EFFECTIVENESS OF A PHARMACIST-LED INTERVENTION IN COPD (EPIC2): STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

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Title

Effectiveness of a pharmacist-driven intervention in COPD (EPIC2): study protocol for a randomized controlled trial

Trial registration

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Roles and responsibilities

ED and JH prepared the protocol, WA contributed to the background research and writing of the manuscript, JMG prepared the sample size calculations and data analysis plan, and all authors (ED, JH, CG, WA, JMG, CM, JF, JL, JMF) contributed extensively to study design, manuscript review and editing. All authors read and approved the final protocol.

Abstract

Background:

Patients with chronic obstructive pulmonary disease (COPD) are often non-adherent with medications and can have poor inhaler technique. Community pharmacists can help improve health related quality of life and overall outcomes in patients with COPD. We aim to measure the effectiveness of a systematic, pharmacist-driven intervention on patients with diagnosed COPD.

Methods/Design:

This pragmatic randomized controlled trial is designed to determine the effectiveness of a multifactorial, pharmacist-led intervention on medication adherence, inhaler technique, health-related quality of life, health care resource utilization including COPD exacerbations, and use of medications. Patients with COPD will be randomly assigned to either the intervention or control group. The intervention group will receive an enhanced form of care that emphasizes COPD management through the Medication Therapy Services (MTS) clinic. The control group will continue to receive usual care and in addition will be given a COPD education pamphlet. Included patients will be ≥40 years of age, have a physician confirmed diagnosis of COPD, and be able to answer questionnaires in English. The primary outcome is the between group difference in the change from baseline to 6 months in medication adherence using the proportion of days covered (PDC). Secondary outcomes are also measured from baseline to 6 months, and include the proportion of patients with a clinically significant change in adherence, the proportion of patients defined as having 'good adherence', defined as 80% of PDC, the mean PDC between groups, quality of life as measured by the St. George's Respiratory Questionnaire, medication inhalation technique using a pharmacist-scored checklist, healthcare resource utilization, and antibiotic and oral corticosteroid use for COPD exacerbations.

Introduction

Background and rationale

Problem

Chronic obstructive pulmonary disease (COPD) is a respiratory disease characterized by a state of chronic inflammation, usually as a result of environmental toxins, leading to a progressive loss of airway function and systemic co-morbidities.[1,2] COPD is a significant cause of morbidity and mortality and also carries a high economic and social burden.[3] It is listed as the 5th leading cause of death in the world[4] which is estimated to become the 3rd leading cause within a decade, and the 4th leading cause of death in Canada.[5] The overall societal cost of COPD in Canada in 2011, including direct and indirect costs of the disease, was $4.52 billion.[6] Moreover, COPD exacerbations account for more than 50% of the total health system costs of COPD.[2,7] The prevalence of COPD is increasing, and although a large proportion of patients remain undiagnosed, they contribute a comparable healthcare burden to those who have been diagnosed.[8]

The approach to COPD management is multifactorial and consists of non-pharmacological as well as pharmacological strategies, in order to reduce symptoms, improve quality of life, reduce exacerbations, and slow disease progression. [1,2,9,18] Unfortunately, rates of adherence for medication use in those with COPD are particularly low. The World Health Organization estimates a 50% adherence rate for patients with COPD,[10] while many studies report adherence rates in clinical practice to be between 40-60%.[11-16] There are factors unique to COPD that predispose patients to adherence issues, including the chronic nature of the disease, complex medication regimens, significant comorbidities, and periods of disease stability between exacerbations. [15,17]

Non-adherence has a significant impact on a patient's outcome, increasing hospitalization and exacerbation rates.[18-20] Indeed, multiple studies have shown an association between non-adherence in COPD and clinical and economic outcomes.[21] A post-hoc analysis of the Towards a Revolution in COPD (TORCH) trial indicated that patients with >80% adherence had a mortality rate of 11.3% as compared to 26.4% in those with adherence of ≤80% with annual hospitalization rates for exacerbations being 15% for adherent patients and 27% for non-adherent patients.[18] Furthermore, another study indicated that better adherence was associated with a 20% reduction in annual hospitalizations.[20]

Role of the Pharmacists in COPD Management

Pharmacists play a unique role in the health care system, as readily accessible primary health care professionals with frequent interactions with patients. Moreover, community pharmacies can act as cost-effective primary care platforms for improving medication adherence, inhalation technique and health-related quality of life in COPD.[22-27] A multifactorial, individualized approach to COPD treatment has been suggested by many studies [2,14,15,22-28] with pharmacists playing a major role.

As pharmacists move away from their traditional role as primarily dispensers of medications, and are starting to expand their scope of practice, novel practice settings are more common. An example of this expanded scope of practice is the Medication Therapy Services (MTS) clinic run by the Memorial University School of Pharmacy. The MTS clinic is a pharmacist clinic where primary care providers can refer their patients to the MTS clinic for comprehensive medication therapy assessment and receive recommendations to optimize patients' medication therapy. Patients are seen on an appointment-only basis, in a primary care clinic setting to receive their consultation with one of the clinic pharmacists. Unique within Newfoundland and Labrador, the MTS Clinic offers a variety of pharmacist-delivered

services with a commitment to assessment and evaluation. The MTS clinic is a licensed pharmacy through the NLPB but does not stock or dispense medications as its purpose is to provide clinical pharmacy services to the community. Using the MTS clinic as the "study setting" will allow us to test our proposed intervention in a specialized community pharmacy setting to determine the efficacy, cost and cost-effectiveness. Moreover, one of the goals is to eventually transfer the intervention and associated positive outcomes to everyday community-based pharmacy practice.

Relevant Literature Regarding Pharmacists Managing COPD

In 2012, a small pilot study was completed in Canada to assess community pharmacists (CPs) ability to improve Asthma and COPD management. [22] Twenty-one CPs evaluated 23 asthma and 59 COPD patients. All CPs completed a brief continuing educational session about COPD and asthma management before the study began. Services offered by CPs included: smoking cessation advice, assessment of the patients' medical condition (medications problems, adherence and disease control), resolving inhalation technique problems if they were present and providing an individualised action plan when needed. As this was a pilot study, the results were presented as recommendation. Fifty-nine recommendations were made by pharmacists to the prescribing physicians, including: implementation of patient-customised action plan (n = 17), change in medications (n = 12), inhaler device change (n = 9) and revaluation of adherence to medications (n = 7). Most of the treating physicians reported that the recommendations made were very useful. Approximate time required to deliver this service was 30 min per patient. Lack of time was identified by CPs as a potential barrier for service delivery.

Wright et al designed a service evaluation model to assess the validity of a community-pharmacy based, expanded support COPD service.[23] The study evaluated the effect of COPD support service by CPs over six months in 34 pharmacies from four pharmacy chains. The provided service included smoking cessation, education and advice about inhalation technique and inhaler checking, patient exacerbation awareness and general life-style advice. Initial consultation involved getting baseline data regarding self-reported medication adherence, clinical outcomes, National Health Services (NHS) resource utilisation and quality of life (QoL). QoL assessments were completed at baseline via a COPD assessment test (CAT) score, EQ-5D, and Medical Research Council dyspnea score, in addition to a Morisky assessment of adherence. Patients were also asked to record exacerbations, hospitalizations, GP visits, COPD pack usage, and productivity lost to illness in the previous 6 months.

After this initial assessment, the pharmacist intervention consisted of medication and lifestyle counseling, smoking cessation service (if patient was interested), and potentially a physician referral to obtain a COPD rescue pack. Following the educational component of the COPD support service, a follow-up was scheduled 6 months later. Data were retained for 137 patients, which showed after 6 months an improvement in patient adherence on the Morisky scale of 0.56 (CI .30-.82, $P<0.001$), as well as an improvement in quality of life scores and a small QALY gain. In addition to this, there was a suggested cost savings per patient of £87.66 based on NHS costs, and £94.12 based on total societal costs. In light of this, the authors concluded that a pharmacist-led COPD support service could be a cost-effective use of health care resources, providing an overall reduction in cost to the NHS as well as improvements in quality of life and adherence measurements.

Ottenbros et al completed a prospective cohort study over 10 months evaluating a pharmacist-led care program for COPD and asthma patients.[24] Pharmacies from intervention and control groups were

matched by day-to-day dispensing quantity, number of employed pharmacists, and level of urbanity. COPD patients were selected based on being over 40 years of age with at least two previous prescriptions for high dose antibiotic/steroid treatments (HDT) in the previous year. Patients in the intervention group were screened for a pharmacy care program that involved working closely with patient and GP to optimize therapy, inhalation technique, and compliance. From 107 treatment pharmacies, 102 497 asthma and COPD patients were screened, with an additional 3 757 patients selected to receive the actual intervention, compared to a control group of 105 507 patients from 105 control pharmacies.

The primary outcome was use of HDT as a proxy for level of disease control. Secondary outcomes were a list of 19 items indicating suboptimal treatment that were assessed at baseline and study end, including inhalation technique, adherence, etc. Compared to the control group, the selected intervention patients received a mean 0.54 less HDT (0.21-0.86). For the unselected group of intervention patients (i.e. not selected to receive the enhanced care) there was a counterintuitive statistical reduction in almost all of the secondary outcomes; the study attributed this difference to pharmacists and GPs being more sensitive to drug therapy problems in the unselected intervention group. A pharmacist-led COPD intervention program can reduce the number of high dose antibiotic/steroid treatments for these patients, subsequently leading to fewer exacerbations and better disease control.

Tommelein et al. evaluated the hypothesis that CPs could improve inhaler technique and medication adherence in COPD patients in Belgium.[25] CPs received education regarding COPD pathophysiology and treatment according to GOLD guidelines prior to the trial beginning. The intervention offered by CPs was structured patient education modified to the patients' needs. The education was offered in written and oral format focusing on medication adherence, information about COPD as a disease and its treatment, COPD self-management, smoking cessation and demonstration on how to use an inhaler. The education was delivered as one-to-one counselling sessions. Patients in the control arm received usual pharmacist care. Inhalation technique was assessed via a device-specific checklists designed by the researchers and medication adherence was assessed via a medication refills adherence score (MRA). The trial lasted for three months. Patients were followed up at one and three months across 170 community pharmacies and involved 7834 patients. The intervention group was found to achieve better inhalation rates (13.5% CI 10.8-16.1; P<0.0001), higher medication adherence (difference of 8.51%; CI 4.63-12.4; P<0.0001), and a lower rate of hospitalization (9 vs. 35; rate ratio 0.28, CI 0.12-0.64; P=0.003). There was a likelihood to obtain a 100% inhalation score as a result of the intervention (odds ratio 3.03, 95%CI: 2.12–4.34; P < 0.0001) in comparison to no intervention. Moreover, it was more likely to achieve a 80% MRA score scores in the intervention groups compared to control (odds ratio: 2.15, 95%CI: 1.46–3.14; P < 0.0001).

van Boven et al performed a cost-effectiveness analysis on the Tommellein et al study.[26] The study had already been proven to be successful in improved patient adherence and inhalation technique, as well as lower hospitalization rates; however, van Boven et al makes an effort to quantify the cost-effectiveness of the intervention through a Markov model and economic analysis. A statistical model was generated with respect to the 3month trial in terms of exacerbation rates, COPD disease progression, costs, and health-related quality of life.

A sensitivity analysis extrapolated the trial parameters to 1, 5 and 12.5 years. After 1 year of results, it was projected that the intervention would result in a cost savings of €227 per patient, mostly due to a reduction in hospital-treated exacerbations of 0.07 per patient. When looking at the long-term model, the intervention results in 1.36 fewer hospital treated exacerbations per patient. The authors go on to

suggest that not only is the intervention a cost-effective means of proving care, but also that current therapies should be optimized with a care plan of this type, as opposed to adding new therapies to a patient regimen.

Wei et al conducted a prospective randomized controlled trial investigating whether enhanced pharmaceutical care delivered to COPD patients would result in better medication adherence, resulting in fewer exacerbations and an improved health related quality of life.[27] Eligible patients were randomly assigned to receive either comprehensive COPD pharmaceutical care (58 patients), or 'usual care' (59 patients).The pharmaceutical care program involved a standardized combination of individualized educational sessions with telephone follow-up. The initial counselling was set up to provide an overview of the disease itself, including how the medications worked and how to effectively use them. Based on the results of the previous encounter, follow-up telephone sessions were provided covering the treatment effect, side effects, and any questions the patient might have. The program continued for 6 months, with outcome assessments at 1 month, 6 months, and a follow-up assessment at 1 year.

The primary outcome measured was patient adherence, done through direct interview and assessed against pill counts. Secondary endpoints were severe exacerbation and health-related quality of life, measured through COPD hospitalization and St. George's Respiratory Questionnaire (SGRQ), respectively. Patient adherence was highest at 6 months following initiation of the program compared to the control group, at 73.4±11.1 vs. 52.7 ±21.9 (P=0.016). At the 1-year follow up, the pharmaceutical care group adherence decreased, but still maintained statistical significance over the control group, with 66.5±8.6 vs 54.4±12.5 (P=0.039). As well, the symptoms and impacts sections of the SGRQ scored significantly lower in the pharmaceutical care group after treatment. The study also found a 56.5% reduction in hospitalization at the one-year follow up assessment. The authors assert that a consistent educational program for non-adherent COPD patients is crucial to improving medication compliance, in addition to reduced hospitalizations and fewer symptoms.

Finally, a hospital based, respiratory ambulatory care clinic utilized physicians and pharmacists working together to develop a new COPD patient care model with the purpose of improving care, reducing exacerbations, and achieving optimal outcomes.[28] This was done via medication adherence assessment, medication therapy optimization and patient education. The care model was broken into four domains which were used to measure success. This included, medication therapy management, evaluation of patient access, assessment of quality measurements and patient education.

The pharmacist provided the above mentioned model to all patients with COPD in an initial patient visit of 45 to 60 minutes. In-person follow-up appointments were scheduled between two and 12 weeks depending upon the individual patient. Patients who had a change made to their COPD medication regimen were followed-up with a phone call one week later to ensure understanding and adherence. All changes made to patient care were document in the electronic health record.

A total of 138 patients were included in the study, all received the care model. There were 70 patients in the control group (they only saw a care provider) and 68 patients in the intervention group (seen by a care provider and a pharmacist). None of the control had all four domains completed compared to 66 of the 68 intervention group (P < .001). Pharmacy services reduced phone call consults at 90 days (P=.04).

Objectives

Goals

To measure the impact of a systematic, pharmacist-driven intervention on patients with diagnosed COPD. This is a modification of a previous trial approved through HREB (HREB # 20161193)

Primary Objective

1. To examine whether the intervention improves medication adherence

Secondary Objective

2. To examine whether the intervention improves health-related quality of life
3. To examine whether the intervention improves inhaler technique
4. To examine whether the intervention affects the frequency of pulmonary exacerbation (both ambulatory and hospitalised) and the required health care resources
5. To explore the feasibility of integrating the intervention into community pharmacy practice
6. To determine if the intervention is cost-effective.

Trial design

This trial is a pragmatic randomized control trial with the primary objective of improving medication adherence in patients with COPD via a pharmacist-run, medication therapy clinic. Patients will be randomized to either intervention or control group and receive either enhanced or usual care, followed by a 6-month follow-up. At the 6-month point, patients in the control group will be offered the option to be referred to the MTS clinic to receive the enhanced care intervention. Data will be analyzed using the individual as the unit of analysis according to a superiority framework.

Methods

Study Setting

Recruitment of participants will occur through three respirologists' ambulatory care clinics. The intervention will take place in the Medication Therapy Services clinic (see Introduction) by pharmacists working at that clinic.

Eligibility Criteria

Inclusion Criteria

Participants eligible for the trial must meet all of the required criteria below at randomization.

1. patients with a diagnosis of COPD by a physician
2. age >40 years at trial enrollment,
3. sufficient ability to answer questionnaires in English.

Exclusion Criteria

1. FEV1/FVC <30%,
2. diagnosis of dementia or having a prescription for cholinesterase inhibitors,
3. the presence of a terminal illness,
4. patients who do not provide consent.

Interventions

Recruitment

Participants will be recruited during routine visits to their respective respirologists at outpatient respirology clinics in Eastern Health. Participants in the intervention group will be referred to the MTS clinic by the respirologists. Participants in the control group will receive standard of care. First contact will occur through the respirologists on site. Consent will be acquired from the participants by the research assistant. The principal investigator will ensure that the consent process is followed and will be responsible for the actions of the research assistant who will be obtaining consent. The research assistant has completed TCPS 2 certification and is fully knowledgeable regarding the research protocol, obtaining consent and the ethical treatment of human subjects in clinical trials. The research assistant is obtaining consent to avoid therapeutic misconduct or any unintentional coercion that may occur when the primary care giver is requesting consent.

Consent will be obtained in the respirologist's clinic, after the respirologist has served as first contact. All participants who will be asked to consent to participate in this study will have to meet eligibility criteria described above. The research assistant will not be in attendance with the respirologist and the potential participant when first contact is occurring. When consent is being obtained, the participant will be informed of: 1. that they are being invited to participate in a research study involving how they take their COPD medications, 2. the purpose of this study, 3. that they are under no obligation to participate, that if they choose not to their care will not be affected, and if they decide to withdraw, any data collected will be provided to them, 4. the results of the study (without providing any participant specific details) and the fact that this information will be presented and published, again without mentioning any participant specific details, 5. what participant information will be collected for this study, who has access to it and how the confidentiality of that information will be protected, 6. the contact information of the person obtaining consent and the contact information of the primary researchers. The participant will be given adequate time to determine if they want to consent, after the research assistant has explained the above material. The research assistant will also not be present with the potential participant, while they are determining if they want to consent. All potential risks, discomforts or inconveniences will be conveyed to the participant. Participants who decide to consent will be provided with all pertinent information or changes that occur with regards to the study during the study period. Research will only begin after consent has been obtained. Consent will be documented by a signed consent form.

We will provide ongoing support and work closely with the respirologists to ensure that there is minimal inconvenience to the flow of care and to the patients themselves. Moreover, we will aim to monitor the recruitment process through regular communication, such as site visits, telephone calls, and emails to discuss any issues or challenges that might arise.

Randomization

Patients will be randomized to either intervention or control group at the respirology clinics. A random number list will be generated using Excel 2013 (Microsoft Corporation) and patients will be assigned to either intervention or control in a 1:1 ratio by the research assistant, as they are recruited. Allocation concealment will be achieved using sequentially numbered, sealed, opaque envelopes containing the group assignments, opened sequentially when patients have consented to participating in the study.

Blinding

It will not be possible for respirologists, research assistant, the MTS clinic pharmacists, or the patients to be blinded to which group they are assigned, due to the nature of the intervention. The data analyst will be blinded to treatment assignment.

Intervention Group

Those participants randomized to the intervention group will be interviewed by the research assistant at the respirology clinic to collect basic demographic data, patient information relevant to the objectives, initial inhaler technique and QoL data. At this time, the research assistant will also provide the participant with COPD specific, patient information. These forms and documents are provided in Appendix A. Patients will be able to withdraw from the study at any time. Research staff will be available to answer questions or provide support as necessary.

The intervention group participants will then be referred to, and contacted by the MTS for their first clinic visit. Services at the MTS clinic are provided free of charge. Staff pharmacists working at the MTS clinic will be offered training on the design of the study, including how to administer questionnaires, how to administer the intervention to a patient as well as an overall “refresher” on COPD management. The participant will be provided with a one-on-one, initial session with the MTS pharmacist that will last up to one hour. The intervention group will be referred to a pharmacist-run (MTS) clinic, based at MUN. The participants will receive a phone call from the MTS Clinic study team within a couple of days after seeing their respirologist. The participant will be given an appointment to come to the MTS Clinic within one week of seeing their respirologist. The participant will meet with the clinic pharmacist for about one hour to discuss their COPD and any medications they are taking. The pharmacists will complete a thorough medication review, provide patient education and develop an "Action Plan" that will help the participants when their COPD is not under control and is causing them to take oral steroids or antibiotics. They will also be given forms to fill out that will refer them to resources such as a smoking cessation program. The pharmacist will answer any questions the participant has and make recommendations that will help them to take your COPD medications better. The pharmacists will also record how much time they spend with each patient per visit. This information will be given to the research team as time spent per patient, identified through study ID. After the visit, the pharmacist will communicate to their respirologist outlining what they told the patient and ask for the doctor’s feedback. If the participant has any questions or conditions that require further follow up they may have to come for more follow up visits. Pharmacists will access meditech and HealthE NL as needed to provide clinical care related to participants’ COPD. This may include the patient’s medical history, medication history, current medications, pulmonary function tests, results of laboratory tests and notes from other health care professionals. Consent for this access will be collected from patients during the consent process and through an RPAC review of our study proposal, once ethics approval has been obtained.

The intervention involves 4 main strategies in addition to the COPD education pamphlet: a) medication review, b) patient education, c) a written COPD action plan provided in collaboration with the respirologist if required (see Appendix B) and d) provision of, or referral to, smoking cessation counseling (where applicable and appropriate)

a) Medication review:

Patients will be given a thorough review of their current COPD medications. The review will consist of current medications, doses, dosage forms, duration and timelines of therapy, appropriateness of

therapy, and patient expectations. Drug-related problems will be identified and recorded, and recommendations for their resolution will be forwarded to the patient's respirologist. Inhalation technique may be repeated at this time.

b) Patient education:
The education will consist of evaluating current inhaler technique and the subsequent correction or teaching where required. Pharmacists will also deliver adherence support strategies by determining knowledge deficits, understanding the patient's expectations of their COPD therapy, and focusing on teaching about medications and administration techniques. The 'teach-back technique' will be used.[26-28]

c) COPD Action Plan:
A written "COPD action plan" form will be provided and explained to the patient. This action plan will inform the patient how to proceed when COPD symptoms worsen. This action plan will be developed in conjunction with the patient's physician, where patients do not already have a standing prescription for antibiotics and oral steroids. The form is divided into two sections, each section having three subcategories. These include: 1) "My Symptoms" (I feel well, I feel worse, I feel much worse); and 2) "My Actions" (stay well, take action, call for help). This action plan is easy to read and simple to follow.[29] A copy of this will be provided to the patient and to the patient's family physician (faxed).

d) Smoking Cessation:
Pharmacists will also refer current smokers who wish to stop smoking to smoking cessation services, or offer smoking cessation counseling through the MTS clinic.

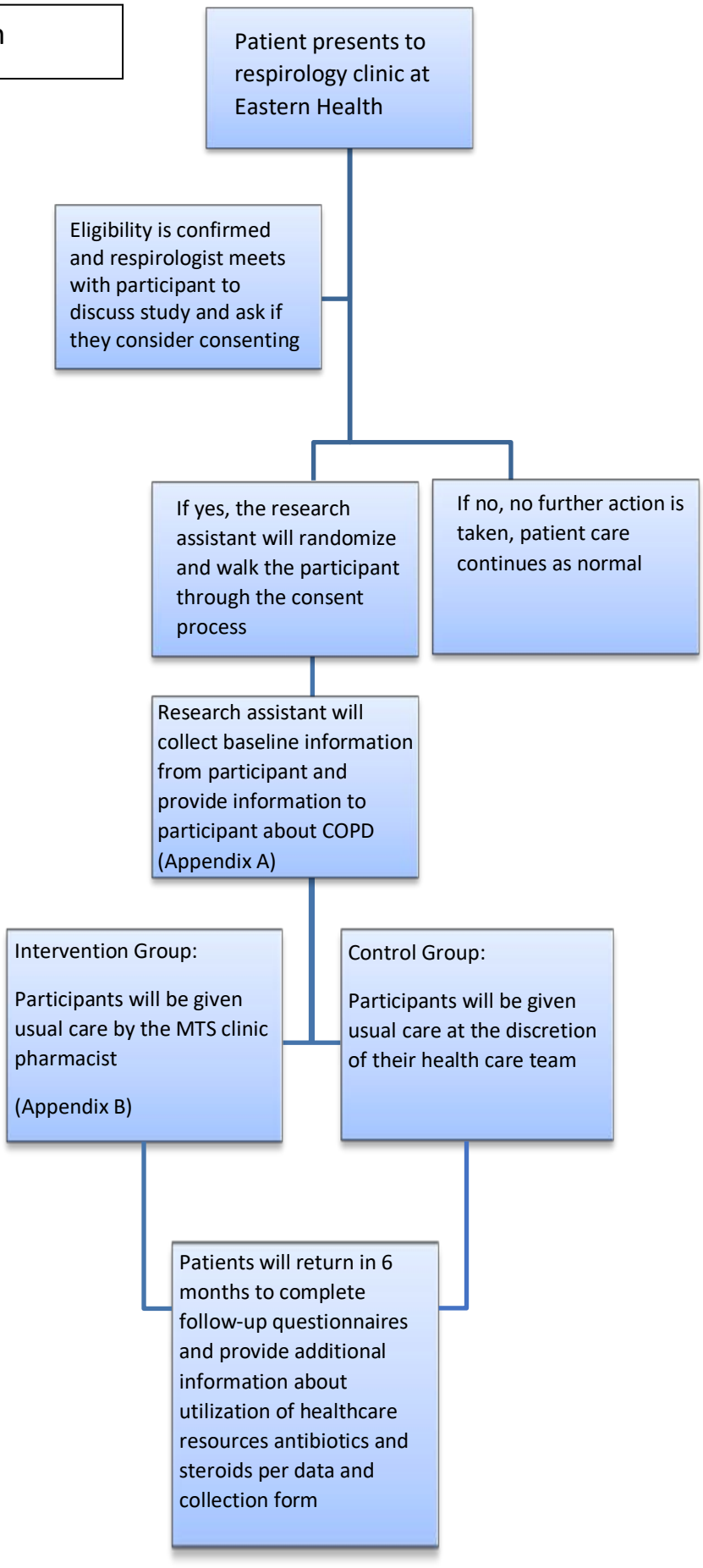
The MTS clinic pharmacist may choose to request additional sessions, based on any interventions suggested, throughout the study period.

Control group:

Those participants randomized to the control group will be interviewed by the research assistant at the respirology clinic to collect basic demographic data, patient information relevant to the objectives, initial inhaler technique and QoL data. At this time, the research assistant will also provide the participant with COPD specific, patient information. These forms and documents are provided in appendix A.

There will be no impact on the provision of care for these patients, as provided by their usual respirologists, family doctor and community pharmacists. Patients in the control group will be offered a referral to the MTS clinic, after the trial has ended for that patient. Care will not be limited or directed by the study team in any way. Patients will be able to withdraw from the study at any time. Research staff will be available to answer questions or provide support as necessary.

Patient Flow Diagram



Safety Considerations

Risks to participants should be minimal given the non-invasive and educational nature of the intervention. This study compares a pharmacist (MTS clinic pharmacist) who is able to spend more time than a community pharmacist would, with the intervention group. The control group who are not receiving the intervention will receive all the care they normally would with their respirologist and community pharmacist, per their professional judgment.

Also, both groups of participants will be receiving information about COPD (pamphlet). This will allow participants be more informed about their condition regardless of the group to which they are randomized. This is expected to have a positive impact on their health care.

Possible risks that could occur might be an adverse drug event if a participant is started on a new drug therapy. This would be mitigated by selecting the best drug for the participant based on that participant's health status. Adverse drug reactions in COPD inhaler medications are rare by nature as the medication is often not systemically absorbed and when do occur are usually rare.

The potential exists for negative emotional reactions or feelings of being overwhelmed. Should participants suffer adverse effects from the administration of study questionnaires or during the educational session, pharmacists will be instructed to allow rest and direct patients to counselling services where necessary.

In any clinical trial where both groups (intervention and control) are considered to have similar care provided, one cannot guarantee that a benefit will occur to a participant for enrolling in the trial. As a result, the research team will be conscious of therapeutic misconception and ensure that during consent, all participants understand that this research is designed to produce new knowledge in this area and that the participant may not gain any therapeutic benefit from the study. This may be especially true in those who may be considered a vulnerable sub-population (those who have a self-perception of "bad COPD") within this already vulnerable population (the entire COPD population). We will make sure that all participants are provided with information that confirms that they will be provided standard of care regardless of which group they are randomized to, and will not be disadvantaged in any way. Moreover, we will not be having the respirologist obtaining consent as we feel this may inadvertently provide an external pressure for participants to consent. We believe that the above mentioned problems will be mitigated by the research assistant obtaining consent as opposed to the respirologist. It will also be acknowledged that the research assistant will adhere to all guidelines and regulations that are required of the research team with regards to the ethical treatment of participants in clinical trials. Finally, the participants in the control group will be offered the chance to participate in the intervention after their 6 months assessment if they decide they would wish to do so.

Potential discomforts might occur for participants in the intervention group. As such, this means extra health care visits (i.e. the MTS clinic) on top of their normal visits to their respirologist, family doctor and community pharmacist. Potential inconveniences may include having to provide extra transportation to the MTS clinic, which is not located at the Health Science or Major's Path Centers of Eastern Health but is within the center of the city. As above, all attempts to minimize this will be pursued. The research team hopes to minimize this by reducing the amount of visits to the MTS clinic to a minimum, where possible, by communicating as much as possible by phone.

Outcomes

The primary outcome of adherence is the difference in the change in proportion of days covered (PDC) from baseline to 6 months between the intervention and control groups. The World Health Organization (WHO) has defined adherence to long-term therapy as "the extent to which a person's behavior (taking medication, following a diet, and/or executing lifestyle changes) corresponds with agreed recommendations from a healthcare provider".[32]

Medication adherence will be measured using PDC at baseline and 6 month follow-up by the research assistant. PDC is the proportion of days covered by prescription claims over the 6-month follow-up[33], which will be calculated using prescription records collected from HealtheNL. Prescription record data will be kept on all of the patient's prescriptions. As in previous studies, a 10% to 15% change in the PDC will be considered a minimal clinically important change.[33,34] Similar to others, we will consider a threshold for good adherence to be a PDC of at least 80%.[18]

Secondary outcomes will be measured at baseline and 6 months and include: 1) quality of life assessed by the St. George's Respiratory Questionnaire (shorter version); 2) medication inhalation technique using a pharmacist-scored scale; 3) healthcare resource utilization (frequency of physician visits, hospitalizations, emergency department visits and pharmacy visits) as reported by the patient at 6 months; 4) antibiotic and oral corticosteroid use for acute exacerbations of COPD (AECOPD) as reported by the patient at 6 months and 5) the amount of pharmacist time spent per participant.

Participant Timeline

Patients will be recruited over a 12-month period, between October 2017 and October 2018 and will be followed for 6 months. We anticipate that we will be able to potentially refer 10-15 patients per week to the MTS clinic. Recruitment will end early if our calculated sample size is met before October 2018.

Sample size calculation

We based our sample size calculation on our primary outcome of change in adherence measured using the PDC. We assumed a baseline adherence of 50%[15,35], a minimal detectable difference of a 10% absolute change, a standard deviation of 30%, a correlation of 0.6 between baseline and follow-up measurement, and a type 1 error rate of 5%.[36] Using these assumptions and accounting for a 10% dropout rate in each group, we estimate that 100 patients in each group will provide 80% power to detect a minimum difference of a 10% change between intervention and control groups.

Data Collection Methods

Patient data will be collected by the research assistant using specific forms (Appendix A) after their consent is obtained. Follow-up will be at 6 months after the delivery of the intervention or usual care. All information will be stored in Erin Davis's office in a locked cabinet. A copy of the information and services provided as part of the intervention will be stored at the MTS clinic as required by law. The research assistant will collect the information in hardcopy for data entry. A data analyst blinded to the patient's treatment status will conduct the final analysis.

Data collected will include: basic contact information (name, mailing address, email and phone/cell number, etc), and information related to the outcomes of the study, including questionnaires and prescription and health care resource utilization information. The data collection forms are to be completed by research assistant at baseline and 6 months. Any harms reported by the participants will

be recorded and included in the final manuscript. All secondary data will be provided by NLCHI, from the Drug Information Services in the form of record level information 6 months after the last person has been enrolled.

Data Management

Directly identifiable information (e.g. name, personal health number) and indirectly identifying information (e.g., date of birth and place of residence) will be removed from information and replaced with a code. Only the principal investigators and research assistant will retain a list that links the participants' study IDs with their name so data can be re-linked if necessary. This information must be retained to link the data from the different sources. Additional situations where linking of patient identity to de-identified information could be the debriefing of participants. It will be necessary to retain this information so we can contact them after the study is over. Another situation that perhaps requires retention of data is to assist internal and external audits that may be required of the research team by local research boards. This information will be store securely in a locked cabinet in the principal investigators office and when stored electronically will be stored on an encrypted device.

Statistical Methods

Baseline characteristics will be compared between the intervention and control groups to assess possible imbalances. Differences in the primary and secondary outcomes between the intervention and control groups will be analyzed using an analysis of covariance (ANCOVA) approach. Specifically, we will use the following regression equation for our main analysis: Follow-up score at 6 months = constant + beta0*baseline PDC score + beta1*group, whereby beta0 and beta1 are estimated coefficients and group is an indicator variable coded 1 for intervention and 0 for control. The effect of interest – the estimated difference in PDC change between the intervention and control groups is given by the coefficient beta1. The PDC at baseline is adjusted for in the analysis and is represented by the variable baseline PDC score.

In addition to our main analysis, we will conduct several secondary analyses to measure the effect of our intervention on all secondary outcomes. These will include, but are not limited to, investigating whether age, sex or disease severity affect study outcomes. Standard model diagnostics will be conducted to check for model assumptions in all analyses. All analysis will be intention to treat. Multiple imputation will be used to account for missing data.

Implications of the Study

The most recent report from the Canadian Institute of Health Information states that COPD accounts for the highest rate of hospital admission among major chronic illnesses. As such, the demand on the healthcare system could be large. However, the literature previously cited suggests that as COPD adherence is optimized, pulmonary exacerbations (both community-treated and those requiring hospitalization) may be reduced. A reduction in hospitalizations has the potential to allow patients to continue to be active members of society, decrease work absenteeism, and reduce overall health care and societal costs associated with the disease. As medications are optimized through ideal inhaler technique and improved adherence, we expect patients' quality of life to improve. As such, we expect that the pharmacist intervention described in this proposal will be a cost-effective if not cost-saving intervention that will make efficient use of scarce resources and improve patient outcomes.

1. Canadian Institute for Health Information. Health indicators.

https://secure.cihi.ca/free_products/HealthIndicators2008_ENGweb.pdf. Updated 2008. Accessed 05/04/2017

Protocol Amendments:

Any protocol amendments will be submitted to the NL Health Research Ethics Board for approval and noted in the registered protocol at the International Standard Randomised Controlled Trial Number (ISRCTN) register, once the trial is registered. Trial participants will be notified should relevant protocol changes be made.

Access to Data:

All investigators, research assistants, and data analysts will have access to the trial data.

Dissemination of Results and Publication Policy

End of Grant Knowledge Translation:

We will disseminate our results to a broader audience of relevant knowledge users and decision makers including healthcare professionals, policy makers, and other researchers. In particular, we will highlight these results to relevant bodies such as the NL Lung Association and the Department of Health and Community Services with the Government of Newfoundland and Labrador. We plan to present results at relevant conferences (e.g., Canadian Pharmacists Association Annual Meeting, Canadian Respiratory Conference) and pursue publication in peer-reviewed journals.

Project Timeline

See study timeline document

Competing Interests:

JH has provided paid pharmacist education on behalf of Boerhinger Ingelheim. CM has been an advisor for Glaxo Smith Kline and Boerhinger Ingelheim and has been given research contracts from Boerhinger Ingelheim Canada and Boerhinger Ingelheim Global. JF has provided paid family physician education on behalf of Glaxo Smith Kline, Boerhinger Ingelheim and AstraZeneca. JL has provided paid physician education and acted as an advisor for AstraZeneca, Glaxo Smith Kline, Boerhinger Ingelheim, Intermune and Roche, and has received conference support from AstraZeneca. ED, JMG, MF, WA and CG have no conflicts to declare.

The study funders have no role in the study design, data collection, management, analysis, or interpretation, the writing of the report or the decision to submit for publication.

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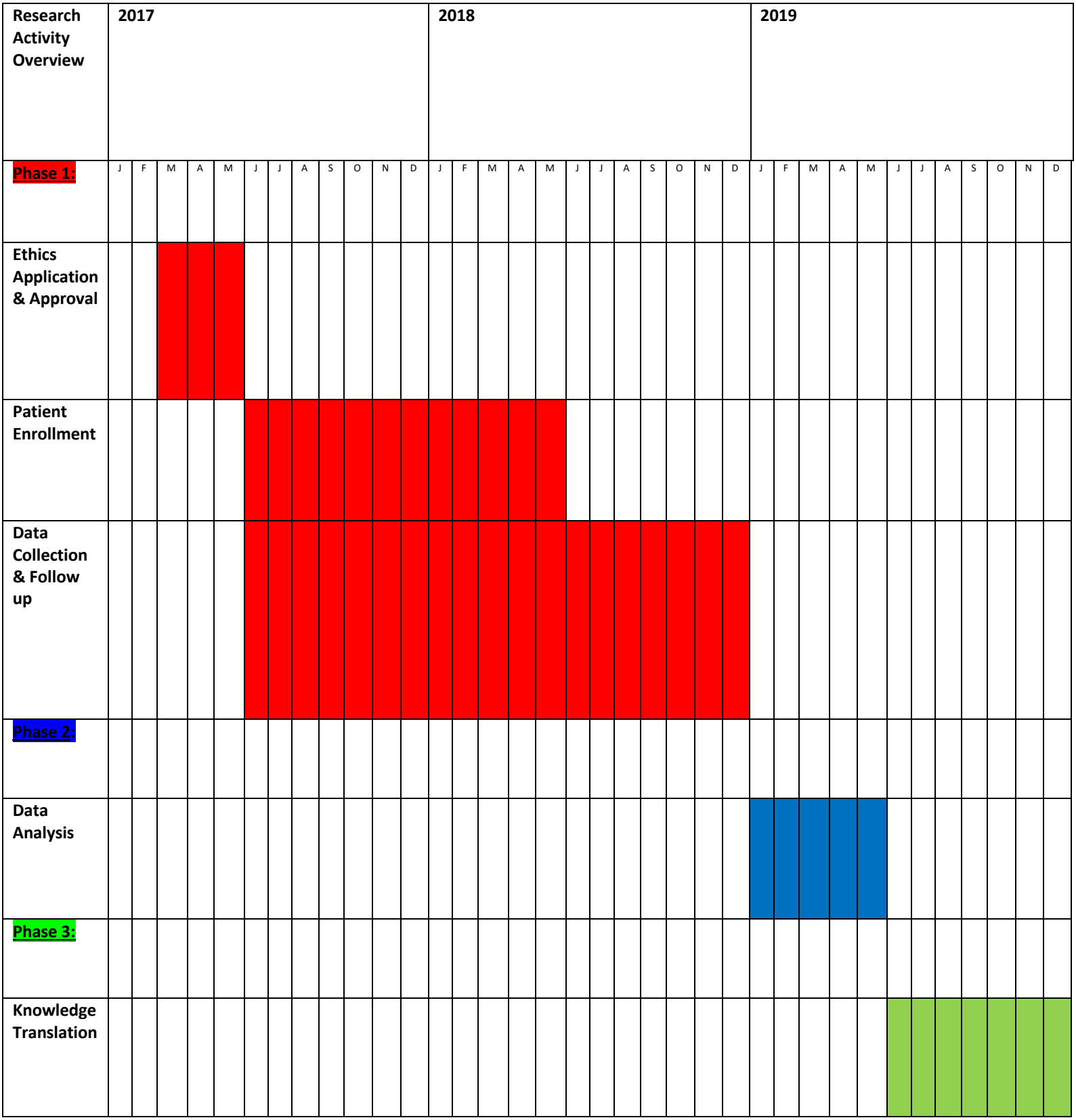
Research Activity Overview
2017
2018
2019
J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D
Phase 1:
Ethics Application & Approval
Patient Enrollment
Data Collection & Follow up
Phase 2:
Data Analysis
Phase 3:
Knowledge Translation

Budget

Item		Year 2	Year 3	Total
RA		31800	31800	63600
Data Analyst				18 000
Materials & Supplies				
	Computer & Software	1800		1 800
	Phone Costs	185	185	555
	Office Supplies	200		400
	Photocopying Costs	150		300
Knowledge Translation				
	International Conference	3800	3800	7160
	National Conference		3800	3800
	Publication			4 000
				100,055

Appendix A

Study Log

	Name, Contact Information	Date (dd/mm/yy)	Consent (check)	Eligible (Y/N)	RA Initials
Subject Number: #____ ____ ____ **Notes:**	**Name:** _____ **Phone #:** _____ **Email:** _____				
Subject Number: #____ ____ ____ **Notes:**	**Name:** _____ **Phone #:** _____ **Email:** _____				
Subject Number: #____ ____ ____ **Notes:**	**Name:** _____ **Phone #:** _____ **Email:** _____				

Patient Data Collection for Control and Intervention Groups Time Zero

Name: (Mr. / Mrs. / Ms.) _____
(Please circle one) Last Name First Name

_____
Street Address Town/City

_____
Province Postal Code Email

Telephone Number(s) Home _____ Cell _____
Area Code Area Code

Date of Birth (dd/mm/yy): _____

Sex: Male____ Female____ Other_____

Weight: _____ pounds OR _____ kg Height: _____inches OR _____ cm

Which best represents your smoking history?

☐Never smoked
☐Previous smoker quite _____ years ago
☐Currently smoke _____ packs per day

MEDICATION LIST FOR COPD: Received information from: ☐ Patient ☐ Physician

INHALED MEDICATIONS (record dose and directions please)		
☐ Advair MDI/Diskus	☐ Anoro Ellipta	☐ Atrovent HFA
☐ Breo Ellipta	☐ Bricanyl Turbuhaler	☐ Combivent Respimat
☐ Combivent UDV	☐ Duovent UDV	☐ Foradil
☐ Onbrez Turbuhaler	☐ Oxeze Turbuhaler	☐ Seebri Breezhaler
☐ Serevent	☐ Spiriva Handihaler	☐ Spiriva Respimat
☐ Symbicort Turbuhaler	☐ Tudorza Genuair	☐ Ultibro Breezhaler
☐ Ventolin MDI/Diskus	☐ Anoro Ellipta	

OTHER: ☐ Roflumilast ☐ Theophylline ☐ _____

Patient Data Collection for Control and Intervention Groups at 6 Months

Name: (Mr. / Mrs. / Ms.)
(Please circle one)

Last Name First Name

Street Address Town/City

Province Postal Code Email

Telephone Number(s) Home _____ Cell _____
Area Code Area Code

Date of Birth (dd/mm/yy): _____

Sex: Male____ Female____ Other_____

Weight: _____ pounds OR _____ kg Height: _____inches OR _____ cm

Which best represents your smoking history?

☐Never smoked
☐Previous smoker quite _____ years ago
☐Currently smoke _____ packs per day

1. MEDICATION LIST FOR COPD: Received information from: ☐ Patient ☐ Physician

INHALED MEDICATIONS (record dose and directions please)		
☐ Advair MDI/Diskus	☐ Anoro Ellipta	☐ Atrovent HFA
☐ Breo Ellipta	☐ Bricanyl Turbuhaler	☐ Combivent Respimat
☐ Combivent UDV	☐ Duovent UDV	☐ Foradil
☐ Onbrez Turbuhaler	☐ Oxeze Turbuhaler	☐ Seebri Breezhaler
☐ Serevent	☐ Spiriva Handihaler	☐ Spiriva Respimat
☐ Symbicort Turbuhaler	☐ Tudorza Genuair	☐ Ultibro Breezhaler
☐ Ventolin MDI/Diskus	☐ Anoro Ellipta	

OTHER: ☐ Roflumilast ☐ Theophylline ☐ _____

<u>6-MONTH ASSESSMENT ONLY</u>

2. HEALTH CARE RESOURCE AND MEDICATION UTILIZATION:

Number of physician visits over the last 6 months: _____
Number of hospitalizations over the last 6 months: _____
Did you attend pulmonary rehabilitation during the last 6 months: ☐ Yes ☐ No

Antibiotics required during the last 6 months:

Name	Dose	Indication

Oral corticosteroid use during the last 6 months:

Name	Dose	Indication

INHALER TECHNIQUE ASSESSMENT

MDI[1]: **Score: ___/8**

1. ☐ Remove cap
2. ☐ Shake well
3. ☐ Breath out normally
4. ☐ Keep head upright or slightly tilted
5. ☐ Seal lips around mouthpiece
6. ☐ Inhale slowly, actuating once during first half of inhalation
7. ☐ Continue slow and deep inhalation
8. ☐ Hold breath for 5 or more seconds

MDI WITH SPACER[1]: **Score: ___/8**

1. ☐ Remove caps
2. ☐ Shake MDI well
3. ☐ Insert MDI into spacer
4. ☐ Breathe out normally
5. ☐ Seal lips around mouthpiece
6. ☐ Actuate MDI
7. ☐ Inhale slowly and deeply
8. ☐ Hold breath for 5 or more seconds

DISKUS[1]: **Score: ___/8**

1. ☐ Open to expose mouthpiece
2. ☐ Slide lever until click heard
3. ☐ Keep level throughout
4. ☐ Breathe out normally and away from inhaler
5. ☐ Seal lips around mouthpiece
6. ☐ Inhale forcefully and deeply
7. ☐ Hold breath for 5 or more seconds
8. ☐ Exhale but not through inhaler

TURBUHALER[1]: **Score: ___/7**

1. ☐ Hold upright without occluding air vents
2. ☐ Turn coloured wheel one way, then back
3. ☐ Breathe out normally and away from mouthpiece
4. ☐ Seal lips around mouthpiece without occluding air vents
5. ☐ Inhale forcefully and deeply
6. ☐ Hold breath for 5 or more seconds
7. ☐ Exhale but not through inhaler

HANDIHALER[1]: **Score: ___/9**

1. ☐ Open lid and mouthpiece
2. ☐ Place capsule in chamber
3. ☐ Close mouthpiece, ensuring click is heard
4. ☐ Holding inhaler upright, press blue button fully
5. ☐ Breathe out normally and away from inhaler
6. ☐ Seal lips around mouthpiece
7. ☐ Inhale forcefully and deeply so that capsule vibrates
8. ☐ Hold breath for 5 or more seconds
9. ☐ Repeat steps 6-8

BREEZHALER[2]: **Score: ___/11**

1. ☐ Pull off the cap and open the mouthpiece
2. ☐ Remove capsule from package and place in chamber
3. ☐ Close mouthpiece until you hear it click
4. ☐ Press side buttons once and release
5. ☐ Breathe out
6. ☐ Seal lips around mouthpiece
7. ☐ Breathe in quickly and deeply (a whirring noise should be heard)
8. ☐ Hold breath for 5-10 seconds
9. ☐ Breathe out
10. ☐ Open the mouthpiece
11. ☐ If capsule is not empty repeat steps 5-9

GENUAIR[3]: **Score: ___/12**

1. ☐ Remove the protective cap by squeezing the arrows and pulling outwards
2. ☐ Hold horizontally with the green button facing up
3. ☐ Press the green button all the way down and then release
4. ☐ Check the control window has turned green
5. ☐ Breathe out fully
6. ☐ Seal lips around mouthpiece
7. ☐ Breathe in strongly and quickly
8. ☐ You will hear a click sound
9. ☐ Hold breath for 5-10 seconds
10. ☐ Remove inhaler from mouth
11. ☐ Ensure control window has turned red
12. ☐ If window is still green repeat steps 5-9

Score: ___/9

ELIPTA[4]:

1. ☐ Hold the inhaler in an upright position
2. ☐ Slide the cover down until you hear a click
3. ☐ Breathe out fully
4. ☐ Seal lips around the mouthpiece
5. ☐ Don't block the air vents with your fingers
6. ☐ Take one long, steady, deep breath in
7. ☐ Hold breath for at least 3-4 seconds
8. ☐ Remove the inhaler from your mouth
9. ☐ Breathe out slowly and gently

RESPIMAT[5]: **Score: ___/9**

1. ☐ Hold the inhaler upright with the cap closed
2. ☐ Turn the transparent base until it clicks
3. ☐ Open the cap
4. ☐ Breathe out slowly
5. ☐ Insert the mouthpiece
6. ☐ Point the inhaler towards the back of the throat
7. ☐ While taking a deep breath, press the dose-release button and continue to breathe
8. ☐ Hold your breath for 10 seconds, or as long as it is comfortable
9. ☐ Then breathe out slowly

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ST. GEORGE'S RESPIRATORY QUESTIONNAIRE for COPD patients

(SGRQ-C)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life.
We are using it to find out which aspects of your illness cause you most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

ID:_____

Date: _____/_____/_____(dd/mm/yy)

Before completing the rest of the questionnaire:
Please select one box to show how you describe your current health:

Very good	Good	Fair	Poor	Very poor
☐	☐	☐	☐	☐

Version: 1st Sept 2005

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ST. GEORGE'S RESPIRATORY QUESTIONNAIRE
PART 1

Questions about how much chest trouble you have.

Please select **ONE** box for each question:

Question 1. I cough:

most days a week…… ☐ **a**

several days a week…… ☐ **b**

only with chest infections…….. ☐ **c**

not at all……. ☐ **d**

Question 2. I bring up phlegm (sputum):

most days a week…… ☐ **a**

several days a week…… ☐ **b**

only with chest infections…….. ☐ **c**

not at all……. ☐ **d**

Question 3. I have shortness of breath:

most days a week…… ☐ **a**

several days a week…… ☐ **b**

not at all……. ☐ **c**

Question 4. I have attacks of wheezing:

most days a week…….	☐ **a**
several days a week…….	☐ **b**
a few days a month……..	☐ **c**
only with chest infections…….....	☐ **d**
not at all……	☐ **e**

Question 5. How many attacks of chest trouble did you have during the last year?

3 or more attacks……	☐ **a**
1 or 2 attacks……..	☐ **b**
none……	☐ **c**

Question 6. How often do you have good days (with little chest trouble)?

no good days……	☐ **a**
a few good days……...	☐ **b**
most days are good……..	☐ **c**
every day is good…….	☐ **d**

Question 7. If you have a wheeze, is it worse in the morning?

no…… ☐ **a**

yes…….. ☐ **b**

ST. GEORGE'S RESPIRATORY QUESTIONNAIRE
PART 2

8. ***How would you describe your chest condition?***

Please select ***ONE:***

Causes me a lot of problems or is the most important problem I have…..	☐ **a**
Causes me a few problems ……	☐ **b**
Causes no problem…….	☐ **c**

9. ***Questions about what activities usually make you feel breathless.***

For each statement please select ***the box*** that applies to you **these days:**

	True	**False**	
Getting washed or dressed……...	☐	☐	**a**
Walking around the home……	☐	☐	**b**
Walking outside on the level……...	☐	☐	**c**
Walking up a flight of stairs……	☐	☐	**d**
Walking up hills……...	☐	☐	**e**

10. ***Some more questions about your cough and breathlessness.***

For each statement please select ***the box*** that applies to you **these days:**

	True	**False**	
My cough hurts……..	☐	☐	**a**
My cough makes me tired…….	☐	☐	**b**
I am breathless when I talk ……...	☐	☐	**c**
I am breathless when I bend over……..	☐	☐	**d**
My cough or breathing disturbs my sleep ……	☐	☐	**e**
I get exhausted easily……	☐	☐	**f**

11. ***Questions about other effects that your chest trouble may have on you.***

	True	**False**	
My cough or breathing is embarrassing in public…….	☐	☐	**a**
My chest trouble is a nuisance to my family, friends or neighbours.	☐	☐	**b**
I get afraid or panic when I cannot get my breath…….....	☐	☐	**c**
I feel that I am not in control of my chest problem……..	☐	☐	**d**
I have become frail or an invalid because of my chest…….	☐	☐	**e**
Exercise is not safe for me……	☐	☐	**f**

Everything seems too much of an effort……..	☐	☐	**g**

12. ***These are questions about how your activities might be affected by your breathing.***

For each statement, please select ***the box*** that applies to you **because of your breathing:**

	True	**False**	
I take a long time to get washed or dressed……..	☐	☐	**a**
I cannot take a bath or shower, or I take a long time……	☐	☐	**b**
I walk slower than other people, or I stop for rests……..	☐	☐	**c**
Jobs such as housework take a long time, or I have to stop for rests	☐	☐	**d**
If I walk up one flight of stairs, I have to go slowly or stop……	☐	☐	**e**
If I hurry or walk fast, I have to stop or slow down…….	☐	☐	**f**
My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls or play golf…….	☐	☐	**g**

My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis, or swim…….	☐	☐	**h**

13. ***We would like to know how your chest trouble usually affects your daily life.***

For each statement please select ***the box*** that applies to you **because of your breathing:**

	True	**False**	
I cannot play sports or games……	☐	☐	**a**
I cannot go out for entertainment or recreation……	☐	☐	**b**
I cannot go out of the house to do the shopping……...	☐	☐	**c**
I cannot do housework…….	☐	☐	**d**
I cannot move from my bed or my chair…….	☐	☐	**e**

14. ***How does your chest trouble affect you?***

Please select ***ONE:***

It does not stop me doing anything I would like to do …….	☐	**a**
It stops me doing one or two things I would like to do…….	☐	**b**
It stops me doing most of the things I would like to do……	☐	**c**
It stops me doing everything I would like to do……	☐	**d**

Thank you for filling in this questionnaire.

Before you finish, would you please check to see that you have answered all of the questions.

ASK THE BREATHWORKS COACH

I know I will always have COPD. What can I do to manage it?

COPD is a chronic disease, which means it cannot be cured. However, there are many ways you can manage COPD so that you can do the things you want to do.
To stay healthy, you need to understand your disease and learn how to manage it.

Here is what you can do:

- quit smoking (most important)
- exercise regularly
- eat well
- get an annual flu shot each fall
- get a pneumonia shot
- wash your hands regularly
- take your medications properly
- learn how to live with COPD
- follow your action plan

1. Quit smoking

It is never too late to quit. Although quitting smoking will not fix the damage that has already been done to your lungs, it can help prevent more damage. Quitting smoking is hard but it is the best thing you can do to feel better.

THE LUNG ASSOCIATION™
When you can't breathe, nothing else matters.

BREATHWORKS™

Fact Sheet

July 06

2. Exercise regularly

Regular exercise is important. If your muscles are in shape, they can work with less oxygen. That means you don't have to breathe in as much air to do the same amount of work. You are stronger and can do more before you feel tired. There are special exercise programs for people with COPD. These programs, called pulmonary rehabilitation programs, are run by health professionals who can help you find the exercise that you can do and enjoy. (To learn more about programs, check out The Lung Association fact sheet: **Pulmonary Rehabilitation**.) Contact your provincial Lung Association to find out if there is a pulmonary rehabilitation program in your area.

3. Eat well

By eating well, you will have more energy to breathe properly and do the things you want to do. Eating healthy foods will help you maintain your weight, feel good about yourself, and reduce your risk of serious health problems like diabetes and stroke.

Tips for eating well:

- Eat a variety of foods, especially fruit, vegetables and whole grains.
- Avoid greasy food or junk foods.
- Limit salt, alcohol and caffeine.

For more information about eating well, refer to Canada's Food Guide. Developed by Health Canada, the Food Guide is available for download at http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/order commander/index_e.html or you can order a copy by calling 1-800-O-Canada. If you have more specific questions about your diet, talk to a dietician.

4. Get the flu shot

To help you to stay healthy, ask your doctor or health-care provider about getting a flu shot. This should be done every year in the fall. A person who has an allergy to eggs should not get the flu shot.

5. Get the pneumonia shot

Another way you can stay healthy is to get the pneumonia shot. The pneumonia shot is not given every year, but some people may need to repeat the pneumonia shot every five to ten years. Talk to your doctor or health-care provider about getting the pneumonia shot.

6. Wash your hands

Proper hand washing can help reduce your chances of getting a cold or the flu. Always wash your hands before eating or preparing a meal and after using the toilet.

Remember, stay healthy and follow your action plan.

7. Take your medications properly

If your COPD medication is not getting in to your lungs, it cannot do its job. That is why it is important to follow your doctor's instructions exactly when taking any medications. Ask your respiratory educator or health-care provider to watch you use your medication device to make sure that your medication is getting in to your lungs.

8. Learn how to live with COPD

COPD affects almost everything you do. It may be hard to do some of the things that you used to enjoy. You may also get tired quickly. When you learn how to manage your COPD, you can enjoy the things you want to do. You can learn to pace yourself. Talk to your doctor or respiratory educator about ways to manage your COPD.

9. Follow your action plan

An action plan is a written set of instructions from your doctor. It explains what medication you should be taking on a daily basis when you feel well and how to increase your medication if your breathing problems get worse. Your action plan can help you to deal with any problems before they get worse.

What can I do to manage flare-ups?

What is a flare-up?

A flare-up is what happens when your COPD starts getting worse. You may have one or more of the following for 48 hours or longer:

- more shortness of breath than usual
- more coughing
- more mucus than usual
- mucus changes colour

What causes a flare-up?

Flare-ups can be caused by:

- infections
- smoke
- dust
- allergens
- air pollution
- strong fumes or odours
- weather changes (cold air, hot air or humid air)
- stress

How can I avoid flare-ups?

You can avoid flare-ups by learning what makes your COPD worse and what to do before it gets worse. For example, if cold air bothers you, cover your mouth and nose with a scarf (wrapped loosely). Another example may be to take your medication before walking on a windy day. Talk to your doctor about preparing an action plan. An action plan can help you recognize early signs of a flare-up and what steps you can take.

What should I do if I start to have a flare-up?

Follow your action plan. It will tell you what to do if your breathing is getting worse, what medications to take and when to seek medical help.

Sometimes flare-ups still happen, despite your best efforts to prevent them. If you learn to recognize when the flare-up is starting, you may have time to start treatment before your flare-up hits full force. Early treatment could save you from having to stay in hospital.

Remember, begin to manage your flare-up as early as possible.

Signs that the flare-up may be getting worse:

- an increase in the thickness or stickiness of your mucus
- chest pain
- fever
- swollen ankles
- needing to sleep sitting up instead of lying down
- morning headaches, dizziness, trouble sleeping, confusion
- blue lips or fingers
- feeling sick

If you notice any of the above signs, call your doctor right away. If you can't reach your doctor, have someone drive you to the nearest emergency room.

If you are ever unsure about what to do, call your doctor and ask for guidance

If you have any of the following, go to the emergency room immediately. Call 9-1-1 or an ambulance. Do not drive yourself.

- sudden, extreme breathlessness
- sudden chest pain
- feeling confused, agitated or drowsy

What can I expect at the hospital?

- You will be asked what medications you currently take so it is a good idea to always have an up-to-date list of all your medications (including how much you take and how often) that you can bring with you.

- You will be asked questions about your COPD.
- You will be given medications to open your airways so you can breathe easier.
- Your pulse, temperature and blood pressure will be taken.
- You may be given oxygen with a mask.
- An attachment may be placed on one of your fingers. This measures the oxygen in your blood.
- An intravenous or IV may be started. This provides another way of giving you medication to open your airways.
- You may be given an anti-inflammatory to decrease swelling in your airways.
- You may be given an antibiotic if your flare-up is due to a lung infection.

What should I do before I leave the hospital?

Make sure you understand any medication changes that have been made at the hospital. This includes medications that have been started or increased during your hospital stay. You should know how long to keep taking each medication and when you should decrease or stop taking them.

If the hospital staff thinks it will take more than a few days for your emergency room record to reach your doctor, it might be a good idea to ask for a copy to take home with you.

What happens when I go home?

Within 2-3 days of leaving the hospital, you should call your doctor for an appointment. You and your doctor need to talk about why you ended up in the emergency room so you can prevent it from happening again.

Your doctor will also need to know about any medications you were given, any new drugs or any increase in the dose of your usual medications. Your doctor can also tell you how long to keep taking the medication prescribed at the hospital before returning to your regular medication routine.

Your doctor may also want you to see a respiratory educator who can help you manage your COPD

Remember, always keep an up-to-date list of your medications including how much you take and how often you take them.

COPD ACTION PLAN FOR _____

CONTACT INFORMATION	
Name: _____	Phone Number: _____
Dr.: _____	BreathWorks Helpline: 1-866-717-2673
Hospital Emergency #: _____	Respiratory Educator: _____
Pharmacist (name): _____	Phone #: _____
Phone #: _____	

I FEEL WELL	WHAT SHOULD I DO?
• My breathing problems have not changed (shortness of breath, cough, and mucus). • My appetite is normal. • I have no trouble sleeping. • I am able to exercise and do my daily activities as usual.	Continue taking my medications as prescribed by my doctor. _____ _____ _____ _____

I FEEL DIFFERENT	WHAT SHOULD I DO?
• I am feeling stressed or have been exposed to things that make my breathing worse. • I am more short of breath than usual. • I am coughing or wheezing more than usual. • I have more mucus than usual.	• Try to avoid or stay away from what is making my breathing worse. • Breathe from my diaphragm or with pursed-lips. • Lean forward. Relax my neck, shoulders and arms. • If standing, lean against a wall with my feet slightly apart. • Take my medications, especially my reliever. _____

I FEEL DIFFERENT (Infection)	WHAT SHOULD I DO?
• I have increased shortness of breath. • I have more mucus than usual. • I have green or yellow mucus with or without a fever.	Call my contact person or doctor. Start my treatment as soon as possible. Start my antibiotic _____ for ____ days. _____ _____ Start Prednisone _____ for ____ days. _____ **IF MY SYMPTOMS DO NOT IMPROVE AFTER 48 HOURS, I WILL CALL MY DOCTOR. IF IT IS AFTER OFFICE HOURS, I WILL GO TO THE EMERGENCY ROOM.**

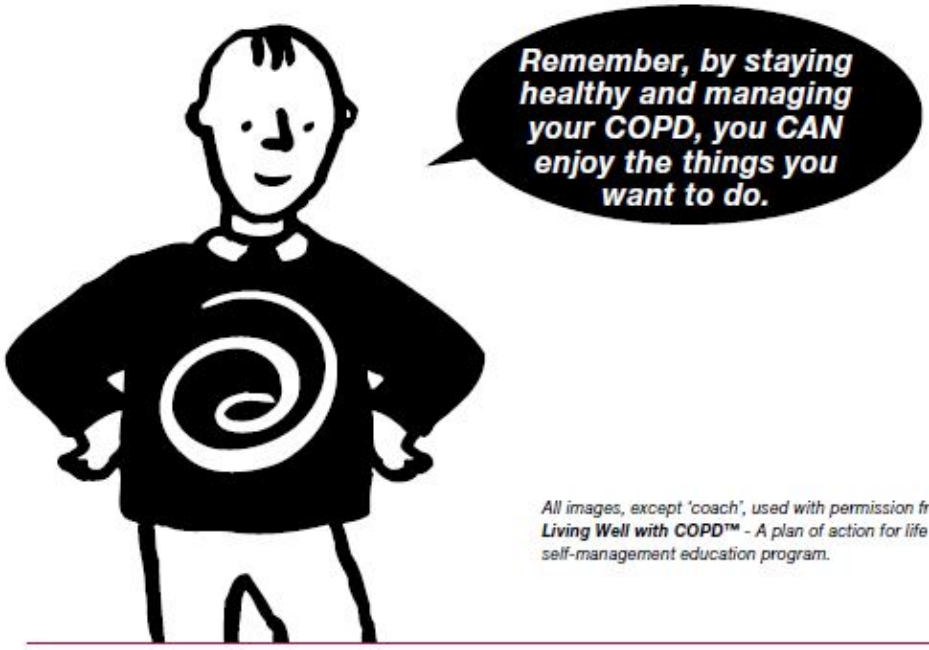
I FEEL I AM IN DANGER	WHAT SHOULD I DO?
• I am extremely short of breath. • I am confused, agitated or drowsy. • I have sudden chest pain.	CALL 911

A respiratory educator can help you to manage your flare-up with an action plan.

It is important to see your doctor on a **regular basis** in order to help manage your COPD.

You should go to emergency when your breathing is getting much worse, your treatment is not improving your breathing or you feel uncomfortable staying at home because of your breathing.

If you do not see your doctor on a regular basis and instead go to emergency for ongoing care, you may not benefit from the follow-up that your doctor and health team can provide.



*All images, except 'coach', used with permission from **Living Well with COPD™** - A plan of action for life self-management education program.*

Get the information and support you need from one of our **Breathworks COPD educators.**

Phone **1-866-717-COPD (2673)** or visit us online at **www.lung.ca/breathworks.**

BREATHWORKS™

My COPD Action Plan _____ Date _____
Patient's Copy
(Patient's Name)

Canadian Respiratory Guidelines

COPD
Treatable. Preventable.

This is to tell me how I will take care of myself when I have a COPD flare-up.

My goals are _____
_____

My support contacts are _____ and _____
(Name & Phone Number) (Name & Phone Number)

My Symptoms	I Feel Well	I Feel Worse	I Feel Much Worse URGENT
I have sputum.	My usual sputum colour is: _____	Changes in my sputum, for **at least** 2 days. *Yes* ☐ *No* ☐ OR	My symptoms are not better after taking my flare-up medicine for 48 hours.
I feel short of breath.	When I do this: _____ _____	More short of breath than usual for **at least** 2 days. *Yes* ☐ *No* ☐	I am very short of breath, nervous, confused and/or drowsy, and/or I have chest pain.

My Actions	Stay Well	Take Action	Call For Help
	I use my daily puffers as directed.	If I checked 'Yes' to one or both of the above, I use my **prescriptions** for COPD flare-ups.	I will call my support contact and/or see my doctor and/or go to the nearest emergency department.
	If I am on oxygen, I use _____L/min.	I use my daily puffers as usual. If I am **more** short of breath than usual, I will take ____ puffs of _____ up to a **maximum** of ____ times per day.	**I will dial 911.**
		I use my breathing and relaxation methods as taught to me. I pace myself to save energy.	**Important information:** I will tell my doctor, respiratory educator, or case manager **within 2 days** if I had to use any of my flare-up prescriptions. I will also make follow-up appointments to review my COPD Action Plan twice a year.
		If I am on oxygen, I will increase it from ___ L/min to ___ L/min.	

Notes:

THE LUNG ASSOCIATION™ L'ASSOCIATION PULMONAIRE

CANADIAN THORACIC SOCIETY SOCIÉTÉ CANADIENNE DE THORACOLOGIE

Produced in collaboration with the *COPD & Asthma Network of Alberta (CANA)*. *The Canadian Thoracic Society (CTS)* acknowledges the past contributions of *Living well with COPD* and the *Family Physician Airways Group of Canada*.

PART 1 OF 2

Canadian Respiratory Guidelines

COPD ACTION PLAN (Patient's copy)

Why do I need this COPD Action Plan?

- Your Action Plan is a written contract between you and your health care team. It will tell you how to manage your COPD flare-ups. Use it along with any other information you get from your health care team about managing your COPD every day.
- Your Action Plan will help you and your caregivers to quickly recognize and act to treat your flare-ups. This will keep your lungs and you as healthy as possible.

How will I know that I am having a COPD "flare-up"?

- You will often see a change in your amount or colour of sputum and/or you may find that you are more short of breath than usual. Other symptoms can include coughing and wheezing more.
- Your flare-up Action Plan is to be used only for COPD flare-ups. Remember that there are other reasons you may get short of breath, such as when you have pneumonia, are anxious, or have heart problems.
- Before or during a flare-up you may notice changes in your mood, such as feeling down or anxious. Some people have low energy or feel tired before and during a COPD flare-up.

What triggers a "COPD flare-up"?

- A COPD flare-up can sometimes happen after you get a cold or flu, or when you are stressed and run down.
- Being exposed to air pollution and changes in the weather can also cause COPD flare-ups. To learn about the daily air quality in your area, visit Environment Canada's Air Quality Health Index (AQHI) website at www.ec.gc.ca/cas-aqhi/ and click on 'Your Local AQHI Conditions'. Ask your health care team about ways to avoid all possible triggers.

When should I use this COPD Action Plan?

- Your COPD Action Plan is used only for COPD flare-ups.
- Remember that there are other reasons you may get short of breath, such as when you have pneumonia, are anxious, or have heart problems. If you become more short of breath but don't have symptoms of COPD flare-up, see a doctor as soon as possible.

REMEMBER:

- Learn about your COPD from a respiratory educator, credible websites, such as www.lung.ca, and education programs.
- Take your regular daily medicine as prescribed.
- Don't wait more than 48 hours after the start of a COPD flare-up to take your antibiotic and/or prednisone medicines. See your pharmacist quickly to get your prescriptions for COPD flare-up.
- When you start an antibiotic, make sure that you finish the entire treatment.
- Quitting smoking and making sure that your vaccinations are up-to-date (for flu every year and for pneumonia at least once) will help prevent flare-ups.
- Be as active as possible. Inactivity leads to weakness, which may cause more flare-ups or flare-ups that are worse than usual. Ask your doctor about pulmonary rehabilitation and strategies to help reduce your shortness of breath and improve your quality of life.
- Follow up with your doctor within 2 days after using any of your prescriptions for a COPD flare-up.

MY NOTES AND QUESTIONS:

My COPD Action Plan _____ Date _____
Patient's Copy (Patient's Name)

Canadian Respiratory Guidelines

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(Name & Phone Number) (Name & Phone Number)

Prescriptions for COPD flare-up (Patient to take to pharmacist as needed for symptoms)

These prescriptions may be refilled two times each, as needed, for 1 year, to treat COPD flare-ups. Pharmacists may fax the doctor's office once any part of this prescription has been filled.

_____ _____
Patient's Name Patient Identifier (e.g. DOB, PHN)

1. (A) If **the colour** of your sputum **CHANGES**, start antibiotic _____ Dose:_____ #pills:_____
How often_____ for #days:____

(B) If the first antibiotic was taken for a flare-up in the **last 3 months**, use this different antibiotic instead:
Start antibiotic _____ Dose:_____ #pills:_____
How often_____ for #days:____

AND / OR

2. If you are **MORE short of breath** than usual, start prednisone _____ Dose:_____ #pills:_____
How often:_____ for #days:____

Once I start any of these medicines, **I will tell** my doctor, respiratory educator, or case manager within **2 days**.

_____ _____ _____
Doctor's Name Doctor's Fax Doctor's Signature

_____ _____
License Date

THE LUNG ASSOCIATION™ L'ASSOCIATION PULMONAIRE

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