Chronic Hepatitis B Therapies

Citizens’ Panel Report

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Prepared by the ODPRN Knowledge Translation Unit, Li Ka Shing Knowledge Institute Knowledge Translation Program, St. Michael’s Hospital

David Flaherty, Alekhya Mascarenhas, Radha Sayal, Sobia Khan, Julia E. Moore
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 chronic hepatitis B therapies drug class review.

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 interest 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 chronic hepatitis B therapies took place on Monday, June 22nd, 2015. Six members attended the meeting. Seven members completed the pre-meeting survey, and 6 members completed the post-meeting survey. Below is a high level summary of findings from the meeting discussion and final (post-meeting) survey.

Overall ranking of options

- Table 1 shows the mean ranking of each option, pre- and post-meeting.
- The most preferred choice pre-meeting was option D. This preference shifted slightly post-meeting as the preferred choice became option C.
- The least favorable choice both pre- and post-meeting was option A.

Table 1. Overall option ranking

<table>
<thead>
<tr>
<th>Option A: Lamivudine Limited Use (LU) and updated Exceptional Access Program (EAP) criteria (entecavir first line option)</th>
<th>Pre-meeting</th>
<th>Post-meeting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option B: Lamivudine Limited Use (LU) and updated Exceptional Access Program (EAP) criteria (entecavir and tenofovir first-line options)</td>
<td>2.6</td>
<td>2.0</td>
</tr>
<tr>
<td>Option C: Lamivudine and entecavir Limited Use (LU) and updated Exceptional Access Program (EAP) criteria (tenofovir first line option)</td>
<td>1.9</td>
<td>1.7</td>
</tr>
<tr>
<td>Option D: Lamivudine, entecavir, and tenofovir Limited Use (LU) and updated Exceptional Access Program (EAP) criteria</td>
<td>1.7</td>
<td>2.7</td>
</tr>
</tbody>
</table>

Ratings of policy options on acceptability domains

- Table 2 shows the mean score and standard deviation (SD) of the specific aspects of each option. Each member of the Citizens’ Panel was asked to rate the extent to which they agreed with each statement on a scale of 1 (strongly disagree) to 7 (strongly agree).
- There was a shift in participants’ opinions with respect to option C. Initially, they believed that it was only good at limiting cost to the system, but following discussion, began to see it as beneficial to those who require the drugs and considered it a good option overall. This could be due to their increased understanding of the efficacy of entecavir’s as compared to tenofovir.
Table 2. Overall aspect ratings for each option

| Aspect                                                                 | Option A | Option B | Option C | Option D | Pre  | Post  | 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.       | 3.4 (1.5)| 4.2 (1.7)| 4.1 (1.4)| 5.0 (1.5)| 4.7 (1.0)| 5.8 (1.2)| 6.1 (0.8)| 6.7 (0.7) |
| The policy will allow those who need the drugs to access them equitably (in other words, regardless of age, income, health status, gender, etc.). | 3.9 (1.4)| 4.2 (1.6)| 3.9 (1.1)| 5.0 (1.3)| 4.6 (0.9)| 5.7 (1.2)| 5.9 (1.1)| 6.5 (0.8) |
| The policy adequately provides coverage for the appropriate types/quantity/doses. | 3.6 (1.2)| 4.7 (2.1)| 3.6 (1.2)| 5.5 (1.6)| 4.3 (0.9)| 5.7 (1.1)| 5.7 (1.0)| 6.5 (0.8) |
| The policy is a good option to make the drugs more affordable.         | 4.9 (1.6)| 4.2 (1.6)| 5.0 (1.7)| 5.8 (0.9)| 5.0 (0.8)| 5.8 (1.1)| 4.9 (1.1)| 3.8 (1.3) |
| The policy is a good option to limit the burden of cost on the healthcare system. | 5.3 (1.0)| 4.8 (1.5)| 5.1 (0.8)| 6.0 (0.6)| 5.1 (0.8)| 5.2 (0.7)| 4.1 (1.6)| 3.0 (1.2) |
| The policy adequately considers the safety and effectiveness of the drugs. | 3.1 (2.0)| 4.7 (2.1)| 4.3 (1.5)| 5.8 (1.1)| 4.9 (1.1)| 5.7 (1.1)| 5.9 (1.1)| 5.8 (0.9) |
| I think this policy will benefit those who require the drugs.          | 3.1 (1.9)| 4.3 (1.6)| 3.9 (1.8)| 5.0 (1.4)| 5.0 (1.2)| 6.0 (0.8)| 5.9 (1.0)| 6.3 (0.9) |
| I think this policy is an acceptable option.                           | 2.6 (1.7)| 3.7 (1.5)| 4.6 (1.6)| 5.0 (1.9)| 4.9 (1.2)| 6.0 (0.8)| 5.4 (1.4)| 4.8 (1.6) |
Comments and key points from meeting discussion

Comments for policy Option A: Lamivudine Limited Use and updated EAP criteria (entecavir first line option)

- Some participants felt that it was redundant, as option B has the same listing, but includes another drug under the EAP.
- Others felt that it was unappealing as patients will most likely be prescribed entecavir (due to resistance) in 5 years anyway. However, others felt that receiving 5 years of affordable care, was worth it.

“This would potentially be a short-sighted cost savings, but patient ability to access appropriate therapy may not be ideal”

“Only the least effective drug is easily accessible. The more effective drugs are not easily accessible as there must be evidence that Lamivudine is not effective and then the process of accessing more effective drugs through the Doctors EAP is the only option.”

Comments for policy Option B: Lamivudine Limited Use and updated EAP criteria (entecavir and tenofovir first-line options)

- Consensus that this option was better than policy option A, but that it still does not provide quick/easy access to the drug of choice, tenofovir.
- There was also discussion about whether or not existing prescribing patterns would continue if tenofovir is no longer the only first line option under EAP.

“Only the least effective drug is easily accessible. The only positive in this option is tenofovir is added to the options under the EAP process.”

Comments for policy Option C: Lamivudine and entecavir Limited Use and updated EAP criteria (tenofovir first line option)

- More members were receptive to this option (and it became the preferred choice overall), as they understood that tenofovir is the most effective, but entecavir is cheaper and fairly similar in efficacy.
- Others were accepting of this option in hope that it can be revisited in 2-3 years if/when tenofovir is genericized.
- While some felt that this option was better than A or B, they would still like to see tenofovir off EAP and more accessible for patients in quick need of it.

“Greater access to entecavir under the Limited Use designation is the key to this option as well as tenofovir as a first line option. By increasing the access to treatment options under Limited Use we can more effectively treat Hep B, but still not the best option.”

“This option makes sense to me if entecavir is generically priced.”

Comments for policy Option D: Lamivudine, entecavir, and tenofovir Limited Use and updated EAP criteria
• This option was the favorite pre-meeting but became the second choice post-meeting.
• Many felt that this option placed too much of a cost burden on the system for it to be a top choice.
• Some members still felt strongly that tenofovir should be as accessible as possible to prevent any delay of treatment to those in acute situations.

"While probably in the best interest of the individual, I am concerned this option will be a cost burden to the system if tenofovir is not available in a generic format. Supporting this option will take away any ability for the system to control costs."

"There are too many 'ifs' in this option to consider it as viable."

“Less cost effective, but therapeutically the best option for reasonable access to required medications and drug of first choice." 

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 chronic hepatitis B. 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 review on chronic hepatitis B therapies. These findings will be used to help frame the final options in the consolidated reports. The consolidated reports will be posted at www.odprn.ca.

References

