ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

TREATMENT OF OVERACTIVE BLADDER

Citizens' Panel Report

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Background

The ODPRN Citizens' Panel, a stakeholder group comprised of members of the general public, provides feedback on drug reimbursement policy options for each ODPRN drug class review. The purpose of this exercise is to understand perceptions of the general public about the feasibility and social acceptability of the draft policy options developed at the end of each drug class review, and to rank the most preferred policy options from the perspective of the Citizens' Panel for the Ontario Public Drug Programs' consideration. This report is a high level overview of the methods and results of the ODPRN Citizens' Panel engagement process for the drug class review on overactive bladder (OAB) therapies.

Methods

Citizens' Panel Recruitment

Members of the general public were invited to join the Citizens' Panel by posting advertisements on public websites, the ODPRN website, and social media (e.g. Charity Village, getinvolved.ca, Kijiji, Craig's list, Twitter, Facebook). Citizens' Panel members were also recruited from the Ontario Citizen's Council (OCC). We aimed to recruit 10 to 15 individuals 18 years of age or older who reside in Ontario, with varied education levels and work experience. Members of the general public who expressed interested in joining the panel were asked to fill out an application form. Follow up interviews were conducted with potential panel members over the phone to make final selections. We assessed each potential panel member on their level of knowledge of the healthcare system and drug policy making in Ontario, with the goal of including diversity of knowledge, experiences, and opinions. A total of 15 panel members were ultimately selected and comprised a panel that we engaged for each of the ODPRN's drug class reviews.

Data collection

All panel members were asked to read the draft report and recommendations from the drug class review to familiarize themselves with the research findings. The report was re-written in lay language to enhance its readability and accessibility. Feedback from panel members was obtained in two surveys and a webinar using a modified RAND Appropriateness Method (also known as The Delphi Method) (Fitch, 2001). First, an online pre-meeting survey was distributed to Citizens' Panel members to collect their input on the policy options rated on domains of social acceptability and pharmaceutical policy acceptability analysis: general access, equitable access, appropriateness, affordability, cost to the system, safety, and overall benefit (Morgan, 2009). Panel members were also asked to rate the general acceptability of each option, as well as to rank the policy options relative to one another in terms of their preferred option. Open –ended responses were provided to enable panel members to contribute thoughts, questions, or justifications for their ratings/rankings. Next, Citizens' Panel members attended a webinar meeting, at which we presented key issues, findings and policy implications, and engaged in deliberative group discussion on the recommendations. Any questions, issues or themes that arose from the first round of surveys were addressed in the meeting. Citizens' Panel members 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 allowed each person to express their idea(s); each person's opinion was taken into account (compared to traditional voting where only the largest group is considered). The findings from the Citizens' Panel surveys and discussion were used by the team to make any necessary revisions to the reports and draft reimbursement options.

Data analysis

Survey responses were analyzed using descriptive statistics and content analysis for open-ended questions. Extensive field notes were taken during meetings and key themes were summarized.

Findings

The ODPRN Citizens' Panel meeting on OAB took place on Wednesday, February 24th, 2016. There were 6 members in attendance during the meeting. Six members completed the pre-meeting survey and 4 members completed the post-meeting survey. Below is a high-level summary of the findings from the discussion and the subsequent survey.

Overall ranking of options

- Table 1 shows the mean ranking of each option, pre- and post- Citizens' Panel meeting. Panel members were asked to rank the options from 1 (most acceptable to 7 (least acceptable).
- The least favorable choice pre-meeting was option A (status quo), while post-meeting it was tied between option A and C.
- Option B4 was chosen as the most acceptable in both pre- and post-meeting surveys.

Table 1. Overall option ranking

	Mean Ranking (1 = Most acceptable, 7 = Least acceptable)	
	Pre-meeting	Post-meeting
Option A: (status quo) Oxybutynin immediate release (IR) as General Benefit (GB), all other OAB medications Limited Use (LU)	6.7 (0.5)	6.5 (0.6)
Option B1: Oxybutynin IR and solifenacin as GB, all other OAB medications LU	4.5 (1)	4 (0.8)
Option B2: Oxybutynin IR, solifenacin as GB, all other OAB medications LU	2.5 (0.8)	2.8 (0.5)
Option B3: Oxybutynin IR, solifenacin and tolterodine (immediate and extended release) as GB, all other OAB medications LU	4.2 (0.8)	4.8 (0.5)
Option B4: Oxybutynin IR, solifenacin or tolterodine (immediate and extended release) as GB, all other OAB medications LU	2.0 (1.5)	1.0 (0.0)
Option C: Enforced use of oxybutynin IR OR solifenacin as initial therapy, all other OAB medications Limited Use	5.0 (2.4)	6.5 (0.6)
Option D: Solifenacin as General Benefit, all other OAB medications Limited Use	3.2 (2.1)	2.5 (1.0)

Ratings of policy options on acceptability domains

- Table 2 shows the mean score and standard deviation (SD) of the specific aspects of each option. Citizen's Panel members were asked to rate each option on a scale from 1 (strongly disagree) to 7 (strongly agree).
- Option B4 scored very high post-panel in all aspects.

- Options A (the status quo), B1, and C scored low overall, with members disagreeing with most aspects.
- All options are looked upon as having equitable access.
- Members thought that options A and B1 did not adequately considering the safety and efficacy of the drugs and also that they did not benefit those who required the drugs.

Table 2. Comparison of each aspect rating

	Mean score (Standard Deviation) 1 = Strongly disagree to 7 = Strongly agree													
	Option A		Option B1		Option B2		Option B3		Option B4		Option C		Option D	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
The policy helps those who need the drugs to access them easily.	3.5 (1.9)	4.5 (1.3)	4.0 (1.9)	4.0 (1.4)	4.5 (1.8)	5.0 (1.4)	5.0 (1.7)	5.0 (1.4)	5.2 (1.6)	6 (0.0)	3.5 (1.9)	4.0 (1.8)	5.2 (1.3)	5.5 (1.0)
The policy will allow those who need the drugs to access them equitably (regardless of age, income, health status, gender, etc.).	5.2 (2.2)	6.0 (0.8)	5.0 (1.8)	5.5 (1.3)	5.2 (1.3)	6.0 (0.8)	5.5 (1.8)	6.3 (1.0)	5.7 (1.0)	6.3 (0.5)	4.3 (2.1)	5.0 (0.8)	5.7 (1.4)	6.5 (0.6)
The policy adequately provides coverage for the appropriate types/quantity/doses	4.0 (2.3)	3.5 (0.6)	4.3 (1.6)	4.3 (1.3)	4.5 (1.8)	4.5 (1.7)	5.0 (1.7)	5.5 (0.6)	5.5 (1.4)	6.3 (0.5)	3.8 (1.9)	4.8 (1.3)	5.0 (1.5)	5.5 (0.6)
The policy is a good option to make the drugs more affordable.	4.2 (1.9)	4.8 (1.3)	4.0 (1.7)	5.3 (1.0)	5.0 (1.7)	4.5 (1.7)	4.5 (1.9)	4.3 (2.1)	5.3 (1.8)	6.3 (0.5)	3.8 (1.9)	5.3 (1.3)	5.3 (1.5)	5.8 (0.5)
The policy is a good option to limit the burden of cost on the healthcare system.	3.8 (1.7)	5.3 (0.5)	4.3 (1.9)	4.8 (1.3)	4.7 (1.2)	5.8 (0.5)	4.7 (1.4)	4.0 (1.8)	5.7 (0.5)	6.0 (0.8)	4.3 (1.9)	5.0 (1.6)	5.3 (2.0)	6.0 (0.0)
The policy adequately considers the safety and effectiveness of the drugs.	2.8 (1.9)	3.5 (1.7)	3.3 (1.8)	3.5 (1.9)	4.2 (1.5)	5.0 (0.8)	4.5 (1.4)	3.8 (2.2)	5.2 (1.2)	6.3 (0.5)	4.0 (2.0)	4.5 (1.3)	4.7 (2.0)	6.0 (0.0)
I think this policy will benefit those who require the drugs.	2.3 (1.2)	3.5 (1.3)	3.5 (1.6)	2.8 (1.0)	4.2 (1.5)	5.3 (0.5)	4.3 (1.4)	3.3 (2.1)	5.2 (1.3)	6.5 (0.6)	3.7 (1.8)	4.5 (1.3)	4.8 (1.7)	5.8 (0.5)
I think this policy is an acceptable option.	2.0 (1.5)	2.5 (1.3)	3.2 (1.6)	3.0 (0.8)	3.8 (1.8)	4.3 (1.5)	4.2 (1.6)	2.3 (1.0)	4.8 (1.5)	6.7 (0.6)	3.5 (1.9)	3.3 (1.2)	4.5 (2.3)	5.3 (1.5)

Reactions and comments from meeting discussion

Option A (status quo): Oxybutynin Immediate Release (IR) as GB, all other OAB medications LU.

Reactions:

- Members felt that status quo is too restrictive, that it doesn't take into account newer drugs, and that it is not cost effective.
- One member was also concerned about oxybutynin's side effects.

- There was also agreement that if the physicians were unhappy with this option, then it did not make sense.

Comments:

"Denies people easier access to drugs that are clearly more effective and [also] as cost effective."

"Side effects are too serious for some patients who need other options."

Option B1: Oxybutynin IR and solifenacin as GB, all other OAB medications LU

Reactions:

- Members were concerned about the options for patients who can't swallow.
- Participants do not like the "AND" option as it forces patients to try products instead of allowing the physician to be able to choose what they think is best.

Comments:

"Do they have to go through these before the gel/patch? That would be difficult for them"

"The AND limits doctors in providing the best care for patients"

***Option B2*:** Oxybutynin IR, solifenacin as GB, all other OAB medications LU

Reactions:

- Members preferred option B2 over option B1 as they perceive the "OR" is not as restrictive, but still not ideal.
- Members felt that it was not appropriate to make patients go through a trial of medication that (potentially) does not meet their needs.

Comments:

"This option is still better than the first 2 options as it reduces the costs/burdens to ODB and the patients as they do not need to try BOTH oxybutynin and solifenacin before potentially needing a step up to a LU-requiring drug"

"Either of these drugs may not be appropriate for a select group of patients who suffer from dementia, inability to swallow etc."

***Option B3*:** Oxybutynin IR, solifenacin and tolterodine (immediate and extended release) as GB, all other OAB medications LU

Reactions:

- Participants considered this to be the last or second last option.
- They felt that it was a waste for patients and physicians to potentially have to try three medications before ultimately prescribing a fourth(if necessary).
- They also wondered if tolterodine was cost effective and perceived that it should not be added until it has a generic version.

Comments:

"I'm still not convinced that everyone should have to go through a trial period of all three before being able to access a Limited Use Drug which better meets their needs."

"Similar to option B1 except even more burdensome for the health care system as well as the patient as potentially 3 drugs must be tried before a LU-requiring drug can be accessed. The good part of this is the additional access to tolterodine which allows physicians access to another long-acting drug in the class."

***Option B4*:** Oxybutynin IR, solifenacin or tolterodine (immediate and extended release) as GB, all other OAB medications LU

Reactions:

- This was the preferred option for many of the members.
- Panel members felt that it gives patients options while providing access to the most effective and cost effective drugs.

Comments:

"A logical option, to ease the access to these 3 drugs by virtue of their GB status, and not require a patient to try all 3 before potentially changing to a LU-status product if necessary; while still keeping costs to ODB reasonable"

Option C: Enforced use of oxybutynin IR OR solifenacin as initial therapy, all other OAB medications LU.

Reactions:

- Many of the members were confused by the "enforced" nature of this option and expressed concern over a step-therapy system since they were unfamiliar with how it would work.
- Panel members rated this option last because they perceive it to be complex and not feasible for all stakeholders involved (e.g., pharmacists, prescribers).
- They said that if there was demonstrated feasibility and software/training/supports available they would be in agreement with this option
- They also questioned whether this class of drugs would be the best option with which to start this process.

Comments:

"Would this class of drug be the best to start this process with? Should we make sure plan worked, then find proper drug?"

"Awkward and inefficient at the current time due to logistics of implementation not yet in place."

"As it stands now, it would mean a lot of additional paperwork for pharmacies and physicians and delays in patients receiving treatment."

Option D: Solifenacin as GB, all other OAB medications LU

Reactions:

- Panel member opinions were somewhat split on this option.

- Some felt that having the majority of the drugs on LU was too restrictive while others felt that solifenacin was the best drug and therefore should be the most accessible.

Comments:

"Seems like an appropriate first drug to offer to the majority of patients at a reasonable cost to ODB. Other drugs are still available if needed, but their LU status will guide prescribing more effectively."

"Too restrictive. Does not take into account the age of those with OAB. Older patients often do not always find their needs met by this drug."

Recommendation 1: No listing is recommended for oxybutynin ER (Ditropan XL).

- Panel members agreed with the recommendation.
- They also expressed that this was the easiest recommendation to understand

Comments:

"If it's not cost effective and there are other beneficial drugs, this recommendation is appropriate"

Recommendation 2: For patients unable to swallow, recommend availability of oxybutynin gel (Gelnique) under Exceptional Access Program (EAP) (but not oxybutynin transdermal [Oxytrol]).

- The majority of members agreed with this recommendation but some questioned if LU should be used instead of EAP.
- Many were interested in whether or not the gel was as effective as the other options.
- They felt it important to consider people who might have a difficult time with the oral pills.

Comments:

"There has to be an option for patients who cannot swallow the medication."

"I am not clear why the recommendation for EAP rather than limited use."

Recommendation 3: It is recommended that consistency in the therapeutic note should be applied to all anticholinergics used for OAB, including oxybutynin IR which currently does not have a therapeutic note.

- All members were in agreement with this recommendation and some believed it morally wrong to have a note for some anticholinergics and not others.
- They were more concerned about whether physicians actually read and abide by the note.

Comments:

"I agree that the Therapeutic Note should apply to all anticholinergics; however, as discussed there should be some dialogue as to how to make the Therapeutic Note more visible to physicians."

Limitations

Since the sample for this this Citizens' Panel was small the results in this report may not be representative of the general public in Ontario. However, the literature on public engagement methods, such as the Delphi, states that group dynamics and diversity play a more important role

than sample size (Bruni, 2008; Okoli, 2004). The Delphi method is separate from traditional survey methods and is considered a type of virtual meeting or a group decision technique (Okoli, 2004). The panel members who participated in this exercise provided a range of diverse and valuable insights from the perspective of Ontario tax payers who do not live with OAB. This information, in combination with additional feedback from various stakeholders (e.g., qualitative interviews, in-person forums, and online submissions) and quantitative research evidence, will aid in the development of the final policy options for this review.

Conclusion

The Citizens' Panel provided important feedback on the feasibility and social acceptability of the draft policy options for the OAB review. These findings will be used to help frame the final options in the consolidated report. The consolidated report will be posted at www.odprn.ca.

References

Fitch, K., Bernstein, S. J., Aguilar, M. D., Burnand, B., LaCalle, J. R., & Lazaro, P. (2001). The RAND/UCLA Appropriateness Method User's Manual. Santa Monica, CA: RAND.

Morgan, S., Kennedy, J., Boothe, K., Mcmahon, M., Watson, D., & Roughead, E. (2009). Toward an Understanding of High Performance Pharmaceutical Policy Systems: A "Triple-A" Framework and Example Analysis. The Open Health Services and Policy Journal TOHSPJ, 2(1), 1-9. doi:10.2174/1874924000902010001

Bruni, R. A., Laupacis, A., & Martin, D. K. (2008). Public engagement in setting priorities in health care. Canadian Medical Association Journal, 179(1), 15-18. doi:10.1503/cmaj.071656

Okoli, C., & Pawlowski, S. D. (2004). The Delphi method as a research tool: An example, design considerations and applications. Information & Management, 42(1), 15-29. doi:10.1016/j.im.2003.11.002