

ODPRN Drug Class Review Proposal: Qualitative Study

Study Title: Triptans for the treatment of migraines in adults

Objectives: To explore factors related to the experience of triptan prescription, dispensing and use for acute migraines.

To determine the social acceptability of resultant policy recommendations.

Study Questions: What are patients', prescribers' and pharmacists' experiences with triptan use for acute migraines, including accessibility of these drugs under Ontario Drug Benefit?

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 triptans drug class review include primary care physicians (PCPs), neurologists, pharmacists, and patients. Inclusion criteria are: clinicians (PCPs, neurologists, pharmacists) who have prescribed or dispensed triptans; and patients with migraine who have current or prior experience using triptans.

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 using triptans. 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, neurologists 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 migraine and migraine therapy
- Experiences accessing triptans through Ontario Drug Benefit
- Experiences accessing triptans through other means
- Experiences treating and dispensing medication to patients with triptans
- Perceived safety and effectiveness of triptans
- 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, neurologists, 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 meant to represent the general population. Feedback from participants will be obtained in a half-day meeting using the RAND Appropriateness Method³. Participants will be invited to attend the meeting by an e-mail invitation sent by the study coordinator. At the workshop, we will present key issues, findings and clinical implications. Group members will then be asked to rate or prioritize a series of questions, 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.

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.

Timelines

Table 1 demonstrates the proposed timeline for Phase 1 of the drug class review in three parts:

- Part 1 begins approximately 2 weeks prior to official start of review. This part will include steps 1 – 3 and will involve general preparation, including developing the interview guide, recruitment pool, and protocol.
- Part 2 (4 weeks) includes steps 4 – 6 and will involve conducting activities that will form the key concepts and messages to develop project proposals. At the end of this phase, a brief report will be delivered to all teams within the FMU to inform these proposals.
- Part 3 (14 weeks) includes steps 7 – 10 and will involve a more in-depth, rigorous qualitative analysis. This phase will end with the delivery of a qualitative report to inform the draft policy recommendations.

At the end of the formulation of draft policy recommendations, the social acceptability phase will begin and will last 4 weeks.

References

1. Kuzel, A.J. (1999). "Sampling in qualitative inquiry." In BF Crabtree 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