

The Ontario Drug Policy Research Network Drug Class Review on Combination Inhaled Corticosteroids and Long Acting Beta Agonists (ICS/LABA) for the Treatment of Asthma

Final Report of Qualitative Study Results

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Executive Summary

Background: The Ontario Drug Policy Research Network (ODPRN) conducted a drug class review of combination inhaled corticosteroids and long acting beta agonists (ICS/LABA) for the treatment of Asthma, which was selected as part of a formulary modernization initiative by the Ontario Public Drug Programs. This report highlights the findings of the qualitative study performed within the drug class review to determine the experiences of managing or treating asthma with ICS/LABA.

Methods: We used qualitative methods in a framework approach. One-on-one telephone interviews were conducted with 19 patients/caregivers and 7 physicians (primary care physicians, respirologists, and allergists). 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 to our framework and the framework was adapted to convey specific experiences and perceptions relevant to ICS/LABA funding policies.

Key Findings: Findings in this report are summarized to represent common experiences and perceptions described across patient and physician groups.

Appropriate management of asthma in Ontario can be hindered by high drug costs and patients’ lack of compliance: The high cost of ICS/LABA medications is a barrier for patients who do not have drug coverage and presents a challenge for physicians who desire to treat in accordance with best practice guidelines. Many patients are non-compliant to ICS/LABA medications for various reasons such as their cost, fear of taking steroid medications, lack of understanding about the purpose of maintenance medications, and their personal perception of asthma severity.

Physician prescription decisions are influenced by various factors: Physician participants described that their prescription habits are influenced by guidelines, research evidence, patient affordability and the ODB formulary, and the product’s ease of use for patients. Some participants shared a perception that not all physicians are prescribing ICS/LABA as recommended by the guidelines and that their preferences for products may be influenced by marketing.

Patient participants wish to have medication that enables maximal bronchodilation, with minimal dosage: Patients generally wished to have an appropriate balance of benefits and inconveniences, such as side effects and multiple doses. Participants found it difficult to comment specifically on the perceived effectiveness of ICS/LABA but those who did perceive a difference noted an improvement in their disease state.

Patients living on a low income, who are not eligible for ODB, may have significant barriers to accessing ICS/LABA drugs: Access to ICS/LABA is not an issue for ODB eligible patients because physicians use the asthma LU code; however, those under the age of 65 years, who are not ODB eligible and who do not have access to third party coverage, face significant financial barriers to

accessing ICS/LABA products because of their cost. Physicians have used various strategies to mitigate barriers such as providing samples and hiring social workers to assist patients.

It should be noted that qualitative findings are not representative of the general population of individuals from which our study sample was drawn. We were unable to capture the views of more parents with asthmatic children as such the patient data results are based mostly on the experiences of adult patients.

Conclusion: The findings from the qualitative study of the ICS/LABA drug class review informed the methods of other ODPRN research units conducting studies as part of the review and helped to contextualize the review's results. Overall, our findings shed light on the experiences of prescribing, dispensing, and using ICS/LABA for asthma treatment and unveil important information that can impact how patients in need access these drugs across Ontario.

Part 1: Introduction and 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) in Ontario. In collaboration with the Ontario Public Drug Programs (OPDP) and the Ministry of Health and Long-Term Care (MOHLTC), combination inhaled corticosteroids and long acting beta agonists (ICS/LABA) for the treatment of asthma was selected as a key priority area and topic for the ODPRN's fifth drug class review.

ICS/LABA is one of multiple groups of drugs used for the treatment of asthma. According to the Canadian Thoracic Society Asthma Guidelines (Lougheed et al., 2012), ICS/LABA should be prescribed to patients with moderate to severe asthma. Symptoms can be alleviated by ICS/LABA combination products through the anti-inflammatory action of the ICS component and the bronchodilation action of the LABA component. As opposed to short-acting products (e.g., salbutamol, ipratropium), ICS/LABA combination products are meant to prevent exacerbations over the long-term.

Currently, there is limited information on physicians' prescribing patterns and patient compliance to ICS/LABA products. Although ICS/LABA is recommended as part of asthma treatment and is listed in the Ontario Drug Benefit (ODB) under a limited use code, it is unclear how patients are accessing this group of drugs.

The purpose of the qualitative study being conducted as part of the ODPRN drug class review on ICS/LABA is to explore the various factors that may be related to ICS/LABA prescription, dispensing, and use for treatment of moderate to severe asthma. This information is needed 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. The findings from the qualitative study were also used to inform the research plans of the other drug class review

research units to ensure that stakeholder issues and priorities were being considered in their analysis.

Part 2: Methods

Design

We used a framework approach to qualitative research (Ritchie & Spencer, 1994). This approach helps researchers focus on specific areas of interest when exploring a topic using qualitative methods, which can make the findings more applicable than alternative qualitative procedures. However, the approach also maintains the flexibility of qualitative methodology to incorporate 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 a drug class when determining policy-relevant issues.

Sampling

Stakeholders identified for the ICS/LABA drug class review included physicians (primary care physicians (PCPs), respirologists, and allergists) who have prescribed ICS/LABA, as well as patients with asthma who have current/prior experience using ICS/LABA. To capture the experiences of accessing ICS/LABA amongst children, we also sampled parents of children with asthma. We aimed to recruit 6 to 8 participants from the physician group and 20 to 25 patients/parents, anticipating that this may be sufficient to reach saturation of findings amongst relatively homogenous groups of participants (Kuzel, 1999). Participants were recruited from across Ontario. 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 ICS/LABA. Recruitment methods included: 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 (e.g., Twitter, Facebook) accounts; and g) 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 June and September 2014. All interviews were conducted with a semi-structured interview guide developed using the “Triple-A” framework for pharmaceutical policy analysis (Morgan et al., 2009) as well as input from clinicians 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 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). This comprised the coding framework, which was reviewed by the qualitative research team and was then applied to the data by two analysts during in-depth analysis. Inter-rater reliability between the two analysts was > 80%. The analysts and the qualitative research team engaged in mapping and interpretation of the coded data to generate the final themes.

Research Ethics

This study was approved by the St. Michael’s Hospital Research Ethics Board in Toronto, Ontario, Canada in May 2014.

Part 3: Findings

Participant Demographics

Patients and caregivers

A total of 16 patients and one parent who spoke on behalf of a patient <18 years participated in the study (patients and parents will hereon be referred to as patients). These patients represented a variety of experiences with asthma and ICS/LABA use. Of these patients, 12 (71%) were female and 5 (29%) were male. The vast majority of participants (n=12, 71%) have been living with asthma for over 15 years and also have coverage for their ICS/LABA drugs (n = 11, 65%).

Physicians

There were a total of seven physician participants in the study. This included four respirologists, two primary care physicians, and one allergist, all of who practice full time and in urban settings. These physicians reported prescribing ICS/LABA on a daily basis.

Detailed participant demographics can be found in **Appendix B**.

Key Themes Related to the Treatment of Asthma with ICS/LABA

The following findings are based on the experiences and perceptions of interview participants, which have been summarized into three themes.

Challenges in Asthma Management

- High Cost of Medications
- Patient Beliefs about Regular Steroid Use
- Patient Perception of Disease

Influences on Prescription of Asthma Medications

- Guidelines & Research Evidence
- Ease of Use
- ODB Formulary
- Perception of Prescription Patterns in Ontario

Perception of Asthma Maintenance Medications

- Patients' Desired Outcomes from Medications
- Perceived Impact on Quality of Life

Factors that Determine the Accessibility of Asthma Treatment

- How Asthma Patients Pay for Medication
- Trillium Drug Program
- Physician Strategies to Mitigate Affordability Barriers

Detailed findings on each of these themes are described below.

Challenges in Asthma Management

Challenges in asthma management were described by both patients and clinicians, although this theme was primarily discussed from the clinician perspective. Participants described barriers such as, the high cost of medications, fear of regular steroid use, lack of education about the purpose of maintenance medications, and poor perception of asthma severity.

High Cost of Medications

“The biggest challenge is access to medications because of cost, so that’s sort of pretty globally that’s a problem...we don’t have a lot of patients on ODB except for the seniors obviously, but most of our patients are working but don’t have third party coverage. And ...most of them are below the poverty line, so they are the working poor and they can’t afford a lot of the medications that they need for asthma management.” –Primary Care Practitioner

“The challenges are not only just having a diagnosis – so you try in all your patients with asthma, you confirm the diagnosis, you talk about management plan, etcetera, you try and find therapy to achieve control. That’s great, but if patients can’t pay for the drugs then it won’t matter that they understand all of the things that you’ve addressed” –Respirologist

Clinician participants described that the cost of maintenance medications, such as ICS/LABA, are \$100-\$200 a month on average and that patients who do not have coverage are less likely to comply with their prescribed medication. Instead of using maintenance medications, patients may be relying heavily on rescue medications, which are significantly cheaper. Clinician participants perceived that an overreliance on rescue inhalers and lack of compliance can lead to increased number of exacerbations and hospitalizations for patients. It was reported that asthma patients are often put on a course of systemic steroids once they are hospitalized, which are a cheap alternative

that can cost as little as \$5 for a prescription, but also have a number of detrimental side effects (e.g., blood pressure escalation, cataracts, osteoporosis, weight gain, and mood swings). With a cheaper alternative available, clinicians perceived that there is less incentive for patients to comply with costly maintenance medications such as ICS/LABA, which can have a negative impact on their quality of life. Clinician participants described examples of patients who went from being completely controlled with regular maintenance medication (e.g., able to participate in society, attend school and/or work), to then stopping maintenance medication and being completely uncontrolled with regular exacerbations (e.g., having to take time off work making frequent urgent care visits). Asthma sufferers who do not have coverage and also have children suffering from asthma are particularly disadvantaged. Clinicians described stories of single parents who will forgo their medication or ration drugs amongst their children and family members. In these cases, no one family member is being appropriately treated.

Patient Beliefs about Regular Inhaled Steroid Use

“Patients don’t like taking medications. Sometimes they are fearful of the steroid...They may not believe that they need it, you know. Just because I tell them they need it doesn’t mean that they believe they need it.” –Respirologist

“I think part of what shapes it for me is that being on prednisone for so long, as a child and seeing the side effects of that now as an adult, it just makes me a little bit adverse to relying on the corticosteroid for preventative measures”—Patient

“If someone has been on prednisone, they may or may not have had the side-effects of prednisone, which can be quite dramatic because it’s high dose and systemic. So I try and use it as a way to say, ‘If we can achieve control with a low dose of inhaled steroids, we will never achieve anywhere near the doses of systemic steroids that were given by one or more courses of prednisone.’”—Respirologist

Nearly all clinician participants explained that some patients can be very hesitant about the regular use of medications that contain an inhaled steroid, such as ICS/LABA. Their patients have expressed concerns about growth stunting in children and various side effects that are commonly associated with systemic steroids, such as prednisone. Clinicians perceived there to be a misconception about inhaled steroids and some have tried to mitigate this by educating and counseling their patients. In addition, some patient participants described that they did not understand the purpose of the ICS/LABA and other maintenance medications and this has affected their adherence. Some patients had doctors who explained the long term benefits of these medications, but others ceased taking the medication because they did not perceive the immediate effect of bronchodilation they experience with rescue medications. Many patients described self-managing their medication regime, some with advice from a doctor and others just based on their own beliefs and fears about medication.

Patient Perception of Disease

“I feel like my asthma is more under control than it was when I was a lot younger, although, from a clinical practice guideline perspective, it’s not. I just am lazy and don’t take the Advair[®]. I often don’t remember to take it. You know I think it’s, out of sight out of mind. If you are not always having symptoms, then you are not thinking to take a preventive thing each day because you are thinking well, is that really working? Is it really something that’s useful, given the side effects?”—Patient

“Some of them would take Ventolin[®] 4 to 5 times a day and you ask them if they have any symptoms they’ll say ‘no’ and ‘what do you mean you’ve taken Ventolin[®]’, ‘oh well yeah because you know that takes away my symptoms so I don’t have any symptoms.’”—Respirologist

Clinicians explained that there is a subset of asthma patients, sometimes referred to as “poor sensors”, who are not aware of the exact severity of their disease. If not probed correctly by their doctor, they may not receive appropriate treatment. One respirologist explained that if patients are not asked specific questions relating to frequency of rescue inhaler use, night time awakenings, and significant lifestyle modifications, it is difficult to determine the true severity of their asthma. The definition of “controlled asthma” was interpreted differently by different clinicians and patients; although Canadian guidelines have outlined that control refers to specific indicators, such as the use of rescue inhaler less than 4 times a week and coughing less than 4 times a week. According to clinician participants, many patients may believe their asthma is under control despite using their rescue inhaler 6-7 times a week or making significant lifestyle changes, such as avoiding exercise or staying indoors. Clinicians also described that patients who believe their asthma is under control are less likely to take their maintenance medications such as ICS/LABA.

Influences on the Prescription of Asthma Medications

This theme describes some factors that may influence a physician’s decision to prescribe ICS/LABA medications, including adherence to guidelines and recent research evidence, the ease of use of products, and the availability of products on the Ontario Drug Benefit formulary. This theme also includes some clinician perceptions of their colleagues and the prescription trends they have noticed in Ontario.

Guidelines & Research Evidence

Physician participants referred to the Canadian asthma guidelines, which have guided their step wise approach to care including the prescription of ICS/LABA for moderate or severe patients. In addition, participants said that they incorporate evidence from specific research studies to influence their decisions on prescribing. Specific studies were not named but there was mention of Cochrane Systematic Reviews and National Institute of Health studies on medications, such as ICS/LABA, that contain inhaled steroids. A couple of physician participants described that research evidence on Symbicort has influenced them to prescribe it using the “SMART” approach, which encourages the use of Symbicort as a maintenance and rescue medication.

Ease of Use

Ease of administration was an important factor considered by clinician participants when prescribing ICS/LABA. In general, Diskus and Metered Dose Inhaler products were described as the easiest to use. Some clinicians preferred to put their patients on the same type of device for all

medications. The Turbuhaler® was described as the most cumbersome to use. Clinicians and patient participants also described that patients may be more likely to comply with once-a-day therapy. Patient participants in this study sample did not express specific preferences for inhaler types; however, a few did express concerns about whether their administration technique was effective. Most had been using these devices for years and were very comfortable with administration.

Ontario Drug Benefit Formulary & Patient Affordability

“The fact that the Ventolin Diskus® is not available on ODB encourages the use of Advair®,...maybe the Diskus® is the one they could actually use properly, and you want them to get some beta antagonist into them regularly, [so] you are going to order Advair®. You aren’t going to order Flovent® because you want them to get the beta agonist and Ventolin Diskus® is not covered. So I think the Ventolin Diskus® not being on ODB actually is encouragement to abuse Advair®.”—Respirologist

Clinician participants described that the list of drugs on the formulary can have an impact on the prescription of ICS/LABA products. One example given was with regards to Ventolin Diskus®, which is not on the formulary and is the only rescue inhaler available in Diskus® form. To ensure that an ODB-funded patient is properly administering a beta-agonist component regularly, a physician may prescribe Advair Diskus®, instead of an ICS alone with another covered rescue inhaler, because the Diskus® products are easier to use. Similarly, patient affordability also impacts decision making related to prescriptions. For example, a patient unable to afford an ICS product may be given an ICS/LABA sample by their physician, regardless of whether the patient requires the LABA component. This is not consistent with the guidelines but it enables the patient to have access to an ICS.

Perception of Prescription Patterns in Ontario

“Why do you think everybody prescribes Flovent® and Advair®...? And look at the evidence they’re not superior to any of the other ones, and yet we know that particular medications tend to cause more side effects, so why does everyone keep prescribing them ... I remember being told well it’s probably marketing. I’m not saying that anyone that I know of is partnering up with a drug company or anything like that but I’m saying that historically a lot of primary care will prescribe those two medications and we can only assume that it would be because of good marketing...cause it’s certainly not cause of evidence of better efficacy or reduced side effects, if anything it’s the opposite..”—Allergist

“I think that the family doctors and specialists have bought into the combination products way too much. Studies have shown, I mean, initial studies show that they are better than the steroids. That you should go at it long with a beta agonist before you go up in the steroids. Now the studies are saying whoa, whoa, whoa, that may not be the best thing and we do not see any change in practice out there. There are too many patients taking Advair® and Symbicort® who should be on Flovent® and Pulmicort®”—Respirologist

When asked, physician participants generally perceived that there may be an overreliance on ICS/LABA products in primary care settings. Respiriologists described receiving referrals for patients who are already on ICS/LABA and who may not be moderate or severe asthma sufferers. This is not consistent with the recommendations from the Canadian guidelines. Participants have speculated that these patterns of prescription may be influenced by marketing from manufacturers. They attributed these trends to a need for new research on safety and efficacy of asthma medications to be incorporated into clinical practice.

Perception of Asthma Medication

This theme describes the patient participant perspective on their desired outcomes from asthma maintenance medications and their perception of the impact of ICS/LABA on their health. Patients generally wished to have an appropriate balance of benefits and inconveniences, such as side effects and multiple doses. Participants found it difficult to comment specifically on the perceived effectiveness of ICS/LABA but those who did perceive a difference noted an improvement in their disease state.

Patients' Desired Outcomes from Medications

"It's two fold - it's a trade off of getting what you need out of the medication but also not having the side effects that for me make life not as enjoyable"—Patient

"To be able to take a puffer once in the morning and have that last throughout the day and be able to be active and go to the gym and do whatever and not be worried about whether my asthma is going to be triggered"—Patient

Overall, when asked, patient participants described that their wish is to have medication that enables maximal bronchodilation so they can breathe easily as well as carry on with various activities, such as travelling, exercising, and socializing. Some patient participants also mentioned the desire to take medication with minimal side effects. The concept of "control" was mentioned in relation to the ability to take the smallest dose of medication and have the maximum effect. Patients shared concerns about taking high doses of medications and about the number of different medications taken. Some expressed a desire to take only one medication, to reduce dosages, or to discontinue medications that contain steroids. A couple of participants actually described achieving success with tapering the use of both maintenance and rescue medications.

Perceived Impact of ICS/LABA

"I don't really feel like it has improved my quality of life. It could be because I'm non-compliant, but I think there are other things that I've done to better manage my asthma in the first place rather than needing to take a corticosteroid."—Patient

“If I had to give rid of one of my medications, I wouldn’t be ICS/LABA, I would probably pick Singulair® or theophylline. I would not pick ICS/LABA as one because of the, well a large part of it is the LABA component in it of course.”—Patient

Participants had mixed perceptions of the impact of ICS/LABA on their quality of life. Many of them were on multiple medication regimens and found it challenging to comment specifically on the effects of their ICS/LABA medications. Some had been taking ICS/LABA medications for over 10 years and were unable to recall or compare their current severity of symptoms with what they were before the introduction of ICS/LABA. Others who admitted to being non-complaint were also unable to comment on the effects of their ICS/LABA medications. A few participants who were recent users of the combination products experienced an improvement in their ability to breathe, less need for rescue inhalers, and fewer asthma attacks.

Factors That Determine Accessibility of Asthma Treatment

This theme describes the factors that influence patient access to asthma medications, such as payment mechanisms, navigating the Trillium Drug Program, and physician strategies to improve access.

How Asthma Patients Pay for Medication

Physician participants described that at least 50% of their patients have private drug plans with full or partial coverage for their ICS/LABA medications. This proportion varied between physicians depending on the location and catchment area of their practice. In general, they described that asthma patients tend to be a younger population who are working and are mostly ineligible for ODB. Those who do not have coverage and who are not eligible for the Trillium Drug Program have to pay out of pocket. In our sample of patient participants, 65% (n=11) had some form of private insurance, 24% (n=4) were on ODB and 11% (n=2) were paying out of pocket.

Trillium Drug Program

“Often they don’t know about the Trillium plan but once you tell them about the Trillium plan, it is, ... it’s a disorganized chaotic life, they’ve not filed their income taxes, they’ve been struggling to pay the next bill, they live from, you know, rent cheques to rent cheques, or mortgage payments to mortgage payments... . They’re stressed, they’ve got kids, they’re two working parents and they’re stressed to the limits and they haven’t taken the time to figure out all of these things.”—Respirologist

When participants were asked about their experience with the Trillium Drug Program, both physicians and patients described a few key barriers. The application process itself was considered challenging and patients require support with providing the necessary information needed for the application. For example, some do not have the skills to do their own income taxes, nor do they have the funds to hire an accountant. In addition, those who are eligible for the Trillium Drug Program are not always able to afford the required deductible. As well, many are unaware of the existence of the program and others are just below the cut off for eligibility.

Physician Strategies to Mitigate Affordability Barriers

*"I work in a very resource-intensive asthma clinic that's quite different than ...a family doctor [or] paediatrician who doesn't have the resources to be able to help patients who do not have coverage." --
Respirologist*

Physician participants described a few different strategies that they use to assist asthma patients who have financial challenges and are without drug coverage. The most common strategy is to provide samples to patients. The challenge with samples is that they may not be the exact drug or dosage that the physician would prefer to prescribe. Some specialists who have more resources have been able to hire a social worker at their clinic who spends time with patients, helping them apply for the Trillium Drug Program or researching alternative subsidies and compassionate programs from manufacturers. One specialist described taking time to teach low-income patients how to budget for their \$150-\$200 per month medication expenses. Other physicians described phoning the local pharmacist for tips on how to advise patients on their options.

Discussion

Key Findings

Our study findings demonstrate many key experiences and perceptions related to ICS/LABA prescription and use. Interview data revealed that clinician prescription habits are influenced by guidelines and research evidence, ease of use of the products, and patient affordability. One important finding is that patient compliance is a barrier to appropriate treatment and this may be affected by multiple factors, such as the high cost of medications, patient fear of the long term use of steroids, and patients' poor perceptions of the severity of their disease. In addition, many patients are lacking coverage and maybe unable to pay for their ICS/LABA prescriptions. These factors related to patient access may have a significant impact on the severity of their disease and result in increased exacerbations and less than ideal use of cheaper medications, such as rescue inhalers and systemic steroids.

Health Equity Considerations

The findings from this study highlight that access to ICS/LABA is not an issue for ODB-eligible patients because physicians use the asthma LU code. However, similar to other drug classes, those under the age of 65 years, who are not ODB eligible and who do not have access to third party coverage, have significant financial barriers to accessing ICS/LABA products because of their cost. ICS/LABA samples may be given to these patients by their physicians to help facilitate access, but this method of dispensing drugs is not a sustainable solution for patients in need. Manufacturers have programs available to assist patients; however, it is unclear whether these programs exist specifically for ICS/LABA products.

Limitations

It should be noted that qualitative findings are not representative of the general population of individuals from which our study sample was drawn. There may be bias in sampling given that those who responded to interview requests may have been more likely than non-responders to be vocal about discussing the impact of asthma and may be more involved in asthma advocacy initiatives. Many of our physician participants were asthma experts or had a particular interest in asthma. In an attempt to limit bias, we engaged in negative case sampling, which is to select interview participants who differ from the response trend observed in the recruited sample to date, so as to introduce different viewpoints. We were unable to capture the views of more parents with asthmatic children, so the patient data results are based mostly on the experiences of adult patients. We did not reach our target of recruiting 20-25 adult patients, however, we reached saturation of themes about half-way (n=8) through patient recruitment and it is unlikely that any new themes would have emerged from 3-5 more interviews.

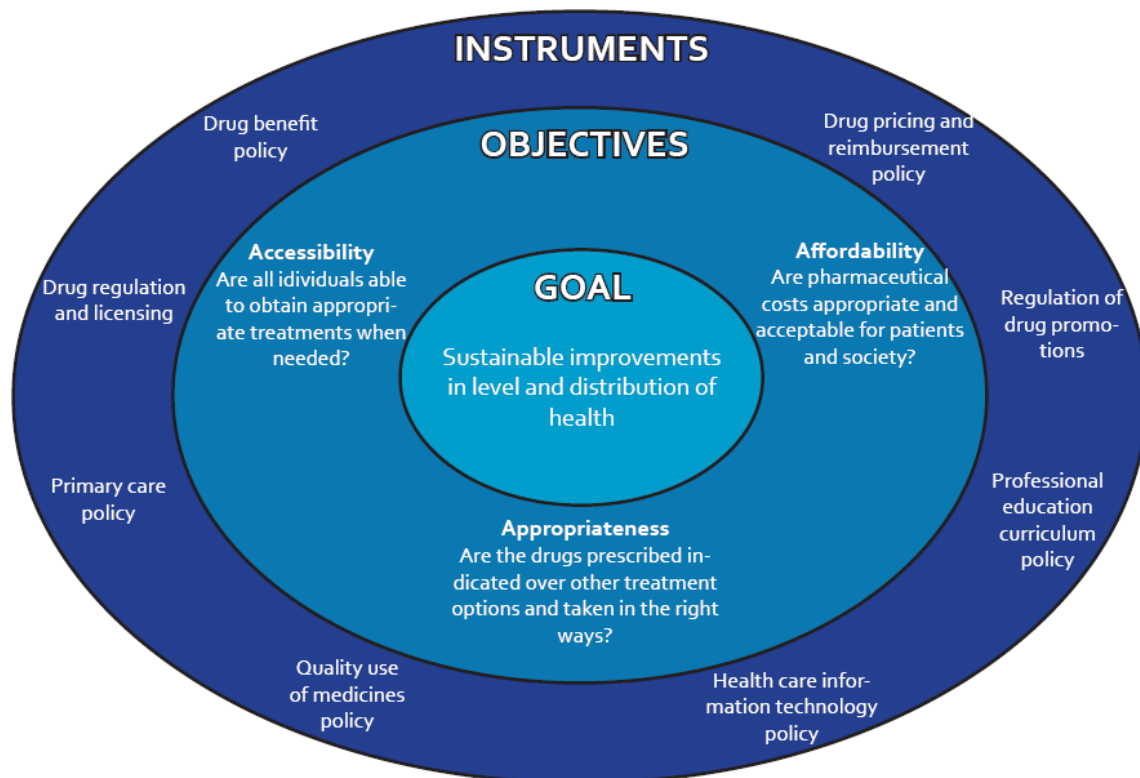
Conclusions

The findings from the qualitative study of the ICS/LABA drug class review aid in contextualizing the findings from other studies within the asthma drug class review. On a broader scale, our study findings fill a gap in knowledge on access to ICS/LABA combination products and how this may be impacted by physician and patient factors. Overall, our findings shed light on the experiences of prescribing, dispensing, and using ICS/LABA for asthma, and unveil important information that can impact how patients in need can access these drugs across Ontario.

References

- Kuzel, A.J. (1999). Sampling in qualitative inquiry. In B. F. Crabtree & W.L. Miller (Eds.), *Doing Qualitative Research* (2nd ed.) (pp. 33-45). Thousand Oaks, CA: Sage Publications.
- Lougheed D, Lemiere C, Ducharme FM, Licskai C, Dell SD, Rowe BH, FitzGerald M, Leigh R, Watson W, Boulet L. & Canadian Thoracic Society Asthma Clinical Assembly. (2012). Canadian Thoracic Society 2012 guideline update: Diagnosis and management of asthma in preschoolers, children and adults. *Canadian Respiratory Journal*, 19(2), 127-164.
- Morgan, S., Kennedy, J., Boothe, K., McMahon, M., Watson, D., & Roughead, E. (2009). Toward an Understanding of High Performance Pharmaceutical Policy Systems: A "Triple-A" Framework and Example Analysis. *The Open Health Services and Policy Journal*, 2, 1-9.
- Ritchie, J., Spencer, L., (1994). Qualitative data analysis for applied policy research. In A. Bryman & R. Burgess (Eds.), *Analyzing Qualitative Data* (pp. 173-194). London: Routledge

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

Patients

Demographic Characteristic (n=17*)	n	%
Gender		
Male	5	29%
Female	12	71%
Age		
18-24	2	13%
25-34	5	30%
35-44	1	6%
45-54	2	13%
55-64	4	25%
65+	2	13 %
Employment Status		
Full-time	6	35%
Part-time	5	30 %
Unemployed (retired, disability)	6	35%
Years since Asthma Diagnosis		
<5	1	6%
5-15	4	24%
>15	12	70%
Coverage for Meds		
Private Insurance	11	65%
ODB	4	24%

Out of Pocket	2	11 %
Experience with ICS/LABA Drug		
Symbicort[®]	6	35 %
Advair[®]	7	41 %
Both	4	24 %

*1 participant was parent of a child with Asthma

Primary Care Clinicians (Primary Care Physicians (n=1), Nurse Practitioner (n=1))

Demographic Characteristic (n=6)	n	%
Years of practice		
5-15	1	50%
>15	1	50 %
Type of Practice		
Full-time	2	100%
Geographic Location		
Urban	2	100%
Prescription Frequency		
Daily	2	100%

Specialist Physicians (Respirologists (n=5) and Allergists (n=1))

Demographic Characteristic (n=7)	n	%
Years of practice		
5-15	2	50 %
>15	2	50 %
Type of Practice		
Part-time	1	17%
Full-time	5	83%
Geographic Location		
Urban	7	100%
Prescription Frequency		
Daily	3	50%
Weekly	3	50%