ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

Drug Class Review: Inhaled corticosteroids (ICS) + long-acting beta-agonists (LABA) combination products for treatment of chronic obstructive pulmonary disease (COPD)

Comprehensive Research Plan: Qualitative Research

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Objectives:	To explore factors related to the experience of ICS/LABA prescription, dispensing and use for COPD. To determine the social acceptability of policy recommendations for ICS/LABA use (COPD indication).
Study Questions:	What is the perceived effectiveness of ICS/LABA? What is the impact of ICS/LABA on quality of life? What is the experience of patients using ICS/LABA regarding the access of these drugs? What is the experience of clinicians/pharmacists in prescribing/dispensing these drugs? To what extent are the policy recommendations feasible and acceptable? *Note that the qualitative component will be conducted in two phases.*

Phase 1: Exploration of factors affecting the dispensing and utilization of drugs within the drug class of interest

Study Design:	This phase will utilize qualitative methods in a framework approach, which is an accepted practice in applied health studies.[2] The framework approach will guide the data collection and analysis processes. The primary source of data for this study will be one-on-one interviews. Field notes from interviews will also be made by the interviewer, and will be used a secondary source of data to incorporate into analysis.
Study Population:	Identified stakeholders for the ICS/LABA drug class review include primary care physicians (PCPs), respirologists, pharmacists, and patients. Patients' caregivers may be considered. Inclusion criteria are: clinicians (PCPs, respirologists, pharmacists) who have prescribed or dispensed ICS/LABA; and patients with COPD who have current or prior experience using ICS/LABA.

Methods	A purposive sampling approach using a convenience sample will be used in order to elicit the specific perceptions and opinions of those who will be involved in or affected by drug policy decisions. Clinicians will be recruited through circles of contact, professional networks and snowball recruitment. Publicly available contact information will also be searched to develop contact lists. An ODPRN member or study coordinator will make contact with clinicians by phone, e-mail or fax. Patients will be recruited through circles of contact. A patient recruitment flyer will also be sent to participating clinicians who agree to distribute the flyer to patients. Patient networks will be used to send recruitment notices by e-mail. General calls for recruitment of all eligible groups will be placed in professional newsletters, e-blasts and social media (Twitter, Facebook). We will aim to recruit 6 to 8 participants from each identified stakeholder group and 20-25 patients, which may be sufficient to reach saturation amongst homogenous groups of participants. [1] *Data Collection and Analysis* Qualitative data will be collected through one-on-one, semi-structured telephone interviews. Interviews with PCPs, respirologists and patients will be 45 minutes in length. Interviews with pharmacists will be 30 minutes in length. All interviews will be guided by a semi-structured interview guide, and will be audio recorded and transcribed verbatim. Interview transcripts will comprise the primary source of data. A secondary source of data will be field notes, made by a note taker that will be present at each interview. Data will be analyzed using a framework approach. A framework for analysis will be developed after an initial review of the primary and secondary data sets. The framework will be applied to the data in subsequent sets to derive key policy-relevant concepts. Emerging codes will be incorporated to the framework to integrate unexpected results.A final framework will be developed and reported to the ODPRN after thorough analysis of all data.

Outcome(s) of Interest:	• Experiences of COPD and COPD therapy • Experiences accessing ICS/LABA through Ontario Drug Benefit • Experiences accessing ICS/LABA through other means • Experiences treating and dispensing medication to patients with ICS/LABA • Perceived safety and effectiveness of ICS/LABA • Perceived barriers to access and health equity issues
Phase 2: Assessment of the social acceptability of recommended policy actions related to the drug class of interest	
Study Design:	RAND Appropriateness Method and Survey
Study Population:	Representatives of the general public, stakeholder groups (PCPs, respirologists, pharmacists, patients), patient advocacy groups, topic-specific interest groups, and industry

Methods

- **To determine the social acceptability of each of the recommendations at the level of the general population**, we will recruit a diverse set of individuals who are members of the general public and have no experience with ICS/LABA or COPD. Feedback from participants will be obtained in a webinar using the RAND Appropriateness Method[3]. Participants will be invited to attend the meeting by an e-mail invitation sent by the study coordinator. At the meeting, we will present key issues, findings and policy implications. Group members will then be asked to rate or prioritize a series of questions related to the feasibility and acceptability of the policy recommendations, discuss these questions, then re-rate and prioritize them. This approach allows each person to express their idea(s); each person's opinion is taken into account (compared to traditional voting where only the largest group is considered).
- **To determine the social acceptability of each of the recommendations among stakeholders**, we will develop and distribute an online survey measuring aspects of social acceptability including affordability, accessibility and appropriateness. The survey will be developed in FluidSurvey. The study coordinator will send the survey link and report through e-mail to participants who took part in the phase 1 interviews and agreed to be contacted for follow-up. The survey link will also be sent to patient advocacy groups, topic-specific interest groups, and industry by e-mail. Contact information for these groups will be obtained through ODPRN circles of contact or on organization websites. Survey analysis will include descriptive statistics (e.g., mean, standard deviation, median) and thematic content analysis for open-ended questions.

Outcome(s) of Interest: Feasibility and acceptability of draft recommendations.