ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

Drug Class Review: Long-acting muscarinic antagonists (LAMAs) for treatment of chronic obstructive pulmonary disease (COPD)

Comprehensive Research Plan: Qualitative Unit

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ODPRN Drug Class Review Proposal: Qualitative Study

Study Title: Long-Acting Muscarinic Agents (LAMAs) for the treatment of Chronic Obstructive Pulmonary Disorder (COPD)

Objectives:

To explore factors related to the experience of LAMAs prescription, dispensing and use for COPD.

To determine the social acceptability of policy recommendations for LAMA use (COPD indication).

Study Questions:

What is the perceived effectiveness of LAMAs?

What is the impact of LAMAs on quality of life?

What is the experience of patients using LAMAs 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 LAMAs 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 LAMAs; and patients with COPD who have current or prior experience using LAMAs. We will be approaching the same individuals who participated in our ICS/LABA drug class review to participate in the current review on LAMAs.

Methods	Individuals who participated in the ICS/LABA qualitative study and who agreed to be contacted for follow up will be approached to complete a follow-up survey regarding LAMAs. Given that many of the issues regarding COPD management from stakeholder perspectives were already captured in the ICS/LABA interviews, as well as information on LAMAs themselves as part of an overall approach to COPD management, the survey will be distributed to probe additional details on the use, prescription and dispensing of LAMAs and associated factors such as effectives, patient adherence and access. If all individuals do not agree to participate in a follow up survey, additional individuals (i.e. those not part of the original ICS/LABA study) will be recruited to participate in full-length one-on-one telephone interviews. Additionally, a sample of patients who are using LAMAs but not ICS/LABA will be invited to participate in interviews. 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 include 6 to 8 participants from each identified clinician (i.e. physicians and pharmacists) group and 20-25 patients, which may be sufficient to reach saturation amongst homogenous groups of participants. [1] For the current study, this sample will include those who were interviewed in the ICS/LABA review and participated in a follow-up survey, as well as those who were newly recruited to the study. *Data Collection and Analysis* Qualitative data were/will be collected through one-on-one, semi-structured telephone interviews. Interviews were/will be 30 minutes in length. All interviews were/will be guided by a semi-structured interview guide, and will be audio recorded and transcribed verbatim. Interview transcripts (from ICS/LABA and LAMA reviews) will comprise the primary source of data. A secondary source of data will be survey data, collected electronically using Fluid Surveys. Qualitative 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. Survey data will be analyzed using descriptive statistics (mean, standard deviation, and frequency of responses). Open-ended survey responses will be analyzed using a content analysis approach; these results will be integrated to the framework of findings.
Outcome(s) of Interest:	• Experiences of COPD and COPD therapy • Experiences accessing LAMAs through Ontario Drug Benefit • Experiences accessing LAMAs through other means • Experiences treating and dispensing medication to patients with LAMAs • Perceived safety and effectiveness of LAMAs • 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 LAMAs or COPD. Feedback from participants will be obtained in a online surveys (Fluid Surveys) and 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. Prior to the meeting, participants will be asked to read the consolidated report of findings produced by the ODPRN, and to respond to a short online survey to rank policy options. At the meeting, we will present key issues, findings and policy implications. Group members will then be asked to discuss and rate or the feasibility and acceptability of the policy recommendations; after the meeting, meeting participants will have the opportunity to re-rate and prioritize policy options in a second online survey. 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 Fluid Surveys. 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.

Deliverables

We will provide a detailed written report of our methods and results. Additionally, we will develop a publication to be submitted to an academic journal when appropriate.

References

1. Kuzel, AJ. (1999). "Sampling in qualitative inquiry." In BF Crabtrree and WL Miller (Eds.) Doing Qualitative Research (second edition). Thousand Oaks, CA: Sage Publications (pp. 33-45).
2. Ritchie J, Spencer L. (1994). Qualitative data analysis for applied policy research. In Bryman A, Burgess R, eds. *Analysing Qualitative Data*. London: Routledge: 173-194.
3. Brook, R.H. (1994). The RAND/UCLA Appropriateness Method. In McCormick, K.A., Moore, S.A., & Siegal, R.A. (eds.) Clinical practice guideline development. Methodology perspectives. US Department of Health and Human Services, Rockville, Maryland, 59-70