ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

The Ontario Drug Policy Research Network Drug Class Review on Cognitive Enhancers for the Treatment of Dementia

Report of Qualitative Study Results

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Executive Summary

Background: The Ontario Drug Policy Research Network (ODPRN) conducted a drug class review of cognitive enhancers for the treatment of dementia, which was selected as part of a formulary modernization initiative by the Ontario Public Drug Programs. The cognitive enhancers drug class review was an extension of a previous review conducted by the ODPRN on atypical antipsychotics for dementia. This report highlights the findings of the qualitative study performed within the drug class review to determine the experiences of managing and treating dementia with cognitive enhancers.

Methods: Mixed methods (interviews and surveys) were used in a framework approach. Given the overlap between the atypical antipsychotics (AAP) and cognitive enhancer reviews, a similar sample was used for both studies. A survey was developed and distributed to newly recruited participants and past interview participants from the AAP review with questions about the use, prescription, and dispensing of cognitive enhancers. One-on-one telephone interviews were conducted with new or past participants, such as physicians (primary care physicians, long term care physicians, geriatric psychiatrists, and geriatricians), family members of patients, health navigators (CCAC workers), and pharmacists. Interviews were recorded and analyzed using a framework for pharmaceutical policy analysis (i.e. the "Triple-A" framework: affordability, appropriateness, and accessibility of medications). Emergent findings were integrated to our framework, and the framework was adapted to convey specific experiences and perceptions relevant to funding policies pertaining to cognitive enhancers. Survey results were analyzed using descriptive statistics (e.g., mean, standard deviation, count, proportion) and content analysis on open-ended responses.

Key Findings: Findings in this report are summarized to represent common experiences and perceptions described across patient, physician, health navigator, and pharmacist groups.

Perception of cognitive enhancers: Clinician and health navigator participants perceived that some family members of dementia patients may have a false expectation that the cognitive enhancer medication will improve the patient's cognition, rather than slowing its decline. Clinician, health navigator, and family member participants found it difficult to perceive the exact effectiveness of cognitive enhancers. Most did not perceive them to be extremely effective. Donepezil was perceived to be the most commonly used cognitive enhancer for patients with Alzheimer's Disease. Other commonly prescribed products were galantamine and memantine.

Prescription of cognitive enhancers: Clinician participants reported that the severity of a patient's dementia is one of the main factors that should influence a physician's decision to prescribe a cognitive enhancer. They described that cognitive enhancers are not useful for patients with severe dementia; some participants suspected that many of these patients may be unnecessarily prescribed cognitive enhancers, particularly in long term care settings.

Clinician and health navigator participants were also asked to comment on their perception of cognitive assessment tools, since these tools are often used to gauge a patient's need for cognitive enhancers. The majority of participants did not prefer to use the Mini Mental State Exam (MMSE) because it is privatized, and participants perceived that it was not a sensitive test and was not applicable for those from different cultural or linguistic backgrounds. Many physician participants preferred the Montreal Cognitive Assessment (MoCA) because they believed that it provided a better measure of executive domain function and was easier to administer and score. Clinician and health navigator participants also described concerns that many patients may not be monitored appropriately once they have been prescribed cognitive enhancers.

Access to cognitive enhancers: Clinician and family member interviewees said that patients over 65 years or those living in long term care do not have barriers to accessing commonly prescribed products on the ODB formulary, such as donepezil and galantamine. Some participants did mention that there are a select few patients who may benefit from memantine, however if they don't have private coverage they are not able to afford it. Clinician interviewees also mentioned the need for the rivastigmine patch formulation, which is not currently on the formulary. In particular, the interviewees said that many patients tolerate the patch better than the pill formulation. Lastly, when asked about the ODB limited use criteria, some clinician and health navigator participants expressed that they wished for the criteria to be revised to include scores from alternative testing such as the MoCA.

Conclusion: Overall, our findings shed light on the experiences of prescribing and using cognitive enhancers for dementia, and unveil important information that can impact how patients in need can access these drugs across Ontario.

Part 1: Background

The Ontario Drug Policy Research Network (ODPRN) recently received funding to conduct a series of drug class reviews as part of an initiative to update the public drug formulary (i.e. formulary modernization). As such, the ODPRN works closely with the Ontario Public Drug Programs (OPDP) and the Ministry of Health and Long-Term Care (MOHLTC) to select key priority areas and topics for formulary modernization, then conduct independent drug class reviews, and disseminate the results of each of these reviews directly to the OPDP to facilitate informed decision making on public drug funding policies. Cognitive enhancers, for the treatment of dementia, were selected as the topic for the eighth drug class review.

Currently, there is limited information on how physicians decide to prescribe cognitive enhancers. Moreover, we require additional information on the factors that contribute to accessing cognitive enhancers. Currently, cognitive enhancers, such as Aricept ®, are listed under the limited use program on the ODB formulary.

Phase I of the ODPRN qualitative unit work involved exploring the various factors that may be related to

the prescription, dispensing, and use of cognitive enhancers for dementia. This information was important for understanding and contextualizing prescription and usage patterns in Ontario, as well as to highlight any health equity issues that may be prevalent but are currently unknown. The findings from the qualitative study expand on those from the atypical antipsychotics for dementia review. Phase II of the ODPRN qualitative work involved assessing the social acceptability and feasibility of the final results and recommendations proposed by the ODPRN research team.

Part 2: Phase I Methods

Design

This study was conducted using mixed methods: interviews and surveys. We used a framework approach (Ritchie & Spencer, 1994), which helps researchers focus on specific areas of interest, resulting in findings that may be more applicable and relevant to policy questions. However, the approach also enables the incorporation of new ideas, emergent issues, or unanticipated results. The framework selected for this study was the "Triple-A" framework (see **Appendix A**) for pharmaceutical policy analysis developed by Morgan et al. (2009). This framework highlights the need to explore affordability, accessibility, and appropriateness of drugs when determining policy-relevant issues.

Sampling

Stakeholders identified for the cognitive enhancers drug class review include: primary care physicians (PCPs), long-term care physicians, geriatricians, geriatric psychiatrists, pharmacists, heath navigators, nurses, support staff, and family members of patients. Inclusion criteria are: clinicians (PCPs, geriatricians, geriatric psychiatrists, long-term care physicians, and pharmacists) who have prescribed or dispensed cognitive enhancers to elderly dementia patients and family members of elderly dementia patients who have current or prior experience using cognitive enhancers. The nursing and support staff group includes nurses or personal support workers who have experience providing care and administering cognitive enhancers to elderly dementia patients. The health navigator group includes staff from community care access centres (CCACs), such as case managers or nurse practitioners, as well as hospital discharge workers or social workers, who may have experience coordinating care for elderly dementia patients.

A purposive sampling approach was used to obtain a convenience sample in order to elicit the specific perceptions and opinions of those who will be involved in or affected by drug policy decisions related to cognitive enhancers. Recruitment methods included: a) cold calling; b) e-mailing and faxing; c) recruiting at primary care and specialist clinics; d) sending recruitment letters through e-mail distribution lists of professional organizations and advocacy groups; e) posting recruitment notices to the ODPRN website and social media (e.g., Twitter, Facebook) accounts; and g) snowball sampling (asking participants to connect with individuals they know who may be able to offer valuable insight to the issue for the

purpose of recruitment to the study).

We aimed to recruit 6-8 participants from all stakeholder groups (clinicians, family members and health navigators). We anticipate this amount of participation may be sufficient to reach saturation amongst relatively homogenous groups of participants.

Two groups of participants were engaged for the cognitive enhancers review. The first group consisted of atypical antipsychotics drug class review participants. These participants were re-contacted because of the similar context around dementia care for both the AAP and CE drug class reviews. To reduce burden and redundancy for participants, an abbreviated interview was conducted that focused on use of cognitive enhancer medications for dementia. The second group of participants was individuals who fulfilled the study eligibility criteria, but had not participated in a drug class review before. These participants engaged in a full-length interview focused on dementia care and cognitive enhancer medications for dementia. Once saturation was reached in the interview stage, a follow-up survey was developed and distributed to newly recruited participants and past interview participants from the AAP review with questions about use, prescription, and dispensing of cognitive enhancers.

Data Collection and Analysis

Qualitative data were collected through one-on-one, semi-structured telephone interviews and electronic surveys. Interviews and surveys were 30 – 60 minutes and 15 minutes in length, respectively. All interviews were guided by a semi-structured interview guide, audio recorded and transcribed verbatim. The semi-structured interview guide was developed using the "Triple-A" framework for pharmaceutical policy analysis (Morgan et. al., 2009) and input from clinicians and the drug class review team. Each interview was audio recorded. Surveys were administered through Fluid Surveys. Interviews and surveys will comprise the primary source of data for the final report. Secondary sources of data consist of a qualitative literature review on cognitive enhancers for dementia and interviewer and/or note taker field notes.

The framework approach was used to guide qualitative data analysis. Two independent analysts engaged in familiarization of the data by reading all primary and secondary data sources and generating initial codes that could be incorporated into the "Triple-A" framework (Morgan et. al., 2009). These codes comprised the coding framework. A modified coding consensus approach was used, due to the small number of transcripts. The framework was received by the qualitative research team and applied to 20% of transcripts by two analysts during in-depth analysis. Inter-rater reliability between the two analysts was > 80%. The remaining transcripts were coded by a single analyst. The analysts and the qualitative research team engaged in mapping and interpretation of the coded data to generate the final themes.

Survey data were analyzed using descriptive statistics (e.g., mean, standard deviation, count,

proportion) and content analysis for open-ended responses.

Phase II of the qualitative research study is described later on in the report.

Research Ethics

This study was approved by the St. Michael's Hospital Research Ethics Board in Toronto, Ontario, Canada.

Part 3: Phase I Findings

A total of 43 participants took part in the study. Thirty-four individuals participated in surveys (10 nurses, 17 physicians, 11 family members) and 9 individuals participated in interviews (3 CCAC workers, 1 pharmacist, 1 nurse, 2 physicians, 2 family members). Detailed participant demographics can be found in **Appendix B**.

Key Themes Related to the Prescription and Use of Cognitive Enhancers for Dementia

The following findings are based on the experiences and perceptions of interview/survey participants, which have been summarized into three themes. Please note that the term 'clinician' may be used to refer to physicians, pharmacists, and nurses and the term "participants" may be used to refer to both survey and interviewee participants. References to "comments" are descriptions of survey responses to open ended questions.

Perceptions of Cognitive Enhancers

- Perceptions of purpose
- Perceptions of effectiveness
- Perceptions of specific products

Prescription of Cognitive Enhancers

- Factor that influence prescription
- Perception of cognitive assessment tools
- Monitoring of effectiveness

Access to Cognitive Enhancers

Detailed findings on each of these themes are described below.

Perceptions of Cognitive Enhancers

Perceptions of the purpose of cognitive enhancers

All clinician and health navigator participants in this study were in consensus regarding their perceptions of the purpose of cognitive enhancers, including that: a) they provide a stabilizing effect on the disease progression; b) improvement in symptoms is not likely; and c) at some point the patient will no longer benefit from cognitive enhancers because the disease will progress in spite of the medication.

Clinician and health navigator interviewees perceived that many family members of patients, and patients themselves, may have a false perception that cognitive enhancers will treat dementia or cause an improvement in symptoms. They speculated that this belief may be perpetuated by general practitioners who lack expertise with dementia or by societal norms which point to pharmacological therapy as the solution to illness. Family member interviewees also shared the hope they had for cognitive enhancers to improve the patient's cognition and the desire to have their loved one take it even if they did not perceive any immediate benefit. Physician survey respondents commented that the false expectations of family members and the "*difficulty in persuading families to discontinue*" is one of the key challenges with the prescription of cognitive enhancers.

> "*Society's got these beliefs about, you know, like, "If I've got a cough, I'm going to go to the pharmacy, buy a cough syrup, and I'll be better. If I've got a headache, I'm gonna pop an Advil, and I'll be better, and then if my mom's got Alzheimer's I'm gonna give her this medication and she's gonna better," and … the very best we can hope for is a reduction in the rate of worsening*" – Pharmacist Interviewee

> "*The families seem to take some solace in the fact that there is a medication that they feel is treating the dementia or, that's usually their perception is that it's treating the dementia and not so clearly communicated to them that it's maybe helping to slow down the progression of the dementia*" –Health Navigator Interviewee

Perceptions of the effectiveness of cognitive enhancers

Physician, nurse, and family member survey respondents were asked to rate effectiveness of cognitive enhancers on a scale from 1 to 7 with 1 being not at all effective and 7 being extremely effective. Interestingly, clinician respondents always ranked outcomes slightly more favorably than family members (Table 1). However, the range of ratings for physicians and nurses was from 3.25 to 5.25, suggesting that they did not perceive these medications to be extremely effective for any of the expected outcomes.

Table 1. Perceived effectiveness of cognitive enhancers according to expected outcomes (1 = not at all effective and 7 = extremely effective).

Expected Outcomes	Physicians (N=15)	Nurses (N=10)	Family Members of Patients (N=9)
	M (SD)	M (SD)	M (SD)
Improving functional status (e.g., ability to carry out daily activities)	3.53 (1.55)	3.28 (1.77)	3.00 (1.80)
Improving cognitive ability (e.g., memory, use of telephone)	3.80 (1.32)	3.25 (1.39)	2.78 (2.17)
Improvement in behavioural and psychology symptoms of dementia	4.27 (0.88)	5.25 (0.71)	2.89 (1.54)
Improvement in quality of life	4.13 (1.13)	5.25 (0.46)	3.33 (1.87)
Preventing decline of cognitive performance	3.47 (1.8)	4.25 (1.39)	3.11 (1.9)
Slowing decline of cognitive ability (e.g., stabilizing dementia)	4.60 (1.35)	4.38 (1.51)	3.56 (2.13)

Physician survey respondents commented that the "*Inability to determine effectiveness*" is another key challenge with the prescription of cognitive enhancers. Since dementia is a progressive disease, clinicians may find it difficult to determine the impact of the medication on the rate of cognitive decline. Family member survey respondents commented that they were unsure of whether the medication had any benefit and that they had no way of assessing how their loved one would have functioned without cognitive enhancers. They were asked to rate their level of satisfaction with the cognitive enhancer medication their family member was currently using on a scale of 1 to 7, with 1 being completely dissatisfied, and 7 being completely satisfied. The average satisfaction rating was 4.80 (SD = 0.84), indicating that participants were neither satisfied nor dissatisfied.

> "*My greatest frustration was understanding whether the enhancer was in any way slowing down the progression… If she had not been on an enhancer from the start, would it have meant she would have needed to go into a home somewhat sooner? I just don't know*" –Family Member

Survey Respondent

Half of family member survey respondents reported that their loved one discontinued cognitive enhancers because of side effects, such as diarrhea and weight gain or because they perceived that the dementia had become very severe (e.g., patient was unable to communicate or carry out activities of daily living). Clinician interviewees described that cognitive enhancers may be effective for slowing the progression of disease in mild dementia patients but did not perceive any effectiveness in severe dementia patients. The two family member interviewees could not describe any firm perceptions of the effectiveness of these medications. Participants did not perceive that adverse events (e.g., kidney malfunction and bradycardia) are common with cognitive enhancers.

> "*No worse, no better, so it seems like you know in a cognitive enhancer sometimes for especially moderate to severe stage of dementia it is like a placebo there, not really doing anything, but not causing side effects either, cause we didn't see them improve without a cognitive enhancer either*" –Nurse Interviewee

Comments on Specific Products

Physician survey respondents reported prescribing various cognitive enhancers to their patients; in order of frequency: donepezil(37%),galantamine (26%), memantine (21%) and rivastigmine (16%). According to family member respondents, donepezil and memantine were the most common cognitive enhancers being used by their loved ones either currently or in the past. In general, donepezil was the most commonly discussed cognitive enhancer by all participants. Physician interviewees explained that they prefer donepezil because it is better tolerated by patients and they perceive that the dose titration is easier. The degree of familiarity with the dose range of a cognitive enhancer was a common influence on physician participant formulation preferences. Second to donepezil, physician interviewees preferred to prescribe galantamine because, similar to donepezil, it is only required once a day and is perceived to have fewer side effects than other products.

Clinician interviewees did not perceive any difference in effectiveness between products, however they did notice that some are more useful for certain types of dementia. For example, rivastigmine was described as most useful for Lewy Body dementia; while donepezil and galantamine were perceived to be more effective for Alzheimer's Disease. Memantine was described as useful for moderate dementia, where patients may be at the "*tipping point*" or a point at which they are transitioning from having trouble with finances or memory, to having difficulty with toileting and dressing.

Clinician participants also described some preferences they had with regards to different formulations. For example, many clinicians preferred the rivastigmine patch formula over the pill because it has a stable release mechanism which results in fewer gastrointestinal side effects. The patch was also

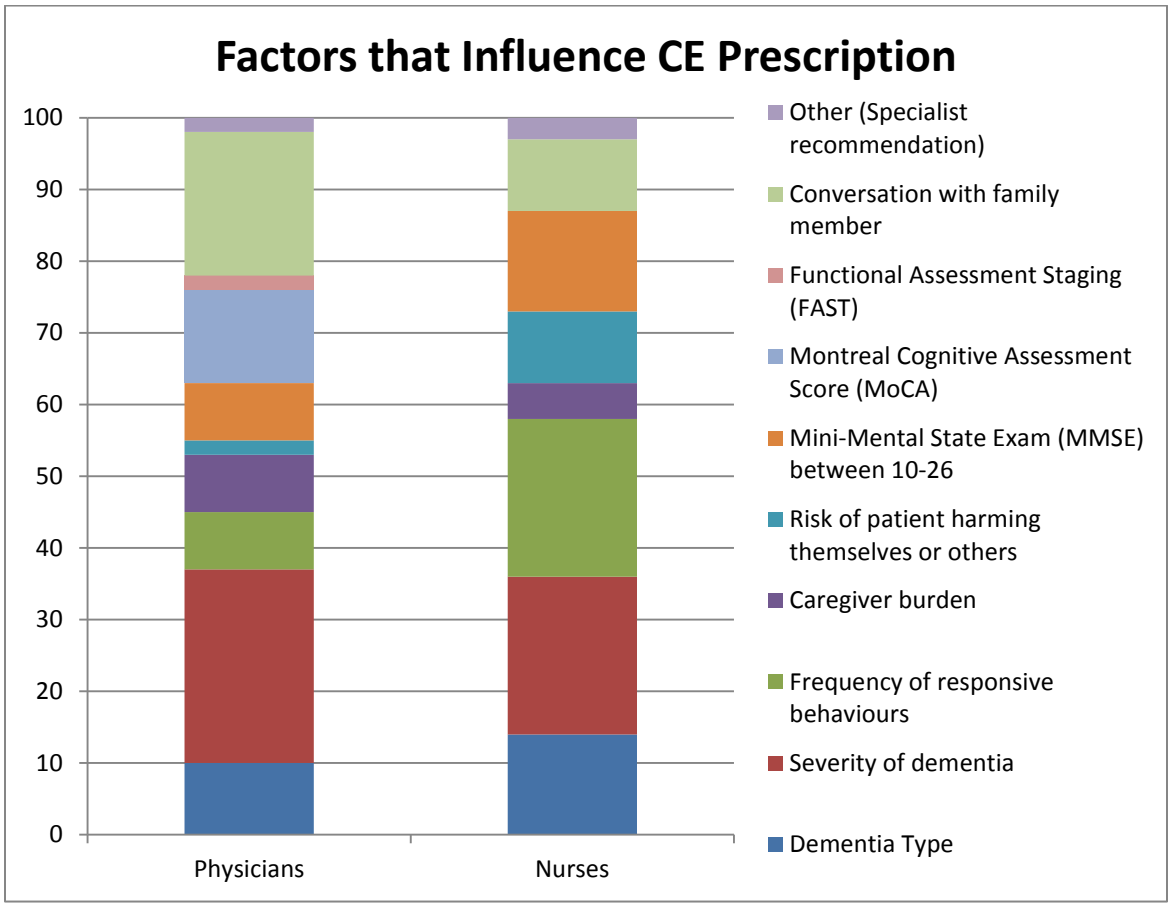
preferred for patients who cannot swallow pills. However, it was also noted that the disadvantage of the patches is that they can be missed, doubled up, forgotten, or ripped off. In general, clinician participants preferred extended release medications because they have a sustained effect and require fewer doses per day.

Prescription of Cognitive Enhancers

Perception of factors that influence prescription

Physician and nurse survey respondents were asked to select all the factors they perceive to have an influence on the prescription of cognitive enhancers (Figure 1.). For physicians, the top 3 factors were the severity of the patient's dementia, a conversation with a family member, and the score from a Montreal Cognitive Assessment (MoCA). For nurses, the top 3 factors were the severity of dementia, the frequency of responsive behaviours, and the score from a Mini-Mental State Exam (MMSE).

Figure 1. Physician's and nurses' perception of factors that influence cognitive enhancer prescription



Interviewee participants elaborated on these factors by explaining that they do not believe that severe dementia patients will benefit from these medications, which is why determining a patient's severity is a key factor in decision making related to prescibing. Survey respondents identified dementia type as another common factor that influences prescription. Interviewees described that patients with vascular dementia do not typically respond well to cognitive enhancers and that the best candidates for these medications are usually those with Alzheimer's disease.

Perception of Cognitive Assessment Tools

Clinician and health navigator survey respondents were asked to choose which of the following tests they prefer for cognitive assessments: the MMSE, the MoCA, the Functional Assessment Staging Test (FAST), or any other testing. The FAST was a test mentioned in interviews, which is why it was included in the survey; however, there is no additional information regarding this test and why it may be preferred by some clinicians. Interviewees did not perceive the MMSE to be a useful diagnostic test for mild or moderate dementia. They explained that they prefer not to use the MMSE because it is

privatized and it is not specific enough for early detection. A survey respondent commented that the $1 copyright chart for the MMSE renders it "*unusable - too difficult to deal with*". They have also described that it lacks applications for those with hearing impairments, low literacy levels, and different cultural or linguistic backgrounds. Some shared the opinion that if the MMSE is used, it should be administered multiple times in different settings and the scores should be interpreted along with other measures of cognition, such as an interview with the patient's family members.

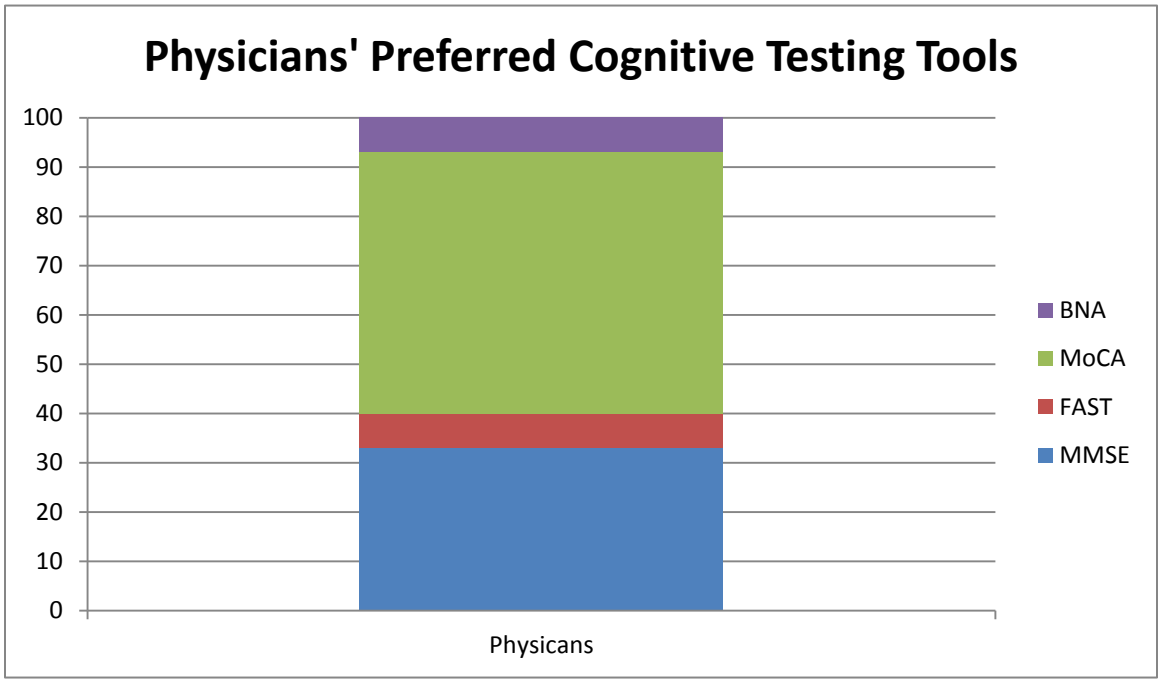
> "*There are so many people that score 30 on the MMSE that are very demented and there are other people that score 15 that aren't demented, so it is an extremely poor test*" – Physician Interviewee

> "*If anyone ever audited my practice or audited the prescriptions I would fail because I don't use the MMSE because it's a test that is privatized now and can't be used in you know in our setting unless you buy it and I have some but not enough, it's also not as good a test as the MoCA*" –Physician Interviewee

The majority of physician survey respondents preferred to use the MoCA test (Figure 2). These participants perceive that the MoCA priovides a better measure of executive domain function and is easier to administer and score. Other preferred tests mentioned by participants included the Resident Assessment Instrument (RAI) and the Behavioural Neurology Assessment (BNA). We do not have any additional information on the BNA.

Health navigator interviewees described that they often use the clock draw portion of the MoCA in combination with the RAI, which they feel is more comprehensive and accessible than other cognitive testing. The RAI was described as a "*more global holistic assessment*", which includes a cognitive performance scale in addition to other output scales. This tool is specifically used by CCAC workers and interviewees described that most physicians do not have the training to adminster or interpret its results. Some CCAC workers are working to develop more collaborative care planning with primary care practitioners, which includes sharing of data collected form the RAI.

Figure 2. Physicians preferred cognitive testing tools.



Monitoring of Effectiveness

The need for proper monitoring of effectiveness was a commonly mentioned theme by many clinician and health navigator interviewees and survey respondants. Participants described that there may be severe dementia patients who remain on cognitive enhancers for longer than necessary. They perceive that while there may be extensive testing and investigation prior to prescription, after the dose is titrated, the patient may remain on the cognitive enhancer for many years.

> "*When we're in the monitoring stage, I don't see MMSEs repeated too much. Like, I see them started, but I don't often see them repeated. That's where I'm thinking that it's not going… We're not doing as well as we should be… Let's say it's decreasing, or, you know, what are the next actions? Like, should we stop them if there's a two-point slide? Should we stop them if there's a three-point slide?*" –Health Navigator Interviewee

Some interviewees expressed concern that patients in long term care may be unnecessarily administered cognitive enhancers. However, participants also said that they have not observed or heard of adverse effects associated with the long term use of these medications. One clinician described that her long term care team uses the MMSE score of 10 as a cut-off. If a patient scores below this, they are taken off cognitive enhancers. Physician survey respondents reported various strategies for monitoring, including conversation with family members and the use of diagnostic tests, such as the MMSE and the

MoCA. Some respondants described that because dementia is a progressive disease monitoring for ongoing effectiveness is a challenge.

> "*Just how much slower is the progression of dementia, when it will progress anyway?*" – Physician Survey Respondent

Affordability of Cognitive Enhancers

Interviewees described that patients who are under 65 years and who do not have private coverage may be disadvantaged. However, family member interviewees of patients under 65 mentioned that they have had success with receiving subsidies through "compassionate supply" programs from drug manufacturers. Clinician interviewees said that patients over 65 years or those living in long term care do not have barriers to accessing commonly prescribed products on the ODB formulary, such as donepezil and galantamine. Some participants did mention that there are a select few patients who may benefit from memantine, however if they don't have private coverage they are not able to afford it.

> "*I'm kicking myself wishing that I had found a way to get that money for the memantine. I don't know if it would've made a difference*" –Family Member Interviewee

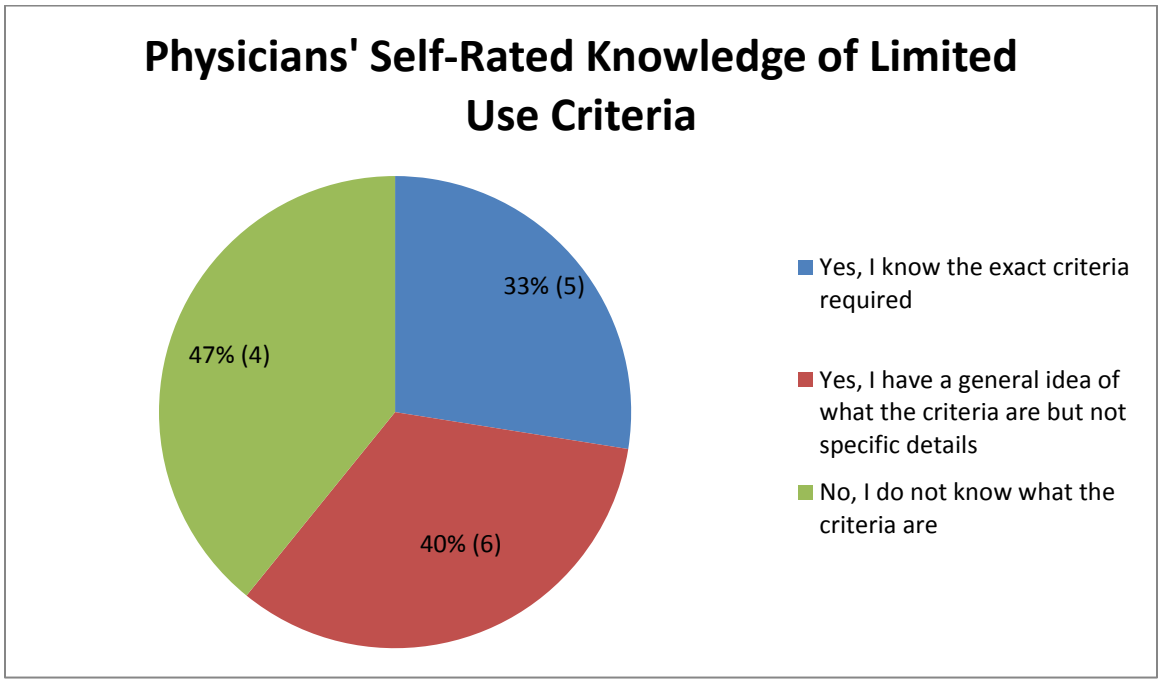
Clinician interviewees also mentioned the need for the rivastigmine patch formulation, which is not on the formulary. In particular, they said that many patients tolerate the patch better than the pill formulation. Patients who do not respond well to the pill formulation may experience side effects, such as acid reflux, loss of appetite, constipation, and increased agitation.

Clinician and health navigator interviewees were asked about their perceptions of the ODB limited use (LU) program. A few participants mentioned that they felt the criteria should be updated to include scores from alternative tests, since the MMSE is now privatized and because they doubt the accuracy of its results.

> *"I don't think the criteria should be based on a specific score on the MMSE. It would be more important to utilize other criteria for initiation and continuation of the cognitive enhancers, e.g. Clinical Global Impression, family input about benefit."* –Physician Survey Respondent

The majority of clinician and health navigator participants were not aware of the exact stipulations of the criteria for the ODB limited use program. Physician survey respondents were asked about their knowledge of the LU criteria and one third did not know what the criteria were (Figure 3).

Figure 3. Physicians' self-rated knowledge of limited use criteria.



Part 4: Discussion

Key Findings

Our study highlights many key experiences and perceptions related to cognitive enhancer prescription and use; we found factors that may be affecting appropriate use and access. One major aspect of our findings was that the benefit of cognitive enhancers was hard to perceive, given that dementia is a progressive disease. Another important finding pertained to clinician and health care provider preferences for cognitive assessment tools. The MMSE was not the most preferred test by participants in our sample. Lastly, appropriate follow-up and monitoring may be lacking and many severe patients may be continually being treated with cognitive enhancers for longer than necessary.

Health Equity Considerations

The findings from this study highlight that access to cognitive enhancers is not an issue for most ODB eligible patients, but cost can be a hindrance for those who are under 65 years of age without third party insurance. In addition, patients (both ODB eligible and ineligible) who only respond to the rivastigamine patch formulation or memantine may be at a disadvantage, since these are not on the formulary. Findings also highlight that some severe dementia patients may not be monitored

adequately after initial prescription of cognitive enhancers in the mild or moderate stages. Since persons living with severe dementia are unable to advocate for themselves, they are more vulnerable and rely heavily on the expertise and clinical judgment of their health care providers. Severe dementia patients who remain on cognitive enhancers, without a regular medication review, may be receiving unnecessary treatment.

Limitations

It should be noted that these interview and survey findings are not representative of the general population of individuals from which our study sample was drawn because the sample size is small and because there may be bias in sampling. The potential bias in sampling may exist because those who responded to interview or survey requests may have been more likely than non-responders to be vocal about discussing the impact of cognitive enhancers and may be more involved in dementia advocacy initiatives.

Part 5: Conclusions

The findings from the qualitative study of the cognitive enhancers drug class review informed the methods of other ODPRN research units conducting studies as part of the review. Moreover, our qualitative study helped to contextualize the results of the systematic review, pharmacoepidemiological analysis, and environmental scan performed within the separate research units of the cognitive enhancers drug class review. On a broader scale, our study findings fill a gap in knowledge on access to cognitive enhancer products and how this may be impacted by physician and family member perceptions of these drugs, as well as cognitive assessment challenges. Overall, our findings shed light on the experiences of prescribing and using cognitive enhancers, and unveil important information that can impact how patients in need can access these drugs across Ontario.

Part 6: Phase II Methods

Following the completion of this study and the accompanying cognitive enhancer research studies, a consolidated report was drafted which included a set of potential reimbursement options for the funding of cognitive enhancers for dementia. Phase 2 of the qualitative work included assessing the social acceptability and feasibility of the options proposed through the two steps outlined below.

Soliciting Participant Feedback

Once the draft reimbursement options were developed, the participants from phase I were invited to review all ODPRN reports from this drug class review. They were also invited to complete a brief survey about their impressions of the reimbursement options and the interpretation of the study results. This process invites participants to provide feedback on the authenticity of the study results, which is an important component of qualitative research. The survey also measured aspects of social acceptability, including affordability, accessibility, and appropriateness of policy recommendations. The survey was

developed online in FluidSurvey. The study coordinator sent the survey link and report through e-mail to participants. The findings from this survey were then used by the team to make any necessary revisions to the reports.

Citizens' Panel

We have recruited a diverse set of 15 individuals from the general public to form a citizens' panel. The citizens' panel provides feedback on recommendations from all drug class reviews. Feedback from participants will be obtained in two surveys and a webinar using the RAND Appropriateness Method (Fitch, 2001). First, an online survey was distributed to citizens' panel members, asking them to read the final report and recommendations, to provide their input and to rank the policy options. Next, citizens' panel members attended a webinar meeting during which key issues, findings, and policy implications were presented and members engaged in group discussion on the recommendations. Citizens' panel members then completed a second survey after the meeting, enabling them to provide additional feedback and giving them the opportunity to re-rank the policy options. 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). The findings from the citizens' panel surveys and discussion were then used by the team to make any necessary revisions to the reports and draft reimbursement options.

Part 7: Phase II Results

Detailed results are censored in this report so as not to preclude publication. Publications (when available) and/or final unpublished reports will be available on the ODPRN website (www.odprn.ca).

Citizens' Panel

The ODPRN Citizens' Panel meeting on cognitive enhancers for the treatment of Alzheimer's disease took place on Monday July 20th, 2015. There were 6 members in attendance during the meeting. Five members completed the pre-meeting survey and the post-meeting survey.

Participants were presented with the following policy options:

Option A: Limited use for cholinesterase inhibitors (status quo)

Option B: Limited use for cholinesterase inhibitors and Exceptional Access Program for rivastigmine patch (mild to moderate severity)

Option C: Limited use for cholinesterase inhibitors (all severities)

Option D: Limited use for cholinesterase inhibitors and Exceptional Access Program for rivastigmine patch

Option E: General Benefit for donepezil and Limited Use for rivastigmine and galantamine

There was not much variation in overall ranking options from pre-meeting to post-meeting. The most preferred choice pre and post-meeting was Option D (see table 2). Members strongly agreed that this option allows for equitable access, that it benefits those who require the drugs, and that it is the most acceptable option. The least favorable choice for pre and post-meeting was Option A. Members felt that this option restricts accessibility to individuals with severe dementia and that it does not improve access for those who respond more favorably to the patch as opposed to oral formulations.

Table 2. Citizens' Panelfinal option ranking

	Mean Ranking (1 = Most Acceptable 5 = Least Acceptable)
Option A	4.6
Option B	3.0
Option C	3.0
Option D	1.4
Option E	3.0

Participant Feedback

Thirty of the forty-three interview and survey participants from Phase I consented to being contacted to participate in a survey on the final report and recommendations. A total of three primary care physicians, one specialist, one nurse, and one family member completed the survey. In contrast to Citizens' Panel members, the majority of participants were in favour of option A. Option E was rated as the least favourable option. Participants chose not to elaborate on their preferences in the open ended survey questions.

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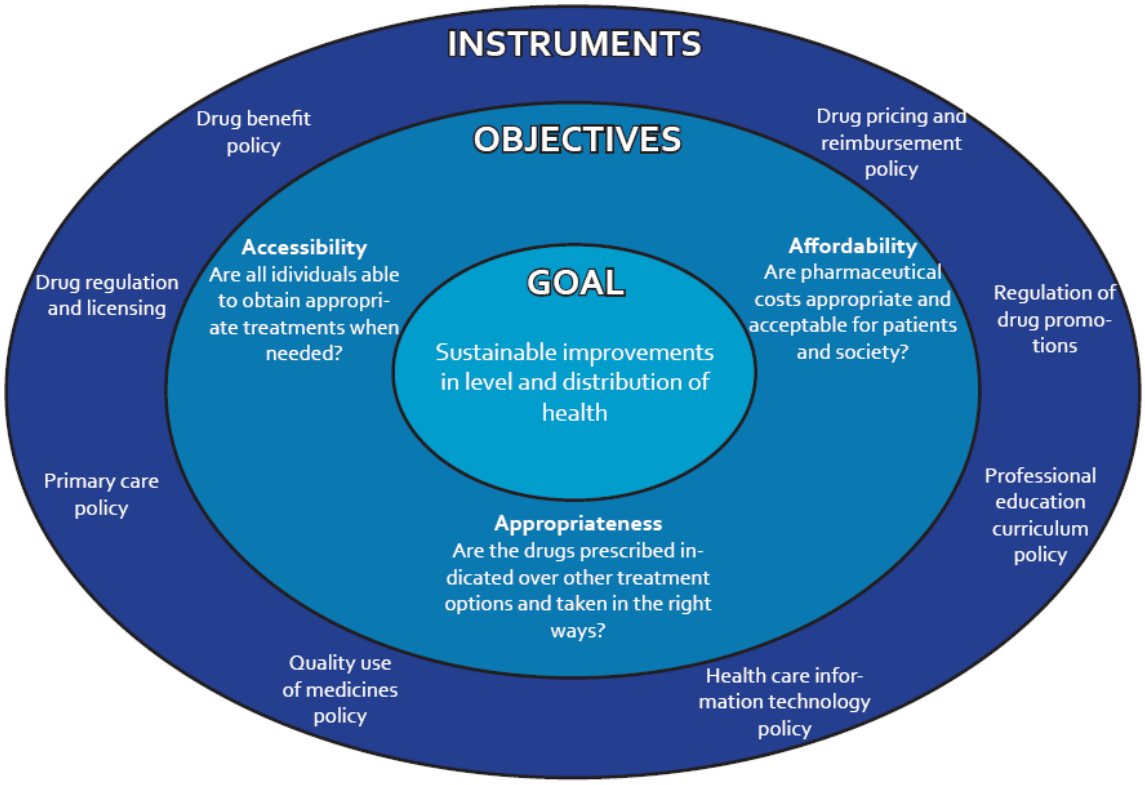
Appendix A: "Triple-A" Framework for Pharmaceutical Policy Analysis



Adapted from: Morgan S, Kennedy J, Boothe K, McMahon M, Watson D and Roughead E. (2009) Toward an Understanding of High Performance Pharmaceutical Policy Systems: A "Triple-A" Framework and Example Analysis. *Open Health Services and Policy Journal:2;* 1-9

Appendix B: Participant Characteristics and Demographics

Participation Rates:

Participants	# of participants (n=43)		# of Surveys (n=34)		# of Interviews (n=9)	
	n	%	n	%	n	%
Family Member of Patients	11	26%	9	26%	2	22%
Physicians	17	40%	15	44%	2	22%
Nurses	11	26%	10	30%	1	11%
CCAC Case Mangers	3	6%	N/A	N/A	3	34%
Pharmacists	1	2%	N/A	N/A	1	11%

Patients

Patient demographic characteristics (n=11)	n	%
Data collection type		
Survey	9	82%
Interview	2	18%
Respondent's relationship to patient		
Spouse	5	45%
Adult child	6	55%
Note: All demographic information displayed below pertains to the patient.		
Age		

65-74	3	27%
75-84	3	27%
85-94	4	36%
95+	1	10%
Type of dementia		
Alzheimer's Disease	7	64%
Vascular Dementia	2	18%
Frontotemporal Dementia	1	9%
Other (Parkinson's disease)	1	9%
Currently on cognitive enhancers		
Yes	4	36%
No, but used in the past	7	64%
Current cognitive enhancers in use		
Donepezil (Aricept ®)	5	62%
Memantine (Ebixa ®)	3	38%
Length of time on cognitive enhancers		
1-5 years	6	55%
5-15 years	2	18%
Not sure	2	18%
N/A*	1	9%
Patient's place of residence		
Not-for-profit LTC	2	18%
For-profit LTC	4	36%
Municipal LTC	3	28%

Community (in their home)	2	18%

*Note: patient was considered for cognitive enhances but was not prescribed due to cardiovascular contraindication

Physicians & Nurses

Physician & nurses demographic characteristics (physicians n=17 & nurses = 11)	Physicians		Nurses	
	n	%	N	%
Data collection type				
Survey	15	88%	10	91%
Interview	2	12%	1	9%
Type of physician				
Primary care physician	11	65%	N/A	N/A
Long-term physician	1	6%	N/A	N/A
Geriatrician	2	12%	N/A	N/A
Geriatric psychiatrist	2	12%	N/A	N/A
Other (director of care)	1	5%	N/A	N/A
Type of nurse				
Front line nurse	N/A	N/A	7	64%
Clinical nurse specialist	N/A	N/A	1	9%
Long-term care	N/A	N/A	1	9%
Nurse practitioner	N/A	N/A	1	9%
Other (Would care coordinator)	N/A	N/A	1	9%
Length of time practicing				

Physician & nurses demographic characteristics (physicians n=17 & nurses = 11)	Physicians		Nurses	
	n	%	N	%
<5 years	2	12%	3	27%
5-15 years	8	47%	3	27%
>15 years	7	41%	5	45%
All practice settings (non-mutually exclusive)				
Acute care	4	18%	1	9%
Long-term care	5	23%	7	64%
Community	12	55%	3	27%
Other (Academic center)	1	4%		
All types of dementia seen in clinic (non-mutually exclusive)				
Dementia with lewy body	8	15%	5	16%
Alzheimer's disease	17	30%	8	25%
Vascular dementia	12	22%	8	25%
Mixed dementia	11	20%	5	16%
Frontotemporal dementia	5	9%	6	18%
Other (Parkinson' disease)	2	4%	0	0%