

The Ontario Drug Policy Research Network Drug Class Review on Medications for Overactive Bladder (OAB)

FINAL QUALITATIVE REPORT

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

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Conflict of Interest Statement

No study members report any affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock options, expert testimony, grants or patents received or pending, or royalties) that may present a potential conflict of interest in the drug class review for medications to treat overactive bladder.

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Study Team

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Note

Some details 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 Publications (when available) and/or final unpublished reports will be available on the ODPRN website (www.odprn.ca).

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Executive Summary

Background: The Ontario Drug Policy Research Network (ODPRN) conducted a drug class review of overactive bladder (OAB) medications in adults, which was selected as part of an initiative by the Ontario Public Drug Programs to update the public drug formulary. This report highlights the findings of the qualitative study performed within the drug class review to determine the experiences of managing and treating adults with OAB.

Methods: Mixed methods (interviews and surveys) were used in a framework approach. We conducted 17 semi-structured telephone interviews and 42 surveys. All stakeholders (patients, primary care physicians, urologists, urogynecologists, and geriatricians) were involved in interviews, however only patients completed surveys. 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 into our framework, and the framework was adapted to convey specific experiences and perceptions relevant to OAB medication funding policies. Survey results were analyzed using descriptive statistics (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 and physician groups.

Participants said that OAB should be a diagnosis of exclusion, since OAB symptoms can manifest from other conditions. Participants described various strategies for discerning a diagnosis of OAB such as collecting detailed information on symptoms, performing a physician exam, and doing formal testing (e.g. cystoscopy, post void residual bladder ultrasound, and urinalysis). However, not all physician participants perform formal testing before diagnosis. Those in favor of testing felt that the tests are crucial for ruling out other health conditions such as urinary tract infections, painful bladder syndrome, enlarged prostate etc.

Physician participants prefer long-acting agents over short-acting agents for the management of OAB. The main factors participants considered before prescription are anticholinergic side effect profiles, patient’s drug coverage, patient physiology, current medication use, and frequency of dosing. In general, they believed the long-acting anticholinergic agents are better tolerated by most OAB patients because they have fewer side effects and once daily dosing.

In elderly patients, products which do not cross or minimally penetrate the blood-brain barrier were preferred (e.g. darifenacin) since they are perceived to have less cognitive side effects. Participants reserved beta-3 agonists for patients who do not respond to anticholinergics and reserved botulinum toxin injections for patients who do not respond to either class of medications.

Physician participants are satisfied with updated ODB coverage but do not agree with the Limited Use (LU) criteria. Participants were pleased with the range of options they have access to prescribe for ODB patients. However, they explained that the LU criteria do not align with their preference to initiate patients on newer long-acting agents. Some participants admitted to using the LU code without following the criteria and others started patients on a range of samples to determine which product is the most helpful.

The majority of patients felt it was important to seek treatment for their OAB and the most commonly used agent amongst current users was the long-acting tolterodine formulation. Only a few participants were using short-acting tolterodine and oxybutynin immediate release demonstrating that patients preferred the newer agents compared to the older agents. Participants stated their main reasons for switching between OAB medications were the efficacy of a medication, the cost of medication, or the tolerability of medication side effects. Participants reported being most adherent to medications and absorbent pads, but least adherent to modifying diet and pelvic floor retraining exercises. The access issues reported by patients included type of drug coverage, availability of prescription at pharmacy, and cost of non-pharmacological interventions.

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

Background

The Ontario Drug Policy Research Network (ODPRN) is conducting 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. Medications for overactive bladder (OAB) were selected as the topic for the eleventh drug class review.

Currently, there is limited information on how physicians diagnose OAB and how they prescribe OAB medications. Phase 1 of the ODPRN qualitative unit work will involve exploring the various factors that may be related to the prescription, dispensing, and use of OAB medications for adults. The focus of this study will be on medications primarily and only on non-pharmacological interventions as they relate to medication use and prescription. We will not explore certain interventions, such as surgery, since these are outside the scope of this study. This information is warranted to understand and contextualize prescribing and usage patterns in Ontario, as well as to highlight any health equity issues that may be prevalent but are currently unknown. Phase 2 of the ODPRN qualitative work will be to assess the social acceptability and feasibility of the final results and recommendations proposed by the ODPRN research team.

Methods: Phase 1

Design

This study was conducted using mixed methods: interviews and surveys. We used a framework approach (Ritchie & Spencer, 1994) that helps researchers focus on specific areas of interest when exploring a topic, which can make the findings more applicable to policy contexts than alternative approaches. 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 the selected drugs when determining policy-relevant issues.

Sampling

Stakeholders identified for the OAB drug class review were primary care physicians (PCPs), urologists, urogynecologists, geriatricians, and patients. Inclusion criteria are clinicians (PCPs, urologists, urogynecologists, geriatricians) who have prescribed OAB medications to adults and patients over 18 years of age who have been diagnosed with OAB. All stakeholder groups were invited to participate in interviews. The literature shows that patients are unwilling to talk to their physicians about OAB because of the sensitive nature of the topic (Andersson et. al; 2008; Basu et. al, 2009; Bradway et. al, 2008; Diokno et. al, 2006; Filipetto, 2014); we anticipated that similar challenges would exist for patient interview recruitment.

Therefore, we created a survey component, which is better suited to measure experience around a sensitive topic than an interview (Fowler, 1995).

A purposive sampling approach using a convenience sample was used in order to elicit the specific perceptions and opinions of those who will be involved in or affected by drug policy decisions related to OAB medications. Given the rapid nature of study timelines, we aimed to recruit six to eight participants from both stakeholder groups (clinicians & patients). We anticipated that this amount of participation may be sufficient to reach saturation amongst relatively homogenous groups of participants (Kuzel, 1999).

The following recruitment methods were used: 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 (Twitter, Facebook) accounts; g) asking Canadians and h) 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).

Data Collection and Analysis

Qualitative data were collected through one-on-one, semi-structured telephone interviews that were 30 to 45 minutes in length and conducted between March and June 2015. All interviews were conducted with a semi-structured interview guide developed using the “Triple-A” framework for pharmaceutical policy analysis (Morgan et. al., 2009) and collaboration from physicians and the drug class review team. Each interview was audio recorded. Interviews were transcribed, and transcripts comprised the primary source of data. The interviewer and/or a note taker took field notes during the interview to serve as a secondary source of data.

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 to the “Triple-A” framework (Morgan et. al., 2009). These codes comprised the coding framework. A modified coding consensus approach was used: the framework was reviewed 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 analyst and the qualitative research team engaged in mapping and

interpretation of the coded data to generate the final themes.

Survey data was collected through an online survey that was developed based on a literature review. The survey questions covered the following categories: quality of life, treatment options, medication use, medication adherence, and medication access. Survey results were analyzed using descriptive statistics (mean, standard deviation, count, proportion) and content analysis on open-ended responses.

Phase II of the qualitative research study is described below.

Research Ethics

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

Part 3: Findings

A total of 59 participants took part in the study: 44 patients, 4 primary care physicians, 9 urologists, 1 urogynecologists, and 1 geriatrician. Detailed participant demographics can be found in **Appendix B**.

Key Themes Related to the Prescription and Use of Medications for OAB in Adults

PHYSICIAN INTERVIEWS

This section describes findings from the physician interviews divided into three key themes that are outlined below. In this section, the term “participants” will be used to refer to all physician participants. Specialists will be referred to as “specialist participants” and primary care physicians will be referred to as “primary care participants”.

Diagnosis of OAB

Management of OAB

- Non-pharmacological strategies
- Medications
- Perceived trends in prescription
- Patient adherence to medication

- Botox treatments

Perceptions of Ontario Drug Benefit Coverage

- Satisfaction with updated formulary
- Comments on LU Criteria

The detailed findings on each of these themes are described below.

Diagnosis of OAB

Participants described various strategies for discerning a diagnosis of OAB but the most common strategy was to begin by collecting detailed information on OAB symptoms.

Specialist physician participants said that, more often than not, patients have been referred to them specifically for investigation of OAB and so they will describe their concerns without prompting. Most primary care participants (PCP) described that they will investigate the condition only if the patient complains of symptoms. However, some PCPs perceived that patients are embarrassed to bring up their symptoms so they will routinely screen for OAB, usually amongst women, during an annual check-up. Many PCPs and specialist participants said that they will start by asking the patient to keep a “voiding diary” where they document their fluid intake and the timing and volume of each of their voids (urination) over the course of one week.

After collecting information on symptoms, most participants said they may also do a physical exam, however, not all felt the necessity to follow-up with diagnostic testing (e.g. cystoscopy, post void residual bladder ultrasound, urinalysis, and urine culture). Some said they prefer to start non-complex, treatment-naïve patients on an OAB medication first and if there is no improvement they may do urodynamic studies.

“it’s primarily a diagnosis on the basis of a history and a physical, and certainly I’ll go on and do a urinalysis or a urine culture – depending on what the symptoms are – but I’ll usually stop there and then I’ll treat on the basis of a very brief and early clinical assessment rather than resorting to any expensive investigations” –specialist physician

Those who were in favor of testing were in the majority, describing it as crucial, because they have seen how OAB symptoms can be manifested by other health conditions such as: urinary tract infections, painful bladder syndrome, enlarged prostate, pelvic floor prolapse, stone disease, bladder cancer, and neurogenic conditions. They also noted that it is important for physicians to take an inventory of a patient’s current medication use, just in case the patient is

using diuretic medications which are affecting the bladder.

“We see a lot of patients in our unit who have what’s called drug induced voiding dysfunction. Ok. They are not emptying their bladder and it’s partially related to all of the pills they are on. So why would you add another pill that could even make it worse without doing some investigations first?” – specialist physician

Management of OAB

Non-Pharmacological Strategies

The majority of physician participants said that once an OAB diagnosis is obtained for a patient, they will start by treating them with non-pharmacological strategies to see if the patient will improve. Other participants said they prefer to start the patient with both medication and non-pharmacological strategies because they do not believe that the strategies can be a stand-alone intervention.

“They help somewhat but I don’t think they help a lot. You know it’s an adjunct, and it’s important, but it’, probably isn’t going to change things enough to significantly affect quality of life and symptoms. You know so it’s good to do and in some people it really does the trick but for most people it’s an adjunct to pharmacologic measures” – specialist physician

Some of the most commonly mentioned strategies were:

- Modify daily fluid intake (take fluids earlier in the day and avoid caffeine or alcohol after dinner);
- Regular scheduled urination (e.g. every 3 hours) to reduce the instances of emergency where the bladder reaches critical volume; and
- Pelvic floor exercises.

Participants had mixed perceptions of the effectiveness of these approaches. Some said they perceive that these strategies are effective for 30-40% of patients who then do not require medication. However, they also noted that the effectiveness depends very much on the patient’s commitment and adherence to implementing the strategy. As a result, participants said they will usually prescribe medication in addition to giving the patient advice or pamphlets on fluid intake and bladder retraining. They believed that patients should be educated about the impact that lifestyle and fluid intake can have on the bladder, even with the use of medication. They may also ask the patient to keep a voiding diary so they can monitor the effectiveness of these interventions.

“My favourite line that I tell them is that they can outdrink any medication that I can

prescribe. So, if they, you know, have indiscretions with the use of lots of caffeinated beverages, or alcoholic beverages, then it doesn't really matter what drug they're on. They're going to fail to see improvement." –specialist physician

Medications

Overall, the majority of physician participants described that anticholinergics are considered the mainstay of pharmacological options for OAB, and that there are a range of agents to choose from within this class. Furthermore, they described a preference to prescribe long-acting anticholinergics instead of short-acting anticholinergics. The second most commonly mentioned drug class was beta-3 agonists that were described as having a different mechanism of action than anticholinergics. Beta-3 agonists (e.g. mirabegron) were perceived to be a good option for patients who do not respond well to the anticholinergic class. The main factors which participants said they consider before prescription are anticholinergic side effect profiles, patient's drug coverage, patient physiology, current medication use, and frequency of dosing (Table 1).

Table 1: Description of factors considered before prescription

| Factor | Main points of consideration |
|---|---|
| Side effect profiles of anticholinergic agents | <ul style="list-style-type: none"> • when prescribing, participants will assess the degree to which the patient is bothered by side effects and switch agents accordingly • participants may give patient samples of different agents in order to see how patient responds before deciding on one • common side effects described were constipation and dry mouth • participants have noted that some agents cross the blood brain-barrier, which means they may cause cognitive changes in the patient (e.g. oxybutynin) • side effect profiles are worse for short-acting agents, therefore participants prefer to prescribe short-acting as PRN only • long-acting agents (e.g. tolterodine long acting, oxybutynin long-acting) have fewer side effects and are preferred |
| Patient's drug coverage | <ul style="list-style-type: none"> • participants prefer to prescribe long-acting agents first, therefore patients with private insurance are more likely to start on long acting agents • participants may go against their preference and prescribe oxybutynin immediate release to ODB eligible patients • for patients without any coverage, participant prescription depends on the availability of samples in |

| | |
|--|--|
| | their office |
| Frequency of dosing | <ul style="list-style-type: none"> participants prefer long-acting agents because there are fewer doses required per day and participants perceive that this impacts adherence |
| Patient demographics/physiology | <ul style="list-style-type: none"> <i>geriatric patients:</i> <ul style="list-style-type: none"> Fesoterodine is the most preferred – comes in multiple doses – there is the option to escalate doses, good for medically complex patients Darifenacin is also preferred - want to avoid potential for cognition related side effects, especially for those with mild cognitive impairment <i>gender:</i> <ul style="list-style-type: none"> men– if symptoms are consistent with benign enlarged prostate and they have not been on an alpha blocker before – may initiate with alpha blocker women- usually initiate with anticholinergic <i>patients who do not respond well to anticholinergics:</i> <ul style="list-style-type: none"> switch to beta-3 agonist <i>history of glaucoma:</i> <ul style="list-style-type: none"> will not prescribe anticholinergics <i>high blood pressure:</i> <ul style="list-style-type: none"> will not use beta 3 agonists |
| Current medications used | <ul style="list-style-type: none"> if patients are already using medications which cause constipation, dry mouth etc. prefer not to prescribe an anticholinergic if patients are on medications for memory (cholinesterase inhibitors) – these have a negative effect on the bladder, so prescribing an anticholinergic may not improve symptoms, but increase side effects |

Participants were also asked about their thoughts on the role of dual therapy for OAB management. Over half of participants did not prescribe dual therapy either because they have not found enough evidence for its efficacy or because they do not have enough knowledge of dual therapy strategies. In particular, PCPs said that if a patient is not responding well to monotherapy, they would rather refer to a specialist than experiment with dual therapy. Those who do prescribe dual therapy described that they will reserve this option for patients who are responding to an anticholinergic but not achieving the level of symptom resolution that they desire. In these cases they would combine the anticholinergic with a beta-3 agonist. Most participants said they would avoid dual therapy with anticholinergics because the side effects would likely be unbearable for the patient and because both drugs would have the same mechanism of action in the body. Some said they would potentially add an alpha blocker, to an anticholinergic, for their male patients if they have some degree of lower inner

tract obstruction.

Perceived trends in prescription:

Participants perceived that there has been an increase in the prescription of newer and long-acting agents for the treatment of OAB (e.g. solifenacin, darifenacin) and a decrease in older short-acting agents (e.g., oxybutynin). They think this shift has occurred in part because more of the newer agents are now covered under ODB and because many OAB patients are older and thus eligible for coverage under the ODB. In addition, they have noticed that their colleagues prefer newer agents because they have better side effect profiles and are more beneficial for vulnerable patients such as the elderly.

Participants perceived that there has been a rise in the prescription of OAB medications. They believed this could be due to more physicians screening and treating for OAB as well as the aging population in Ontario. Though OAB presents in men and women of all ages, they perceive that it is slightly more common in the elderly. They also described that OAB is not a condition that many patients like to bring up on their own, so more physicians are being educated to ask patients about OAB symptoms during annual check-ups.

Patient adherence to medications:

When asked about adherence, many participants perceived that patient adherence rates to OAB medication after one year are very low. In general, they described that their patients are more likely to be adherent to their medication if OAB symptoms improve and if they are able to tolerate medication side effects. In short, if the perceived benefits outweigh the perceived harms, participants believe adherence will increase.

“An example would be someone gets a dry mouth but it’s helping their OAB symptoms and they have a drier bladder. They are going to shrug off the dry mouth because they are having a drier bladder, so efficacy trumps side effects in most cases, unless they are big, big bad side effects” –specialist physician

Many patients may choose to take medication PRN (as needed) because they perceive that they can manage the symptoms and would rather not deal with the side effects on a daily basis. Participants explained that these patients may take their medication for special events where they know they will not be in close proximity to a bathroom. Some physicians also noted that a patient’s perception of harms and benefits may be influenced by their expectations of the treatment. They have observed that those who have false expectations that the medication will provide a cure, or those who are not properly informed about the side effects, are less compliant to their OAB medication.

Additional factors mentioned by participants that may affect adherence were drug coverage and multi-day dosing. Participants explained that patients who have complex drug regimens may find it difficult to remember to take all their medications on the correct dosing schedule. They also described that patients are more likely to adhere to OAB medication if they are able to get it covered through private insurance or the ODB.

Botox[®] treatments:

Participants described that they will try Botox[®] (OnabotulinumtoxinA – 100 units) injections if a patient does not respond to any of the OAB medication options. It was described as a temporary measure but one that can be effective for managing symptoms. Since the effects of the injection wear off after six months, participants described that some patients may take medication to sustain them between injections. The injections are done with a local anesthetic. Participants perceived that there is a risk for infection which should be mitigated with antibiotics. Urinary retention was also another risk described by participants that they perceive can happen in anywhere from 15% to 30% of patients. In order to mitigate this, some participants will perform intermittent catheterization on the patient to get rid of residual urine, or will ask the patient to wear catheter. Lastly, it was noted that not all urologists or specialist physicians perform Botox[®], but the number of those who do is increasing.

Perceptions of Ontario Drug Benefit Coverage

Satisfaction with updated coverage

Physician participants described that they are pleased with the recently expanded ODB coverage for OAB medications. They indicated that it is helpful to have more options for patients once they fail a trial of oxybutynin immediate release since each patient may respond differently to different medications. In the past, participants would prescribe tolterodine after oxybutynin but now many have said they may start with solifenacin.

“You can’t just sort of paint everybody with the same brush, people do respond differently to different medications, so I think they should maintain access to various types of medications – even though they’re different medications in the same class.” – specialist physician

Participants did note that the only OAB product they wish would be covered is Gelnique[®] (i.e. oxybutynin gel). They believed this may be beneficial to cover for patients who respond poorly to other formulations or for patients who are unable to swallow. However, they believe that this applies to a small segment of the OAB patient population. Overall, in the context of costs

to the public system, they said that the current list of covered options is satisfactory without the inclusion of the Gelnique[®]. Participants also described that they are pleased that Botox[®] is now covered under limited use (LU) as it provides an option for ODB eligible patients who do not respond to medication.

Comments on Limited Use Criteria

When asked about their perceptions of the LU criteria, physician participants unanimously expressed that they feel the criteria do not align with their preferences for OAB management. The criteria dictate that all patients should start on oxybutynin immediate release and they prefer to start with a newer long-acting agent because they perceive that oxybutynin immediate release is one of the oldest agents, has the worst side effect profile, and is not tolerated well by most patients.

“I think it denies people access to drugs that are clearly better, I mean for example, Ditropan[®], very old OAB agent, clearly associated with delirium and cognitive impairment versus a new drug like fesoterodine or Myrbetriq[®], you know so what would you want your father who has got some mild cognitive problems to go on? But according to the letter to the law, they are supposed to be tried on a crappy agent and get side effects before they go on an agent that is clearly a drug of choice if you just cared about caring for patients.” –specialist physician

When asked how they would revise the criteria to align with their preferences, one suggestion was to open access to require that a patient is tried on at least one long-acting generic OAB medication (e.g. an anticholinergic), before moving to brand name products. Participants perceived that this would benefit patients because they could start a trial of generic solifenacin or tolterodine instead of oxybutynin immediate release, both of which have better side effect profiles and do not require multi-day dosing. They believe that patients will be more compliant to their medications if they are on drugs with fewer side effects.

A number of participants went on further to say that they do not believe in the value of the LU program in general because they are aware of physicians who use the LU code without following the criteria. Some participants personally admitted to using the LU code without going through the step of starting the patient on oxybutynin immediate release. Others described that they will give a patient samples of both the newer agent and oxybutynin immediate release and wait for them to try both. They do this in order to save time because they have observed that the majority of their patients will come back saying that they cannot tolerate the side effects of oxybutynin. They have observed that some patients who respond

poorly to oxybutynin immediate release may subsequently be reluctant to try any other medications and may not finish the oxybutynin immediate release they filled through ODB coverage. Given this context, some physician participants suggested that OAB medications be moved from LU to the general benefit program.

“Cheaper is not always good because when you’re trying to reach for something cheaper you might end up using cheaper medication, wasting it, and still reaching for something more expensive.” –primary care physician

PATIENTS

There were 44 OAB patient study participants (two interviews participants and 42 survey respondents), with 33 (75%) being female. Participants ranged from 25-95 years, with 29 patients (66%) between the ages of 55 to 74 years. Participants varied in number of years since OAB diagnosis with 24 participants (55%) being diagnosed for less than five years, 14 (32%) being diagnosed for 5-15 years, and six (13%) being diagnosed for more than 15 years. Recruitment for patient interviews was a challenge and the interviews conducted did not contain rich data. The following section primarily summarizes findings from survey participants and is organized in three categories: OAB treatment options and adherence, OAB medication and quality of life, and OAB treatment access.

OAB Treatment Options and Adherence

- Treatment seeking behaviour
- OAB treatment options
- Adherence to OAB treatment options

OAB Medication and Quality of life

OAB Treatment Access

The detailed findings on each of these themes are described below.

OAB TREATMENT OPTIONS & ADHERENCE

Survey participants were asked to report their decisions about treatment for OAB and about their adherence to various treatment options.

TREATMENT SEEKING BEHAVIOUR

Survey participants were asked to report how they prioritize treatment for OAB, what kind of

physician they seek treatment from, and what factors influence their choice to seek treatment. On a scale of 1 to 5, with 1 being not at all important and 5 being extremely important, participants rated the importance of seeking treatment for their OAB. Thirty-one participants (74%) indicated it was moderately important to extremely important, three participants (6%) took a neutral stance, and eight participants (20%) indicated it was slightly to not at all important. When it came to seeking treatment, the majority of participants consulted their primary care physician (n = 30, 72%), whereas the remainder of participants consulted specialist physicians (urologists [n = 7, 17%], urogynecologists [n = 3, 7%], bladder surgeons [n = 1, 2%], or nurses at continence clinics [n = 1, 2%]).

Survey participants were also asked to report the factors that influence their choice to pursue treatment for OAB symptoms. The main facilitators for seeking treatment included the desire to gain control of life, to increase the quality of life, to avoid embarrassing accidents (i.e. urine leakage), to minimize discomfort or pain, to prevent surgery, and to use medication that is effective. The main barriers to seeking treatment included a personal preference to avoid medication (i.e. treat with natural remedies or non-pharmacological methods), experience with ineffective medication, a personal belief that OAB is manageable without treatment or that it is a natural part of aging, the severity of OAB symptoms, the cost of treatment, the inconvenience of medication dosing, and the side effects of medication. In conclusion, after OAB diagnosis, there are many factors which may influence OAB patients' choice to pursue treatment.

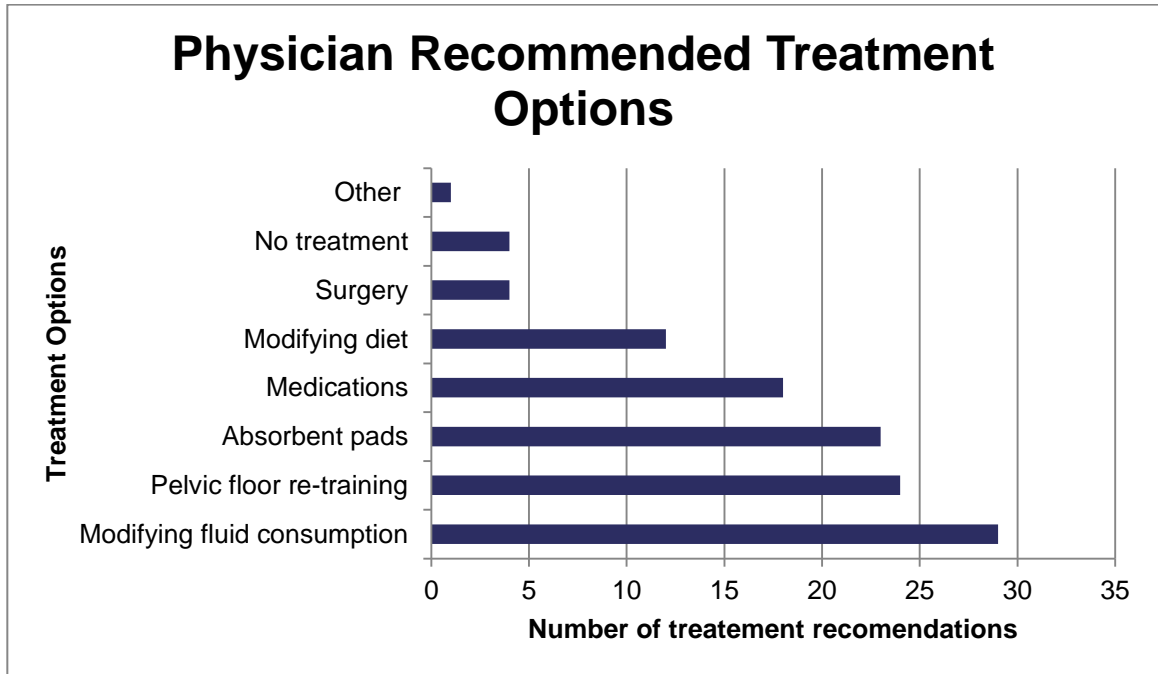
OAB TREATMENT OPTIONS

Survey participants were asked to report about the treatment options that were recommended to them by physicians and about their experiences with different OAB medications. In order of frequency, the four most commonly recommended treatment strategies were to modify fluid consumption, pelvic floor re-training, absorbent pads, and medications (Figure 1).

Eighteen participants (43%) from our sample have past or current experience using OAB medications. The most common agents ever used for this subset of the sample were oxybutynin and tolterodine (Figure 2). Of patients with medication experience eight (44%) have switched between one or multiple agents since initial diagnosis and two (25%) were using a dual anticholinergic therapy. The most commonly used agent by current users was tolterodine long-acting, potentially indicating a preference for long acting versus short acting medications (Figure 3). In addition, fewer participants were using tolterodine regular release and oxybutynin immediate release potentially demonstrating that patients preferred the newer agents compared to the older agents. Participants stated their main reasons for switching

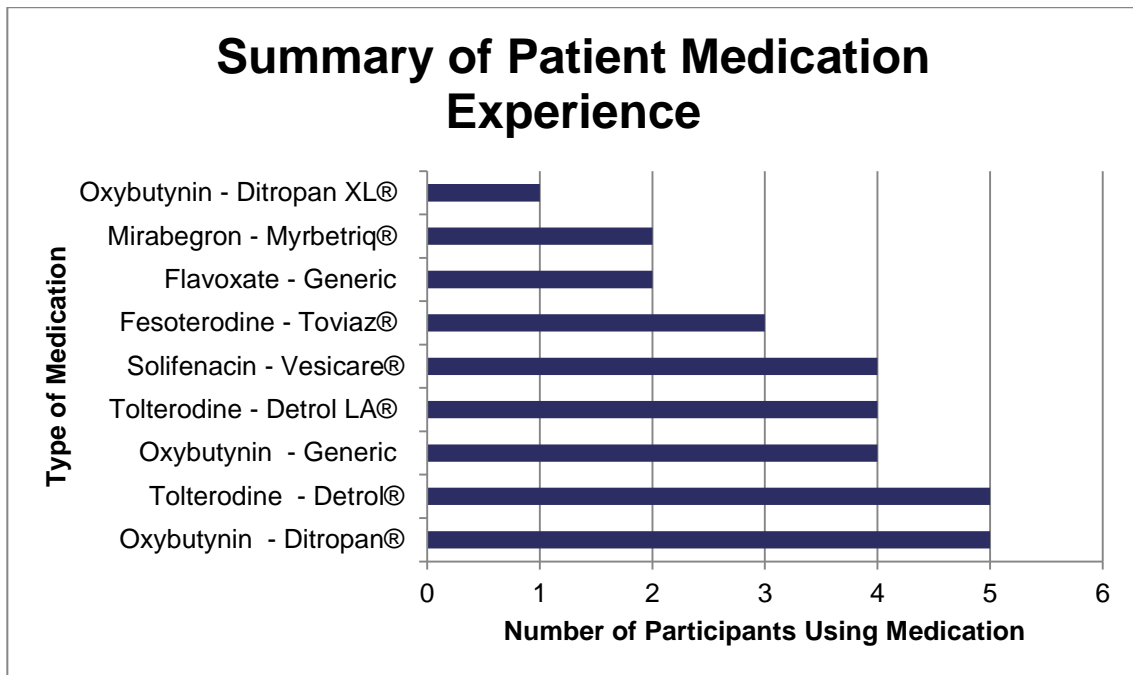
between OAB medications were the ineffectiveness of medication, the cost of treatment, and the tolerability of side effects.

Figure 1: Physician Recommended Treatment Options



Participants (N=42) were instructed to indicate all treatment options their physician had recommended from a pre-defined list.

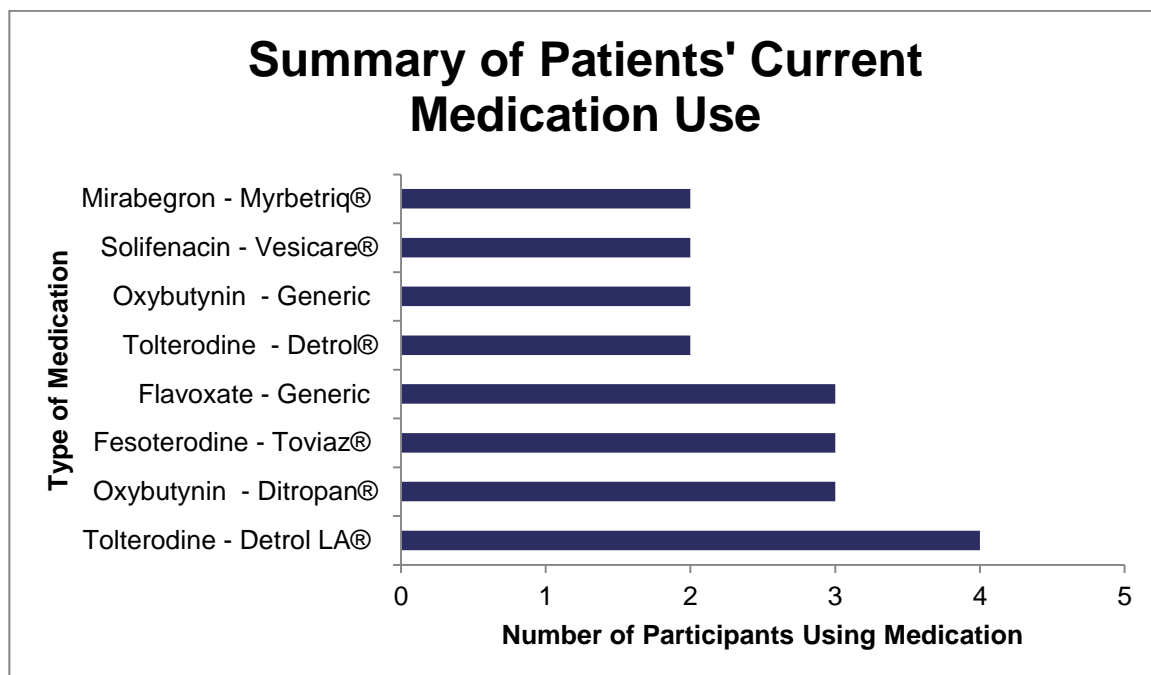
Figure 2: Summary of Patient Medication Experience (past and current use)



Participants that indicated having medication experience (n=18) were instructed to indicate all

medications they have ever tried from a pre-defined list.

Figure 2: Summary of Patient's Current Medication Use



Participants that indicated having medication experience (n=18) were instructed to specify which medication(s) they were currently using from a pre-defined list.

ADHERENCE TO OAB TREATMENT OPTIONS

This section explores factors that influence patient adherence to OAB treatment strategies. Participants indicated all OAB treatment strategies prescribed by their physician and then rated their adherence to them on a scale of 1 to 5, with 1 being not at all adherent and 5 being extremely adherent (Table 1). Adherence to absorbent pads (n= 23, M = 4.38, SD =1.08) and medications (n= 18, M = 4.28 SD = 0.98) were the highest whereas adherence to modifying diet (n = 12, M = 3.33 SD = 1.56) and pelvic floor retraining exercises (n =24, M = 3.25, SD = 1.33) were the lowest. One interview participant described the reason why adherence to medication is important to her:

“You know some days you just forget. I forget to take my medication in the morning and then I know, the reason I know I forgot to take it is that all of a sudden I am going to the bathroom a lot and I have this urge a lot, so I am going, ah, cripes, didn’t take my pills this morning” –patient interview participant

Participants who had difficulty adhering to their OAB treatment plans ranked how much cost of treatment, side effects of treatment, inconvenience of treatment schedule, forgetfulness

and lack of treatment efficacy influenced their overall adherence. The most common reason for nonadherence across treatment strategies was inconvenience. One interview participant did elaborate on the inconvenience of modifying fluid intake:

“They did suggest that I limit my liquid intake after about 5:00 so that I am not being awakened in the night, but that doesn’t always work for me... I find it hard to limit them at that hour and I work on, oh a very odd non-regulated schedule as far as work goes, so sometimes that 5:00 is my lunch, not my dinner, and to stop drinking like with a meal and stuff is hard.” –patient interview participant

Modifying diet and pelvic floor retraining exercises (e.g. kegel exercises) had the lowest adherence. Six participants found modifying their diet was difficult; they attributed nonadherence to forgetfulness (67%), lack of efficacy (33%), side effects (17%) and cost (17%). Similarly, the 12 participants who had difficulty adhering to pelvic floor retraining exercises also stated forgetfulness (58%) as the most common factor that influenced non-adherence; other factors included inconvenience (25%), lack of efficacy (17%), and side effects (8%). Participants also responded to an open-ended question about factors that influence OAB treatment adherence. They listed similar reasons to the pre-defined list they ranked, however additional factors mentioned were lack of physician involvement and other health conditions.

OAB MEDICATION & QUALITY OF LIFE

This section describes participants’ perception of their quality of life prior to and while using OAB medications. On a scale of 1 to 5, with 1 being no effect and 5 being a major effect, participants rated the degree that their OAB has negatively impacted their daily life prior to medication use and while on medication. Thirty-one (74%) participants indicated that their bladder condition had a moderate to major effect on their overall quality of life without the use of medication. Eighteen (43%) participants decided to take medication to treat their OAB; when these participants were asked to re-rate their quality of life, only 7 (39%) indicated that OAB still has a moderate to major effect on their quality of life (Figure 4). For some respondents, their OAB medication was associated with better symptoms management, which resulted in an improvement to quality of life.

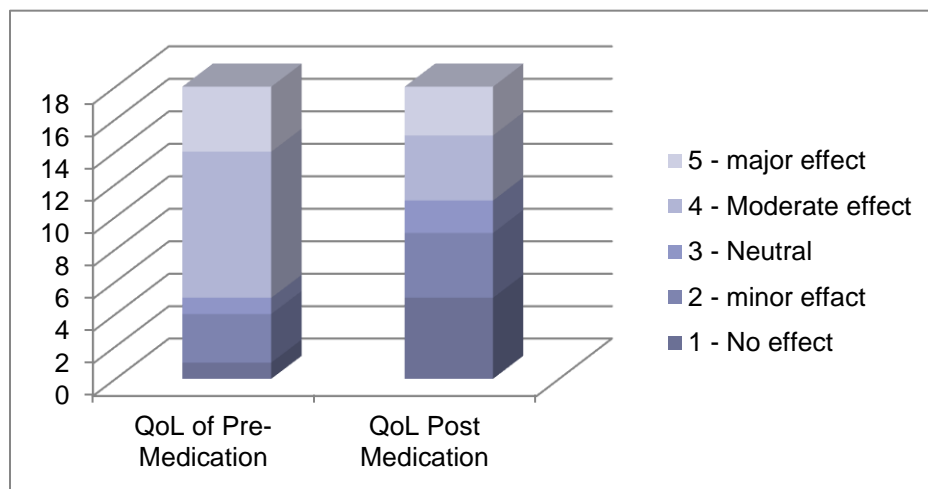
On a scale of 1 to 5 with 1 being not all bothered and 5 being extremely bothered, participants rated to what degree a set of five pre-defined OAB symptoms bothered or interfered with their daily life. Prior to medication use, participants found nocturia (i.e. sleep disruption due to

frequent night urination) to be the most bothersome OAB symptom whereas stress incontinence (i.e. urine leakage when laughing, coughing, sneezing or exercising) was the least bothersome OAB symptom. In contrast, while using medication participants reported the overall severity of all OAB symptoms to be reduced (Table 2). One interview participant described the impact of OAB medication on her quality of life:

“I take it in the morning and that sort of gets me through the day, and it means that I am not constantly running to the bathroom. If I take it twice a day like if I had a lot to drink at night I will, I will take it so that I don’t have to get up in the middle of the night, my bladder doesn’t like go into spasm or whatever and wake me up and tell me it’s got to get up and then not do what it’s supposed to do.” –patient interview participant

In conclusion, respondents who currently use OAB medication reported less severity of symptoms and subsequently an improvement in their quality of life. Participants described how OAB impacted their daily life and how some symptoms were not as troublesome while on medication (Table 3). The balance between symptom relief and medication side effects influenced patients’ adherence to OAB treatment options.

Figure 3: Quality of life pre- and post-medication



Medication users’ (n=18) pre- and post-medication quality of life scores.

Table 2: Severity of overactive bladder symptoms prior to medication use

| Overactive Bladder Symptom | Entire Sample (n=42) | No Medication Experience (N=24) | Medication Experience | |
|---|-------------------------|------------------------------------|-----------------------|----------------|
| | | Pre-med Use | Pre-med Use | Post-med Use |
| | M (SD) | M (SD) | M (SD) | M (SD) |
| Going to the bathroom many times over the course of a day (i.e. urinating too often). | 4.17 (1.03) | 4.25 (0.90) | 4.06 (1.21) | 3 (1.68) |
| Difficulty controlling the urge to urinate (i.e. intense need to urinate). | 3.98 (1.12) | 3.83 (1.90) | 4.17 (1.15) | 2.94 (1.70) |
| Urine leakage due to a strong need to urinate (i.e. urge incontinence) | 3.57 (1.58) | 3.58 (1.50) | 3.56 (1.72) | 2.72 (1.74) |
| Urine leakage when you laugh, cough, sneeze, or exercise (i.e. stress incontinence) | 3.43 (1.71) | 3.46 (1.59) | 3.39 (1.91) | 2.56 (1.76) |
| Sleep disruption due to getting up to urinate during the night (i.e. nocturia) | 4.26 (1.25) | 4.63 (0.71) | 3.78 (1.63) | 2.33 (1.91) |

The sample can be classified into three categories: the entire sample (n=42, 100%), non-medication users (n=24, 57%), and medication users (n=18, 43%). Participants ranked OAB symptom severity on a scale of 1 to 5 with 1 = not at all bothered and 5 = extremely bothered.

Table 3: Patient participants quotes about impact of OAB on quality of life (QoL)

| Impact of QoL prior to medication use | Impact of QoL while on medication |
|---|---|
| "Often I miss parts of entertainment (e.g., concert, movie) because I need to go to the washroom." | "Daily life is somewhat controlled" |
| "Always having to wear pads. Planning trips around accessibility to washrooms. NOT going places because of it." | "Very little interference with my daily life while using medications" |
| "Can't participate in some sports for fear of leakage." | "Slight decrease in frequency/urge to go." |
| "Have to carry around extra clothes for emergencies." | "I still need to wear a pad for occasional leaks" |
| "1 cup of fluid has me going to the washroom 3 or 4 times therefore I tend to dehydrate myself as a result" | "dry mouth, the recent meds have given me headaches" |
| "I have to get up many times in the night and that does not allow me to get a good night's sleep." | "I travel a lot, must carry medication." |

OAB ACCESS TO TREATMENT

Participants with experience using OAB medication (n = 18, 43%) paid in various ways, with nine (50%) participants having third party coverage, seven (39%) participants having ODB coverage, and the remaining two (11%) paying out of pocket. One interview participant who had partial private insurance commented on her desire to continue on the medication despite the cost:

“It would be nice if I didn’t have to take medication. That would just, you know, that would be great, it would save money and everything else, but...I know that on the days that I don’t take it my life is very different” –patient interview participant

Three access issues were identified for OAB treatment. First, across the payment types some participants mentioned coverage issues; meaning they had to ask the pharmacist to substitute the prescribed medication with one that was covered by their insurance plan or the ODB to avoid paying out of pocket. Second, a few participants mentioned experiencing pharmacy availability issues, such as wait times of up to a week before their OAB prescription could be filled. Third, some patients mentioned that cost was a barrier for other management strategies, such as incontinence pads and physiotherapy for pelvic floor re-training. In summary, access barriers participants experienced in managing their OAB were medication coverage, pharmacy availability, and cost of non-pharmacological interventions.

Part 4: Discussion

Key Findings

The experiences and perceptions from our interview and survey participants have pointed to some key findings related to the prescription and use of OAB medications for adults. A surprising finding was that physician participants perceived that OAB may be over diagnosed if there is no appropriate investigation to rule out health conditions such as urinary tract infections, painful bladder syndrome or pelvic floor prolapse. The most prominent finding which cut across both physician and patient data was that the long-acting newer OAB agents are preferred over the short-acting older agents. Physician participants perceive that this is because these agents have better side effect profiles and because they have once-daily dosing. Now that some of the long-acting agents are on the ODB formulary, physicians feel they have more options for ODB eligible patients who do not respond well to short-acting agents. Medication cost and tolerability of side effects were amongst some of the main reasons that patient participants reported they switched between OAB agents. The most commonly used agent amongst current medication users in our patient sample was the long-acting formulation of tolterodine. Lastly, physician participants did not feel that their preferences for prescription of long-acting agents align with the LU criteria. Some participants admitted to using the LU code without following the criteria and some give samples of various medications to their patients in order to save on time and resources.

Healthy Equity Considerations

The findings from this study highlight a few key access issues for adult OAB patients. Those who are under 65 and who do not have private insurance will have barriers to access the medication they need; this is common finding across the drug class reviews. In addition, vulnerable OAB patients, such as the elderly, may have to suffer through side effects of short-acting medications before being able to access medication with better side effect profiles. In particular, the cognitive side effects of some of the anticholinergic agents may exacerbate an elderly patient's existing co-morbidities such as mild cognitive impairment.

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 OAB medications in adults and may be more highly involved in OAB advocacy initiatives.

Part 5: Conclusions

The findings from the qualitative study of this review on OAB medications 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 this review. On a broader scale, our study findings fill a gap in knowledge on access to OAB products for adult patients and how this may be impacted by physician and patient perceptions of these drugs. Overall, our findings shed light on the experiences of prescribing and using OAB medications for adults, 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 ODPRN OAB research studies, a consolidated report was drafted that includes a set of potential reimbursement options for the funding of OAB medications for adults. 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 Citizen's 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 will be 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 will attend a webinar meeting, at which we will present key issues, findings and policy implications, and engage in group discussion on the recommendations. Citizens' Panel members will complete 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 will be 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).

Participant Feedback

All interview participants from phase I were invited to participate in a member checking and acceptability survey exercise. A total of seven participants (one primary care physician, five

urologists, and one patient) completed the survey.

Participants were presented with the following policy options:

- Policy Option A: (status quo) Oxybutynin Immediate Release (IR) as GB, all other OAB medications LU
- Policy Option B1: Oxybutynin IR and solifenacin as GB, all other OAB medications LU
- Policy Option B2: Oxybutynin IR, solifenacin as GB, all other OAB medications LU
- Policy Option B3: Oxybutynin IR, solifenacin and tolterodine (immediate and extended release) as GB, all other OAB medications LU
- Policy Option B4: Oxybutynin IR, solifenacin or tolterodine (immediate and extended release) as GB, all other OAB medications LU
- Policy Option C: Enforced use of oxybutynin IR OR solifenacin as initial therapy, all other OAB medications Limited Use
- Policy Option D: Solifenacin as General Benefit, all other OAB medications Limited Use

Most participants found policy options A and C to be the least acceptable options as they did not believe that Oxybutynin IR should be enforced due to the side effects. Participants ranked policy options B2, B4, and D as the most acceptable options (refer to Table 4). Participants preferred the options with Solifenacin and options that did not require patients to try various options before gaining access to LU medications.

Table 4. Ranking of policy options in terms of acceptability (1 = most acceptable and 7= least acceptable)

| Policy Option | Mean Ranking (SD) (1 = Most Acceptable 7 = Least Acceptable) |
|----------------------|---|
| Policy Option A | 5 (2.1) |
| Policy Option B1 | 4.4 (1.1) |
| Policy Option B2 | 2.8 (0.8) |
| Policy Option B3 | 4.6 (1.8) |
| Policy Option B4 | 3 (1.9) |
| Policy Option C | 5.2 (2.4) |
| Policy Option D | 3 (2.8) |

Participants were also asked to review the following three recommendations:

- Recommendation 1: No listing is recommended for oxybutynin extended release (Ditropan XL[®]), oxybutynin gel (Gelnique[®]), oxybutynin transdermal (Oxytrol[®]).
- Recommendation 2: For patients unable to swallow, recommend availability of oxybutynin gel (Gelnique[®]) under Exceptional Access Program (but not oxybutynin

transdermal [Oxytrol[®]]).

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.

Most participants were in favour of the recommendations; however, there was a suggestion to include Gelnique[®] under LU to increase accessibility of patients to the medication. There was some variability in participant comments for the third recommendation. Some agreed with the third recommendation. Others had a perception that the note prevents patients from accessing the most appropriate treatments because it is oversimplified and suggests that oxybutynin IR should not be included with the new generation of OAB medications.

Citizens' Panel

The ODPRN Citizens' Panel meeting on overactive bladder therapies took place on Wednesday February 24th, 2016. There were six members in attendance during the meeting. Six members completed the pre-meeting and four members completed the post-meeting survey.

Table 4 shows the post-meeting mean ranking of each option. The least favourable choices post-meeting were policy options A and C. Policy option B4 was chosen as the most acceptable option. Panel members felt that B4 gives patients more options while providing access to the most effective and cost effective drugs. They felt option A was too restrictive and option C was not feasible without significant system-level changes and engagement of key stakeholders (e.g., prescribers and pharmacists).

Table 4. Overall post-meeting option ranking

| | Mean Ranking (1 = Most Acceptable 7 = Least Acceptable) |
|---|--|
| | Post-meeting |
| Option A: (status quo) Oxybutynin IR as GB, all other OAB medications LU | 6.5 (0.6) |
| Option B1: Oxybutynin IR and solifenacin as GB, all other OAB medications LU | 4 (0.8) |
| Option B2: Oxybutynin IR, solifenacin as GB, all other OAB medications LU | 2.8 (0.5) |
| Option B3: Oxybutynin IR, solifenacin and tolterodine (immediate and extended release) as GB, all other OAB medications LU | 4.8 (0.5) |

| | |
|--|-----------|
| Option B4: Oxybutynin IR, solifenacin or tolterodine (immediate and extended release) as GB, all other OAB medications LU | 1.0 (0.0) |
| Option C: Enforced use of oxybutynin IR OR solifenacin as initial therapy, all other OAB medications Limited Use | 6.5 (0.6) |
| Option D: Solifenacin as GB, all other OAB medications Limited Use | 2.5 (1.0) |

Similar to interview participants, panel members were in favour of the proposed recommendations. In particular, they were glad to see recommendation 2 included as they had concerns about individuals who are unable to swallow. Some questioned if LU should be used instead of EAP. Participants were also glad to see recommendation 3 but had some questions about how physicians access the therapeutic notes and whether the notes have any impact on practice.

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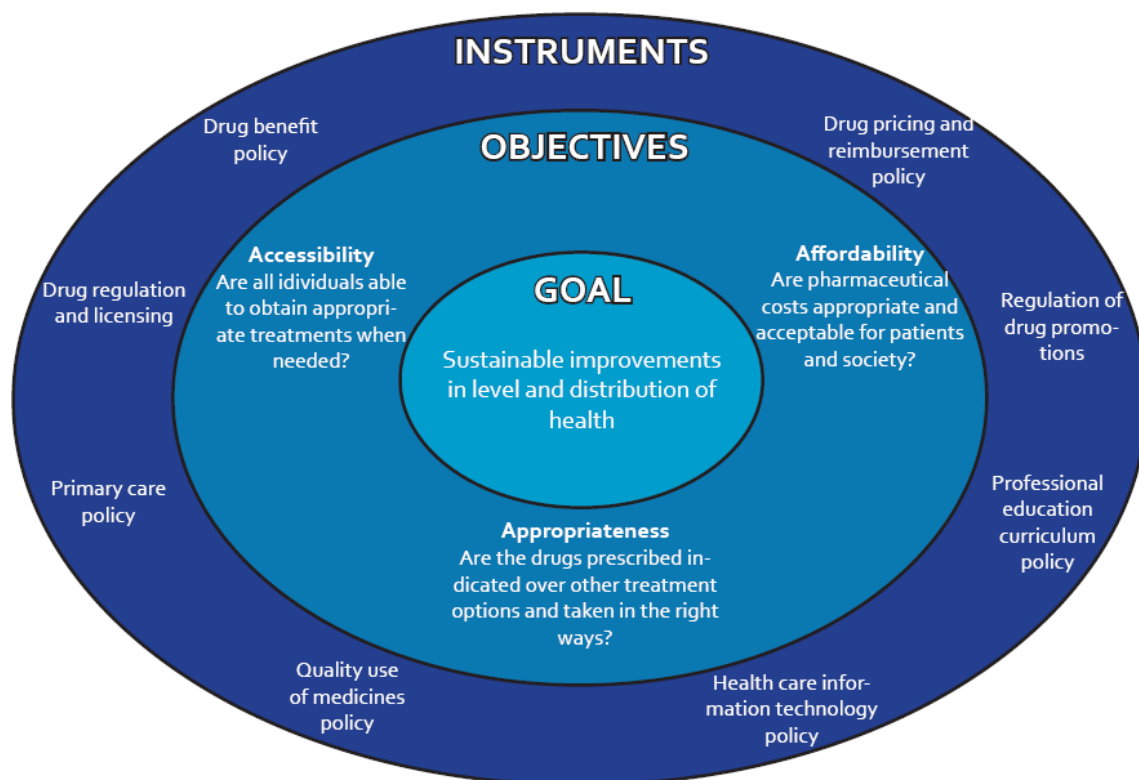
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Appendix A: “Triple-A” Framework for Pharmaceutical Policy Analysis



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

| Patient Demographics Characteristics (n = 44) | N | % |
|---|-----------|------------|
| Type of Data Collection | | |
| Interview | 2 | 5% |
| Survey | 42 | 95% |
| Gender | | |
| Male | 11 | 25% |
| Female | 33 | 75% |
| Age | | |
| 25-34 | 2 | 5% |
| 35-44 | 5 | 11% |
| 45-54 | 6 | 14% |
| 55-64 | 21 | 48% |
| 65-74 | 8 | 17% |
| 75+ | 2 | 5% |
| Years Since Diagnosis | | |
| Less than 5 years | 24 | 55% |
| 5-15 years | 14 | 32% |
| More than 15 years | 6 | 13% |
| Current Medication Use | 20 | 45% |
| Oxybutynin - Ditropan [®] | 2 | 10% |
| Oxybutynin - Generic | 1 | 5% |
| Tolterodine – Detrol LA [®] | 3 | 15% |

| | | |
|--|-----------|------------|
| Tolterodine – Detrol® | 3 | 15% |
| Solifenacin – Vesicare® | 2 | 10% |
| Fesoterodine – Toviaz® | 2 | 10% |
| Flavoxate – Generic | 2 | 10% |
| Mirabegron – Myrbetriq® | 2 | 10% |
| Dual Therapy | 2v | 10% |
| Other (Baclofen) | 1 | 5% |
| No medication | 24 | 55% |
| Medication Access (medication experience n=20) | | |
| Ontario Drug Benefit (ODB) | 8 | 40% |
| Private Insurance | 10 | 50% |
| Out of pocket | 2 | 10% |
| Clinician Demographics Characteristics (n = 15) | | |
| | N | % |
| Type of Clinician | | |
| Primary Care Doctor | 4 | 26% |
| Urologists | 9 | 60% |
| Urogynecologists | 1 | 7% |
| Geriatrician | 1 | 7% |
| Years of Practice | | |
| <5 years | 1 | 7% |
| 5-15 | 1 | 7% |
| >15 years | 13 | 86% |
| Work setting | | |
| Urban | 15 | 0% |