/or Adverse Drug Reactions in patients must be reported to University Hospitals of Leicester NHS Trust with the following basic elements (where available):

- a. a suspect drug
- b. an identifiable patient
- c. an identifiable reporter
- d. the “reported term(s)” of any adverse events

The Pharmacist will be responsible for reporting cases of adverse experience or adverse drug reaction as soon as possible but, in any case, no later than 24 business hours from first awareness.

Resources

Pharmacists will be provided with resources to assist them in recruiting people into the service.

Professional responsibility

The Responsible Pharmacist must ensure:

- The entire pharmacy team is made aware of the SIMPLE COPD Service
- Only appropriately* trained and competent staff take part in this service.
- Patients that are enrolled onto the service meet the eligibility criteria
- All paperwork and documents have all relevant sections completed and that all information provided is (to the best of their knowledge) correct
- The pharmacies responsibilities under Information Governance are maintained at all times
- Any adverse effects relating to the service must be reported immediately

** those staff who have attended the SIMPLE/7-Steps to Success Inhaler Technique training programme.*

Patient, public and staff safety

Providers will be required to demonstrate that evidence based clinical protocols are being used.

Clinical audit and review

Providers will need to ensure that staff have appropriate clinical audit skills and identify a programme of clinical audit to support the delivery of the service. Staff should work within their Standard Operating Procedures (SOPs), and these should be reviewed regularly.

Clinical Governance and Confidentiality

The project team reserves the right to view any relevant paperwork kept in the pharmacy or GP practice, pertaining to this scheme. Processes will be subject to Information Governance and Confidentiality requirements.

- All participants are required to sign a “Participant’s information and consent form” prior to enrolment

- All patient data will be kept within the community pharmacy in a locked filing cabinet. Any transfer of information for analysis will be anonymised
- Instances where pharmacists or pharmacy staff enter false information, when claiming payment, or on accompanying paperwork will be considered fraudulent
- All required data fields (paperwork or electronic) must be filled in clearly and accurately
- Data forms for individual pharmacists and participants will be randomly reviewed by a specialist respiratory pharmacist to assess the quality of service provision

Data Analysis

All anonymised data will be transferred to an independent researcher at DeMontfort University to evaluate the efficacy of the SIMPLE COPD programme. The evaluation has been statistically powered on the primary outcome measure CAT score. Secondary outcomes, such as healthcare utilisation, MRC dyspnoea score, inhaler technique, pharmacist interventions will also be analysed.

Review Procedure

The above procedure will be reviewed annually or in the case of critical incident. Any review resulting in change will require the implementation of a new SOP.

Known Risks

- Staff unaware of the process and procedure
- Failure to follow processes for the intervention service
- Failure to follow information governance requirements
- Failure to record data and send communications to and from the service hub

SIMPLE COPD SERVICE (PILOT)

Discharge Medicines Service Protocol and SoP

Prepared by: Rosemary Plum and Kaldeep Singh

Date: 04/12/2013

This Service Specification is agreed between:



(Signature)

*Dr Anna Murphy,
Consultant Respiratory Pharmacist
University Hospitals of Leicester NHS Trust*

AND

(Signature)

*Authorised Agent
On behalf of the Community Pharmacy Provider*

Print Name:

Date:

Pharmacy Name & Address:

(Pharmacy Stamp)

Community Pharmacy

SIMPLE COPD Service Overview

