Testosterone Replacement Therapy (TRT) for Men

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 of testosterone replacement therapies (TRT).

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 Citizen’s Panel meeting on TRT took place on October 20, 2014. Approximately one week prior to the meeting date the members were sent a lay version of the consolidated report on TRT. Members were asked to rate each of the policy options in relation to each other, while considering which option was the most acceptable from a societal standpoint. During the meeting, Citizen’s Panel members had the opportunity to ask questions about the different options and discuss the research and policy options as a group. Immediately following the meeting, Citizen’s Panel members were given the opportunity to re-rate their original survey responses based on the meeting discussion by completing the online survey.

Overall, 10 of the 15 (67%) Citizen’s Panel members participated in the pre-meeting online survey. There were some technical difficulties and only 6 of the 15 (40%) Citizen’s Panel members were able to participate in the meeting. Eight (53%) Citizen’s Panel members completed the post meeting survey.

Responses to the pre- and post-meeting surveys, as well as a brief description of key points discussed during the meeting, are presented below.

Overall ranking of options

- Table 1 shows the mean ranks of each option, pre and post citizen’s panel.
- The most preferred choice pre-meeting was a tie between options 2 and 4, whereas after the meeting, the preferred choice was option 3.
- Option 1 was the least acceptable choice in both pre and post surveys.

Table 1. Overall option ranking

<table>
<thead>
<tr>
<th>Option 1: Limited use (LU) listing for all TRT products</th>
<th>Mean Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre Panel</td>
</tr>
<tr>
<td></td>
<td>Post Panel</td>
</tr>
<tr>
<td>Option 2: Exceptional Access Program (EAP) listing for all TRT products</td>
<td>3.3</td>
</tr>
<tr>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Option 3: Exceptional Access Program (EAP) listing for oral and topical products; limited use listing for injectable products</td>
<td>2.5</td>
</tr>
<tr>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Option 4: Exceptional Access Program (EAP) listing for topical products; limited use (LU) listing for oral and injectable products</td>
<td>2.1</td>
</tr>
<tr>
<td></td>
<td>2.5</td>
</tr>
</tbody>
</table>

Ratings of policy options on acceptability domains

- Table 2 shows the mean score of eight specific aspects for each of the four policies that the Citizen’s Panel rated. Overall, respondents felt that policy options 1 and 4 increased accessibility to TRT, while policy option 2 was more affordable to patients and the healthcare system. Respondents tended to rate the options slightly lower in the post-survey compared to the pre-survey.
Table 2. Overall aspect rankings for each option

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Option 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>The policy helps those who need TRT to access them easily.</td>
<td>The policy will allow those who need TRT to access them equitably (in other words, regardless of age, income, health status, gender, etc.)</td>
<td>The policy adequately provides coverage for the appropriate types/quantity/doses of TRT.</td>
<td>The policy is a good option to make TRT more affordable.</td>
</tr>
<tr>
<td>Pre: 4.82 (5.83) Post: 5.38 (7.92)</td>
<td>Pre: 4.73 (4.75) Post: 5.25 (6.99)</td>
<td>Pre: 5.64 (8.74) Post: 4.25 (6.20)</td>
<td>Pre: 3.73 (3.94) Post: 3.00 (4.50)</td>
</tr>
<tr>
<td>The policy is a good option to limit the burden of cost on the healthcare system.</td>
<td>The policy adequately considers the safety and effectiveness of TRT.</td>
<td>Pre: 2.82 (3.06) Post: 1.50 (2.9)</td>
<td>Pre: 2.36 (2.96) Post: 2.38 (2.71)</td>
</tr>
<tr>
<td>Pre: 2.38 (3.18) Post: 4.13 (3.15)</td>
<td>Pre: 2.82 (3.06) Post: 1.50 (2.9)</td>
<td>Pre: 4.4 (4.99) Post: 3.88 (3.95)</td>
<td>Pre: 4.6 (5.22) Post: 5 (6.34)</td>
</tr>
<tr>
<td>The policy adequately considers the safety and effectiveness of TRT.</td>
<td>I think this policy will benefit those who require TRT.</td>
<td>Pre: 4.13 (3.15) Post: 4.6 (5.22)</td>
<td>Pre: 4.5 (4.24) Post: 4.00 (5.03)</td>
</tr>
<tr>
<td>Pre: 2.82 (3.06) Post: 1.50 (2.9)</td>
<td>I think this policy is an acceptable option.</td>
<td>Pre: 4.13 (3.15) Post: 4.6 (5.22)</td>
<td>Pre: 4.5 (4.24) Post: 4.00 (5.03)</td>
</tr>
<tr>
<td>Pre: 3.82 (3.51) Post: 3.50 (2.14)</td>
<td>I think this policy is an acceptable option.</td>
<td>Pre: 4.5 (4.24) Post: 4.00 (5.03)</td>
<td>Pre: 4.5 (4.24) Post: 4.00 (5.03)</td>
</tr>
<tr>
<td>Pre: 3.50 (2.14) Post: 2.73 (2.43)</td>
<td>I think this policy is an acceptable option.</td>
<td>Pre: 4.00 (5.03) Post: 4.5 (4.24)</td>
<td>Pre: 4.5 (4.24) Post: 4.00 (5.03)</td>
</tr>
</tbody>
</table>

*Please note that the pre- survey had 10 respondents whereas the post- survey had 8.*
Comments and key points from meeting discussion

Option 1: Limited use (LU) listing for all TRT products

- Concern that this policy is too liberal; that there are safety risks of allowing those who don’t need the drug to take it; and that it is a burden to health care system.
- Particular concern of continued coverage for the drugs when there is a lack of evidence for efficacy of TRT.

“Without enforcement, there can be abuse and lack of benchmarking.”

“TRT becomes easily accessible because there are very little restrictions. This policy does not take into consideration the health risks of those who use TRT even though they do not medically require it or are diagnosed with relevant illness.”

Option 2: Exceptional Access Program (EAP) listing for all TRT products

- Overall, respondents felt that this was a good option as increased restrictiveness would decrease the number of people receiving TRT without a diagnosis.
- There were some respondents that felt that it was potentially too restrictive and it could possible deter physicians from prescribing TRT to those in need. Also, this option may marginalize already marginalized populations, such as HIV-infected men.
- Additional considerations for this policy option should include whether changes can be made to the application process itself in order to facilitate access to those who require TRT.

“The only issue I have with this option is that MDs may be reluctant to fill out the EAP forms and disqualify/discourage patients with legitimate needs. Otherwise it is a good option. Streamline EAP.”

“Easily the best option. With all products moved under EAP only those individuals that truly need the treatment will receive it.”

Option 3: Exceptional Access Program (EAP) listing for oral and topical products; limited use listing for injectable products

- Option 3 was the most preferred choice.
- The balance between EAP listing for the oral and topical with the LU listing for the injectable was a key factor.
- Respondents believed that those who actually needed TRT would be able to receive it.
- A few felt that the option was still not restrictive enough, especially given that TRT use is continuing to rise. Also discussed was the potential for physicians to switch the type of TRT product they prescribe so that they can facilitate access without having to apply to EAP.

“I think this option provides the best balance at this time. It allows for change to occur without being so drastic. I think it’s fair to make this change and then re-evaluate the stats around prescribing behaviours and patient meds in a couple of years.”

“This option appears to be the best as oral and topical users don’t need to see a doctor once
prescribed meds. Therefore, EAP limits abuse and discourages over use.”

Option 4: Exceptional Access Program (EAP) listing for topical products; limited use (LU) listing for oral and injectable products

- Option 4 was the preferred choice pre-panel, but fell to the third most acceptable option after the meeting.
- There were still concerns about option 4 making TRT too accessible and over-used.
- Keeping injectable forms under limited use was acceptable as injectables would require more contact with a physician on a regular basis and are the cheaper option.
- Respondents also felt that it was unnecessary to have the oral formula on the LU list when they are not as effective.

“Restricting access to TRT is a step in the right direction however as mentioned with previous options, this does not do nearly enough to consider potential health risks of such wide access to TRT, and will decrease health system burden as much as option 2 “

“I think this is still too liberal. It’s not much different from option 1. Although it takes into consideration the burden on the health care system since topical are more expensive, it does not address other factors like inappropriate use and prescribing and potential safety concerns.”

General comments

- Participants felt that a clinical issue still needs to be addressed– physicians sometimes prescribe medications if patients are persistent enough. Additionally, prescribing without performing lab tests and making a formal diagnosis was worrying to participants. Many felt that restrictive measures are justified because of these factors.
- A highly discussed issue was about the continuation of funding for these products when there is no evidence for efficacy. It should be noted that these products are standard treatment for people with confirmed diagnoses of conditions that lead to primary and secondary hypogonadism. The lack of efficacy was demonstrated in studies of men who do not have these conditions.

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 use TRT. 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 TRT review. 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


