

# The Ontario Drug Policy Research Network Drug Class Review on Long-Acting Muscarinic Antagonists (LAMAs) for the Treatment of Chronic Obstructive Pulmonary Disease (COPD)

## 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 long-acting muscarinic antagonists (LAMAs) for the treatment of chronic obstructive pulmonary disease (COPD), which was selected as part of a formulary modernization initiative by the Ontario Public Drug Programs. The LAMA drug class review was an extension of a previous review conducted by the ODPRN on combination inhaled corticosteroid/long-acting beta agonist products (ICS/LABA) for COPD. This report highlights the findings of the qualitative study performed within the drug class review to determine the experiences of managing or treating COPD with LAMAs.

**Methods:** Mixed methods (i.e., interviews and surveys) were used in a framework approach. Given the overlap between the ICS/LABA and LAMA reviews, the same sample was used for both studies. One-on-one telephone interviews were conducted with physicians (i.e., primary care physicians and respirologists), patients and caregivers, and pharmacists. 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 LAMA funding policies. A follow-up survey was developed and distributed to interview participants to probe further on the use, prescription, and dispensing of LAMAs. Survey results were analyzed using descriptive statistics (i.e., mean, standard deviation, count, and proportion) for quantitative data and content analysis of the open-ended responses.

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

There are several considerations in determining the appropriateness of COPD therapies: When physicians make decisions about prescribing COPD medications, they consider the following factors: level of evidence, guidelines, patient history with disease, number of medications already tried, and product ease of use. All participant groups generally perceived LAMAs to be effective and patients reported experiencing minimal side effects; these factors may enhance perceptions of appropriateness and encourage patient compliance.

Many factors facilitate or hinder access to LAMA products: Challenges with diagnosing COPD may initially hinder access to appropriate medications. However, once diagnosed and receiving a prescription for LAMAs, few patients experience any barriers to accessing their medications as most are ODB eligible based on age criteria. For patients under 65 years of age who do not have third-party insurance, affordability of LAMAs can seriously hinder access and can lead to decreased compliance. The introduction of LABA/LAMA combination products may reduce prescribing of single LAMA products in the future.

**Conclusion:** Overall, our findings shed light on the experiences of prescribing, dispensing, and using LAMAs for COPD and unveil important information that can impact how patients can access these drugs across Ontario.

## Part 1: Background

The Ontario Drug Policy Research Network (ODPRN) recently received funding to conduct 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) at the Ministry of Health and Long-Term Care (MOHLTC) to select key priority areas and topics for formulary modernization, conduct independent drug class reviews, and disseminate the results of the reviews to the OPDP to facilitate informed decision making on public drug funding policies. Long-acting muscarinic agonists (LAMAs) for the treatment of chronic obstructive pulmonary disease (COPD) were selected as the topic for the third drug class review.

Currently, there is limited information on how physicians decide to prescribe LAMAs and how patients decide to adhere to their prescribed treatment. Moreover, there is a need for additional information on the factors that contribute to LAMA access. Currently, LAMAs (i.e., tiotropium (Spiriva®) and glycopyrronium (Seebri®)) are listed under the general benefit program within Ontario Drug Benefit (ODB).

The purpose of the qualitative component of the ODPRN drug class review on LAMAs is to explore the factors that may be related to prescribing, dispensing, and using LAMAs to treat COPD. This information is important for understanding and contextualizing prescription and usage patterns in Ontario and to highlight health equity issues that may be prevalent but currently unknown. The findings from this qualitative study expand on those from the inhaled corticosteroids/long-acting beta-agonists (ICS/LABA) for COPD review.

## Part 2: Methods

### Design

This study was conducted using mixed methods: interviews and surveys. We used a framework approach (Ritchie & Spencer, 1994), which allows researchers to focus on specific areas of interest and obtain findings that may be more applicable and relevant to policy questions. However, the approach also enables researchers to incorporate new ideas, emergent issues, or unanticipated results. The framework selected for this study was the “Triple-A” framework for pharmaceutical policy analysis developed by Morgan et al. (2009; see **Appendix A**). This framework highlights the need to explore affordability, accessibility, and appropriateness of drugs when determining policy-relevant issues.

### Sampling and Data Collection

Given the overlap between the ICS/LABA and LAMA reviews, the same sample was used for both studies. Stakeholders identified to take part in the review included physicians (i.e., primary care physicians [PCPs] and respirologists) and pharmacists who have prescribed or dispensed ICS/LABA and/or LAMAs and patients with COPD who have current or prior experience using ICS/LABA and/or LAMAs. We also recruited caregivers of patients if the patients themselves were unable to

participate. Qualitative data were collected through one-on-one, telephone interviews that were 30 to 45 minutes long and conducted between November 2013 and April 2014. All interviews were conducted with a semi-structured interview guide that was developed using the “Triple-A” framework for pharmaceutical policy analysis (Morgan et. al., 2009) and input from clinicians and the drug class review team. Each interview was audio recorded and transcribed. The interviews 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.

We aimed to recruit 6 to 8 physicians, 6 to 8 pharmacists, and 20 to 25 patients based on the assumption that these sample sizes would be sufficient to reach saturation of findings among relatively homogenous groups of participants (Kuzel, 1999). A purposive sampling approach using a convenience sample was used to recruit participants who will be involved in or affected by drug policy decisions related to LAMAs. 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 accounts (i.e., Twitter, Facebook), and g) snowball sampling (i.e., asking participants to connect with individuals they know for the purpose of recruitment to the study). Participants were recruited from across Ontario.

A follow-up survey was distributed to interview participants to probe for information about LAMAs that may not have emerged in the interview data.

## Data Analysis

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 into the “Triple-A” framework (Morgan et. al., 2009). These initial codes comprised the coding framework, which was reviewed by the qualitative research team and 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 mapped and interpreted the coded data to generate the final themes.

Follow-up survey data were analyzed using descriptive statistics (i.e., mean, standard deviation, count, proportion) for the quantitative data and content analysis for open-ended responses.

## Research Ethics

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

## Part 3: Findings

A total of 26 patients (including one caregiver), 7 physicians, and 6 pharmacists participated in one-on-one interviews. Follow-up survey respondents included 14 patients, 4 physicians, and 3 pharmacists. Detailed participant demographics can be found in **Appendix B**.

## **Key Themes Related to the Lived Experience of COPD and the Treatment of COPD with LAMAs**

The following findings are based on the experiences and perceptions of interview and survey participants and have been summarized into three themes. Please note that the term “clinician” will be used to refer to both physicians and pharmacists. Also note that themes may have been described in detail in the previous report on ICS/LABA for COPD and will therefore only be mentioned briefly in this report.

### **The Experience of Living with COPD**

#### **The Appropriateness of COPD Treatment**

- Factors Affecting Physician Decision Making
- Effectiveness of LAMAs
- Side Effects of LAMAs

#### **Factors that Determine Access to LAMAs**

- Diagnostic Challenges
- ODB Formulary & Patient Affordability
- LABA/LAMA Combinations

Detailed findings on each of these themes are described below.

### **The Experience of Living with COPD**

Patient participants described their experiences of living with COPD. Specifically, participants offered insights on their COPD diagnosis and any associated risk factors, the progression of the disease, the experience of COPD symptoms, and the impact COPD has had on their quality of life (QOL). This theme was described in detail in the ICS/LABA for COPD full qualitative report.

### **The Appropriateness of COPD Treatment**

This theme describes perceptions of patient, physician, and pharmacist participants on appropriate treatment strategies for alleviating the symptoms and progression of COPD. Appropriateness is described in terms of the physician decision-making process regarding drug prescription, the perceived effectiveness of LAMAs as part of a treatment strategy, and the side effects of LAMAs.

#### *Factors affecting physician decision making*

Physician participants stated that LAMAs are the second line of drugs most often prescribed to COPD patients. They described many factors that are used to decide how to escalate treatment and incorporate LAMAs into COPD therapy with or without additional medications. First, physicians cited existing COPD guidelines and clinical trials as an important factor that affects their decision to prescribe LAMAs. Second, COPD phenotype may dictate which medications physicians prescribe to their patients (e.g., asthma phenotypes are more responsive to certain medications than bronchitis

phenotypes). Details on the factors related to appropriate prescribing can be found in the full qualitative ICS/LABA for COPD report.

When asked to identify the factors related to a patient’s history that most strongly influence their decision to prescribe LAMAs, all physician survey respondents ( $n = 4$ ; 100%) indicated that disease severity was the most influential factor, followed by number of hospitalizations and exacerbations ( $n = 3$ ; 75% each) and the number and types of medications that the patient has already tried ( $n = 2$ ; 50%).

Participants noted that drug characteristics can also factor into physician decision-making processes. For example, method of medication delivery may influence the types of medications that are prescribed: drugs that are perceived to be easier to use are more likely to be prescribed than drugs that are perceived to be more difficult to use because of concerns about patient adherence. One physician interview participant described LAMA products as easy for patients to use given that these drugs are taken only once each day (although Tudorza® is taken twice daily). All physician survey respondents ( $n = 4$ ; 100%) indicated that patient comfort levels with the medication device contribute to treatment adherence. When asked to describe patient compliance to appropriate LAMA use, all participant groups rated compliance as high (mean > 5, where 1 = not at all compliant and 7 = extremely compliant), and the majority ( $n = 15$ ; 88%) of patient respondents commented that they have had no problems using LAMA devices.

### *Effectiveness of LAMAs*

When asked to rate the effectiveness of LAMAs on a scale from 1(not at all effective) to 7(extremely effective), physician and patient survey respondents reported that LAMAs are effective for improving daily functioning (e.g., household chores) and quality of life, improving lung function, decreasing exacerbations, and decreasing hospitalizations and emergency department visits. However, physician respondents generally rated the effectiveness of LAMAs slightly higher than patients did (Table 1).

**Table 1.** Perceived effectiveness of LAMAs according to expected outcomes (1 = not at all effective and 7 = extremely effective).

	<b>Physicians (<math>n = 4</math>)</b>	<b>Patients (<math>n = 17</math>)</b>
	<b>Mean (SD)</b>	<b>Mean (SD)</b>
Improving functional status and quality of life	6.25(0.50)	5.59 (0.87)
Improving lung function	5.25 (1.71)	5.47(1.07)
Decreasing exacerbations	5.50 (0.58)	5.06(1.30)
Decreasing hospitalizations and ED visits	5.50(0.58)	4.94(1.39)

Physician respondents commented that LAMAs are “effective, safe, and well tolerated drugs, and are [the] first choice in management of symptomatic patients with COPD.” Patient respondents

commented that LAMAs are generally effective for reducing their COPD symptoms ( $n = 5$ ; 29%), and some respondents indicated that LAMAs are more effective than other COPD medications they have tried (e.g., ICS/LABA;  $n = 4$ ; 23%).

*“I’ve been on Spiriva® for so long I don’t notice the difference until I have delayed a dosage. Then I notice how tight my chest is and a heaviness that is relieved after using my inhaler.”*

– Patient

Three respondents (18%) found it difficult to comment on the effectiveness of LAMAs versus other COPD medications whereas two patient respondents perceived LAMAs to be no different or no less effective than other drugs (12%). Inability to comment on the effectiveness of the drugs was likely due to challenges in distinguishing the effects of the drug from those of confounding factors, such as lifestyle changes and taking multiple medications.

*“I am on Spiriva® and Symbicort® and have COPD. These long acting meds at my present dosages are fairly effective, I think. It is difficult to compare long-term as I smoked until November 2011. Stopping smoking had been the primary indicator for me as I have fewer exacerbations since I quit smoking and no hospitalizations since, but quite a few before then.”* – Patient

When comparing LAMAs to one another, two patient respondents who had used various LAMA products noted that they prefer Spiriva® over the other products due to higher perceived effectiveness and better dose delivery.

*“I take the drug every day at the same time. I have taken Spiriva®, Seebri®, Onbrez, and Tudorza®. I like Spiriva® the best. Tudorza®’s powder is not as fine as Spiriva® and [I] found it coated my mouth.”* – Patient

*“Spiriva® seemed to markedly improve my lung function -- but I’m allergic to it. Seebri® and Tudorza® didn’t seem to improve lung function or the quality of my life.”* - Patient

### *Side effects of LAMAs*

In general, patient, physician, and pharmacist survey respondents reported very minimal side effects of LAMAs. They noted that dry mouth and sore throats were the most common side effects. Less common side effects described by patient participants included face swelling, muscle cramps, joint pain, and constipation. Physician, patient, and pharmacist participants all stated that decisions to switch between LAMA products were mostly based on side effects experienced by some patients.

## Factors that Determine Access to LAMAs

### Diagnostic Challenges

As described in the ICS/LABA for COPD full qualitative report, participants from both patient and clinician groups described the diagnostic challenges of COPD. Some physician participants admitted having difficulty with both remembering the correct diagnostic criteria for patients who present with respiratory symptoms and with interpreting spirometry results. Challenges in appropriately diagnosing COPD may delay timely access to necessary medications.

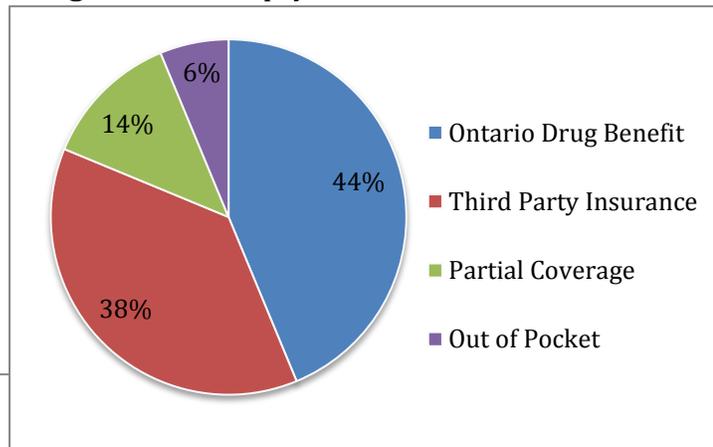
*“So I think there’s probably a problem in terms of accurate identification. I know what the criteria are, and for some reason I just... you know, the spirometry tests come back and they don’t... they say, “Oh, probably has COPD,” but when you look at the criteria they don’t meet the criteria, or I didn’t look at the criteria, or forgot what the criteria were and mislabelling half.”* –Primary Care Physician

### ODB Formulary & LAMA Affordability

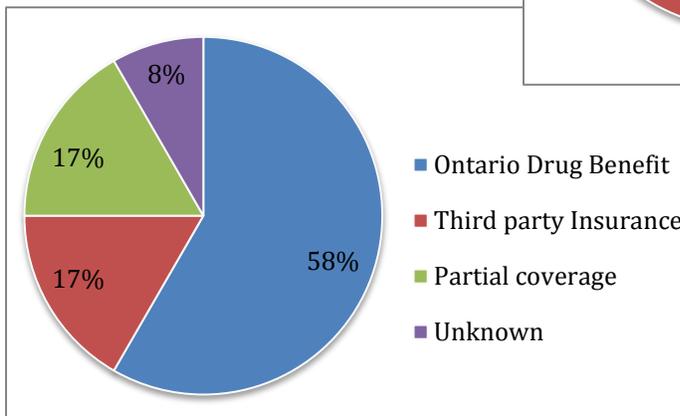
Most physician and pharmacist participants stated that the majority of patients are over the age of 65 years and are therefore eligible for LAMA coverage through ODB. Thus, there were very few access issues identified by these groups. All physician survey respondents ( $n = 4$ ; 100%) indicated that the ODB formulary dictates the type (i.e., formulation) of LAMA prescribed, and 75% of physician respondents ( $n = 3$ ) indicated that the ODB formulary dictates the form (i.e., device) prescribed. Physicians did not describe any increase or decrease in frequency of prescribing LAMAs as a result of the listing for LAMAs on the formulary.

Of the 16 patient respondents who indicated the payment mechanism for their LAMAs, the majority were receiving their LAMAs through the ODB ( $n = 7$ ; 44%). The remaining participants received their medication through third-party insurance ( $n = 6$ , 37%), partial coverage (i.e., split between ODB, third-party insurance and out-of-pocket payment; ( $n = 2$ ;

**Figure 1.** Patient payment methods for LAMAs



13%), and out-of-pocket payment ( $n = 1$ ; 6%) (Figure 1).



Of the 12 patient respondents who were ODB eligible based on age criteria alone (>64 years of age), most

**Figure 2.** ODB-eligible patient payment methods for LAMAs

were, in fact, receiving LAMAs through the ODB ( $n = 7$ ; 58%) while others were obtaining LAMAs through third-party insurance ( $n = 2$ ; 17%) or partial coverage (i.e., ODB, third-party insurance and out-of-pocket payment;  $n = 2$ ; 17%). These participants indicated that they use tiotropium bromide monohydrate (Spiriva®), which is available on the ODB formulary. Thus, it is unclear why these patients were obtaining LAMAs through third-party insurance or partial coverage. One ODB-eligible participant did not report the payment method for his/her LAMA prescription (Figure 2).

In general, patient participants stated that they have not experienced any difficulties accessing LAMAs. However, one patient participant who is under 65 years of age and who pays for LAMAs out of pocket indicated that the cost of Spiriva® can impede access to the medication when necessary.

*“Due to the high cost of Spiriva®, there are a few months during the year that I just cannot afford to purchase it which saddens me because then I have trouble breathing for that entire month and my Ventolin® use sky-rockets. If there is any way possible to convince the drug manufacturers to lower the cost, please do so. Spiriva® allows me to walk around and be a normal person without huffing and puffing trying to draw air into my lungs, but if I can't afford to purchase it and use it, then it also cuts into my social activities.” - Patient*

Similarly, physician and pharmacist participants stated that “the working poor are seriously disadvantaged when trying to afford medications” and that “those without coverage do not use medication as prescribed. Patients will skip doses to save on refills. Some form of coverage or relief from payments would help.” All physician and pharmacist survey respondents ( $n = 7$ ; 100%) stated that a patient’s ability to afford LAMAs affects adherence to their prescription.

#### *LABA/LAMA Combination Products*

When asked how prescribing of single-product LAMAs would change when a LABA/LAMA combination product is made available, all physician survey respondents ( $n = 4$ ; 100%) indicated that their prescription of a single product would decrease. These respondents perceived that the combination product would increase compliance strictly as a result of ease of use even if the products need to be taken twice a day versus once a day. Physicians also described the impact of the availability of LABA/LAMA combination products on LAMA prescribing during interviews:

*“when they become available, the once a day LABA/LAMA combo will likely become standard of care. It will likely, probably become first-line in patient, patients who are moderate to severe, you just know they're going to need two long-acting agents. Probably just go right off the bat with the LABA/LAMA once a day combo”*

Pharmacist participant responses were more mixed: one pharmacist stated that single-product LAMA prescribing would decrease while others believed that prescription depends on several other factors.

*“[It] may take time - will first need ODB coverage. Patients who are stable and doing well will probably not change. There may be some resistance from family docs until greater benefits are more apparent in comparative studies.” - Pharmacist*

*"I am not sure if this will help. Combinations are not always the right answer to treatments."* - Pharmacist

## Discussion

### Key Findings

Our study findings highlight many key experiences and perceptions related to LAMA prescribing and use that affect the appropriate use of and access to these medications. One key finding was that LAMAs are perceived to be effective and easy to use, which facilitates physician prescription of these drugs and patient adherence to them. Another important finding was that the challenge of diagnosing COPD can affect both the appropriateness of treatment and access to appropriate medications.

### Health Equity Considerations

The findings from this study highlight that access to LAMAs is not an issue for ODB-eligible patients. However, cost can be a major hindrance to access for those who are under 65 years of age and do not have third-party insurance. A patient's inability to afford LAMAs was seen as a major hindrance to prescription adherence, which may ultimately jeopardize health outcomes.

### Limitations

It should be noted that qualitative findings are not representative of the general population of individuals from which our study sample was drawn. For example, patient participants who responded to interview requests may have been more likely than non-responders to be vocal about discussing the impact of COPD and involved in COPD advocacy initiatives. In addition, many of our physician participants were COPD experts or had a particular interest in COPD. To limit bias in our samples, we used negative case sampling, which involves introducing different viewpoints by selecting interview participants who differ from the response trend observed in the recruited sample to date.

### Conclusions

The findings from the qualitative study of the LAMA drug class review informed the methods of other ODPRN research units that are 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 the LAMAs for COPD drug class review. On a broader scale, our study findings fill a gap in knowledge on access to LAMA products and how this may be affected by physician and patient perceptions of these drugs and diagnostic challenges. Overall, our findings shed light on the experiences of prescribing, dispensing, and using LAMAs for COPD treatment. They also unveil important information that can affect how patients access these drugs across Ontario.

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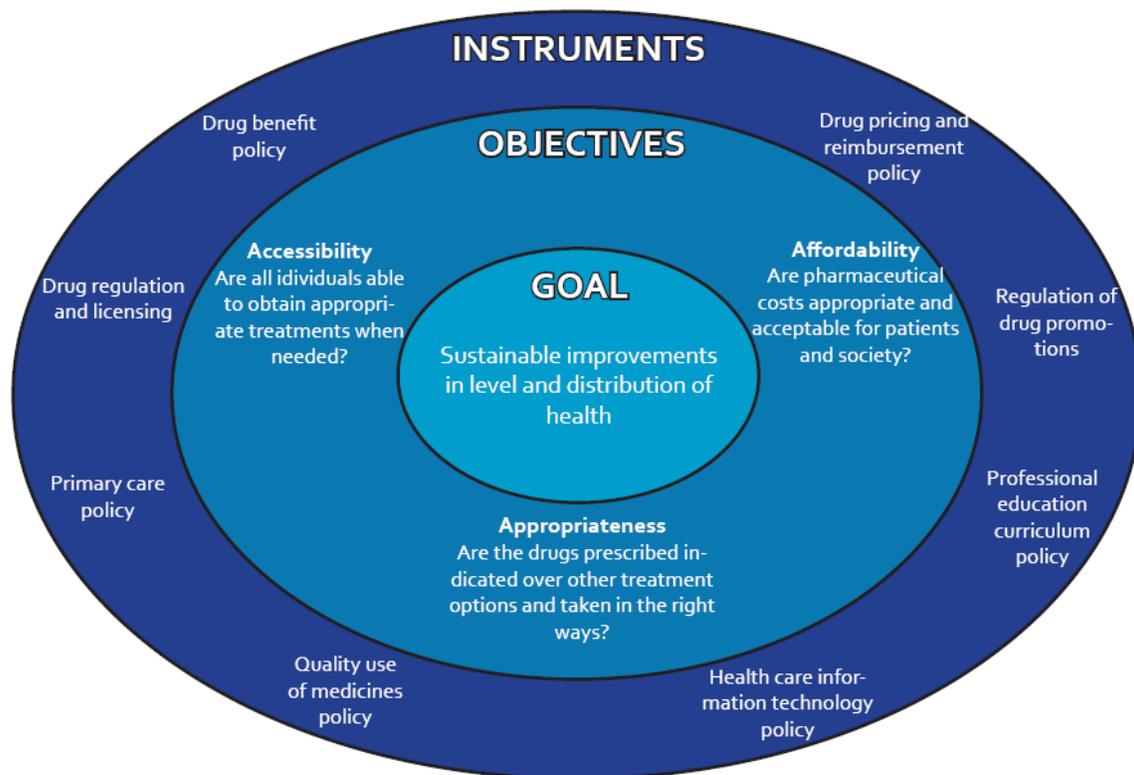
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## Appendix A: “Triple-A” Framework for Pharmaceutical Policy Analysis



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

### Patients

Demographic Characteristic (n=26)	n	%
<b>Gender</b>		
Female	12	46%
Male	14	54%
<b>Age</b>		
25 -34	0	0%
35-44	0	0%
45-54	1	4%
55-64	6	23%
65+	19	73%
<b>Employment Status</b>		
Full-time	1	4%
Part-time	3	11%
Unemployed (retired, disability)	22	85%
<b>Years Since COPD Diagnosis</b>		
<5	6	23%
5-15	14	54%
>15	6	23%
<b>Past Smoker?</b>		
Yes	22	85%
No	4	15%

## Physicians (Respirologists and Primary Care)

Demographic Characteristic (n=7)	n	%
<b>Years of practice</b>		
<5	1	14%
5-15	0	0%
>15	6	86%
<b>Type of Practice</b>		
Full-time	5	71%
Part-time	2	29%
<b>Geographic Location</b>		
Urban	6	86%
Suburban	1	14%
<b>Frequency of Prescribing ICS/LABA</b>		
Daily	4	57%
Weekly	1	14%
Monthly	1	14%
Annually	1	14%

## Pharmacists

Demographic Characteristic (n=6)	n	%
<b>Years of practice</b>		
5-15	0	0%
>15	6	100%
<b>Type of Practice</b>		
Full-time	6	100%
<b>Geographic Location</b>		
Urban	2	33%
Suburban	2	33%
Rural	2	33%
<b>Frequency of Prescribing ICS/LABA</b>		

<b>Daily</b>	5	83%
<b>Weekly</b>	1	17%