ODPRN ONTARIO DRUG POLICY RESEARCH NETWORK

ALLERGEN IMMUNOTHERAPY

Citizen's Panel Report

September 2015

Background

The ODPRN Citizens' Panel, a stakeholder group comprised of members of the general public, provides feedback on drug reimbursement policy options or recommendations 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 or recommendations developed at the end of each drug class review, and to rank the most preferred policy options or recommendations 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 review of allergen immunotherapies.

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 or recommendations 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 or recommendation, as well as to rank the policy options or recommendations relative to one another in terms of their preferred option or recommendation. 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 or recommendations. 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 or recommendations.

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 Citizen's Panel meeting on allergen immunotherapies took place on Tuesday, September 15th, 2015. There were six members in attendance during the meeting. Three members completed the pre-meeting survey and five completed the post-meeting survey. Below is a summary of the findings from the discussion and the subsequent survey.

Ratings of recommendations on acceptability domains

- Table 1 shows the mean score and standard deviation (SD) of the specific aspects of each recommendation, which we asked the Citizen's Panel to rate on a scale from 1 (strongly disagree) to 7 (strongly agree).
- Overall, there was no substantial shift in opinion from pre- to post-meeting, with the panel generally being in favour of the 6 recommendations.
- After the meeting, all members were unanimously in strong agreement with recommendation C (clinical criteria for use of subcutaneous allergen immunotherapy should be developed).

Table 1. Overall aspect ratings for each recommendation

	Mean score (SD) 1 = Strongly disagree and 7 = Strongly agree											
	REC. A		REC. B		REC. C		REC. D		REC. E		REC. E	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post
The rec. is a good rec. to limit the burden of cost on the healthcare system.	6.3 (0.5)	6.4 (0.8)	5.0 (0.8)	6 (1.3)	4.7 (0.9)	7 (0)	6.0 (0.8)	4.8 (2.1)	5.3 (1.2)	6 (0.9)	5.3 (1.2)	6 (1.3)
I think this rec. will benefit those who require the drugs.	4.7 (0.5)	6.4 (0.8)	6.3 (0.5)	6.6 (0.8)	6.3 (0.5)	7 (0)	5.7 (1.2)	6.6 (0.5)	6.3 (0.9)	6.2 (1.0)	6.0 (1.4)	6.6 (0.8)
I think this is an acceptable rec.	6.0 (0.8)	6.4 (0.8)	6.7 (0.5)	6.6 (0.8)	6.3 (0.5)	7 (0)	6.3 (0.5)	6 (1.5)	6.7 (0.5)	6.4 (0.8)	6.0 (1.4)	6.8 (0.4)

Reactions and comments from meeting discussion

Recommendation A: Limit duration of therapy to 5 years for aeroallergens.

Reactions:

- Looked upon favourably by the panel.
- Asked some questions about whether or not the patient can reapply for treatment after 5 years.
- Liked that the recommendation provides flexibility to try other treatment plans after the 5 year duration, if therapy was unsuccessful

Comments:

"As long as there is an opportunity for individuals who stop therapy for a period (and there may be rationale to determine what period is acceptable) to reapply for the program, this recommendation is well thought out and meets the needs of patients."

"Treatment term limits allow for physicians to consider any other treatment options that might have been developed during that time period."

Recommendation B: Require drug identification numbers (DIN) on all prescriptions for subcutaneous allergen immunotherapy.

Reactions:

- Perceived as an acceptable recommendation.
- Asked questions about Drug Identification Numbers (DIN) numbers (e.g., who controls the DIN? Do all of the compounds that comprise of the specific therapy need to have DIN?).
- Perceived that this was crucial information to have, especially in cases where patients reacted negatively to a given compound.

Comments:

"This is the only way to standardize and document patient safety."

"Definitely assures consistency in preparation along with better assurance of patient safety."

Recommendation C: Clinical criteria for use of subcutaneous allergen immunotherapy be developed.

Reactions:

- Perceived it was a clear, understandable recommendation, and was the most well received.
- Liked that the physicians would have to state what has already been tried and in what dosage/concentration.

Comments:

"…I strongly agree with a well thought out protocol to justify the need to use of subcutaneous allergen immunotherapy. Means careful supervision of patient and justification for use of the SCIT. Assurance of greater oversight and patient safety."

"Positive step in discussing previous/alternative treatments that could be more cost effective or offer better treatment options prior to a patient receiving SCIT treatment."

"Excellent suggestion as it ensures patient safety and the patient's needs and treatment are appropriately aligned. There is also a paper trail of need for escalation of treatment should it be required."

Recommendation D: Coverage of sublingual immunotherapy be limited to commercially available SLIT products.

Reactions:

- Looked upon favourably by the panel.
- Pleased to know that there would still be effective SLIT options available and surprised to know about the "off label use" of some of the SLIT products.
- Asked questions surrounding the motivation for this recommendation (e.g., is it because the drops aren't as effective? Or is it to have more control and standardization?), and whether this would prevent people who are adverse to injections from receiving therapy.

Comments:

"This is not as effective but could be used for children or rural areas where a weekly visit to a physician is not feasible."

"Strongly agree. Research shows that drops are not as effective and the amount administered more difficult to determine."

Recommendation E: Develop pricing structure for patient-specific allergen immunotherapy.

Reactions:

- Thought it would be wise to collect more data first, so that a more accurate and standardized pricing structure can be developed.
- Perceived that there should be a consumer group at the table when this pricing structure is made to avoid it being completelyindustry driven.
- Favor any strategies to reduce variation in pricing structure and ensure this does not become an accessibility issue associated with cost.
- Raised concerns that region and exposure should be taken into account in the pricing structure as some areas are "hit harder".

Comments:

"There does not seem to be accountability or checks and balances on the wide range of fees. This needs to be tightened up without burdening the red tape for physicians."

"Less variation in price of treatments can create greater accessibility to treatment options and therefore may lead to better care being received by patients"

"Pricing structure makes sense however it was strongly felt by the committee that the pricing structure should take into account those geographical areas where there is a greater need for allergen immunotherapy due to the unique needs of a community (geographical areas that have a record of higher need due to the local conditions that are more conducive to the development of seasonal allergies)."

Recommendation F: Develop guidelines for safe manufacturing.

Reactions:

- Some perceived that the guidelines should be actively enforced, and that the individual

putting together the compounds be held accountable (e.g., fined) if they don't abide (some members were surprised that this was not already the case).
- Others perceived that accountability measures might be an unnecessary use of resources and the guidelines would suffice.
- General agreement that anything we can do to increase the standardization and subsequent safety should be done.

Comments:

"Strongly feel that these should be standards of practice and not just guidelines as guidelines do not carry the same weight as standards. These standards of practice need to be monitored and enforced."

"Recommend adopting international guidelines for best practice. Ideally there could be accreditation same as laboratory practice standards but this may be unfeasible in doctor's offices as it would require monitoring and auditing."

"Would help increase patient safety"

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 use allergen immunotherapies. 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 recommendations for the allergen immunotherapy review. These findings will be used to help frame the final recommendations in the consolidated reports. The consolidated reports will be posted at www.odprn.ca.

References

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