Project Title: Patients with COPD preferences, activities, and participation survey

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1.0 Rationale

Chronic obstructive pulmonary disease, also known as COPD, is a debilitating disease that affects a growing percentage of the Canadian population (Public Health Agency of Canada, 2007). COPD is characterized by chronic and progressive airflow limitations causing shortness of breath, chronic cough, and sputum production (Public Health Agency of Canada, 2008). COPD includes chronic bronchitis and emphysema, as well as other similar respiratory illnesses and is primarily caused by smoking cigarettes, though other causes do exist (Public Health Agency of Canada, 2008). The airflow limitation can affect oxygen transfer in the lungs, increasing the effort required to perform activities of daily living such as: walking, climbing stairs, and gardening (Annegarn et al., 2012). To date, COPD is not fully reversible, but various treatments (e.g., exercise, medications) are available to help manage the disease. Approximately 4% of the Canadian population report being diagnosed with COPD; however, 13% of Canadians were found to have a lung function score indicative of COPD (Statistics Canada, 2013). It is believed that COPD will become the third leading cause of death by 2030, and according to the last World Health Organization estimate in 2004, 64 million people are currently living with COPD (World Health Organization, 2015).

COPD has a large impact on the well-being and quality of life of patients living with the disease. Individuals living with COPD are aware of their worsening well-being and quality of life (Disler et al., 2014). They are required to make drastic lifestyle changes in order to minimize lung function declines. These lifestyle changes include smoking cessation, adoption of an exercise program to maximize oxygen transfer in muscle and reduce whole body oxygen demands, and an extensive medication regime (George, Kong, Thoman, & Stewart, 2005). Patients mostly rely on their health care providers to present them with the necessary information about their disease and how to modify their lifestyle. However, patients appear to have different expected outcomes from COPD interventions compared to their health care providers; such as, for end of life care (Cooke & Campbell, 2014). These conflicting expectations can reduce the positive impact that providers can have on their patients. For this reason it has become critical to understand the patients' perspectives and priorities related to their health care, as well as, to the COPD research that may influence their care. In fact, it is not until recently that patient involvement in health research has become recognized as an important next step to identify the outcomes that matter most to

individuals who are diagnosed with COPD (Celli et al., 2015). Recent evidence suggests that research does not necessarily align with the underlying needs of patients suffering from life-limiting illness such as COPD (Cooke & Campbell, 2014). This evidence is concerning as patient-centered outcome-focused interventions have been found to work better with COPD patients than interventions that aim to improve surrogate outcomes (Celli et al., 2015). It is now necessary to understand patients' main concerns regarding COPD (e.g., alleviate dyspnea), what they wish to see in future COPD research and what information they would like from their health care provider. It is only by getting their perspectives on these matters that we can move to enhance the well-being and quality of life of adults living with COPD. This study therefore aims to fill these critical gaps in the COPD literature.

To get a better understanding of the life domains that are most important and critical for adults with COPD, we need to identify key daily activities and examine the extent to which participating in these activities are difficult and the reasons that may hamper participation (e.g., breathlessness). To get at this understanding we have grounded the study in the International Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2002) and focused on the activities and participation domains of the ICF. The ICF defines activities as "the execution of a task or action by an individual" and participation as "involvement in a life situation" (World Health Organization, 2002). Activities includes all daily activities that individuals partake in on a regular basis; such as, walking, bathing, and preparing meals. Participation focuses on social and leisure activities; such as, maintaining relationship with friends and family or accessing community services. By identifying which items in the activity and participation domain of the ICF are difficult for people living with COPD, we will be able to generate a better understanding of their needs and priorities. This knowledge could then inform health care providers and health researchers about the activities that patients want to participate in and which barriers are limiting the potential for participation. In addition, we can have a better understanding of the activities that have the most positive and/or negative impact on their well-being and quality of life.

2.0 Purpose

The overall goal of this study is to identify the priorities of individuals living with COPD in terms of their activities and participation, as well as their research priorities and health care concerns. To achieve this overall goal, the study is divided into three phases (see Figure 1). The purpose of the *first phase* is to develop and pilot test a questionnaire created for individuals living with COPD to assess their activities, participation, and health care and COPD-related research priorities. The Activities, Healthcare and Research Priorities Questionnaire (AHRPQ) was developed based on past research, then verified by a panel of COPD and participation experts to gather their opinions and recommendations. The AHRPQ was then examined by adults with COPD in focus groups, where they provided feedback on the content and readability of the questionnaire. Five focus group participants were also invited to complete the full survey online as an initial pilot test.

The purpose of the *second phase* of the study is to compare across diagnosed COPD stages and disease severity the extent to which adults with COPD participate in the listed activities and identify their primary research and health-care related priorities. The AHRPQ will be administered at three sites across Montreal where clinical data for each participant will be available. This phase will also help establish the reliability of the questionnaire.

In the *third phase*, the purpose is to administer the questionnaire to a pan-Canadian sample to identify the activities that individuals living with COPD participate in, the barriers that limit their participation in these activities, the activities that are of most importance for this population, and their health concerns and research priorities. We will also be examining the relationship between participation and quality of life related outcomes. The questionnaire will be distributed to a larger population of individuals living with COPD who self-report their COPD diagnostic/severity.

This amendment is to add the protocol for the *second phase* of the study. We presented the overall goal in order to contextualize the current application.

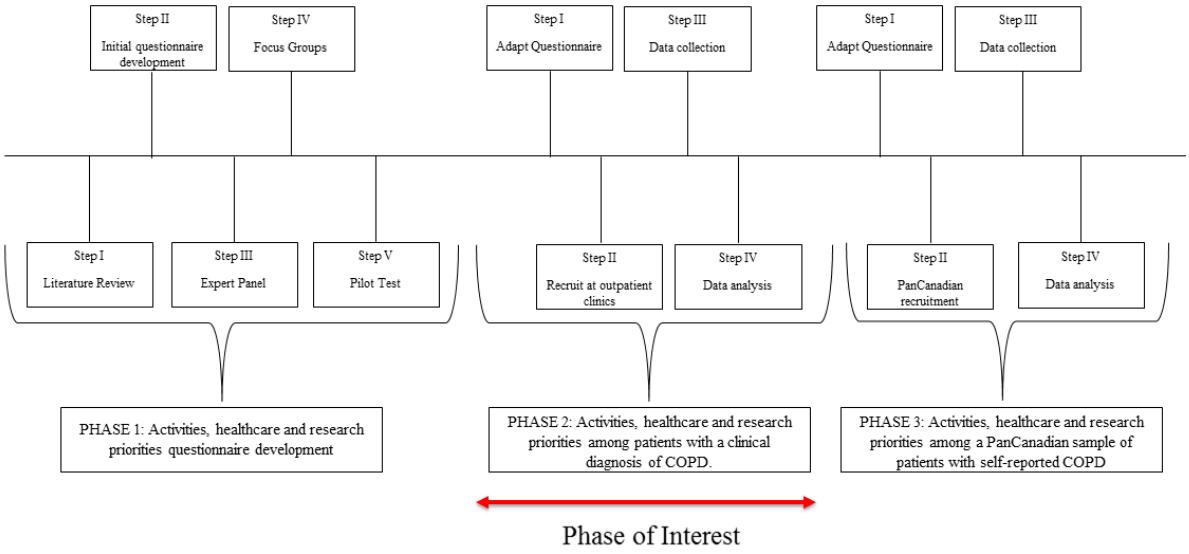

Figure 1: The three phases of the study, broken down into each step of the phases. The identified phase (Phase 2) is the following protocol amendment.

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2.1 Expected Outcomes

Patients living with COPD are not always provided with sufficient information to answer their questions concerning the disease and its impact on quality of life. The debilitating nature of COPD has a large impact on the daily, social and community activities performed by people living with COPD. By gathering information on the extent to which people with COPD want to participate in various activities and the barriers to their limit their participation, we will better understand the needs of this population. This information can then be disseminated to health care providers and health researchers. A second benefit of this study is understanding the specific health topics that are most important to people living with COPD. Because health care providers are the primary source of information for this population, prioritizing these health topics can greatly improve patient care. Lastly, identifying the patients' COPD research priorities can guide future research on the domains that are most important to this population. By improving our understanding of the specific activities and topics that are prioritized by people living with COPD, we can better inform future research and hopefully improve the care and management of COPD.

The results of the study will be disseminated through conference presentations and publications in peer-reviewed journals. A lay summary will be distributed to the COPD community (e.g., through the Quebec Lung Association) and related health care professionals once the results have been finalized.

3.0 Protocol

Phase 2 of the study will take place in the participants' location of choice as they will either complete the study online or over the telephone with a research assistant.

Recruitment will take place at the three sites involved in the project, the Chest Institute at the MUHC Glen site, Mount Sinai Hospital, and the Lakeshore General Hospital. In collaboration with the COPD clinic at each site, research assistants will obtain permission to approach participants in the waiting rooms or before/after COPD rehabilitation sessions to explain the study and questionnaire package. The research assistants will then inform interested participants of three possible options to complete the questionnaire package: (a) on a tablet and onsite (e.g., in waiting room or another room nearby), (b) at home, online, (c) at home over the telephone with a research assistant. Participants who choose (a) the research assistants will provide a tablet and remain with them until the questionnaire is complete. If participants choose (b) or (c), the research assistant will collect the person's email address and/or telephone number and subsequently either email them the link to the survey or call them to complete the survey. If participants are undecided, the research assistant will give them a business card (APPENDIX C) with an email and a phone number to contact.

Across all three methods of data collection (a to c), participants will complete the screening form and consent form (APPENDIX A and B) prior to answering the questionnaire package. The screening form assesses the eligibility of potential participants by determining whether participants have been diagnosed with COPD by a health care professional, are above the age of 18 and able to read and write in English or French. Participants who consent to the study will agree to complete the questionnaire package and to provide the research team access to their medical information for comparative analyses. For participants who want to respond to the questionnaire over the telephone, the research assistant will complete the forms directly online.

Before the questionnaire package has been completed, participants will be prompted to provide their full name, date of birth and street name to gather their medical chart information. Their street name will be asked to ensure that the correct individual in the system has been identified. Participants will be compensated $50 for their time and any inconveniences experienced by answering the questionnaire. If they choose to stop taking part in the study, they will not be compensated for the study.

The questionnaire package contains the AHRPQ (APPENDIX D) and additional questionnaires (APPENDIX E) to gather information on other aspects of their lives. Specifically, these additional questionnaires are: the Godin Leisure Time Physical Activity Questionnaire, the Medical Research Council Questionnaire on Breathlessness, the Charlson Comorbidities Index, the COPD Assessment Test, the Satisfaction with Life Questionnaire, the St. George's Respiratory Questionnaire, the Canadian Cohort Obstructive Lung Disease CanCOLD questionnaire, and demographic information (i.e., age and gender).

The information gathered from the medical charts includes participants: COPD status/severity (GOLD stage, % predicted FEV_1, FEV_1/FVC); comorbidities (confirming the self-report responses from the Charlson Comorbidities Index questionnaire (Appendix E; e.g., diabetes, cardiovascular disease, mental health, asthma)); Smoking cessation (confirming the self-reported smoking cessation answered by the participant in the Medical Research Council

questionnaire on breathlessness (Appendix E); and gather other health related information such as height and weight.

4.0 Potential harms and risks

We do not foresee any potential harms to the participants by completing the questionnaire. The participant has the right to skip any question he or she feels uncomfortable answering in the questionnaire as outlined in the consent form.

The risks of the proposed research are acceptable given the potential benefits of the research. Although there are no known risks of participating in this study, participants are informed that they do not have to answer any questions that make them uncomfortable, without providing a reason for abstaining from said question. They can leave or skip a question in the questionnaire at any time, without providing a reason, by exiting the web page containing the questionnaire or if answering by phone letting the research assistant know. There is no penalty for skipping or leaving the questionnaire.

5. 0 Confidentiality

All information presented during the study is confidential and will be available only to Drs. Sweet and Jensen and their research assistants. Any information obtained in connection with this study and that can be identified in connection with the participant will remain confidential and will be disclosed only with the participants' permission. The participant will also be assigned an identification number upon completing the questionnaire package. All of their data will be referred to by this identification number to ensure anonymity of all information received. We are also asking permission to access the participants' medical records, as highlighted in the consent form. Information from the medical records will be assigned the same identification number to keep the data confidential. This identification number will be used for comparative purposes only. Data collected from medical records will be entered in a database and only be connected through the participant's identification number. Therefore, after all data have been extracted they will be confidential.

Participants who complete the questionnaire online or with a research assistant will be asked to provide their mailing information for compensation purposes. The link provided to those who complete the questionnaire is a secure link (https://www.surveygizmo.com/s3/3030935/COPD-questionnaire-Phase-2) specific to the questionnaire hosted on the survey developing website SurveyGizmo. The mailing information collected while completing the questionnaire will be gathered on a separate survey within SurveyGizmo, and therefore, will not be linked with the data they provided. Only the principal investigators (Dr. Shane Sweet and Dr. Dennis Jensen) and their research assistants will have access to the electronic and hard copies of the study material. Participants mailing information will also be used to confirm participants medical chart information if there is more than one individual with the same name.

The results from this study will be published in academic journals, presented at scientific conferences, and distributed to related health care professionals and the COPD community. The participants name will not be disclosed in either of these circumstances. Information collected will be erased seven years after the publication of the results.

5.1 Data storage

All data used for analyses and reporting purposed will be unidentified and replaced with identification numbers. Only Drs. Jensen and Sweet and their research assistant will have access to the list of identification numbers. The list will be stored in a password-protected file on password-protected computer in a locked office in Currie Gymnasium (room 235/236) at McGill University. The questionnaire information will be stored on the SurveyGizmo servers (with project data encryption) and later downloaded to a password protected computer/laptop for data analyses purposes. Medical chart information will be stored in a password protected file on a password protected computer/laptop. Only the principle investigators (Dr. Shane Sweet and Dr. Dennis Jensen) as well as their research assistants will have access to the questionnaire data and medical chart information gathered. The mailing information, used for compensation purposes and to confirm the participant's identity in the medical charts, will be stored in a password protected file on a password protected computer/tablet for seven years after the study has been published.

Data will be stored for seven years after the publication of the results of the study. After this time, electronic data will be completely deleted from the computers.

5.2 Exceptions of confidentiality

Any information provided by the participants will be kept confidential. Identifiable information will only be used to gather participant specific information. Participant confidentiality will be maintained expect for the mailing information provided by the participants to the research team. Participants mailing information will be provided to McGill Finance and will not be attached to any submitted questionnaire data. McGill Finance will be provided the mailing information of the participants for compensation purposes only. This mailing information data will be used to compensate participants for their time and any inconvenience; as well as, confirm the participants in the medical charts in the event multiple people have the same name. Any other information will only be shared with the principle investigator (Dr. Dennis Jensen and Dr. Shane Sweet) and their research assistants.

6.0 Informed consent process

Individuals who are interested in participating in the study on site will be provided with a tablet to answer the questionnaire and will read the consent form prior to answering the questionnaire. They will be providing consent online, by selecting next when presented with the statement "By clicking on the Next button below you are consenting to participate in this research study".

Those who chose to answer the questionnaire at home online will be provided with a secure link to the consent form. Individuals who complete the questionnaire online will need to provide electronic consent prior to advancing on to the questionnaire. They will read over the information

and consent letter and click the Next button to indicate consent to participate (APPENDIX B). Participants who chose to answer the questionnaire via telephone will be given the consent information either by email, mail or read the consent form by a research assistant prior to answering the consent form online. In these instances, verbal consent will be accepted.

Consent will be obtained from all participants prior to completing the questionnaire online or over the telephone.