

THE UNIVERSITY OF ONTARIO INSTITUTE OF TECHNOLOGY

# Primary Care Physicians' Perspectives on the Ontario Drug Benefit Program (ODB)

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## **Dedication**

To one of the strongest women I know, I would like to dedicate this thesis to my lovely sister; Mirna Karam. She is my inspiration and my biggest fan. Her smiles that shine through her constant difficulties have provided me with great inspiration to pursue my dreams and always accomplish what I put my mind to.

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## Abstract

**Introduction:** The *Canada Health Act* (CHA) requires provincial/territorial governments to publicly fund prescription drugs when delivered in the hospital. This coverage does not continue once individuals are discharged under the terms of the CHA. Governments do provide additional public coverage for drugs outside of the hospital for specific groups. The Ontario Drug Benefit Program (ODB) was implemented in 1974 to provide public funding for prescription drugs for seniors 65 years and older.

**Methodology:** The data collection for this case study is based on a scoping review (peer review and grey literature) and semi-structured interviews. Relevant documents were identified from the Ontario government's websites, professional associations, and searches with Medline, PubMed, Econlit and Ovid. Ten physicians working in a Durham region primary care clinic in Ontario were interviewed to determine their views on the ODB program. An iterative approach was used to analyze the data and resulted in the identification of several different themes related to both the benefits and challenges of the ODB for physicians and their patients.

**Results:** Physician views were concentrated on transparency regarding the ODB's decision making process for inclusion/exclusion on the ODB formulary, the need for timely information when brand name drugs are replaced with generic drugs (i.e., communication about and information on the generic), and on the challenges of completing ODB forms to request coverage for non-formulary drugs. Concerns were raised about the potential negative side effects of the replacement drugs for their patients. While it was recognized that generic drugs are less costly, this saving needs to be balanced with the costs associated with the impact the replacement drug may have on patient outcomes. Procedures to request public funding for prescription drugs not covered under the ODB program need to be streamlined to ensure patients have timely access to the appropriate drug within the publicly funded program (i.e. the Exceptional Access Program). The primary care physicians did also express that they were pleased with the fact that Ontario had such a program to offer to the senior population as they are the population suffering with the most co-morbidities.

**Discussion/Conclusion:** The implementation of a national pharmacare program in Canada has the potential to reduce costs and increase access. Results from this study suggest that certain challenges exist in obtaining the most appropriate drugs for individual patients. Challenges exist that impact the quality of care and costs associated with procedural requirements. Other lessons learned from this study suggest the importance of including physicians when making policy based decisions in healthcare because they are the gatekeepers of medicine.

**Key Words:** Ontario Drug Benefit (ODB), Ministry of Health and Long-term Care (MOHLTC), Health Canada, Canada Health Act, Drugs, Section 8, Limited use codes.



## Pre-Introduction

### *Why me and the Ontario Drug Benefit (ODB) Program?*

As a student, I always knew I would like to pursue a career heavily involved in healthcare. As such, I was given an amazing opportunity as a young teenager to work for six general practitioners in a very busy clinic. I have been a part of this healthcare environment for the past eight years and have grown to love the healthcare environment as time progressed. The experience I gained at a very young age, allowed me to learn aspects of the healthcare system that only would be learned with age, and with a career in the healthcare system. I am truly grateful for this amazing opportunity, and as such, it has shaped me into the driven person I am and has fed my passion for the healthcare interface. Throughout the eight years that I have worked in the clinic, I have been given opportunities to work in several different offices, as well as the urgent care clinics in town.

My exposure at an early age to the healthcare interface allowed me to learn about certain aspects of healthcare delivery and health policy, and to observe from firsthand experience, some of the weaknesses, strengths, pros, and cons of different aspects of the current healthcare system in Ontario. As such, I decided to pursue a graduate degree in healthcare with the hopes of pursuing a future career in health promotion. As I began a Master's degree at the University of Ontario Institute of Technology (UOIT), I took the opportunity to focus on one aspect of health policy. I decided to formulate my research question surrounding the Ontario Drug Benefit program (ODB) because it is an area in need of more research. This area included working with the ODB program, more specifically, examining *Section 8 Forms*, *The Exceptional Access Program (EAP)* and *Limited Use Codes*, from the primary care physicians' perspectives.

## Glossary of Terms

### C

CED: Committee to Evaluate Drugs (formerly known as the Drug Quality and Therapeutics Committee)

### D

DQTC: Drug Quality and Therapeutics Committee (was established in 1968, now is referred to as the Committee to Evaluate Drugs)

### E

EAP: Exceptional Access Program

### L

LU codes: Limited Use codes

### M

MOHLTC: Ministry of Health and Long-term Care

### N

NICE: National Institute for Clinical Excellence

### T

TPD: Therapeutic Products Directorate of Health

TDP: Trillium Drug Program

# Chapter 1

## Introduction

### 1.1 Statement of the Problem

The *Canada Health Act (CHA)* requires provincial/territorial governments to cover prescription drugs when delivered in the hospital (CHA, 1984). This coverage does not continue once individuals are discharged. However, governments do provide additional public financing for some groups of people. The Ontario Drug Benefit program (ODB) was implemented in 1974 to provide public funding for drugs for seniors 65 and older and needing financial assistance (Ministry of Health and Long-term Care [MOHLTC], 2011). Beginning August 1, 1975 all seniors 65 years and over were eligible for coverage under the ODB program (MOHLTC, 2011). Not all drugs, however, are covered by the ODB program. It is especially challenging for seniors on fixed incomes suffering from multiple chronic conditions to privately fund drugs not covered by the ODB program. Non-adherence to necessary drug therapies can potentially negatively impact seniors' health conditions and outcomes. Seniors who are unable to adhere to their medication regimens due to the inability to pay are at a greater risk because they are the population suffering from the most co-morbidities (Irvine, Ferguson & Cackett, 2005).

According to Laupacis (2002) the policies and procedures that govern the ODB program can make it difficult for prescribing primary care physicians. Godwin, Chapman, Mowat, Racz, McBride and Tang (1996) indicates that there is a need for research on how primary care physicians can be included in future formulary decision making changes.

Limited information is available in the literature on the ODB program. Furthermore, there is no data in the literature on primary care physicians' perspectives regarding the ODB program. The aim of this study was to explore some of the advantages and disadvantages present in the ODB formulary coverage program and how it can be limiting for prescribing primary care physicians. The aforementioned will be examined from primary care physicians' perspectives based on a series of semi-structured interviews.

## 1.2 Research Questions

The purpose of this study was to:

- a) Explore and analyze the advantages and disadvantages of the ODB program, and
- b) Explore how the ODB impacts primary care physician prescribing behaviour for Ontarians aged 65 and older who qualify for coverage under the ODB program.

The following were the research questions for this study:

1. What is the Ontario Drug Benefit program?
2. What is the purpose of the Ontario Drug Benefit Program?
3. Who is eligible to receive services under the Ontario Drug Benefit Program and why?
4. How can the Ontario Drug Benefit program be improved from the primary care physicians' perspective?
5. What are the advantages and disadvantages of the Ontario Drug Benefit program from the primary care physicians' perspective?

### **1.3 Overview of the Steps Taken to Address the Research Questions**

The following overview summarizes how the rest of the chapters in the thesis project identify the research questions that are listed above.

Chapter 2 provides an overview of what is available in the literature in terms of national health policy, provincial health policy, the ODB program, the history of the ODB program, generic drug costs in Canada, and the importance of health policy research. This information constitutes the scoping review, and its purpose is to answer the first three research questions. Chapter 2 also supports why studying the ODB program is important and illustrates the lack of research found in the literature related to this field.

Chapter 3 outlines the methodological approaches used for this study. Chapter 4 contains the results and analysis from the key informant interviews. Chapter 5 is a discussion of the specific details and findings of the research project; the conclusion to Chapter 5 addresses the implications of the study findings.

## Chapter 2

### Scoping Review

#### 2.1 Background

The Canadian healthcare system is publicly funded, but privately delivered (Irvine, Ferguson & Cackett, 2005). It is based on five principles: health care must be *universal*, *portable*, *comprehensive*, *accessible*, and *publicly administered* as defined in the *Canada Health Act* (Canada Health Act, 1984).

*Universality* requires that all Canadians must be insured for all public health services, meaning all insured services are available to the residents, everywhere. *Portability* demands that the provinces and territories in Canada must cover insured health services to all Canadians even when they are out-of-province or territory of residence or out of Canada. *Comprehensiveness* describes that all medically necessary procedures are insured and covered for Canadians. *Accessibility* defines that all Canadians have equal access to insured health services without discrimination against income, age, or health status. Lastly, *publicly administered* healthcare can be defined as each province or territory must insure all medically necessary services for which Canadian citizens are not required to pay according to the *CHA* (Canada Health Act, 1984; Madore, 2005).

Despite the fact that these five principles are required to be met by each province or territory in Canada to receive federal funding for healthcare (Canada Health Act, 1984; Madore, 2005), these principles have been frequently debated and implemented inconsistently (Charles, Lomas & Giacomini, 1997). The comprehensive principle says drugs are funded in hospital but this funding does not continue once the patient is discharged from the hospital. As noted above,

the principle of comprehensiveness ensures that all services deemed medically necessary are insured (Canada Health Act, 1984; Madore, 2005). Furthermore, the *CHA* does not specify exactly which services will be covered for Canadian residents, and therefore each province/territory defines which services will be covered and which will not. According to Madore (2005), many people believe that the concept of comprehensiveness is not necessarily being reflected when delivering healthcare services because the definition differs depending on which province/territory the healthcare services are being offered in.

## **2.2: What is the Ontario Drug Benefit Program (ODB)?**

On September 1, 1974, the Ontario Conservative government implemented the ODB program for seniors 65 years of age or older. The ODB program provides public coverage for a variety of medications. The ODB formulary is a list of 3,800 medications that are publicly funded for Ontario residents 65 years of age or older, for those on social assistance, for those living in special care homes and long-term care facilities, and for those receiving professional services at home (Ministry of Health and Long-Term Care, 2011). In an effort to use cost-effective measures, the *Committee to Evaluate Drugs (CED)*, formerly called the *Drug Quality and Therapeutics Committee (DQTC)*, makes a recommendation to the *Executive Officer* of the MOHLTC about which drugs should be included on the ODB formulary (Laupacis, 2002; Paus Janssen, Singer, & Detsky, 2003; Ministry of Health and Long-Term Care, 2013). These recommendations are available to the public on the MOHLTC website. To assist in this process, in 1996, the Ontario government required that pharmaceutical companies who want their drug product listed on the ODB submit a formal economic analysis that outlines the drug's cost-effectiveness (Paus, Janssen, Singer, & Detsky, 2003). The *CED* is made up of 16 members who

are appointed by Orders in Council (Ministry of Health and Long-Term Care, 2013). Two of the 16 members are patients, and the rest of the 14 members are physicians, pharmacists, and an economist (Ministry of Health and Long-Term Care, 2013). For each drug that is brought to the committee's attention from a pharmaceutical company, a recommendation is made to the *Executive Officer* of the MOHLTC who decides whether that particular drug makes it to the formulary or not. Once the *Executive Officer* has decided that the drug will be added to the formulary, there are three categories in which the drug can be categorized. These categories include *General Benefit*, *Limited Use (LU)* and *The Exceptional Access Program (EAP)/Section 8*.

### **2.2.1 General Benefit.**

General Benefit means the drug is covered for all patients who qualify under the ODB program with no restrictions. The drugs found in the ODB formulary are all considered as a General Benefit.

### **2.2.2 Limited Use (LU).**

Limited Use (LU) is defined as the drug will only be fully covered if the patient meets certain clinical medical conditions or criteria for the drug. If a drug is not on the formulary under a General Benefit, then the drug may be considered an LU product. In order to ensure that the patient who qualifies for LU coverage receives the funded drug, the physician will write the prescription for the LU medication by including the code or the number that signifies funding eligibility. For example, Ciprofloxacin is a common antibiotic used to treat skin/soft tissue joint infections, urinary tract infections, or some sexually transmitted diseases (Ministry of Health and Long-Term Care, 2013). The LU code that qualifies patients for funding for Ciprofloxacin for a



urinary tract infection for instance is 333. When the pharmacy receives the prescription with an LU code on it, the pharmacist submits the code to the MOHLTC and in most cases, funding is granted (MOHLTC, 2013). However, if the patient needs this medication for a reason that is not listed under the code, then the patient does not receive public coverage for it and therefore needs to pay for the drug.

### **2.2.3 Exceptional Access Program (EAP)/Section 8 Request.**

The Exceptional Access Program (EAP) is a program that gives certain patients access to drugs that are not funded by the ODB program (Ministry of Health and Long-Term Care, 2011). If the drug is not listed as either a General Benefit, or an LU product, then the patient may qualify for coverage under the EAP. In some cases, the drugs listed in the formulary may not be clinically effective for some patients. Thus, the primary care physician prescribes medication that is not a General Benefit or an LU product, possibly resulting in economic burden for patients. However, a request (i.e., Section 8 form) may be made to the MOHLTC through the EAP to determine funding eligibility for particular patients for the unlisted drug (Ministry of Health and Long-Term Care, 2002). An example of the *Section 8* form can be found in Appendix 1. Once the prescribing physician has completed the form with the necessary information, it is then reviewed by the CED and is either approved or denied by its Executive officer. The MOHLTC states that the majority of rejections occur because the physician did not give sufficient information on the form. Most requests take approximately three weeks to be processed and are sent back to the physician who made the section 8 request (MOHLTC, 2013). The EAP is not only related to the ODB program; those on social assistance through the *Trillium Drug Program*

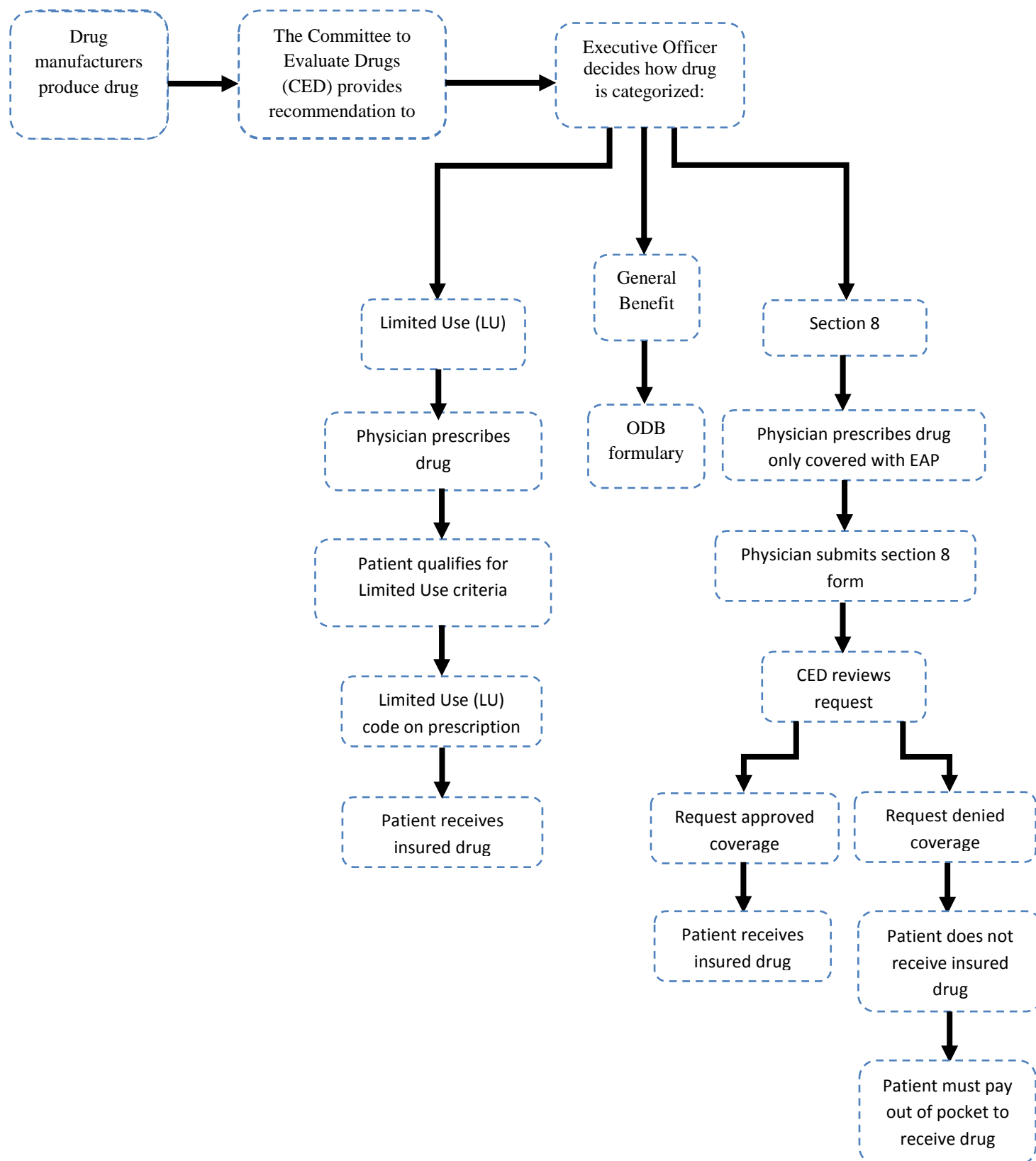
(TDP) may also apply for coverage through the EAP. More information about the TDP appears below.

#### **2.2.4 Trillium Drug Program (TDP).**

The MOHLTC offers other programs including the Trillium Drug Program (TDP). The TDP provides drug coverage to patients in Ontario who have valid health cards, very high prescription costs, are below 65 years of age, are not eligible to receive social assistance, are not receiving Home Care services, and do not have private insurance coverage (Ministry of Health and Long-term Care, 2011; Godwin et al., 1996).

The following chart (Figure 1) provides an overview of the process involved in identifying which drugs are included in the formulary and the process for identifying coverage for those drugs not considered a general benefit. Figure 1 (below) depicts the sequence of events that takes place when categorizing a medication as General Benefit, Limited Use (LU), or EAP/Section 8.

**Figure 1. Overview of the Drug Categorizing Process for the ODB Formulary**



### **2.3 Changes to the ODB program**

For those seniors on a very low income, they only pay a \$2.00 deductible per prescription, however higher income seniors annually pay \$100 plus \$6.11 per prescription filled (Towers Watson, 2012). The new budget contained a proposal that high income single seniors (with an income greater than \$100,000 per year) will be required to pay a \$100 deductible plus 3% of their income. For senior couples with a combined income of \$160,000 or more, they will be required to pay a \$200 deductible as well as 3% of their income. The co-payment per prescription will stay the same (Towers Watson, 2012). The purpose of the deductible is to help the government sustain the ODB program (Towers Watson, 2012).

### **2.4 The History of the ODB Program**

The following section provides some background information on the development of the ODB program.

The purpose of introducing publicly funded drug programs in Canada was to address the needs of those individuals who experienced financial barriers when accessing the drugs they medically need (Jacobs & Bachynsky, 2000). In 1974, drug coverage was introduced to the health care system in Ontario. Other provinces and territories followed but they created their own programs and policies for drug coverage as the health care system differs from province to province, since health is considered the responsibility of the province or territory (Deber, Gamble, Mah, 2010; Decter, 2005). Before the year 1970 however, there were very few drug coverage programs available for patients across Canada. The reason for this is that between 1955

and 1970, several new and expensive drugs were released into the market (Decter, 2005). These new drugs were mainly for the elderly population who were suffering from chronic illnesses (i.e. co-morbidities), as well as from a limited income (Decter, 2005). The Ontario government then initiated two programs that helped the elderly pay for their medications. These programs were generally referred to as Old Age Security (OAS) and Guaranteed Income Supplement (GIS). Although the OAS and the GIS were not directly linked to drug coverage, they still helped the elderly afford their medications (Jacobs & Bachynsky, 2000). Subsequently following the OAS and the GIS, drug benefit programs for the elderly, as well as those in need of social assistance were introduced to Ontarians such as the ODB program (Jacobs & Bachynsky, 2000).

## **2.5 Potential challenges and concerns with the ODB Program**

The following section illustrates some common challenges and concerns in regards to the ODB program reported in the literature. This section illustrates the importance of studying the ODB program from physicians' perspectives.

Many physicians believe that the decisions made by the *CED* limit their ability to prescribe suitable medications for their patients. Suitable medications are especially important for those suffering from chronic diseases such as diabetes, hypertension, chronic pain, chronic obstructive pulmonary disease (COPD), and cardiovascular disease because they are required to be on numerous medications (Laupacis, 2002). As pointed out by Laupacis (2002), there are four reasons why a drug may not be considered as a General Benefit and therefore not included on the formulary;

- Cost effectiveness when compared to treatments already on the market.

- The cost may be much higher than other already available treatment options.
- The drug's clinical effectiveness is not very well established in the available literature.
- If the drug is only shown clinically effective for a certain group of patients and is not generalizable for most patients.

Laupacis (2002) identified additional challenges with the ineffectiveness of the LU system as it poses problems to physicians who need to continually remember the specific codes, and pharmacists who need to contact the primary care physician's office to retrieve the proper LU code on a prescription when the primary care physician forgets to include one. Often a patient is given a prescription with an LU code even though the patient may not qualify. The reason for this is to ensure the patient receives public coverage for a drug not listed under General Benefits but prescribed by the physician (Laupacis, 2002). This further reflects the challenges of the LU system since healthcare professionals are required to work around the policies and to provide their patients with the most appropriate medication. However, it is important to note that an LU drug is not as controlled as a drug that must go through the EAP and have a Section 8 form completed. In other words, it is not as complex of a process to provide a patient with coverage for an LU product compared to proceeding with the EAP with a section 8 request.

For example, the Multiple Sclerosis (MS) Society of Canada participated in the Government of Ontario's drug strategy review in 2003, and as such they found that there were many areas in terms of drug coverage policies that needed improvement and that could in turn save the system money (Multiple Sclerosis Society of Canada, 2003). Their findings parallel

Laupacis' points stated above, in that they provide a valid argument describing that four of the most effective MS treatments are not covered under the ODB formulary but are covered under the EAP and must have a Section 8 form in order to request coverage. The MS Society of Canada described their concerns that more recently, the Section 8 system has been used more as a cost saving tool as opposed to being something that can help offer Ontarians suffering with multiple sclerosis, better treatment (Multiple Sclerosis Society of Canada, 2003). This information provides further information supporting the need for more research regarding the rules and regulations governing the ODB program. There are concerns with the effectiveness of the Section 8 forms and drugs that are covered under the formulary.

## **2.6 A Review of Drug Coverage Programs in Canada with Examples from Other Countries**

The following section outlines some information regarding other public drug coverage programs around the world in comparison to Ontario's program. There are several other countries that, like Canada provide publicly funded healthcare to their citizens, and also have a similar public drug coverage program. Much can be learned from the procedures other countries have followed successfully. The following information can help to outline some of the pros and cons of the publicly funded drug coverage programs around the world.

Drugs (both prescription and non-prescription) expenditure (including both public and private sources) is the second largest health expenditure category in Canada (Canadian Institute for Health Information, 2012). The sources for funding of drugs includes the public sector (i.e., provincial/territorial governments) and private sector which includes out of pocket payment by the individual and through private insurance such as employee benefits and/or individual private insurance (Canadian Institute for Health Information, 2012). Coverage for prescription drugs is

largely provided by the private sector at about 55% over the last 10 years (Canadian Institute for Health Information, 2012). A study comparing provincial drug coverage by Demers et al. (2008) demonstrated considerable variation in public coverage across Canada. In 2005, \$24.8 billion was spent on drugs with \$4 billion of this amount paid out of pocket by Canadian patients. Between 1998 and 2007, prescription drug spending increased from \$8 billion to \$19 billion (Canadian Institute for Health Information, 2011). In 2010, about half of the spending for prescription drugs came from the public sector (Canadian Institute for Health Information, 2011). Inequities exist; not all Canadians have similar levels of access to drug public coverage (Demers et al., 2008).

A comparison of drug costs in Canada, the United Kingdom, Australia, and the United States demonstrated that drug expenditure is the fastest growing area in terms of total health expenditures for all countries (Clement, Harris, Li, Yong, Lee, & Manns, 2009; Gagnon, 2010). A cross country comparison by Clement et al. (2009) demonstrated that due to the increasing cost of drug measures have been put in place to control drug expenditures. This is achieved by creating groups of agencies that will determine which new pharmaceutical drugs will be covered in a publicly funded drug formulary, such as the CED in the case of the ODB program.

However, resistance to the strategies put in place by governments exists. For instance, Godwin et al. (1996) made an observation that 60% of physicians in Scotland were against delisting some medications from their public drug formulary. This formulary is similar to the ODB formulary. The physicians were against these changes as they believed this affected the quality and delivery of care to their patients. They also found that the changes implemented limited their prescribing abilities and challenged their autonomy (Godwin et al., 1996).



## 2.7 Generic vs. Branded Drugs

The majority of the drugs that are found on the ODB formulary are generic. According to a contact at the Ministry of Health and Long-term Care (MOHLTC), as of March 31, 2013, 60% of all the medications on the formulary will be generic. The following section outlines information on the generic drug market in Canada, but focuses specifically on the province of Ontario.

Generic drugs are much more expensive in Canada when compared to the United States (Skinner & Rovere, 2008). The Canadian prices of the branded drugs are regulated by the Patented Medicine Prices Review Board (PMPRB) established by parliament in 1987 (CIHI, 2012). Furthermore, Law, Ystma and Morgan (2011) conducted a study on generic drug pricing in Canada and noted that Canadians pay the most money for generic drugs compared to all other countries in the world (Skinner & Rovere, 2008). Generic drugs are known to help control the drug costs in Canada and they promote competition for brand name products once their patent protection has ended (Competition Bureau Canada, 2007).

In 2006, Ontario attempted to make changes in the policies to reduce the costs expended by public drug plans such as the ODB program (Law, Ystma & Morgan, 2011). The determination of generic prices changed from 60-70% of the branded cost to approximately 50% in the ODB formulary at that time. Additionally in 2010, the government undertook initiatives to lower the drug cost expenditures so that the generic drugs covered in the ODB formulary would cost 25% of the branded cost instead of 50%. However, private insurers would continue to pay 50% of the branded cost. By April 2012, generic drugs would cost 25% of the branded cost by law (Law, Ystma & Morgan, 2011). Improvements and changes were implemented in an effort

to reduce the cost of the generic drugs priced in Canada; although costs have been reduced, the generic drug pricing is still notably more expensive in Canada.

The Competition Bureau in Canada has the responsibility to encourage and protect the competitive markets in Canada (Competition Bureau Canada, 2007). Despite the Canadian government's efforts to eliminate the competition amongst branded and generic drug manufacturers, a competition still exists. Once a branded drug's patent expires, a generic form of the drug can be manufactured. Before the drug patent expires, the branded drug manufacturers develop a strong relationship with the healthcare providers trying to build consumer loyalty to the drug even after it becomes generic (Skinner & Rovere, 2008). This can be referred to as direct consumer advertising where pharmaceutical companies encourage patients to ask their physicians to prescribe a specific medication (Skinner & Rovere, 2008; Ventola, 2011).

The competition between generic and brand name drugs relies on demand, dispensing, distribution, and manufacturing (Competition Bureau Canada, 2007). The demand is determined by the prescribing primary care physicians in a given community based on the clinical effectiveness of the drug (Competition Bureau of Canada, 2007). In terms of dispensing the drug, most of the time the generic form is given to the patient, unless the primary care physician stated that the patient is unable to take the generic drug. Furthermore, some coverage plans may only cover generic drugs as this can be a cost-saver; patients may not have a choice regarding their preference for the generic or branded name. Manufacturing is based on the researchers who make generic drugs that are considered bio-equivalent to the branded name (Competition Bureau Canada, 2007). Approval must come from Health Canada for a generic drug to be released into the market (Competition Bureau Canada, 2007).

Davidoff (2001) argued the notion of “cost effective” drug treatments in health care. He reviewed a number of studies and challenged that a treatment that is considered “cost-effective” does not mean that money is being saved. In fact, he argued that it only provides medical treatment to the ill and it adds to the overall cost of care (Davidoff, 2001). He also concluded that the only treatments that are cost-effective are ones that are considered “cost-saving” meaning the treatment is proven most clinically effective and cheaper than other similar treatments (Davidoff, 2001). Therefore, the question remains, is it really worth it for the MOHLTC to only provide coverage for generic drugs for patients when it is evident that the generic drug is not that much cheaper than the branded one? Evidently, many controversies exist in the health care system in regards to prescribing generic versus branded drugs, and generic drug costs versus branded drug costs. It is important to understand the differences in opinions within the healthcare system when it comes to comparing generic and branded drugs. There are strong arguments that state that choosing a generic drug does not mean that it is a cost saver. In this case, in an effort to use cost-effective measures, the CED tends to choose the medication that costs the system less and still is shown to be clinically effective. That is why the majority of the drugs found on the ODB formulary are generic (MOHLTC, 2011).

## **2.8 Current Issues.**

The following section outlines some important issues that are currently in the media regarding public drug coverage policies. This section strengthens the importance of this study as it adds to the current discussion regarding issues around public drug coverage programs such as the ODB program.

Recently, in June of 2012, Shoppers Drug Mart announced that they were launching a Health Care Portal website with the aim to improve healthcare delivery by providing primary care physicians with a tool to access drug reimbursement information. The portal also provides a number of different clinical tools, such as providing primary care physicians and nurses the ability to access drug reimbursement and clinical eligibility criteria for over 200 medications (Smitham, 2012). According to Smitham (2012) drug reimbursement policies can be very confusing for both the primary care physician and patient. Therefore, having a tool such as this one will help to improve delivery of care to patients to receive their necessary medications. The purpose of the tool is to provide clarity to assist in decision-making about which drug to prescribe.

Universal Pharmacare in Canada has been addressed several times in discussions, conferences, and in the news (Picard, 2012; Gagnon, 2010). Picard (2012) stated that if Canada had a national public drug coverage policy, Canada would save more than \$10.7 billion out of the \$25 billion drug bill per year (Picard, 2010). Some comparisons were made with other countries adopting a publicly funded healthcare system such as the U.K., France, Australia, New Zealand and Sweden. All these countries have much lower drug prices compared to Canada (Picard, 2010). As indicated previously, generic drug prices in Canada are much higher compared to other countries (Lexchin, 2010). Furthermore, a recent article was released to the media in the summer of 2012 about Julie Easley's struggle to survive. She was a recent graduate from the University of New Brunswick and was just diagnosed with Hodgkin's lymphoma (Picard, 2012). Although her in hospital drugs were covered, her out of hospital care and her medications were not. While Ontarians have some access to drug coverage if they are on social assistance or suffering from chronic diseases and cannot afford their medications, (such as with

the Trillium Drug Program), New Brunswick did not have such a program. It was argued that Canada should have a national drug plan to help patients who are suffering from financial burdens due to the cost of their treatments. In response to this article, Steve Morgan, associate director of the centre for Health Services and Policy Research at the University of British Columbia in Vancouver, stated that there are many gaps in drug coverage policies within Canada which further supports the need for this type of research (Picard, 2012).

In 2006, Ontario implemented the *Transparent Drug System for Patients Act (TDSPA)*. The implementation of this Act caused a lot of controversies (Gagnon, 2010). The Executive Officer of the ODB program announced the implementation of the Act. The Act was implemented for several reasons, some of which include:

- To improve patient access to drugs
- To implement rapid drug reviews
- To recognize pharmacists play a valuable role in patient care and patient counselling
- To have funds set aside for conducting research to show drugs play an important role in healthcare treatment
- To improve transparency and accountability in the drug system by allowing patients a role in the drug listing decisions and appoint an Executive Officer who will manage the publicly funded drug system
- To reduce paperwork for primary care physicians by replacing the Section 8 process.

(Ministry of Health and Long-Term Care, 2013).

There is limited information about this Act in the literature. It seems as though there have been some improvements that have been implemented in the ODB program; however, it is

unclear whether these changes have been successful. The Act did, however, include a list of medications that are eligible for funding through the EAP through a phone service called the *Telephone Request Service (TRS)*, as opposed to the traditional method of submitting a form. In this case, the physician would phone this service and request permission for coverage for a specified medication not covered as a general benefit on the formulary (Ministry of Health and Long-Term Care, 2013).

## **2.9 Rationale for Study**

The following section provides a rationale for this thesis. Its aim is to summarize information from the scoping review above, and to support the need for this type of research.

Laupacis (2002) states that further research is needed in the areas of LU codes and Section 8 policies in the ODB program. In accordance with Laupacis, Zwarenstein et al. (2007) indicates that there are gaps between what primary care physicians do in their clinical work and what the research evidence states should be happening in practice. Primary care physicians are affected by the policy decisions made by the MOHLTC in regards to the ODB formulary. Many primary care physicians feel that their opinions and perspectives should have been taken into consideration before the MOHLTC made changes to the ODB formulary (Godwin et al., 1996). In Godwin's et al. (1996) study, they reviewed how delisting drugs from the ODB formulary affected the attitudes of prescribing primary care physicians in Kingston, Ontario. Throughout their review of the literature, they were able to find additional information from other countries in regards to primary care physicians' opinions. However, they also stated that they were not able to find any reports on the effects of delisting drugs from the formulary in Canada. This further strengthens the need for this kind of research. Evidence is important to inform, develop,

and improve policies, practice, and public perception of a specific issue, such as with the ODB program (Suri & Clarke, 2009).

Because the elderly in North America are considered the fastest growing population, they have the highest rates of co-morbidities (Grootendorst, O'Brien, & Anderson., 1997; Canadian Institute for Health Information, 2011). In 2015, it is predicted that there will be more seniors aged 65 and older than young youth (Canadian Institute for Health Information, 2011). With the growing senior population, several concerns have been raised about the Canadian healthcare system not being able to sustain the needs of the senior population. The senior population is known to frequently need healthcare services (Canadian Institute for Health Information, 2011). Due to this fact, researchers have gained more of an interest in healthcare policy for this age group, especially in prescription drug coverage, according to Grootendorst (et al., 1997). Furthermore, Allin and Laporte conducted a study in 2011 on the socioeconomic status of seniors and the use of medications in the ODB program. Their research aim was to find a gap in the drug policy in Ontario due to the potential inappropriate drug use in Ontario (Allin & Laporte, 2011). Their results showed that those individuals with a low income use more medications than those with a higher income. These facts further help to validate the rationale for this research project. Policy changes need to be made and the gaps in the ODB formulary policies need to be recognized amongst policy makers in Ontario.

The Romanow report; *Building on Values: The Future of Healthcare in Canada* that was released in 2002 stated that prescription drugs are just as important medically compared to hospital and primary care physician visits, drugs for treatment, and other necessary health expenditures (Romanow, 2002). Kapur and Basu (2005) stated that there is evidence that the health and well-being of Canadians can be compromised if they do not have the proper access to

drug treatments for their health conditions. Furthermore, the Romanow report reveals several disparities in drug coverage across the nation (Romanow, 2002).

Jacobs and Bachynsky (2000) have advised that a national initiative for a public pharmaceutical benefits program would further ensure proper prescribing, utilization, and cost effectiveness for the medications prescribed. This argument relates to the current discussion around the initiative of national pharmacare. If the governments in each province and territory agree to come together offering one national drug benefit program, it may be possible to realize improvements in the utilization of the program. Also, it would be much more feasible to study effectiveness by examining the nation as a whole (Jacobs & Bachynsky, 2000). Arguably, Rovere and Barua (2012) state that Ontario should follow in British Columbia's footsteps and offer universal coverage for prescription drugs in the province based on need and not on age.

A comprehensive review of the literature yielded limited literature in regards to the ODB program and primary care physicians' perspectives on the ODB program. There were very few studies that examined drug coverage policies using the case study approach and interviews as a data set.

Primary care physicians are the gatekeepers of the healthcare system (Health Council of Canada, 2010). They act as the main connection between patients and the healthcare system (Health Council of Canada, 2010). A report by the Health Council of Canada (2010) indicated that it is important to study the factors that influence primary care physician decision making. In doing so, the policies set in place can be improved in order to aid primary care physicians in making the best cost-effective choices to ensure best delivery of care (Health Council of Canada,



2010). This further supports the need for research in this area and provides a strong rationale for studying the ODB program from primary care physicians' perspectives.

Although the ODB program provides services for several people in the population, this study focused on the senior population. To further support the need for this research, CIHI (2010) released a report outlining that between the years 2001 and 2006, the senior population in Canada grew to approximately 14% of the entire population. They also stated that because the senior population is growing this rapidly, there is a need for researching information in relation to seniors' drug use in order to improve management of public drug programs (Canadian Institute for Health Information, 2010). This research will help inform those in the healthcare sector about the ODB program in Ontario.

## **Chapter 3**

### **Methodological Approach**

The goal of this study was to determine primary care physicians' perspectives on the Ontario Drug Benefit (ODB) program. This thesis explored the following research questions:

1. What is the Ontario Drug Benefit program?
2. What is the purpose of the Ontario Drug Benefit Program?
3. Who is eligible to receive services under the Ontario Drug Benefit Program and why?
4. How can the Ontario Drug Benefit program be improved from the primary care physicians' perspective?
5. What are the advantages and disadvantages of the Ontario Drug Benefit program from the primary care physicians' perspective?

The study is based on a case study approach (Yin, 2003). Data for this study was collected using semi-structured interviews. The analysis for this study is based on the theoretical framework that recognizes the interplay between ideas, interests and institutions which is explained further later in this chapter (Tuohy, 2003; Doern & Phidd, 1992; Béland, 2003). The scoping review conducted in Chapter 2 answered the first three research questions stated above. Primary care physicians' perspectives were examined through semi structured key informant interviews. The key informants were asked about their views about the ODB program, their personal experiences with it, as well as their opinions on the advantages and disadvantages, and ways of improving the program. My role in this research project included being the principal investigator, conceptualization of the project, development of the research questions and the

research design, recruitment of key informants, conducting the key informant interviews, data collection, transcription of the data, and data analysis. The following sections describe in detail the methodology followed while conducting this research project.

### **3.1 Study Design**

#### **3.1.1 Case Study.**

This research project is qualitative in nature. The research design used in this study is the case study approach. This method is most appropriate for this type of study since case studies are useful in the earlier stages of research project since this research project is meant to be a first step in developing a bigger project (2009). This method is used in order to achieve an understanding of the phenomena of which little is known as noted in Chapter 2. The purpose of this study is not to track physician prescribing behaviour through time, (e.g., prospective cohort study) but to better understand the current views of physicians on the ODB program. A case study design is advantageous because it allows the researcher to study contemporary phenomenon in its real-life context (Yin, 2011). Cases can be classified as individuals, groups, neighbourhoods, programs, organizations, cultures, or regions (Patton, 2002). The case study approach is most appropriate for this study due to the type of questions being asked. The case study approach allows the researcher to be able to address the “how” and “why” questions to the research problem. For example, answering why the ODB program was introduced and how the ODB program can be improved. Unlike an experimental design, this approach also does not involve any control over behavioural events and thus allows the researcher to study a phenomenon within its real life context (Yin, 2003). A survey design can focus on contemporary events like a case study; however this approach is better suited for answering questions about “how much” and “who.”

The purpose of this study is not to determine how many prescriptions physicians write but their experience with the ODB program.

The case study approach works best when the consumers or users of a service are the unit of analysis, and in this case, the primary care physicians are the primary users of the service of the ODB program and they control patient access to the service (Yin, 2003). However, patients are also recipients and users of the service.

As noted by Keen and Packwood (1995) the case study approach is very useful when investigating important policy questions in health care. They also stated that primary care physicians are interested in knowing how new government policies may affect the health of their patients. The ODB program was developed and implemented by the Ontario MOHLTC to ensure that the senior population has access to publicly funded medications. This study seeks to understand both the advantages and disadvantages of the ODB program. Results may potentially positively impact patient care by identifying gaps within the policy and suggesting changes that can improve delivery of the service. Primary care physicians will be asked to elaborate on personal encounters with their patients when they found themselves restricted in delivering what they thought was the best approach to treating their patients (Keen & Packwood, 1995).

This case study focuses on a group of primary care physicians in a primary care clinic in a small town in Ontario. This is not the intent of the study. Rather the goals of this study:

- Focuses on one primary care clinic in a small town in Ontario
- Focuses on one group of primary care physicians in a small town in Ontario
- Is not representative of all primary care clinics in Ontario or Canada
- Is not designed so the results are generalizable

(Yin, 2003)

### **3.2 Scoping Review.**

A research method commonly referred to as a scoping review was used when reviewing the literature for information on the ODB program. Scoping studies are used when the area being researched has not been extensively reviewed before (Arksey & O'Malley, 2005). Scoping reviews are slowly becoming more popular as a research methodology. In this study, the scoping method is most appropriate because the ODB program is a topic that is under-researched and not much is known about it (Arksey & O'Malley, 2005). In comparison to a systematic review, the scoping method is used when the topic being studied has not been studied much in the literature and allows the researcher to gather more general information about the topic being studied (Arksey & O'Malley, 2005; Goldner et al., 2011; Levac, Colquhoun & O'Brien, 2010).

The scoping method has four main objectives:

- To “map” what is currently available in the literature regarding the topic being studied.
- To determine whether conducting a systematic review is appropriate for the topic being studied.
- To provide a summary of the information available in the literature to the audience.
- To identify gaps or areas that require more research about the topic being studied.

(Goldner, et al., 2011)

The scoping method for this study followed one similar to Goldner's et al. (2011) approach:

1. Developing the research questions
2. Locating relevant publications/documents

### 3. Organizing publications used for study

#### 1. Developing the research questions:

The first three research questions were used to guide the scoping review. The research questions were developed based on the difficulties experienced finding information about the ODB program. Since there was limited information available in the literature, I developed the first three questions which aimed to gather as much information as possible regarding the ODB program. The following were the questions used:

1. What is the Ontario Drug Benefit Program?
2. What is the purpose of the Ontario Drug Benefit Program?
3. Who is eligible to receive services under the Ontario Drug Benefit Program and why?

#### 2. Locating relevant publications/documents:

Several literature searches were conducted to ensure that all information available in the literature that was related to the ODB program was identified. Several research databases were used from Brock University and UOIT's library database. Searches using Google Scholar, Medline, PubMed, Econlit and Ovid (Medline) were conducted using the following search terms:

- The Ontario Drug Benefit program
- ODB
- Limited Use codes
- Section 8 requests
- Generic drug costs
- Branded drug costs

- Drug formulary
- Health coverage
- Physicians and the ODB program
- Primary care physicians and the ODB program
- Insurance plans
- Pharmaceutical services

There was very little information available in the literature in relation to the ODB program and as a result, an extensive search was completed. The criteria for the identification of articles to include for this study were based on the following;

- Drug Formularies in Ontario, Canada and internationally,
- Drug funding in Ontario and Canada, and
- Views on drug formularies in Ontario, Canada and internationally.

**The following exclusion criteria was used:**

- Private insurance formularies, and
- Cancer formularies.

This criteria was selected because the purpose of this study was to better understand the ODB program which is a publicly funded program (i.e., not privately insured) for all Ontario seniors and not just for seniors requiring cancer treatment.

Once articles were identified using the keywords and multiple search engines, another search strategy was employed by reviewing the reference list of the identified articles. The review of the reference list also identified further articles to be included in the scoping review. The papers that were included in the scoping review needed to include information about the ODB program or drug coverage policies in Canada. All papers that were found were screened for relevance to the research questions (Arksey & O'Malley, 2005).

### **3. Organizing publications used for study.**

All the relevant information gathered specifically regarding the ODB program was organized based on the following themes; *Background information regarding the CHA, What is the ODB program? Changes to the ODB program, The history of the ODB program, Potential challenges and concerns with the ODB program, A review of drug coverage programs in Canada and other countries, Generic vs. Branded medications, Current Issues, and Rationale for Study* as illustrated in Chapter 2. As previously noted, the information gathered also informed the development of Figure 1 found in Chapter 2. This figure illustrates the drug categorizing process for the ODB formulary.

### **3.3 Semi-Structured Interviews.**

Interviews allow researchers to study direct quotations from people involved in the study, about their experiences, opinions, feelings and knowledge in regards to the subject matter. This study used semi-structured interviews to collect the data from primary care physicians in a medical facility in Ontario

#### **3.3.1 Sample and Recruitment.**



A letter was written and signed on behalf of a primary care clinic in a small town in Ontario to grant me permission to recruit physicians for the interviews. Thirty primary care physicians were initially invited to take part in the study and out of that number, ten agreed to be interviewed. The primary care physicians were e-mailed an invitation to participate in the study. This invitation can be found in Appendix 4. To increase the participation, after one month of sending out the invitations by e-mail, invitations were hand delivered to the primary care physicians present in the building, or they were placed in their mail-boxes. An interview time, date and location was set up *as per* their convenience for physicians who agreed to participate in the study.

### **3.3.2 Data collection.**

The semi-structured interviews were conducted one on one with each primary care physician involved in the study. The length of the interviews varied, the majority were between 20 to 30 minutes in length. Prior to the start of the interviews, the primary care physicians were asked to sign the consent form (Appendix 3). If they did not feel comfortable being audio-recorded, notes were taken instead. Out of ten primary care physicians interviewed, two did not wish to be audiotaped. Audio-recordings of the interviews were deleted and destroyed after they were transcribed.

### **3.3.3 Interview Questions.**

The questions were developed with the help of the scoping review, and using other research interview guides as examples. Examples of interview questions from another qualitative case study were also used in developing the interview questions (Rifkin et al., 2010; Auduly, Asplund, & Norbergh, 2012; Martin et al., 2003).

Since the number of people involved in the interview process is not very large, one on one interviews were a good choice (Gillham, 2000). Furthermore, other characteristics of the study that support one on one interviews as opposed to focus groups include:

- The primary care physicians involved in the study are readily accessible.
- Although the material being asked in the interview is not considered personal or sensitive, trusting the researcher is very important since personal opinions will be exposed.
- The questions asked are open-ended and require a detailed response from the primary care physicians.
- Responses from all primary care physicians involved in the study are crucial for the results and data of the study.
- Lastly, the research aims to have a deeper understanding of the ODB program, as well as the views of the primary care physicians in regards to the program and its policies.

(Gillham, 2000).

Transcription of the recorded interviews was done by the principal investigator. All identifying information in the audiotapes was removed during transcription. Once the transcriptions were done, the principal investigator listened to the tapes a second time while following along with the transcribed notes to ensure accuracy. The interviews were conducted wherever was most convenient to the primary care physicians. The interviews were conducted in a private, quiet area to ensure a clear recording for transcription and to ensure privacy and confidentiality. The interview questions were tested for clarity and face validity. Clarity is

defined as whether the informants will understand the questions, and face validity is defined as whether the questions asked will answer what they are intended to answer (Yin, 2003). A primary care physician who was not part of the interview process and who did not contribute to the data collected, reviewed the questions. He provided feedback on their clarity and face validity prior to the commencement of the interview process.

Primary care physicians were interviewed using the questions below to better understand the ODB formulary, drug coverage policies, *Limited Use codes*, and *Section 8 forms/EAP*.

**Interview Questions:**

1. In general, tell me about your experience with the Ontario Drug Benefit Program?
2. Do you feel the Limited Use Codes and Section 8 Forms limit your prescribing abilities as a physician?
3. Tell me what do you like most about the ODB program?
4. How do you feel about the design of the ODB program?
5. How could the program be improved?
6. What are some changes you would like to see in terms of the rules, regulations and policies that surround the ODB program?
7. Is there anything else you would like to say about the ODB program that was not covered in these questions?

**3.3.4 Sample Size, and Data Saturation.**

In terms of sample size, according to Patton (2002), there are no set rules that one should follow for sample size when conducting qualitative research. However, choosing the ideal sample size does depend on what is being researched, the purpose of the interview, the resources available or not available to the researcher, as well as the time available (Patton, 2002). Sample

size also depends on whether the researcher is looking for breadth or depth in regards to the research question. The greater the sample size, the broader the results become. However, the smaller the sample size, the more in depth the data and analysis becomes. The purpose of this study is to collect in depth data on primary care physicians' views on the ODB program because little is known about the ODB program.

The nature of the topic of this research is fairly well known amongst the primary care physicians and thus according to Morse, if the nature of the topic is clear and obvious, fewer participants are needed (2000). Morse (2000) also suggests that the exact sample size cannot be determined prior to collecting the data. She advises researchers to be flexible with the sample size in order for it to be determined once data collection has begun. Ten primary care physicians responded during the three month timeframe set aside for data collection. The first ten primary care physicians who responded during this timeframe were included in the study.

### **3.3.5 Advantages and Disadvantages: Interviews.**

Although there are other techniques to collect data, data collected through interviews does have many advantages. One main advantage associated with face to face interviews includes the advantage of "social cues," which may include voice, and body language that might indicate where the participants may feel uncomfortable with a question, or whether or not they are familiar with the topic under study (Opdenakker, 2006). Another benefit to face to face interviews includes no time delay between the question and the answer amongst the interviewer and the key informant. Additionally, having the face to face interview recorded provides a benefit to the interviewer where they have the chance to critically analyze the interviewed data in depth (Opdenakker, 2006). Lastly, an advantage to using face to face interviews would be the

ability the researcher has to reword, or explain a question that may not be understood by the key informant (Appleton, 1995).

It is however important to note that there are disadvantages that accompany the interview process. Face to face interviews can be time consuming in terms of the length of the interview, as well as traveling time for the researcher and possibly the key informant. This was not the situation in this study as the interviewer traveled to the physicians and conducted the interviews where it was convenient for them. Due to the limited number of interviews this was not a problem. Accurate transcription is key for proper analysis and this depends greatly on the skills of the researcher (Appleton, 1995). This was dealt by listening to the audio-recordings a second time while reviewing the transcribed data to ensure reliability that the transcribed material is accurate.

### **3.4 Research Ethics Board (REB) Approval.**

This research proposal was sent to the Research Ethics Board at UOIT and received approval August 9, 2012. The REB file number is 12-023. The REB approval letter can be found in Appendix 2, as well as all other REB documents in Appendices 2 to 6.

### **3.5 Data Analysis: Compiling, Disassembling and Reassembling.**

Data analysis proceeded in three steps. The data analysis part of this study followed a similar approach to that of Martin et al. (2003) study. A study was conducted in Canada at the University Health Network (UHN) by Martin et al in 2003 on the decision making process of which drugs make it to the hospital formulary. The researchers adopted a case study approach as

well and also conducted semi-structured key informant interviews. They used the case study approach because they felt it was the most appropriate methodological approach to use for the nature of their study and also, they stated that it is appropriate to use because priority settings in the hospitals is “complex, context-dependent and involves social processes” (Martin et al., 2003). Their study is quite similar to this one as they investigated the hospital drug formulary, they conducted semi-structured key informant interviews, and they also followed a case study approach to develop strategies that will help to improve the decision making process that the hospital follows when determining what drugs make it to the formulary and which do not.

The data analysis for this study followed the steps illustrated below according to Yin (2011);

#### *Step 1: Compiling*

In the first step, the interviews were transcribed verbatim. Any identifying information was removed in order to ensure confidentiality of the participants. A coding sheet was kept and stored in a locked cabinet to further ensure confidentiality. The coding sheet revealed the participants’ names and their interview. Once all identifying information was removed from the transcribed data, the transcribed data was confirmed by listening to the interview tapes again. The transcribed data was then organized by interview question in order to make it easier for the next steps of the analysis process (Yin, 2011).

#### *Step 2 and 3: Disassembling and Reassembling*

In the disassembling stage, the data was further broken down into smaller sub-categories to highlight specific themes found throughout the interview results. The reassembling stage involves reorganizing and rearranging the data in lists or in tabular form (Yin, 2011). The data was organized in tabular form (Please see Audit trail in Appendix 7, Table 2).

#### *Step 4: Interpreting*

In step 4, the data was further broken down into the main themes that emerged from the transcribed data. In this stage, the reassembled data is used to create a more organized result of analysis of the data. Here, the main themes were laid out and specific quotes were chosen to illustrate these themes (Yin, 2011). Please see Table 2 in Appendix 7.

#### *Step 5: Concluding*

Here, the review of the literature was synthesized with the data collected to highlight and support the common themes found (Yin, 2011). The description was compared with the theoretical framework illustrated in Chapter 3, section 3.6; Historical Institutionalism. The results of the semi-structured interviews helped inform the researcher in writing the discussion section of the research. A primary care physician was part of the thesis supervisory committee. His contribution helped enhance the reflexivity of the analysis and was able to verify the findings to help address the validity of the findings (Martin et al., 2003). The committee member also contributed to the discussion and helped contextualize the data analysis once reviewing the results.

### **3.6 Theoretical Framework: Historical Institutionalism.**

The theoretical framework is based on historical institutionalism which is defined as the interplay between ideas, structure and process (Doern & Phidd, 1992). This theoretical framework is used as a lens to guide data collection from the physicians. Theory helps to connect the researcher to the existing knowledge available in the literature and enables the researcher to

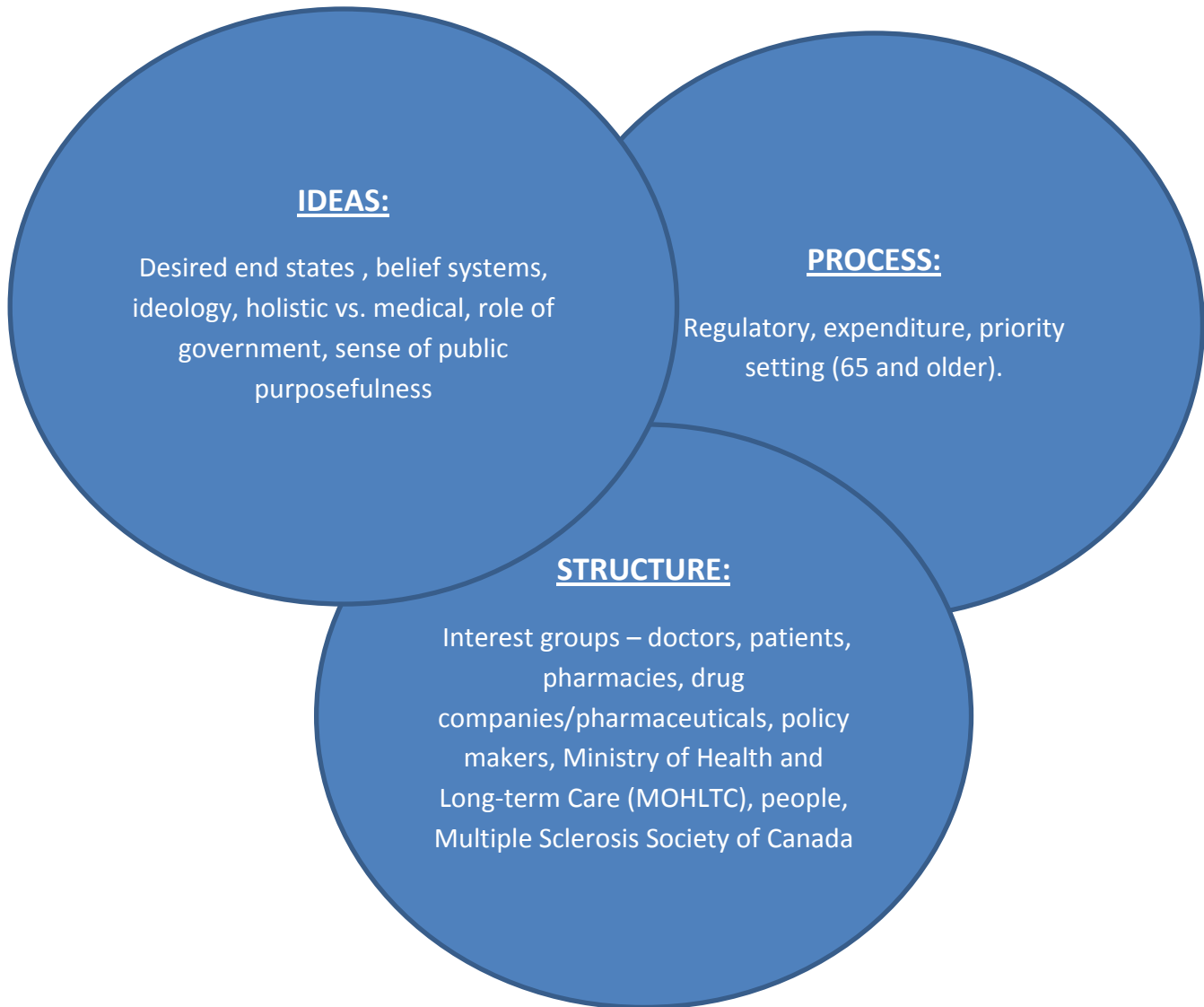
answer the questions why and how the phenomena are occurring as is the goal in this study (Brazil, Ozer, Cloutier, Levine & Stryer, 2005).

Historical institutionalism is a theoretical approach to help understand the changes that have occurred in the healthcare system over time (Tuohy, 1999; Klein & Marmor, 2005; Béland, 2010; Doern & Phidd, 1992). Furthermore, Putnam indicated that history plays a very important role in what occurs in the future (Putnam, 1993). According to this framework the decisions that were put in place in the past, whether intentional or accidental, have paved the road to the policy decisions that are made now and continue to be made by policy makers (i.e., decision-makers in government). In this study, as indicated earlier, the *Canada Health Act (CHA)* principle of comprehensiveness determines what healthcare services gets publicly funded. Drugs are universally publicly funded when delivered in a hospital. Drugs outside the hospital setting are not universally publicly funded. As a result provinces and territories have sought alternative strategies to provide public funding for specific groups outside of the hospital. Doern and Phidd (1992) describe policy as the result of the interactions amongst ideas, structure and process. Ideas are defined as the goals government hopes to achieve. In this study, government has a desire to provide public funding for seniors who need prescription drugs. Primary care physicians also share this goal in terms of their patient's having access to medically necessary prescription drugs. Structure refers to the interest groups involved in the decision-making process and implementation of policy. For this policy area, interest groups include the primary care physicians, patients, government, pharmaceutical companies and pharmacies – all who have an interest in drug funding. Note that this study examines the views of physicians in regards to the ODB program. Process is defined as the instruments used to reach the desired goals. This study examines the regulation and funding strategies used to implement a drug formulary program.



The aim of this project is to view the ODB program from the primary care physicians' perspectives. As such, the interplay framework guides data collection for this study as defined by Doern and Phidd. Physicians are one of few key stakeholders when discussing the ODB program. They are the frontline healthcare providers and therefore they can offer valuable information which supports data collection for this study. Similar frameworks have been developed by other researchers to understand policy development, decision making, implementation and goals (Doern & Phidd, 1992, Beland, 2005, Tuohy, 2003, Klein & Marmor, 2005). The following figure illustrates how the interplay framework relates to studying the ODB program.

**Figure 2. Historical Institutionalism: The Interplay Framework- Ideas, Structure, and Process**



**Created based on:**

**Doern & Phidd, 1992, Beland, 2005, Tuohy, 2003, Klein & Marmor, 2005.**

## **Chapter 4**

### **Interview Qualitative Results**

This chapter presents the results from the semi-structured interviews of 10 primary care physicians working in a primary care clinic in Ontario. Results are categorized based on the themes identified during the analysis. The main themes are illustrated in Table 1 below. The first section presents the overall views on the ODB program. The next section presents views on the overall sustainability of the ODB program. The third section presents the benefits and challenges of the ODB program. The fourth section presents views on Generic vs. Branded Drug use and prescription. Suggestions made by physicians are presented in the last section.

## Table 1: Overview of the Major Themes That Emerged From the Interview Data

- 4.1 General Opinions about the ODB Program: Views Vary
- 4.2 Questioning Sustainability of the ODB program
- 4.3 Advantages and Disadvantages of the program
  - 4.3.1 Advantages
    - i. Increase access for those who are unable to pay
  - 4.3.2 Flexibility in prescribing medication on the formulary
  - 4.3.3 Drug coverage by the ODB program
  - 4.3.4 Disadvantages
    - i. Adding new Drugs to the ODB formulary
- 4.4 Generic vs. Branded drugs
  - 4.4.1 Generic coverage
- 4.5 Policy and Regulation Governing the ODB program
  - 4.5.1 Limited Use Codes
  - 4.5.2 Removal of LU codes and EAP (Section 8)
  - 4.5.3 Timely review of EAP requests
  - 4.5.4 EAP rejections
- 4.6 Transparency
  - 4.6.1 Updating the ODB formulary
  - 4.6.2 Importance of Evidence based practice to physicians
  - 4.6.3 Reasons behind policies and procedures
  - 4.6.4 Informing physicians when drugs are delisted or added to the formulary
- 4.7 Recommendations and Suggestions

#### **4.1 General opinions about the ODB program: Views vary**

The physicians were asked about their general experiences with the ODB program. Their views on the ODB program varied from physician to physician (see Table 2 in appendix 3). The general experiences described by physicians were either described as “excellent” or “not very good.” Each physician had their own personal opinion regarding the ODB program based on their own experiences with the ODB program. If their experiences were positive ones, they generally had very positive opinions about the program. However, if they had experienced difficulties with the policies surrounding the program or had not found it useful with their patient practice, they did not think highly of it. All physicians, however, did begin the interview by expressing their appreciation that a program such as this one exists. The physicians who have the majority of their practices made up of seniors, used the ODB program more than those who did not have as many elderly patients.

Other physicians expressed their positive opinions about the existence of the ODB program:

“...For the moment, as it is, it certainly goes a long way to help me and my ability to manage my patients’ illnesses.”

“It’s an excellent program. It’s an essential program... So the program is essential and I think for the most part, is managed very, very well.”

“I am happy ODB is covering medications for patients who have no other access to medications.”

“Ok, well first of all I guess I’m glad that it’s there because it is an important safety net for so many people who live in Ontario... I think overall it is a good thing and I’m glad it is there.”

Although there were several positive aspects associated with the existence of the ODB program, some physicians had opposing views. Depending on their experiences, some of the primary care physicians were not as pleased with the program as others. The primary care physicians who had not been practicing for longer than five years or who had immigrated to Ontario from another country, found it difficult to work with the ODB program. There are several policies and rules that govern the program:

“I don’t think it’s the best program out there.”

“Very limiting for prescribing medication”

#### **4.2 Questioning the sustainability of the ODB Program: costs associated with the program**

Some primary care physicians described their concerns with the costs associated with sustaining a program such as the ODB program. It can be quite challenging for primary care physicians to put their trust in the system when there is fear that it may not be realistically sustainable. Specifically when they agree the program is very beneficial to their patients:

“The biggest challenge is the affordability of the strategy in the long term. You know as we have a population that is aging, a larger percentage of elderly, our use of this system will keep growing and what does that mean for the system as a whole? So I guess we will find out in time. For the moment, as it is, it certainly goes a long way to help me and my ability to manage my patients’ illnesses.”

The primary care physicians also recognized that some of the policies set in place governing the ODB program are essential in its sustainability. Although they are limiting and difficult to work with, the LU codes do seem to serve some purpose for some physicians. However, are the LU codes used properly? The lack of research in this area does pose several questions associated with the LU codes and other policies that are set in place with the ODB

program. Physicians should be made aware of these potential issues as it makes their understanding of the program much better and allows them to use the program to provide the best care for their patients:

“Is this something we can afford? I feel that the government is already using some ways like using the LU codes, so that physicians don’t abuse it in such a way that you don’t always use the most expensive drug, in lots of cases you can choose the less expensive drug and still do the job well, but because of marketing from drug companies, we have been bombarded by that and influenced by that somehow right?”

“The problem is that, our whole healthcare system has a problem – we just don’t have enough money to fund everything.”

“The biggest challenge is the affordability of the strategy in the long term. You know as we have a population that is aging, a larger percentage of elderly, our use of this system will keep growing and what does that mean for the system as a whole?...”

### **4.3 Advantages and Disadvantages of the program**

#### **4.3.1 Advantages.**

##### *i. Increase access for those who are unable to pay.*

Although there are some disadvantages associated with the program, several primary care physicians did admit to the many advantages the program has to offer. One main advantage is definitely that the program caters to the senior population who suffer from the most co-morbidities. There seems to be a gap in the system with patients who need certain medications but do not qualify for coverage (are not 65 or older) or who do qualify, but the medication is not available as a general benefit on the formulary

“I don’t mind trying new medications for patients who have failed older medications, I’m just left giving them samples to see if it does work but it is a problem if it does work and

they don't have the finances, or they are not in the program, or the program doesn't accept coverage."

"I like the fact that it is available to people who are most disadvantaged."

"I've experienced better compliance after 65 compared to prior to 65."

"I guess it makes available to a large majority of our citizens who don't have the means to afford medications, it makes medications easily available to them for the management of their health issues and chronic diseases so that's probably the biggest single benefit as I'm sure you and I will benefit one day!"

#### **4.3.2 Flexibility in prescribing medication on the formulary.**

Other primary care physicians described some positive aspects with prescribing medications on the formulary. The fact that the formulary provides coverage for more than one drug in each drug class provides the physicians with flexibility in their treatment options for their patient:

"The positive thing is they cover medications in the same groups (i.e. GI meds, cardiovascular meds etc...) giving me a chance to choose best one for patients. Gives us opportunity to choose in case patient reacts to one of the medications that they are prescribed."

"Now the business you run into is when you need to prescribe someone something that isn't on the ODB list and then you have to decide yourself just how much of a fight you are going to put up with it because there are certainly products that are as equal as whatever you have chosen and certainly in lots of cases a whole lot cheaper. And that's why the ODB – that's their administration, they look after this drug, this drug, this drug and pick the one that's going to be the cheapest if they are all going to be totally equivalent. I think I'm all in favour, I think it is an essential program and for the most part it is very well managed I don't have much of a problem with it."



“It is a good program – it cost government a lot. ODB is a good program but the section 8 and de-listing of drugs and writing prescriptions differently to get coverage is what bothers me the most. If it is covered, it should be covered either way no matter how I write the prescription.”

“But the fact that the program exists and I can always find something for my patients is what I like about it.”

“In general, I’d been very happy with it, a large percentage of our patients who are on routine medications are often ODB candidate and by and large, most of the key medications that we prescribe are listed on the ODB so I have been happy with it.”

“There is no medical problem that I have not found a medication for, it may not be the best, it may not be the newest or it may not be the one that has the most data out there but there is something for everybody on the program. That is what I like most about it.”

Primary care physicians recognized the advantages of having a program such as the ODB program as it sets Canadians apart from the American healthcare system. The quality of care is important to primary care physicians.

“I think if we didn’t have ODB, didn’t have drug coverage for these patients, it will be like the States, you have to choose between eating one day and your medication which is horrible so absolutely, there are good things about the ODB program.”

#### **4.3.3 Drug coverage by the ODB program**

When asked about the drugs that are available for coverage on the formulary, primary care physicians recognized the difficulties policy makers have when deciding which drugs are added to the formulary and which are not. Although there were several primary care physicians who did mention that it was beneficial for them to have more than one drug per class of drugs covered on the formulary, some described that this might be unnecessary. Reviewing the ODB formulary and how many drugs per class of drugs do qualify for a general benefit may provide more resources that can be allocated toward other more expensive drugs that are most commonly

used by physicians. The following quotes illustrate some physicians' views on the inclusiveness of the drugs that make it to the formulary for coverage:

“I think it’s good, I think its ok. I mean a lot of people might think they are restrictive, they are not very open to taking in more medications but I think whatever they are doing, they are doing well in a sense that there are quite a number of medications that I see there that I’m surprised that they are there, they are approved a lot. Not as much as the medical healthcare professionals would want, and I think the reason is this – the bias is – there is this new medication in town, and everybody feels is the wonder drug and the first question they ask is what about coverage? And I think it is because of the medical system we have in Canada, the universal healthcare, where everything in quote is free so you expect coverage.”

“The way they take time and put medications on the ODB makes sense to me. Let’s say we have six medications that you can use for blood pressure. I don’t think all six should be put on the ODB. Maybe two, maybe three, they are doing the same thing, So I like the way they streamline medications.”

#### **4.3.4 Disadvantages.**

##### *i. Adding new drugs to the ODB.*

Primary care physicians expressed what is unknown about the program. There is concern with what drugs make it to the formulary as a general benefit, and which do not, and why. There is a lag in the system with the new drugs that are introduced to the market and when those drugs are approved for coverage or not on the formulary:

“Well I think for the most part, it is a pretty well run program. The only thing would be is the lag between what we think is a drug that should be covered and what they are going to cover...”

“I would like to see more drugs covered under ODB like the new ones on the market...”

“I wish the ODB would consider covering for more medications and provide less limitations specifically for medications most often used or prescribed.”

“I don’t think they should be de-listing drugs patients need unless they show studies that show they are not as effective as other meds etc... they should allow doctors to use discretion in prescribing meds.”

These primary care physicians described their frustration with the different levels of benefit (I.e. General Benefit, LU codes and Section 8 requests/EAP). What is meant by different levels of benefit is the general benefit, LU codes, and the Section 8 requests/EAP. Primary care physicians asked for more consistency within the program. Making those drugs available for coverage provides physicians more flexibility in their prescribing abilities.

“I think what’s frustrating is that the ODB has different levels of benefit, which requires different levels of process in order to get the benefit and that is frustrating, I’d like to see – if something is covered by ODB, then cover it, don’t give me different hoops to jump through to get it covered...”

De-listing drugs from the formulary is also of concern. Primary care physicians are unaware when drugs are removed from the formulary until they try to prescribe it to a patient and are notified that it is no longer a general benefit. There are also some inconsistencies with how prescriptions are written. Some prescriptions are approved for coverage when written a certain way. These inconsistencies inhibit seamless delivery of care:

“It is a good program – it cost government a lot. ODB is a good program but the section 8 and de-listing of drugs and writing prescriptions differently to get coverage is what bothers me the most. If it is covered, it should be covered either way no matter how I write the prescription.”

“Very limiting for prescribing medication.”

## 4.4 Generic vs. Branded Drugs

### 4.4.1 Generic coverage

The majority of physicians mentioned their concerns about the eligibility of medications that make it to the formulary, and how the majority of them are generic products. Some had strong opinions when comparing the generic and branded drug products on the market. For the most part, there seems to be consistency in that most primary care physicians feel confident that a generic form of a drug is just as effective as its branded form and therefore do not have any problems prescribing generic medications:

“I have no problems with generic drugs because scientifically they should provide the same effects, I mean there are strict guidelines.”

Some mentioned that they would like to see more testing and research done on the generic drug products. There seems to be more inconsistencies in generic vs. branded drug testing. Primary care physicians are concerned with the effectiveness of the generic forms of the medications on the formulary. Several questions arise such as how does the MOHLTC deal with some of the data in the literature that provides evidence that the generic form of certain medications are not as effective as their branded form? Policies need to be set in place to provide for more rigorous testing of generic drugs, and to provide stricter guidelines for generic manufacturers to meet:

“There is some data that is out there that shows that generic drugs are not as effective as the name brand drugs and some of the policy changes that need to happen is a more rigorous testing of generic drugs...”

“...I would say not all medications are created equal. There are certain ones that I don’t have problems with but there are a few of them that have those kinds of issues.”

“...I think if they were much stricter with the generic competitors with the tolerances in terms of the potency of medication so instead of plus or minus 15% make it plus or minus 5%. Make the generics much closer to what the brand names are in terms of potency, that would reduce the number of people who have complaints as they are making the transition.”

Allowing more flexibility in prescribing behavior may help to address the issues with the generic medications:

“I do have some patients – who do notice some differences for certain medications, but it is unusual for patients to say they want the original brand because it is not as effective...”

One physician mentioned that there are times when a patient is automatically switched from the branded to the generic form of a medication once they turn 65 and are eligible for coverage under the ODB program. When the patient is automatically switched from the branded to the generic form of the medication, there is not a policy set in place that requires the pharmacists to notify the physician. There were some instances where physicians recognized that if they had been notified that their patients were no longer on the branded form of a medication, they would have been able to avoid the occurrence of adverse reactions to the generic medication. A policy should be set in place where the pharmacists must notify the physicians when their patients are switched from the branded form of a drug to the generic. Notifying the primary care physicians will allow them to be more prepared when treating patients and to be aware that certain changes in their health may occur due to the change in the medication. It is crucial for the health and well-being of the senior population that physicians know when their patients are switched from the branded form of a medication to the generic. Unnecessary adverse health effects can be prevented:

“The pharmacy would probably come into play, like I would say, I don’t know if there could be a policy in place to say to the pharmacists once a patient starts on this medication, they need to stick with it and don’t change it, and if there is absolutely no way of doing it, then change it, but you need to notify the doctor...”

#### **4.5 Policy and regulation governing the ODB**

When it comes to the Limited Use (LU) codes and the Exceptional Access Program (EAP), several primary care physicians had very strong opinions towards these two aspects of the ODB program. Several mentioned the need to eliminate the EAP, and some mentioned that the LU codes could also be eliminated. On the other hand, there were also some primary care physicians who did not find a problem with the LU codes or the EAP.

##### **4.5.1 Limited Use Codes (LU).**

When asked about the LU codes, a couple of physicians mentioned that they are limited in their prescribing abilities if they need to follow the LU criteria. Some also mentioned that they still always somehow find a way to use the LU code and still provide their patients with the medication they need, even though the LU code they listed on the prescription is not completely correct. There seems to be ways around the policies set within the ODB program. Some primary care physicians become comfortable with the policies and find gaps within the program and are able to work around them and thus write prescriptions for their patients that they know will be completely covered:

“...well LU also limits, due to the criteria you need to use...”

“The LU code which I don’t honestly see the point of, I’m sure other physicians feel the same way, really doesn’t inhibit me from prescribing medications because you are always able to find an indication which may not necessarily be the total honest way of doing it but if you feel the patient needs it you will circumvent that to get the medication.”

“LU is ok, for most seniors. Once patient is able to get medication that they need, then I’m fine.”

#### ***4.5.2 Removal of LU codes and EAP***

If the LU codes are not always followed correctly, then they are not serving their purpose. Several primary care physicians expressed their frustration with the LU codes and the Section 8 requests. Primary care physicians believe that removing the LU codes and the Section 8 process will improve the ODB program and improve delivery of care to their patients. Primary care physicians should be given the autonomy to prescribe medication that they feel is appropriate for their patients:

“Eliminate the red tape when it comes to other or newer medications which also have strong supportive evidence don’t go down the paths of LU codes or section 8.”

“I would be happy to see the LU codes and section 8 forms – just get rid of them.”

“They need to remove section 8.”

“I don’t see the point for us requesting special access for medications we think are best for our patients.”

#### ***4.5.3 Timely Review of EAP Requests***

Many physicians described their frustration with the issue of the lengthy time it takes for the MOHLTC to return the EAP requests with a response. Little is known about the section 8 process in the literature.

“...I remember for a while, the EAP or section 8 process took a long time often times it takes months before the return of a notice whether it is supported or rejected...”

“Most drugs we use with an LU and it goes through fine – but section 8 – they deny everything.”

#### ***4.5.4 EAP Rejections***

Several physicians described their concerns with EAP rejections. Although there is limited information in the literature regarding the EAP program and section 8 requests, most physicians expressed that the majority of section 8 requests they have submitted to the MOHLTC have been rejected. The primary care physicians also mentioned that, sometimes, the section 8 requests that they have submitted take a very long time to be approved, leaving the patient with no treatment during that time period. Policies should be set in place to help primary care physicians deliver better care to their patients. However, if some primary care physicians are avoiding the section 8 requests, then there certainly is a problem within the system:

“... I have never had an experience where they have actually okayed it and said I could use it. My experience with section 8 is terrible.”

“I hardly even do it now, if the medications are not easily covered on ODB, or LU, I probably avoid it...”

Although there were concerns with EAP rejections, some physicians expressed no concern with the EAP, and noted that their requests were almost always approved in a timely manner. Inconsistencies toward this policy are apparent. Some physicians expressed extreme difficulty with receiving approval from the section 8 requests, and others mentioned that they do not have any concerns. Some primary care physicians submit the requests and receive an approval with no problems from the MOHLTC:

“I don’t think after I have done it properly and dotted the I’s and crossed the T’s, I have ever had one refused. They are very, very good about that...”



“I don’t have experience with section 8 request being rejected – I am lucky so far”

## **4.6 Transparency**

One very common theme that came up in every interview was the issue of transparency. Physicians wanted to know how the decisions are made in terms of implementing the policies surrounding the ODB program. Physicians wanted to also be included in the decision making process for the ODB formulary. Lastly, increasing education about the ODB program’s policies, rules, and regulations to physicians was also requested.

### **4.6.1 Updating the ODB formulary.**

Physicians began by questioning how often the ODB formulary is updated and when it is updated. They want to be notified of the updates and changes when they are made. Somehow, the MOHLTC should provide primary care physicians with this information on a timely and regular basis:

“They have a good number of medications really, I don’t know how often they update it, I’m not sure and it is difficult, I would say it’s me, because I guess I should find a way to actually know the medications that are there, but there are so many of them, how am I supposed to put them in my head?!”

“I think for the most part, the ODB is fair, in terms of – it is evidenced based, they have tried to get the best evidence for which treatments work best for which diagnosis, there are some things that are clear – black and white, but there are a lot of things that are not clear and I think ODB has been very conservative in that and I think that is a good thing – being conservative in covering or not giving benefits to questionable treatments, so I do see ODB as being a very good program,…”

“I would like to see more transparency in how they make decisions, right now it is really a black box…”

#### **4.6.2 Importance of Evidence Based Practice to Physicians.**

Some physicians mentioned the importance of evidence based practice when making decisions in healthcare. The physicians are referring to how important it is for the MOHLTC to respond to the information resulting from evidence based medicine. They would like to see newer medications that are shown to be more clinically effective than the traditional ones found on the formulary. Sometimes it takes a long time before the MOHLTC recognizes the evidence and adds a new medication to the formulary or sometimes a medication that is shown to be clinically effective is not added at all. Doctors especially wanted to know whether the decisions are based on evidence based practice within ODB formulary:

“It needs to be evidence based. Review the formulary more frequently than it is being reviewed from my experience, I mean I have only been here 6 years but I haven’t seen big changes in the formulary over the last six years, and medication that is already gone generic that shouldn’t be too costly, I can’t see on the program.”

“Lack of evidence based, and lack of timely review. We do not get any notice of reviews, doctors are not aware of it. “

#### **4.6.3 Reasons behind the policies and procedures.**

Another important subject that arose from the interviews is physicians wanting to be given detailed reasons as to why the government makes the decisions to include LU codes and the EAP program. Increasing the transparency in the decisions that are made that are associated with the ODB program is a recurring theme with the interviews:

“I would like to know the reasons why we have to complete these codes and these forms. If they are just a pure financial reason, then they should be upfront about it.”

“... I’d like to know who makes the decisions when we complete these forms, who actually determines the patients’ needs based on a piece of paper, and how objective that

can be and how they are able to determine the patients' needs better than their own physicians.”

“Be very transparent of the criteria for how medications get approved. So that the medical community - I mean they probably are and I don't spend enough time to research it but just ensure that we have medications available to us that are widely recognized by evidence to be effective.”

The primary care physicians have not necessarily requested that all the policies be completely changed, but they have asked for increased education about the ODB program. If the MOHLTC creates a yearly conference or workshop for physicians, providing them with the chance to learn more about the program and about the policies set in place, then they will better understand the program:

“We are cautious when it comes to cost and if they don't think so, then they can educate us about cost effectiveness.”

#### **4.6.4 Informing physicians when drugs are delisted or added to the formulary.**

More physicians would like to be notified when drugs are delisted from the ODB formulary. The ODB formulary changes on a regular basis and sometimes drugs are delisted or added to the formulary and the primary physicians are not aware of these changes:

“They take off drugs at various times on the list it's hard to keep up with what they cover and what they don't”

Another physician admitted that the government does notify physicians of the changes made to the formulary: however, they would like a more productive way for the government to notify them.

“...you know they do send updates all the time on what medications have been added to the formulary, what medications have been removed, it might be worthwhile to put a little

sheet that serves as a basic reminder of what basic policy is with the ODB, in other words, how do they select medications to stay, how do they select medications to be removed, why the policy, why the necessity of a LU code and a section 8 strategy.”

#### 4.7 Views on Recommendations and Suggestions

Throughout the interviews, physicians made several recommendations and suggestions for improving the ODB program. One of the physicians expressed their belief in having one formulary for the entire country as opposed to it being broken down per province, also known as universal pharmacare.

“My biggest – the thing that I really suggest and that’s the problem with the whole of Canada that’s what I have experienced because I lived in Manitoba and then moved to Ontario, it’s like we live in 8 different countries in one country. That’s the biggest problem. I think if they can have their buying power consolidated and have a single formulary for the whole country, that can be cost containment. The way they do it now is very expensive.”

“I’m a novice at this but I expect every province has its own program running a different criteria, so medical care in Canada is not really universal as they would like it but you can imagine if you had one buyer for the whole 30 million people rather than 7 million here and one million there, you can argue much better pricing, you would have better medication on the formulary you wouldn’t be able to afford otherwise.”

“You know, it always sounds nice in theory to make it more universal, in practice, I’m not really sure how feasible that is and how affordable that is.”

One physician suggested designing a hybrid program for seniors as some seniors have more than enough money to fund their healthcare needs and some do not have a lot of money and cannot afford their medications.

“...maybe some hybrid would be appropriate in the long run because we also have a population of 65 and 70 year olds who probably could afford to pay more than they do for their meds and as we are trying to create a cost containment strategy while maintaining the population health, I could a scenario arising where there is a means test

and what kind of subsidy you get for the medication depends on what your ability is to pay and afford and that might be more broadly applied as opposed to be age restricted.”



## Chapter 5

### Discussion and Conclusions

The purpose of this study was to understand the ODB program from primary care physicians' perspectives. This research can inform the MOHLTC so that they may benefit from the results of this study. This approach can be expanded upon to view the ODB program from other primary care providers, medical specialists, policy makers, pharmacists, patients, and other healthcare workers. Gaps in the literature as well as in the results will provide the evidence base for recommendations and suggested areas for improvement. This chapter section outlines a discussion regarding the themes that emerged from the results of the interviews.

#### **5.1 Theoretical Framework: Historical Institutionalism: Interplay Framework - Ideas, Structure, and Process.**

Historical institutionalism was used as the theoretical framework in contextualizing the results of this study and to support data collection from the physicians since they are the frontline healthcare providers. The framework allows the researcher to understand the changes that have occurred over time in the healthcare system (Tuohy, 1999, Klein & Marmor, 2005; Béland, 2010; Doern & Phidd, 1992). The ODB is governed by the rules and regulations put in place by the MOHLTC which is the “structure” in the interplay framework; those who are affected by the policies fall under “process” and “ideas” which refers to the doctors, pharmacies, patients, the MOHTLC, and drug companies. The following discussion is presented while keeping in mind all those involved in the interplay framework, in other words, all those affected or influenced by the ODB program.

## 5.2 Views on the ODB Program

There were 10 primary care physicians who took part in the semi-structured interviews for this research project. Each primary care physician was asked the same questions and their responses to the questions helped to provide insight into the ODB program – its advantages, disadvantages, and areas which require improvement. Physicians talked about the policies surrounding the ODB program, the problems with these policies, and suggested ways to change the program to improve delivery of care and to help them make the right informed decisions when it comes to patient care. In this case, physicians questioned the process used to decide what drugs make it to the formulary and which drugs get funded (as illustrated in Figure 2).

Every primary care physician was asked about their general views on the ODB program and some responses overlapped, while others varied. There were definite themes that were common such as the discussion around branded vs. generic medications, transparency of the program, education for primary care physicians, and other suggestions for improving the ODB program. All physicians began by stating that they are quite satisfied that a program such as the ODB exists and it allows seniors and those on social assistance the opportunity to receive drug coverage for their medication needs. Although the literature did not contain any studies that have been published on the ODB program specifically, there were studies that showed the importance drug coverage has for the health of Canadians (Canadian Institute for Health Information, 2011; Irvine, Ferguson & Cackett, 2005). When recognizing the health outcomes, those who are eligible for public drug coverage are more likely to follow a medication regimen compared to those who do not have any drug coverage. Physicians also noticed that those who are 65 and older or who are on social assistance have better compliance to the recommended drug treatment regimen than those who do not have any drug coverage at all.



### 5.3 Generic vs. Branded Medications.

The literature has shown that there is a lot of controversy about generic drug costs in Canada (Competition Bureau Canada, 2007; Skinner & Rovere, 2008; Law, Ystma & Morgan, 2011; Demers et al., 2008; CIHI, 2002; CIHI 2012; McMahon, Morgan and Mitton, 2006). Although the primary care physicians were more concerned with effectiveness rather than cost with respect to the branded vs. generic drug debate, there is a great need for more research with generic drug products. The key informants requested that there be more evidence-based studies conducted and that they be informed of the evidence prior to a generic form of a medication being listed on the ODB formulary. They did confess that there are some patients who strictly request branded medications; however, there are some who simply cannot handle the generic makeup of the medications (Competition Bureau Canada, 2007; Skinner & Rovere, 2008; CIHI, 2012; Law, Ystma & Morgan, 2011).

According to Health Canada's standards, a generic drug may be no less than 80%, or no more than 125% of the brand name (CADTH, 2012). However, there are some patients who react adversely to the differences in ingredients between the two drugs. The literature also suggests that, within Canada, there is not a very large difference in terms of cost between the generic and branded drugs. Davidoff (2001) wrote an editorial arguing that "cost effectiveness" in terms of health care does not necessarily mean that money is being saved. The argument still stands that it may not be worthwhile for the MOHLTC to provide coverage for generic drugs when it is evident that the generic drug is not much cheaper than the branded one. The results of this study showed that the argument between generic and branded drugs remains and that there are some physicians who do not have a problem prescribing generic drugs. However, there are some who have many concerns. There are some primary care physicians who showed concern about patient

safety with the use of generic products as opposed to branded ones (Kesselheim et al., 2008). More transparency in the decision making process of listing and de-listing drugs, as well as providing evidence-based literature to support these decisions will help to close the gap between the differences in opinion about generic drug use and branded drug use.

#### **5.4 Importance of Transparency/Increasing Education for Physicians .**

For the most part, physicians were quite content that a program such as the ODB exists; however, some suggested that it is not “the best program out there.” Several key informants mentioned that they would like to be a part of the decision making process when it comes to policy decisions in terms of the ODB program. The key informants would also like to see more transparency in the rules and regulations that govern the program. Several of them were not sure if there were some physicians who were part of the policy decision making process, although according to the MOLHTC, there are some physicians on the committee. With that said, the MOHLTC should make efforts to deliver information more clearly to physicians about the policies surrounding the ODB program. This leads to several of the primary care physicians’ requests to be more educated, not only with the MOHLTC and ODB program policies, but with changes that occur within the program, as well as any new evidence based decisions that are made within the ODB program.

Zwarenstein et al. (2007) proposed that there are gaps between what physicians do in their clinical work, and what the research evidence states should be happening in practice. The LU codes were designed for a reason: however, they do not seem to be carrying out their initial purpose which is essentially to “limit” the use and prescription of that particular medication to ensure that the patients who will benefit most from the drug are using it. It seems as though

physicians are finding ways around the policies and procedures surrounding the LU codes and therefore the LU codes are not being used for their intended purpose. This is an example of an ineffective policy which can relate back to problems in the “process” as outlined in Figure 2.

The primary care physicians had more concerns with the EAP, also referred to as the Section 8 requests. Just like the LU codes, there is minimal information in the literature about the EAP program. It is not very clear how effective the EAP is, and how often it is reviewed. Several physicians expressed that “They need to remove section 8.” Similar to the case with the LU codes, some primary care physicians indicated that they do not have a problem with the EAP program; however, there were more physicians who expressed difficulties with the EAP. Their main concern was the timely review of the *EAP* requests which is also concern with the “process” also outlined in Figure 2. Some physicians also stated that they have had little to no success with the EAP and that they no longer use the program. This may explain why none of the primary care physicians mentioned the Transparent Drug System for Patients Act (TDSPA). There is no supporting data in the literature regarding the *EAP* or the TDSPA. However the Multiple Sclerosis Society of Canada participated in the Government of Ontario’s drug strategy review in 2003 and they concluded that there were many areas within drug coverage policies that needed improvement. The MS Society of Canada had some concerns with the ODB program as four of the most effective MS treatments are not found on the ODB formulary and an *EAP* request must be sent to the MOHLTC in order to request coverage for those medications (Multiple Sclerosis Society of Canada, 2003). Currently, the MS Society of Canada website has updated their information and lists a number of medications that are not covered under ODB and patients who qualify for ODB coverage must have their physician fill out an EAP form (section 8 form) and submit it to the MOHLTC. The content from the MS Society of Canada was the only

available information in the literature that discussed the EAP. There is a need for further research in this area, especially for certain vulnerable patients in the population who may not be able to receive drug coverage for illnesses such as MS. A major concern with this is that patients may not be receiving the best quality of care. What is also of concern is that McMahon, Morgan and Mitton (2006) conducted a study and concluded that drug benefit providers around the world are investigating more restrictions on drug coverage policies as cost-effectiveness has become more important than clinical effectiveness and quality of life. Here, the problem lies within the “process” as illustrated in Figure 2. The concern is that one of the main goals of healthcare delivery is for the betterment of the patient. If we are beginning to move more towards the cheaper option for treatment rather than the best quality of care, then our healthcare system is not improving.

At the same time as the McMahon study was published, the TDSPA was implemented (2006) in an effort to improve the public drug system in Ontario. Specific changes were expected to occur when the act was implemented; however, this research did not find any evidence that these changes had been implemented. One of the goals of the act was to eliminate the Section 8 process (MOHLTC, 2012). Although this act has been implemented for more than six years, none of the primary care physicians mentioned anything about this act during the interviews. In fact, all of the primary care physicians referred to the *Section 8* process still as a form that needs to be completed. The “process” as illustrated in Figure 2 is being compromised. The policies that have been set in place to improve the *Section 8* process are not working very well. The MOHLTC does not clarify on the website the process for the new and improved *Section 8* process. When the researcher called the MOHLTC to request clarification on the *Section 8* process, it was confirmed that primary care physicians are aware that they no longer need to fill

out the forms. This is an example where the “process” is being compromised. They are supposed to be able to call the MOHLTC and submit a request for coverage for a specific medication for a patient on the phone, and receive approval or disapproval of the request in a timely manner. It is evident that not all primary care physicians were made aware of this change that occurred more than six years ago. This was also evident when a pharmacist was approached and also was not clear on the TDSPA. This also provides more support for the need for improved education from the MOHLTC to the frontline healthcare providers, as well as for greater transparency. The primary care physicians are unaware of these changes; therefore, neither they nor their patients are benefitting from these changes. This is an example that affects not only the “process” but the “structure” as well, as illustrated in Figure 2.

## **5.5 Suggestions/Improvements.**

The results of this study have revealed areas for improvement and change within the ODB program. The rules and regulations that govern the ODB program need to be revised and any changes need to be clearly implemented with education to ensure the frontline workers are aware of and following the changes to benefit the patients.

### ***5.5.1 Limitations for Prescribing Physicians***

Several physicians expressed their concerns with the limitations they encounter when writing certain prescriptions. In Laupacis’ editorial (2002), he stated that physicians find some of the policies surrounding the ODB program to be limiting for prescribing physicians. The LU codes specifically were what Laupacis (2002) was referring to. Some key informants described their frustration with the LU codes and described how they feel they are unnecessary; however, some key stakeholders did not elaborate about any difficulties with the LU codes. It was

noticeable that some physicians were able to learn how the system works and were able to “follow” the rules and regulations surrounding the LU products with no problems at all. One unknown is how much time and effort is undertaken to manage the LU system by MOHLTC and healthcare workers. Although there is a noticeable struggle with the LU codes, currently there are few known studies in the literature other than this one that discusses the LU codes and their possible limitations to prescribing physicians and how the LU codes may be affecting delivery of care to patients. Therefore, Laupacis (2002) argues that further research in this area is needed and the results of this study support this statement and his point of view.

### **5.5.2 The De-listing of Drugs from the Formulary.**

The literature search suggests that there is a lack of evidence about the ODB program, as well as drug coverage policies in general. Primary care physicians expressed concern about the de-listing of drugs from the formulary without being informed. Information in the literature supports the idea that family physicians are affected by decisions made by policy makers. Godwin et al. (1996) conducted a study where they reviewed the delisting of drugs from the ODB formulary and how that affected the attitudes of prescribing physicians in Kingston, Ontario. Although Godwin et al. (1996) found that physicians were negatively affected by the de-listing of drugs, their review also concluded that there is not any information in the literature about the de-listing of drugs from the drug formulary in Ontario. This suggests that more physicians should be involved in the decision making process in terms of the ODB program, especially because the elderly in North America are the fastest growing population and have the highest rates of healthcare use (Suri & Clarke, 2009). Although physicians were concerned with the de-listing of drugs from the formulary without being informed, the information is available to the public through the MOHLTC website. There are a number of documents listed that describe

the changes that have been implemented within the ODB formulary (MOHLTC, 2013). These documents are fairly long, and most of them are more than 200 pages in length. The recommendation from the Committee to Evaluate Drugs (CED) is also available along with the Executive Officer's final decision. Although the information is available to physicians, it is evident that they are not accessing the information. There are obvious gaps in communication amongst physicians and the MOHLTC. This is an example of a problem with the "process" associated with the ODB program as illustrated in Figure 2. The MOHLTC is recognized for providing the information to the public; however, the physicians are not taking advantage of the availability of the information. Improving communication and educating physicians about the changes that occur over time to the ODB program is a recommendation that can be formulated from the results of this study to improve the delivery of services offered by the ODB program.

There was some concern with eligibility criteria of the program. Although all seniors 65 and older are eligible for coverage with the ODB program, there is some concern with eligibility prior to the age of 65. A few primary care physicians confirmed that they believe that 65 may not be the most appropriate cut off age for eligibility for the ODB program. Future evaluation of the appropriate initiation age may help to improve health outcomes amongst the elderly population. This is an example of the "process" as well as the "structure." Physicians are questioning the "process" and "structure" as illustrated in Figure 2.

## **5.6 Future Implications**

The purpose of this research was to study the ODB program from the physicians' perspectives. This study not only helped outline the advantages and disadvantages associated

with the ODB program, but also identified areas that can be undertaken in future research projects.

### **5.6.1 Universal Pharmacare.**

Future research implications include comparing the different drug coverage programs from province to province. This study only included interviewing physicians specifically about the ODB program; however, key informants identified that it would be worthwhile to assess the adoption of a countrywide pharmacare program (Romanow, 2002). Having a universal pharmacare program could save the healthcare system a significant amount of money according to several researchers (Law, Ystma & Morgan, 2011; Demers et al., 2008; Romanow, 2002; Clement et al., 2009; Gagnon, 2010). A second part to this study would be to compare how often the drug coverage programs are used across the provinces and territories in Canada, and compare their successes to the provinces and territories that do not have a drug coverage program.

Concentrating on cost containment for future research projects is also essential when determining if a universal pharmacare program is more beneficial for Canada. Evaluating several documents such as progress reports from the governments of each province and territory will provide a clearer idea on how much money is spent on drug coverage programs and how they can be improved.

Lastly, expanding research on generic drug products is also important. Physicians showed some concern about generic drugs in comparison to their branded drug form. Physicians requested that there should be more research conducted on generic drug products before they are allowed to enter the market. Also, researching drug prices across the nation, as well as internationally, could provide some insight as to why the cost of drugs is much higher in Canada



compared to other parts of the world. The cost of generic drugs in Canada is decreasing however, more research needs to be done to ensure that these costs continue to decrease so that the drug coverage programs can continue to improve.

### **5.6.2 Expanding this Research.**

This research only included family physicians in a medical clinic in a small town in Ontario. Future research studies can include specialists in the field, as well as pharmacists, nurses, policy makers, and patients. By including more physicians, nurses, pharmacists, policy makers, and patients in a study evaluating the ODB program, more insight will be attained about the ODB program because a greater number of and more diverse key informants will be included in the study. This is based on the theoretical framework illustrated in Figure 2. The significance of this framework is that it illustrates the key stakeholders who are affected by the policy decisions regarding the ODB program. Each person will bring new information to light regarding the ODB program. Evaluating the ODB program from different perspectives will also provide a deeper understanding of the areas that need improvement to improve delivery of care. The results of a study such as this may help to identify the importance of including physicians, pharmacists, policy makers, and patients when making policy decisions and when developing and improving a health program such as the ODB program.

### **5.7 Limitations**

The document review was also limited due to the fact that there was not a lot of information available in the literature regarding the ODB program. Another limitation is the

approach chosen which was to examine the ODB program from primary care physicians' perspectives and not from the patients' or policy makers' perspectives.

Furthermore, I must make the readers aware of the levels of bias that I brought to the research. With a background working in a doctor's office for several years, seeing firsthand how some of the policies work, or do not work for that matter, have influenced the conclusions and findings that I have gathered. The conclusions I will have were affected by my perspectives as a former administrative assistant for the past nine years. Another limitation is the fact that the data was interpreted by one person only to identify the findings and thus make recommendations.

Although I am confident in my scoping review and searching methods, further limitations include those from my scoping review. I had difficulty finding papers that have studied the ODB program and its flaws and weaknesses. My literature search may have been flawed since there are not very many research papers available in the literature about the limitations of the ODB program, my search terms may not have been able to target all the important papers regarding this topic. Another limitation that I must be aware of, is time restraints. Lastly, since some primary care physicians did not feel comfortable being audiotaped, notes were taken by the interviewer instead. The scoping review was limited to English only. This may limit my findings as it may potentially disallow the discovery of different perspectives of the ODB program. This may yield some limitations as transcription of interviews not audio-recorded, are not as detailed as transcribed interviews. Reassurance of the appropriate transcription of non-audio-recorded interviews was assured by confirming the written notes from the interview with the primary care physician.

Another limitation lies in the methodology. The case study approach does work with this type of study however a case study is more credible when data is collected from numerous sources such as one-on-one interviews, focus group interviews, observation and documentation. This study only used one data collection method; semi-structured interviews with primary care physicians (Yin, 2003). However this is a first step to better understand the views of prescribing physicians on the ODB program. The data collected will help to inform future studies as illustrated above.

### **5.10 Conclusion.**

Studying the ODB program provided insight on the importance of evaluating a program such as the ODB, as well as the importance of including physicians when making policy based decisions in healthcare. Although it was revealed that there were many advantages associated with the ODB program, there are areas that need improvement. Physicians requested that there should be more transparency with the rules and regulations that make up the program and ongoing education and follow up to ensure the program is working the way it was intended. Furthermore, the implementation of a national pharmacare program in Canada has the potential to reduce costs and increase access to medications. Additional results from this study suggest that certain challenges exist in obtaining the most appropriate drugs for individual patients with the limitations of the ODB program. Challenges also exist that impact the quality of care and costs associated with procedural requirements.

Although there seems to be routine information sharing between the MOHLTC and the primary care physicians, the communication that exists is not as efficient as it should be. It is evident that physicians are not all informed about some of the policies and changes implemented

in the ODB program. To address this form of miscommunication, we recommend that the MOHLTC examine this process and modify how they deliver their information. Establishing routine seminars or presentations should be offered to groups of primary care physicians twice a year or when major changes are implemented into the program.

# Appendix 1: Section 8 Form



**Ministry of Health  
and Long-Term Care**

Exceptional Access Program Branch  
5700 Yonge Street 3<sup>rd</sup> floor  
Toronto ON M2M 4K5

## Request for an Unlisted Drug Product Exceptional Access Program (EAP)

Please fax completed form and/or any additional relevant information to 416 327-7526 or toll-free 1 866 811-9908; or send to Exceptional Access Program Branch (EAPB), 3<sup>rd</sup> floor, 5700 Yonge Street, Toronto ON M2M 4K5. For copies of this and other EAP forms, please visit [http://www.health.gov.on.ca/english/public/forms/form\\_menus/odb\\_fm.html](http://www.health.gov.on.ca/english/public/forms/form_menus/odb_fm.html)

The Ministry of Health and Long-Term Care (the "ministry") considers requests for coverage of drug products not listed in the Ontario Drug Benefit Formulary under Section 16 of the Ontario Drug Benefit Act. This form is intended to facilitate requests for drugs under the Exceptional Access Program. The ministry may request additional documentation to support the request.

Please ensure that all appropriate information for each section is provided to avoid delays.

### Section 1 – Prescriber Information

First name	Initial	Last name
Mailing Address		
Street no.	Street name	
City		Postal code
Fax no. ( ) ( )		Telephone no. ( ) ( )

### Section 2 – Patient Information

First name	Initial	Last name
Health Number		
Date of birth (yyyy/mm/dd)		

**New request**

**Renewal of existing EAP approval** (specify EAP#) \_\_\_\_\_

### Section 3 – Drug Requested

Requested drug product	DIN
Strength / Dosage form	Frequency of administration
Expected start date	Duration of therapy

### Section 4 – Diagnosis and Reason for Use

Diagnosis for which the drug is requested:

Reason for use over formulary alternatives:

If the patient is currently taking the requested product, please provide start date & objective evidence of its efficacy:

### Section 5 – Current and / or Previous Medications

a) Please provide details of alternatives (listed drugs and/or non-drug therapy) tried for this condition:

Name of drug (indicate if currently or previously taken)	Dosage	Approximate timeframe of therapy	Reason(s) why formulary alternatives are not appropriate
<input type="checkbox"/> current			
<input type="checkbox"/> previous			
<input type="checkbox"/> current			
<input type="checkbox"/> previous			
<input type="checkbox"/> current			
<input type="checkbox"/> previous			
<input type="checkbox"/> current			
<input type="checkbox"/> previous			

b) Provide patient's concomitant drug therapies for other conditions:

### Section 6 – Clinical Information

Please provide relevant medical data (e.g. culture and sensitivity reports, serum drug levels, laboratory results):

The information on this form is collected under the authority of the *Personal Health Information Protection Act, 2004, S.O. 2004, c.3, Sched. A (PHIPA)* and Section 13 of the *Ontario Drug Benefit Act, R.S.O. 1990c.O.10* and will be used in accordance with PHIPA, as set out in the Ministry of Health and Long-Term Care "Statement of Information Practices", which may be accessed at [www.health.gov.on.ca](http://www.health.gov.on.ca). If you have any questions about the collection or use of this information, call the Ontario Drug Benefit (ODB) Help Desk at 1 800 668-6641 or contact the Director, Exceptional Access Program Branch (EAPB), Ministry of Health and Long-Term Care, 3rd floor, 5700 Yonge St., Toronto ON M2M 4K5.

Prescriber signature (mandatory)	CPSO number	Date
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## Appendix 2: Research Ethics Board Letter of Approval



**RESEARCH ETHICS BOARD  
OFFICE OF RESEARCH SERVICES**

**Date:** October 1<sup>st</sup>, 2012

**To:** Rima Karam (PI), Brenda Gamble (Faculty Supervisor)

**From:** Amy Leach, REB Chair

**REB File #:** 12-023

**Project Title:** Physicians Perspectives on the Ontario Drug Benefit Program (ODB)

**DECISION:** CHANGE REQUEST APPROVED

**CURRENT EXPIRY:** August 9<sup>th</sup>, 2013

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The University Of Ontario Institute Of Technology Research Ethics Board has reviewed and approved the change request. The application in support of the above research project has been reviewed by the Research Ethics Board to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) and the UOIT Research Ethics Policy and Procedures.

Please note that the Research Ethics Board (REB) requires that you adhere to the protocol as last reviewed and approved by the REB.

**Always quote your REB file number on all future correspondence.**

**Please familiarize yourself with the following forms as they may become of use to you.**

- **Change Request Form:** any changes or modifications (i.e. adding a Co-PI or a change in methodology) must be approved by the REB through the completion of a change request form before implemented.
- **Adverse or unexpected Events Form:** events must be reported to the REB within 72 hours after the event occurred with an indication of how these events affect (in the view of the Principal Investigator) the safety of the participants and the continuation of the protocol. (I.e. un-anticipated or un-mitigated physical, social or psychological harm to a participant).
- **Research Project Completion Form:** must be completed when the research study has completed.
- **Renewal Request Form:** any project that exceeds the original approval period must receive approval by the REB through the completion of a Renewal Request Form before the expiry date has passed.

All Forms can be found at [http://research.uoit.ca/EN/main/231307/Research\\_Forms.html](http://research.uoit.ca/EN/main/231307/Research_Forms.html).

REB Chair Dr. Amy Leach, SSH <a href="mailto:amy.leach@uoit.ca">amy.leach@uoit.ca</a>	Ethics and Compliance Officer <a href="mailto:compliance@uoit.ca">compliance@uoit.ca</a>
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University of Ontario, Institute of Technology  
2000 Simcoe Street North, Oshawa ON, L1H 7K4  
PHONE: (905) 721-8668, ext. 3693

## Appendix 3: Physician Consent Form

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RESEARCH ETHICS BOARD

### CONSENT FORM

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**Dear Doctor** \_\_\_\_\_

**Title of Research Project:**

Physicians' Perspectives on the Ontario Drug Benefit Program (ODB).

**Investigator(s):**

**Principal Investigator:**

Rima Karam

Faculty of Health Sciences

University of Ontario Institute of Technology

2000 Simcoe St. North

Oshawa, ON; L1H 7K4

(905) 243-9897

rima.karam@uoit.ca

**Faculty Supervisor:**

Brenda J. Gamble, Ph.D.

Faculty of Health Sciences

University of Ontario Institute of Technology

2000 Simcoe St. North

Oshawa, ON; L1H 7K4

(905) 721-8668, ext. 2934

brenda.gamble@uoit.ca

### **Purpose of the Research:**

The purpose of this study will aim to a) explore and analyze the strengths and weaknesses of the Ontario Drug Benefit (ODB) program. b) to document how the ODB influence physician prescribing behaviour for Ontarians aged 65 and older who qualify for coverage under the ODB program. As part of this study, we will be conducting one on one interviews with physicians.

### **Description of the Research:**

We plan to collect information from physicians through individual in-depth interviews conducted in person. You are being asked to participate in one individual interview conducted with the principal investigator. We will be asking you to share your views about the Ontario Drug Benefit Program (ODB). The interview will take approximately 30 to 60 minutes.

We will contact you either by e-mail or phone, to set up the day and time of the interview according to your preference. The interviews will be audio-taped and transcribed. If you do not wish to be audio-taped, the principal investigator will take notes throughout the interview instead. Only the principal investigator will be able to identify you. The interviewer and transcriber is the same person (Rima Karam).

Once the interview has been completed, the audio-tape will be kept in a locked, safe place in Dr. Gamble's office and your name will not be marked on either the tape or any paper material. You will not be identified in any reports or publications.



**Potential Harms:**

There are no known harms that we are aware of that are associated with participation in this study but there may be harms that we do not know about.

**Potential Discomforts or Inconvenience:**

Sometimes people involved in discussions like these feel stress and anxiety. If this happens to you, you may stop the interview at any time. In addition, there is no guarantee that the proposed research will result in any change specific to the policies or procedures in the healthcare sector in Ontario.

**Potential Benefits:**

Participants will have the ability to make their views known about the Ontario Drug Benefit Program (ODB). This study will add to the knowledge of the ODB program and the need for change and improvement.

**Confidentiality/Anonymity:**

The data is initially not anonymous, however once the audiotapes are transcribed, they will be permanently deleted. All identifying information will be removed from the data collected prior to analysis of the data and release of its findings. Once the audiotapes have been transcribed, they will be permanently deleted and no identifying information will be included in the transcripts. The principal investigator; Rima Karam, will have primary access to the data and any identifying factors. Dr. Gamble will have access to the data but will not have access to any identifying factors, and neither will the rest of the research team. Your privacy shall be

respected. No information about your identity will be shared or published without your permission, unless required by law.

### **Participation:**

This project has been approved by the Research Ethics Board at UOIT (REB file# 12-023). Your participation in the interview is purely voluntary and as such, you may choose to refuse to answer any question you wish and you may leave at any time. You are not waiving your legal rights by participating in this study. However, once information is written down/audiotaped, it can no longer be withdrawn/erased due to the anonymity of the interview.

### **Conflict of Interest:**

The Principal Investigator; Rima Karam, may have some conflict of interest as she may end up interviewing physicians she has worked with before.

### **Consent to Participate:**

By signing this form, I agree that:

1. “I have read the consent form and understand the study being described”;
2. “I have had an opportunity to ask questions and my questions have been answered. I am free to ask questions about the study in the future.”;
3. “I freely consent to participate in the research study, understanding that I may discontinue participation at any time without penalty. A copy of this Consent Form has been given to me for my records.”

I understand that I have the right not to take part in the study and the right to stop at any time.

- 4) I am free now, and in the future, to ask questions about the study.
- 5) I understand that no information about who I am will be given to anyone or be published without first asking my permission.

- 6) I also agree to be audiotaped during this study. These tapes from this interview session will be used to assist with transcription of important information that will be discussed in the written thesis. If I do not agree to be audiotaped, the principal investigator will take notes throughout the interview instead.
- 7) I am free now, and in the future, to ask questions about the taping.
- 8) I have been told that my transcripts will be kept private. You will give no one any information about me, unless the law requires you to.
- 9) I understand that no information about me (including these tapes) will be given to anyone or be published without first asking my permission.
- 10) I have read and understood this consent form. I agree, or consent, to take part in this study and to having my voice being audiotaped as part of the study.

---

(Name of Participant)

---

(Date)

---

(Signature of Participant)/

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(Signature of Researcher)

## Appendix 4: Physician Invitation Letter



July 30, 2012

Rima karam  
2000 Simcoe St. N  
Oshawa, ON L1H 7K4

Hello Dr. \_\_\_\_\_

### **Physicians' Perspectives on the Ontario Drug Benefit Program (ODB).**

You are being invited for an interview to provide a deeper understanding of the limitations of the Ontario Drug Benefit Program (ODB). This interview will be approximately 30 to 60 minutes in length and tape recorded. You will be asked about your views on the Ontario Drug Benefit Program (ODB).

The purpose of this study will aim to a) explore and analyze the strengths and weaknesses of the Ontario Drug Benefit (ODB) program. b) to document how the ODB impacts physician prescribing behaviour for Ontarians aged 65 and older who qualify for coverage under the ODB program. As part of this study, we will be conducting one on one interviews with physicians.

Participants will have the ability to make their views known about the Ontario Drug Benefit Program (ODB). This study will add to the knowledge of the ODB program and the need for change and improvement. The expected duration for this research project is approximately August 2012 to December 2013.

The interview will be audiotaped. These tapes will be transcribed for analysis and deleted at the end of transcription. All data obtained during all parts of this study will be kept confidential and anonymous. You are welcome to withdraw from the study at any point of the project.

If you are interested in participating in this study, please e-mail me or contact me by phone.

With Thanks,

Rima Karam

e-mail: [rima.karam@uoit.ca](mailto:rima.karam@uoit.ca)

Phone: 905-243-9897

If you have any pertinent questions about your rights as a research participant, please contact the Compliance Officer at 905-721-8668 ext. 3693, or [compliance.uoit.ca](mailto:compliance.uoit.ca)

## Appendix 5: Beginning of Interview Script

### **Physicians' Perspectives on the Ontario Drug Benefit Program (ODB).**

#### **Key Informant Interviews Script – What will be said at the beginning of the interview**

Hello Dr. \_\_\_\_\_,

Thank you for taking part in our research project studying the **“Physicians' Perspectives on the Ontario Drug Benefit Program (ODB).”**

As part of this research study, you were invited for a key informant interview. The purpose of this interview is to obtain your views on the Ontario Drug Benefit Program (ODB) as a prescribing physician.

The interview will take approximately 30 to 60 minutes in length. You will be asked about your views on the ODB program, Limited Use Codes (LU) and Section 8 requests, and how they may influence your prescription ordering behaviour.

During this interview, I kindly ask that you refrain from using the names of, or any identifying information of your colleagues, patients, other individuals or institutions.

The interviews will be audiotaped using a digital recorder and will be transcribed for data analysis. The interviews will be coded and all identifying information will be removed. The code sheet will be kept in a separate file from the data and locked in a secure filing cabinet. The data and consent forms will be kept in a locked file drawer in Dr. Gamble's office (supervisor). All data will be kept confidential and anonymous.

If, during this interview, you feel uncomfortable with a question, you have the option of avoiding it and may do so by indicating your choice to the interviewer. If you would like to discontinue your participation in the interview, you may do so at any time. Your consent form and any data collected prior to your withdrawal will be destroyed at the time of the withdrawal.

Once again, I thank you very much for your participation. Your contribution will help inform about the Ontario Drug Benefit Program in the healthcare sector in Ontario.

## **Appendix 6: End of Interview Script**

### **Physicians' Perspectives on the Ontario Drug Benefit Program (ODB).**

#### **Key Informant Interviews Script – What will be said at the end of the interview**

Dear Physician \_\_\_\_\_,

Thank you for participating in this study. Your time and patience are greatly appreciated and your contribution to this research is invaluable.

I will follow up with you on the results of the study once it is completed via a letter. The principal investigator will be the only one who will have access to the follow-up letter to ensure confidentiality.

Thank you,

## Appendix 7: Audit Trail of Interview Themes

**Table 2: Audit Trail of Interview Themes**

	<b>Direct Quotes</b>
<b>General opinions of the ODB:</b>	<ul style="list-style-type: none"> <li>- I don't think it's the best program out there</li> <li>- Very limiting for prescribing medication</li> <li>- It is a good program – it cost government a lot. ODB is a good program but the section 8 and de-listing of drugs and writing prescriptions differently to get coverage is what bothers me the most. If it is covered, it should be covered either way no matter how I write the prescription.</li> <li>- So for myself, being an international medical graduate, it is completely foreign. What I know about the program is what I've learned in practice and in the office and it does appear at times cumbersome. And the complete extent and the workings of it, I may be lacking in complete understanding of it, but what I know if what I have experiences at the office.</li> <li>- Well for myself, just having a program like that was foreign because coming from a third world country, we don't have social support, it is a great idea and I think it is an excellent idea, it is a very socially responsible program so I appreciate having such a thing for the vulnerable population. Where I see a big benefit sometimes is in the older population, just before they turn 65, prior to 65, they can't afford second prevention for diabetes or post MI. they don't have the money to pay for that because normally they will be on 4 or 5 drugs like they will be on an aspirin, a statin and an ace and beta blocker and a diabetic medication and as soon as they turn 65, the compliance improves because now they have access to those medications so that's where I see a benefit for my patients.</li> <li>- I've experienced better compliance after 65 compared to prior to 65.</li> <li>- It's an excellent program. It's an essential program. The biggest cost to healthcare I think in Ontario is not the cost for paying for doctors, it is therapies and hospital care and their therapies; drugs and so forth and for those people who do not have insurance plans, without an ODB, they wouldn't get anything. And that is a big problem. Because you can go to the best doctor around, still not have to see a bill from that individual but if he writes you a prescription for a medication for \$1000 a month and you can't pay for it, you walk out of the office and</li> </ul>



throw it away. So it is an essential program. And I think that's one of things that is very very important to all of us but I think it encompasses probably two things; 1. Is for looking after those individuals who can't pay for therapy which is very very important, the rest of the society like anybody else who has got health insurance, or extended healthcare benefits they always pick up the cost of drugs, pick up the cost of physio and so forth. But for those individuals that can't afford those types of programs, being able to get medicines of any sort, even if they are pre-registered under the ODB plan, it is an essential thing. Otherwise all the therapies that we can suggest mostly go out the window. Particularly as a general practitioner because most of my job is talk therapy and prescriptions. Now, you can still get your appendix taken out even if you don't have the money for the antibiotics, but if you needed the antibiotics on discharge from the hospital and you can't pay for them then you are going to be out of luck, or painkillers – very simple kinds of therapies. So the program is essential and I think for the most part, is managed very, very well.

- I really have not had very much of a problem with it ever when somebody comes in with drug cards. Now the business you run into is when you need to prescribe someone something that isn't on the ODB list and then you have to decide yourself just how much of a fight you are going to put up with it because there are certainly products that are as equal as whatever you have chosen and certainly in lots of cases a whole lot cheaper. And that's why the ODB – that's their administration, they look after this drug, this drug, this drug and pick the one that's going to be the cheapest if they are all going to be totally equivalent. I think im all in favour, I think it is an essential program and for the most part it is very well managed I don't have much of a problem with it.
- I haven't given a whole lot of thought to that and the reason is that the program works very, very, very well. The whole point to me would be that the people who need those therapies can get them and at the end of the day that's all to me that really matters, I'm not a big policy guy. I'll work within your framework and I'll cheat if I have to but I'm not the guy that wants to set and make policies so for now I'll live with that. But it does work well enough for me that I don't have a big problem with it. Now, it would be very interesting just to see what the patients' aspect on this program is, you know, they might have a completely different point of view when all of a sudden you know they go to the pharmacy and the pharmacy says well you are three days early, you have to come back three days from now. But that would make the pharmacists a bit of a hard ass and I don't know many of them that are most of them are pretty decent people too. And if they see somebody who is going to be short a few days, they will say ok we will sort it out but make sure you go back and tell your doctor he has to write the next prescription for a few days earlier to cover you when

you come in early next month. And again it all comes down to the compassion people in healthcare field have to have for the people that are requiring the healthcare. They might have a different opinion though, you know, but I think anybody who needs an ODB card for example, particularly a young person who is supposed to be out in the working world like all the rest of them, anybody can fall on hard times. And it's really, really nice to know that that thing is off your mental plate if you had a kid that was sick or something, you are not going to have to worry about coming up with the 80 bucks for the antibiotics or whatever is costs. For the elderly, because they are the other group that are ODB covered – right everybody over 65, they are for the most part, very, very compliant with the advice the physician is going to give and if the physician says I think we should try this first, very seldom you get a rejection on that one, I don't anyway. They will say ok fine, we will go with this and see what happens but they are willing to be very flexible and they will say ok if the government doesn't pay for this, that's fine, but if they have been on something, and it has worked for them, they are resistant to change. And that's why when they click over from 64 to 65, there is no grandfather clause in there that says ok you have been on this nice drug because your insurance company has picked up the tab until you were 65, now the government picks up the tab and they don't pay for whatever you want. There might be some proviso in there, that they can still get at least the cost of what the generic drug would have been paid for, and they will pick up the tab for the balance of that drug. But I'm not sure if they can do that. I think it's an all or nothing thing. That might also be something to investigate as whether or not – because the government will say we are going to pay for this drug, but this drug here, if you want it, you pick up the entire tab for, that's not really fair. A person might be willing to come up with the difference. But if they are supposed to be their particular drug paid for to some degree, they would appreciate that being the case, even if they want the drug that costs more. You know, the government will pick up the first 60 bucks, I'll pay the next \$40. But I don't want to have to pay the \$100.00, and a lot of times people will also – again, depending on financial situations, might bite the bullet and go with the generic one, but then they will complain about that.

- I guess it makes available to a large majority of our citizens who don't have the means to afford medications, it makes medications easily available to them for the management of their health issues and chronic diseases so that's probably the biggest single benefit as I'm sure you and I will benefit one day!
- again, overall, I still am a big supporter, we arbitrarily make 65 the cut off, I know people are on social assistance, so there is an arbitrariness to it because we don't suddenly need it at 65, I know they tried to align it with our retirement age, which is now changing, so not withstanding

– there are some arbitrary features, but overall I am still happy. So long they maintain a policy of doing a good job of evaluating the evidence behind the use of medication and they apply those criteria, we should be fine. The biggest challenge is the affordability of the strategy in the long term. You know as we have a population that is aging, a larger percentage of elderly, our use of this system will keep growing and what does that mean for the system as a whole? So I guess we will find out in time. For the moment, as it is, it certainly goes a long way to help me and my ability to manage my patients' illnesses.

- Good question. My experience would be mainly prescribing the medication covered by the program to patients, and I guess initially when I started, it was a bit difficult because most medications that I was used to were not covered by the program but as time has gone on, I kind of have an idea of the medications covered by ODB so I'm not having that problem with the pharmacy returning the prescription and saying this is not covered. On the positive aspect, they do a pretty good job to at least cover most medications, they may not be the best, they may not be the newest out there, but I assure the patients do have what they need. So it has been positive in a way and negative in a way, in the sense that I want more, but at least I have something.
- I find the Ontario Drug Benefit program is used by the majority of patients that I see because the majority of patients that I see are elderly...and usually the poorer the patient is, the more medical problems they have, and so again, I see a lot of patients who are poor who are on the Ontario Drug Benefit Program, but they are called trillium for those who are low wage order, and on social assistance who are on ODB. So in terms of the percentage of patients that are on ODB, it is a high percentage.
- In ODB's mind, medications are not on their formulary because they have shown to have little benefit or little efficacy in treating particular illnesses, and some of these illnesses are nonsense illnesses, not to say they are not legitimate illnesses, but IBS is a diagnosis of exclusion, meaning there is nothing else you can find for a cause for abdominal pain, diarrhea, constipation, is considered IBS, those are a cluster of symptoms that give you that diagnosis. But again, the good news of the diagnosis of IBS, is that it is not going to affect the long-term, length of life, or risk of death or anything like that, but it is more how uncomfortable patient is and QOL that they have as a result of that illness, so those kinds of things, ODB doesn't have good treatment for, or has delisted some treatments and it affects people's qualities of life, and that's more concerning in a lot of these people who need these medications are elderly, are poor, they don't have money to get certain treatments outside ODB benefits and they don't have the resource to work or get money in order to buy the treatments that are helpful for them given the QOL because the QOL is so bad, so it is kind of a

	<p>vicious cycle like that.</p> <ul style="list-style-type: none"> <li>- Diabetes medication is not covered. I'm not even sure the lancets – maybe the strips or the lancets are covered, but I'm not sure. So that would be something that could be included given the epidemic of diabetes. I imagine it is due to cost.</li> <li>- It is a big list of medications, I think I do like the Trillium Drug program, because it does allow people who aren't older than 65 but have a high cost of medications relative to their income, gain access to medications, I haven't looked at the application process for the program but I think it is based on your net income up to 4% of your net income, it may be a little complicated for patients to apply to it, but it allows wider access of the program, not just for people in ODSP or over 65.</li> </ul>
<p><b>Advantages of the ODB program for physicians and patients</b></p>	<ul style="list-style-type: none"> <li>- I'm happy it covers Pradox in some cases, it is new and it has helped me better deliver healthcare to them</li> <li>- The positive thing is they cover medications in the same groups (i.e. GI meds, cardiovascular meds etc...) giving me a chance to choose best one for patients. Gives us opportunity to choose in case patient reacts to one of the medications that they are prescribed.</li> <li>- I am happy ODB is covering medications for patients who have no other access to medications</li> <li>- Ok, well first of all I guess I'm glad that it's there because it is an important safety net for so many people who live in Ontario. So our senior population who do not have employment income coming in as well as people on social assistance, so people who are the working poor who do not have access to a drug plan, or to people who are unable to work because of disability so I think overall it is a good thing and I'm glad it is there.</li> <li>- I think it's good, I think its ok. I mean a lot of people might think they are restrictive, they are not very open to taking in more medications but I think whatever they are doing, they are doing well in a sense that there are quite a number of medications that I see there that I'm surprised that they are there, they are approved a lot. Not as much as the medical healthcare professionals would want, and I think the reason is this – the bias is – there is this new medication in town, and everybody feels is the wonder drug and the first question they ask is what about coverage? And I think it is because of the medical system we have in Canada, the universal healthcare, where everything in quote is free so you expect coverage. The way they take time and put medications on the ODB makes sense to me. Let's say we have six medications that you can use for blood pressure. I don't think all six should be put on the ODB. Maybe two, maybe three, they are doing the same thing, So I like the way they streamline medications. There might be medications I don't know about maybe cancer medications they need to put on it, but for my practice, what they have is good and I like the way they do it.</li> </ul>

	<ul style="list-style-type: none"> <li>- That it exists! They have a good number of medications really, I don't know how often they update it, I'm not sure and it is difficult, I would say it's me, because I guess I should find a way to actually know the medications that are there, but there are so many of them, how am I supposed to put them in my head?! But the fact that the program exists and I can always find something for my patients is what I like about it. There is no medical problem that I have not found a medication for, it may not be the best, it may not be the newest or it may not be the one that has the most data out there but there is something for everybody on the program. That is what I like most about it.</li> <li>- In general, I'd been very happy with it, a large percentage of our patients who are on routine medications are often ODB candidate and by and large, most of the key medications that we prescribe are listed on the ODB so I have been happy with it.</li> <li>- I think for the most part, the ODB is fair, in terms of – it is evidenced based, they have tried to get the best evidence for which treatments work best for which diagnosis, there are some things that are clear – black and white, but there are a lot of things that are not clear and I think ODB has been very conservative in that and I think that is a good thing – being conservative in covering or not giving benefits to questionable treatments, so I do see ODB as being a very good program, given the fact that majority of patients that need it have no other way of getting the type of medications that they need. I think if we didn't have ODB, didn't have drug coverage for these patients, it will be like the states, you have to choose between eating one day and your medication which is horrible so absolutely, there are good things about the ODB program.</li> <li>- It's been a positive one, except for trying new medications, recently approved medications or medications that are experimental; I don't find it restricts me in prescribing the best medication for the patients who fall under the program.</li> </ul>
<p><b>Disadvantages of the ODB program for physicians and patients</b></p>	<ul style="list-style-type: none"> <li>- I wish it would be covered for all patients not just for those who qualify for the LU code because I feel the cost of INR monitoring is high so if it is covered for all – patients don't need to monitor blood work every week and it saves doctors' time, nurses' time, lab time, and money etc....</li> <li>- That's where you have to help me because I don't understand the design completely. My biggest – the thing that I really suggest and that's the problem with the whole of Canada that's what I have experienced because I lived in Manitoba and then moved to Ontario, it's like we live in 8 different countries in one country. That's the biggest problem. I think if they can have their buying power consolidated and have a single formulary for the whole country, that can be cost containment. The way they do it now is very expensive. By fragmenting the programs, it is very expensive. They could have the basis of one buyer for the whole country and argue much, much</li> </ul>

	<p>lower prices. And then be able to afford better benefits to the patients. My biggest advice to them would be consolidating all the programs. I'm a novice at this but I expect every province has its own program running a different criteria, so medical care in Canada is not really universal as they would like it but you can imagine if you had one buyer for the whole 30 million people rather than 7 million here and one million there, you can argue much better pricing, you would have better medication on the formulary you wouldn't be able to afford otherwise.</p> <ul style="list-style-type: none"> <li>- It needs to be evidence based. Review the formulary more frequently than it is being reviewed from my experience, I mean I have only been here 6 years but I haven't seen big changes in the formulary over the last six years, and medication that is already gone generic that shouldn't be too costly, I can't see on the program. I would feel more time to review, more evidence based, more discretion to the people that approve it they don't need to follow strict guidelines, I'm sure when they get the request, they follow a set of boxes, and I don't feel that is the best way to do it, it should be a knowledgeable person doing that because medicine is not "cookie cut" everyone has its own way of metabolizing medicine, everyone has a unique history etc... to tick the boxes is not the way to do it.</li> <li>- More timely review of the formulary, more discretion with use of the formulary, more evidence based application of the medications on the formulary I mean there are medications on there that I wouldn't prescribe to anyone anymore just because there is not a lot of evidence of its safety, its efficacy compared to newer medications. I would use imovane again as an example – I wouldn't want to prescribe tomazepan to anyone if I don't have to, but with an older patient, when I have to prescribe benzo, in my experience, the imovane Is a cleaner drug, gives you better REM sleep and less addictive and you can use it ad hoc compared to the benzos.</li> </ul>
<p><b>The need for increased accessibility for senior population</b></p>	<ul style="list-style-type: none"> <li>- (when asked since those prior to 65 can't afford their medication, and thus will that yield their health to be worse?) Absolutely. I mean we have lots and lots of evidence out there that if you treat diabetes early on, you can prevent all the major vascular complications from strokes and heart attacks, the micro-vascular complications like kidney, eye, peripheral neuropathy, you can prevent all of that. It is good that you touched on that because if you don't treat that early on, you are going to deal with that at 65, you will start you secondary prevention later on, but you will have to deal with amputations, eye problems, laser, so is it cost effective not to be able to access that completely for my patients? Maybe not because the cost in the end, its over loaded now because now they get their injectable biologicals, their laser treatments, and those are very expensive that could have been prevented with cheap drugs initially. So it is costing more in the</li> </ul>

end. It is great for 65 and over but what happens to patients before?

- I like the fact that it is available to people who are most disadvantaged.
- Eliminate the red tape when it comes to other or newer medications which also have strong supportive evidence don't go down the paths of LU codes or section 8. I'm sure for very expensive medications; I can understand their reluctance to make those drugs easily accessible. I'm not sure what strategy they should employ to ensure that the drugs are used appropriately and as indicated, that is probably their big concerns, is that you know, people use drugs beyond their indication and when drugs are prescribed that way, it costs the system and we are not practicing evidence based medicine. So I'm not really sure how they would police that but certainly you know, if the evidence is there, I guess it would be helpful if they looked at other strategies beyond making it difficult to get the medication, so does it have to be red taped, or can there be an appropriate process that defines them and us that the patient is getting the medication for a medically acceptable reason and do it in a way that isn't so challenging. That is probably harder than it sounds but that would certainly I think make it better for consumers and physicians.
- I would think in isolated circumstances that might be true. But I would think that by and large, there are often enough options on the formulary to not create that kind of scenario on a regular basis but there can be incidence where there is that potential and then that becomes a question of what the physician in general will end up doing? Will they adjust their own strategy to try and get a drug covered or will they simply just tell the patient it is up to them.
- You know, it always sounds nice in theory to make it more universal, in practice, I'm not really sure how feasible that is and how affordable that is.
- I: when you say universal, do you mean throughout Canada, or ...?
- P: no I meant not restricting it to 65 and plus crowd. Right now people's options are pay out of pocket, have a private insurer, or have ODB coverage, so if you are employed and you have a private insurer then yes your coverage is pretty good anyways, and I guess there are other options for folks who have very expensive medications, there is the trillium program, but I can't say I understand how effective it is compared to ODB in terms of coverage, it is not as generous and it certainly creates much higher expectation on the patient maybe some hybrid would be appropriate in the long run because we also have a population of 65 and 70 year olds who probably could afford to pay more than they do for their meds and as we are trying to create a cost containment strategy while maintaining the population health, I could see a scenario arising where there is a means test and what kind of subsidy you get for the medication depends on what your ability is to pay and afford and that might be more broadly applied as opposed to be age restricted.

## Generic vs. Branded Drug Products

### - The need for more testing of generic drugs

- There is some data that is out there that shows that generic drugs are not as effective as the name brand drugs and some of the policy changes that need to happen is a more rigorous testing of generic drugs so that the bio equivalency, that the same effects occur with generic as the name brand drugs. So right now, I think they need 12 people in a study, in drawing blood levels, - so long that the blood levels achieve 80% of what the name brand drug is, the generic drug is considered bioequivalent – it's not!! There is a huge variability in the generic drugs as a result of that, and having more stringent testing of generic drugs is important, second thing would be, I think I'm ok with having different processes for specific drugs that are on the drug benefit list, so long they give us some transparency about the rationale, because now it feels like it is very arbitrary for some of us, and education wise, it is important for ODB to be educators of prescribing habits, because they are the ones that have the formulary of what they cover and what they don't cover, and to a certain degree they have very powerful influence in terms of what we use for particular indications, so having an education component, not just here is a blank list and give no reason behind this list as to why you should be using them, they have a real opportunity to make this an educational vehicle as well to help clinicians and providers not only make good clinical decisions, but the reasons behind those decisions. So for example, a new drug comes out, people will be asking is this on ODB, and it is under review, etc, so once a decision is made, even a quarterly newsletter that says we considered these medications and these medications are listed under EAP, LU, or not covered at all, that's fine, that would give us an understanding about their decision making and give us clarity about our own clinical decision making when we are using these drugs, I think that would be helpful, they would have a very good audience since everybody uses ODB (all physicians).
- I certainly appreciate the government's need for cost containment. The challenge is occasionally that the rules regarding generics, they can be plus or minus 15% in terms of their potency so you can get medications that are more potent or less potent than the brand name and it can occasionally lead to problems for some patients. I would say the majority it's certainly not a major problem but I have had more than a few patients who had difficulty either with tolerance or with lack of full efficacy probably related to that reality.
- I: so in that case you would ask the patient to pay for the branded drug?
- P: No, what I do is I would – they may try a different generic brand, or I write no generic substitution and to be honest with you when I write that, I'm not sure what the pharmacy does with that. What I'm finding more



recently is the name brand products are now starting to offer up themselves through different avenues, once their patents expire and they are genericized, some of them are still finding ways to allow ODB patients to get brand name products. They either drop the price or they make them available in another way. So I see that market growing as well. But ya, by and large if someone has a problem with tolerance, they will either try a different generic or will try and see if they can get no generic substitution approved based on their specific complaint or reaction.

- (what is your take on generic drugs in terms of their effectiveness?) well scientifically, scientific studies have shown while they may vary in the term of their active component of ingredient, that has to be tested to be the same. I do have some patients – who do notice some differences for certain medications, but it is unusual for patients to say they want the original brand because it is not as effective or giving them side effects. Although with the change in oxy-contin to oxy-neo, I have had patients who have complained, but that's understandable, that is a different issue (laughing).
- The other problem is the generacized brand you have to use – for example there is a medication, three or four years ago, was generacized and is no longer branded, it is a high blood pressure medication, it is supposed to be an extended release medication to last the full day, and the generacized one is supposed to perform the same way, but they found that the generacized one actually did not protect the patient the same way as the brand name medication, but once the generacized name is on the market, the brand name medication was no longer part of the ODB, so you have a number of patients coming back with the generacized brand but the blood pressure no longer controlled. In that case, the drug company supplied the doctors with a card to tell the pharmacy to substitute the generic with the branded, but if I ran out of cards, then what do I do? Certain stomach medication, the ones for the acid, they don't work the same so the brand name works way better compared to the generacized, I would have patients who were on the brand name medication, when it came generacized, went to the generic, and they would come back and say this doesn't work, it used to work all the time, it doesn't work anymore. Same with certain birth control medication, they substitute it with this generic brand, and the generic brand gives the side effects of more breakthrough bleeding, so instead of keeping your cycle regular, the generacized brand, would cause, mid-way through, you would bleed, so we have to switch to a different brand that is not generacized or a different brand that works for the patient.
- (when asked about opinions on generacized drugs): there are certain specific instances where you have a generic drug that wouldn't be preferable. If you are giving antibiotics to kids, the generic always taste lousy and you will have a tough time getting into a picky kid. But that is a small point. But in terms of all the other medications, the generic and brand name thing are identical. And when people come in and say I can't take this, I want the real version and not the generic, I always debate them

about it, because at that level, chemistry is chemistry, there is not whole lot of difference. Now if they swear up and down I'll take them off it, I'll buy into it because I'm not in your body, but I have my skepticism, I certainly think generic drugs – and as I said, the generic list on the ODB, you can practice a ton of medicine and do very well with it. What is covered will do a lot of work for ya.

- I have had a handful of individuals that would say the genericized version didn't work for them and they can tell that in a backwards way. I would prescribe them the branded drug first when they are 64 and when they turn 65 and they go on ODB coverage and get genericized version and they say I can't take generic one I need the branded one. And I don't know if it is simply human beings giving brand loyalty, and deciding that they want that or whether or not they think the more expensive drug is the better drug, I'm not sure, but that would certainly be worth investigating as well. But again I tell them, I'm not going to argue with you if you think it is worse, but I think if you stay with it for a while you might find that it doesn't make any difference at all. Sometimes I win that argument and sometimes I don't. sometimes they come back three weeks later and say it is still a piece of crap and sometimes they say it works. So it is one of those things that you can't predict ahead of time. I mean if you give a person a generic drug and they have a full anaphylactic reaction I'm going to wonder how could they have been on it in the first place, right? Because they should have gotten sick while on it when it was a brand name, so that makes me skeptical that it wouldn't have been the drug whatsoever and it was probably something else that got them in the soup so then you have to practice medicine and do a bit of thinking as to how they got the way they were.
- I didn't do the research so I can't argue, but certainly from my experience with patients coming back, you see the difference. And the one with the blood pressure, there are numbers that show you it doesn't work the same! And you can't argue with that either. I mean they can say that, but I don't know, I would say not all medications are created equal. There are certain ones that I don't have problems with but there are a few of them that have those kinds of issues. I don't think you can 100% say across the board that there are no problems, I think that would be wrong. They are not problems; they just don't work the same. The one with the high blood pressure one, it is supposed to last 24 hours, but they noticed it would work for the first 6 hours and it would lose its effectiveness by the evening so you would get fluctuations with the blood pressure as the day goes on, that doesn't work! For blood pressure medication to work, you don't want to have that amount of fluctuations on a daily basis, that is when you want to protect your heart and arteries and all that stuff, so I wouldn't say it is the same. I was talking to my colleague about this; and they were saying about warfarin; Dupont did a study that compares the generic brand and the name brand, and the conclusion is that – with warfarin, as you know, as a blood thinner, with whoever is taking it, it will vary in terms of your

<p>- <b>The Generic vs. Branded Drug Product Debate</b></p>	<p>INR levels, which is how thin your blood is, and if you switch from one brand to the next, it will change you INR and it can sometimes increase your risk for stroke and bleeding. So, what happens when this patient goes to the pharmacist and one day they get this brand, and the next month they got the next brand, is the patient notified? And the answer is; We don't know! So the onus is on the patient to say ok, look at the bottle and see if it is the same brand on a regular basis. If it is the same brand, then you are ok, but If it is not, then you might have a fluctuation in your INR that is not explainable. So my colleague tries to tell his patients if there is a different brand, then you will have to come in to do your INR test earlier, just so we can see if there is a fluctuation but then I'm thinking, you are using more money in terms of the healthcare system! And that potentially, with warfarin, can be a huge issue, and for the elderly, most of them have no idea – oh I'm taking that yellow or pink pill, they don't necessarily look at if it is generic, or a different brand. It is hard enough for them to just take that medication you know? So that makes things a little more complicated. I don't know whether the pharmacists alert people to those kind of issues or not.”</p> <ul style="list-style-type: none"> <li>- The pharmacy would probably come into play, like I would say, I don't know if there could be a policy in place to say to the pharmacists once a patient starts on this medication, they need to stick with it and don't change it, and if there is absolutely no way of doing it, then change it, but you need to notify the doctor, that might be a more safe way of doing it...but would be up to the policymaker or we mention to them that this is a problem, and can we have a policy that says you use the same brand but then there will be times that certain brands may not be available so you are forced to change brands because it is better for you to continue with some kind of medication than nothing at all.</li> <li>- There are certain drugs that are covered (In ODB) that are still brand name, until they become generic.</li> <li>- I have no problems with generic drugs because scientifically they should provide the same effects, I mean there are strict guidelines. Having said that, I can't be sure if every drug company, and every generic drug companies, I assume there is some government oversight, so I can't really compare different generic drug companies and generic brands, I just can't make that distinction. Certainly if I notice any change in effect of a generic compared to a brand name, then I will quite readily complete a form to get them access to the original form. Whether it is a patient request or I see it necessary.</li> <li>- I have touched on some of it already. I think if they were much stricter with the generic competitors with the tolerances in terms of the potency of medication so instead of plus or minus 15% make it plus or minus 5%. Make the generics much closer to what the brand names are in terms of potency, that would reduce the number of people who have complaints as they are making the transition.</li> <li>- I'm picky for generic versus brand because it is all about affordability. Do</li> </ul>
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I think the brand names do a better job? Yes. But they are very expensive, we have to deal with the cost. So the generic to me is not a big deal, it is to get the job done. I have had to switch people from brand to generic and I think they had a problem or their blood pressure increased a bit so I know there is a difference, it is not life threatening unless you are allergic to whatever they use in the generic, I have seen people like that. So to me, it is not a big deal.

- I: so even the increase in blood pressure is not a big deal?
- P: no, you can always increase the dose or add a little bit more medication – if there is anybody to fix that issue, it is the pharmaceutical companies – they should decrease their prices. To me it's usually not a big change, even if there is increase in blood pressure, it is not too much, it is not life threatening.
- I think the issue that has come up with the oxycontin issue, so oxycontin going to oxyneo, I think the government was aware that there were problems with oxycontin for years before it was discontinued abruptly this spring. First of all, we had no warning that oxycontin was going to be discontinued but the government said that they were stopping it because of its addictive potential and it was a dangerous drug, well if it was so dangerous, again, they could have stopped it sooner, but also they didn't put any increased addiction services and chronic pain services in place for those who needed to do the transition. Another issue is with the duragesic patch, I don't know if you are aware of that, so duragesic is the brand name for the fentanyl patch and the government stopped paying for that a few years ago but the patch they covered is apparently more easily abused by people who want to abuse it. So the government says they are concerned about drug abuse and addiction yet the only patch they cover is the one that is most easily abused. Whereas the brand name might be a bit more expensive, but again, the information I have been told, is that it is harder to abuse the duragesic brand patch, so again I think the government is giving mixed messages. They say they are concerned about addiction but they don't provide resources, you know. They are paying for essentially the cheapest brand but that might not necessarily be the best way to go.
- I: when you mentioned problems with oxycontin for several years, did you meant problems with addiction
- P: yes, so addiction, misuse, now being sold on the street, prescriptions being diverted – patients would get a large prescription and sell it on the street.
- I: so oxyneo is its equivalent?
- P: yes, so it is a different – the tablet can't be – if you try to crush it or melt it or snort it, it turns into a snot like gel, so it is apparently harder to abuse, although there are ways to do it apparently.
- I: I was told that it doesn't work as well either, I have heard that there are a lot of patients complaining in comparison to the branded version.
- P: yes that is right, it is not as effective.

- I: so have you seen that over other medications when comparing branded to generic?
- P: you get anecdotal, I have individual patients that say that when the company – well I had a patient yesterday who's pharmacy has switched from one generic brand of warfarin which is a blood thinner to another brand, and then her blood work was actually different, and she asked me if that could affect it, but then in the end I found out she was taking Naproxen which is an anti-inflammatory that will definitely affect that. But ya, I have seen differences between when one generic is substituted for another, or when the brand name goes off the list, and then they are switched to a generic, changes with say thyroid –
- I: Is the switch concerning to you?
- P: it can be upsetting to the patient, but there are always ways to work around it, so in the big picture maybe it doesn't make a big difference if you are having a different clinical effect.
- I: I know I have also heard that sometimes physicians do not know patients are given the generic from the branded at the pharmacy? What is your opinion?
- P: ya that is an issue, I guess in my point – I have to have some trust that the scientists that are looking at these drugs within the ODB program, that are providing – or the scientists that are providing advice to the program have the qualifications to say it – you know be confident that the generic brand is close enough to the brand name. And I guess you are also trusting that the generic drug manufacturer has quality controls in place and that every drug they produce is standardized and there is good quality control. So there is a lot of ways along the chain where the patient might end up getting a slightly different dose or slightly different effect than the branded. I also think that sometimes the brand name pharmaceutical companies make this a bigger issue than it is for marketing. I mean as physicians we are exposed to a lot of direct marketing by the brand name pharmaceutical companies so there are a lot of incentives to prescribe brand name, so again, I think at times the benefits of the brand name drugs are overstated compared to the generic.
- I find patients complaining about side effects of generic of generic drugs and they say it doesn't work as well as branded so I have to switch my patients sometimes from generic to branded
- Maybe ODB should add one branded medication per group of medications to the formulary for those patients who cannot handle generic drugs due to side effects.
- I see it as individual based in terms of effectiveness between generic and branded drugs.
- lots of patients complain and want branded drugs
- in general, not a lot of differences between generic and branded so I don't know if it is the patient's impression because they are told to switch to a cheaper drug, or they actually react to the slight difference in ingredients between branded and generic. It is obvious they are complaining though.

	<ul style="list-style-type: none"> <li>- I can understand their reasons for all the groups that they have umbrella'd under this program, there are certain aspects I don't understand, is the way they pay pharmacists- I think up until a few years ago, generic drugs were calculated at 50% of the branded products, so that's what they were paying pharmacists (the government) for those drugs and generic drug prices are still considerably higher here than in the U.S. and I think recently they changed that to 25%, so they pay pharmacists 25% for that generic brands, which is still considered too high, and it prevents competition, it prevents consumers from getting the cheapest prices. I think a better method is to pass the cost on to the consumer and let the government reimburse the consumer for the drug that they get and that should create that competition - no incentive for pharmacists to lower their prices if they are getting a flat fee for each generic product that is dispensed. It just allows generic drug companies to try and provide incentives for pharmacies to stock their products.</li> </ul>
<p><b>Cost</b></p> <p><b>Drug pricing</b></p>	<ul style="list-style-type: none"> <li>- I think a faster track for newer medications, if these drugs are proven to work and they are often proven to work before they come out, before they are available for use by us, maybe a quicker way of streamlining the process to get newer drugs on the program. As I said, maybe a different way of the government reimbursing – I mean paying for these drugs, rather than just flatly paying 25% to pharmacies. I don't know if that may reduce the cost of medications for all people who don't fall under the program, maybe be a little more inclusive – I haven't looked at the trillium program to know how it excludes say a middle class family who has a sizeable part of their income devoted to healthcare, whether they would probably benefit from being included in it. Other than that, I think get rid of the LU codes, get rid of the EAP, just have the drugs on the formulary, have them available without stipulations. Just trust doctors to make the right decisions.</li> <li>- The single most important thing about it is that people won't go without care and therapies. How could you take a mom who is on welfare and has a kid who has a strep infection and decide not to give her the medication for it because she is deciding whether to get formula or the antibiotic and she can't afford either. The whole thing about the country we live in, is we are pretty decent at looking after those individuals at the poverty line, we are not perfect but we certainly try and we try harder than the boys down south. The most important thing undoubtedly is people get the therapy they need and I don't think it is sub-standard. As I said, you can practice a lot of medicine on the ODB program and do very well. If that was the only book you had to pull drugs out of, you would be the popular physician in town believe me.</li> <li>- Well I think for the most part, it is a pretty well run program. The only</li> </ul>

<p><b>Cost containment within the healthcare system</b></p>	<p>thing would be is the lag between what we think is a drug that should be covered and what they are going to cover. And there can be situations where they grind their heels in the ground and say we are not going to put this on the list and that is important when you come up with good innovative new therapies that are expensive because the drug companies are trying to recruit the R and D on it so if you want to put people on fentanyl patches which is an excellent method of giving people chronic pain relief without popping pills all day long, that is an expensive delivery mechanism and that is going to be born by the program and at some point if you are the program director, you will say wait a minute we do the checks and balances on what this is going to cost us and some things we can afford and some things we can't and I respect that that is why I'm glad I'm not the person making those decisions. But I think when enough pressure comes to bear and enough people make a noise that they are filling in all kinds of EAP forms for a particular therapy, I think that they are going to wake up and smell the coffee and say ok we better re visit that drug and put it on the ODB formulary. I'd like to think that is how it happens, of course another thing is they may just say that there is no way we are paying for this. I don't know. So your question about the design of the system is such that: The people that I know that can't pay for drugs, get drugs because of the ODB – that part of the design is perfect.</p> <ul style="list-style-type: none"> <li>- I don't think so, I think that is it. You know, I would like to see them promote among the brand name drug companies a strategy that once the patent has run out, that they routinely drop their prices so it gives us the option of sticking to the brand name if we choose.</li> <li>- P: well I think I've seen more efforts, you know one example would be the proton pump inhibitors, you know the PPI drugs that are used for acid suppression, they require a LU code now, but I have seen information saying you know it is reasonable to start with something like zantac which is in a different class of stomach drugs, which is much less expensive because again we get pushed to prescribe the more expensive PPI's so a lot of those are prescribed when something less expensive would probably do the job for 80% of the people. So I think there has been communications like that, I think there is some minimal effort to encourage us to think about what are you prescribing, is there something less expensive, is there an alternative, same as antibiotics.</li> <li>- The problem is that, our whole healthcare system has a problem – we just don't have enough money to fund everything. And to continually have new medication that are expensive all the time, that can suck up a lot of money, so you do need kind of checks and balances to limit the amount that you use, so you can still benefit everyone. In utopia, you would have money that falls from the sky, and you can supply everything, but in real life, it just doesn't happen.</li> <li>- So I think Canadians in general are very spoiled to a point where you can't be short sighted to a point that cash is limited and you cannot expect the</li> </ul>
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	<p>government to pay for everything and to be able to have access – personally, I feel, to be able to have access to what we already have, is a huge benefit already, of course there are always going to be ways to improve it, but you also have to think of, in some ways, the big picture, can we afford it? Is this something we can afford? I feel that the government is already using some ways like using the LU codes, so that physicians don't abuse it in such a way that you don't always use the most expensive drug, in lots of cases you can choose the less expensive drug and still do the job well, but because of marketing from drug companies, we have been bombarded by that and influenced by that somehow right? So you might choose the more expensive rather than the ones that are potentially cheaper. I do feel that ya, there has to be some kind of limitation, otherwise, we can't afford it, it is a good way to have some checks and balances, and I think they are doing their best, but I sometimes wish there are ways to communicate that this is a more urgent approval, look at this first – especially for section 8 requests. The process of getting that to happen takes physicians to advocate for their patients more. Luckily there are people who advocate for their patients more and so it works well that way.</p>
<p><b>More Transparency</b></p>	<ul style="list-style-type: none"> <li>- I would like to see more transparency in how they make decisions, right now it is really a black box...</li> <li>- I would like to know the reasons why we have to complete these codes and these forms. If they are just a pure financial reason, then they should be upfront about it. I don't think we try to waste money, and we certainly don't want to prescribe more expensive drugs if the cheaper ones are just as effective but sometimes trials may not tell you exactly what patients need. Patients are more informed these days and are requesting newer products and they even have access to studies and are able to research studies, especially is these drugs have been approved south of the border, I don't want to not be able to prescribe these medications.</li> <li>- No, I'd like to know who makes the decisions when we complete these forms, who actually determines the patients' needs based on a piece of paper, and how objective that can be and how they are able to determine the patients' needs better than their own physicians either me or a specialist. I imagine they sometimes feel physicians cower to demands of their patients and without specific scientific reason, or objective reason to do it – and that sounds reasonable to me.</li> <li>- They take off drugs at various times on the list it's hard to keep up with what they cover and what they don't</li> <li>- No I think I covered everything. It's quite foreign to me, I mean I have only been here for six years, and being in a country that you have a program like this, it is a great societal justice to have something like this, not everyone has this. Even a country like the U.S. they don't have as good as a system. It is great to have the program, but is there room for improvement? Absolutely. It is going to a little bit of investment, special</li> </ul>



training, and timely review, update it frequently.

- Do you know if it has been updated since 2005?
- I: personally throughout my thesis writing experience, I have had an incredible amount of difficulty finding information.
- P: because it is not published, it doesn't look like it. I can still use – all the drugs I use today are the same ones I used in 2005, I haven't seen a lot added or changed.
- I: I have seen a lot of documents on the MOH website but specific literature reviews or studies, I could not find.
- P: there is a lack of that, do you agree with me? Lack of evidence base and lack of timely review.
- I: yes, it is either a lack of it, or it is done and nobody knows.
- P: exactly, if they do do it, we don't get any notice of it, you know, you are not aware of it. I mean why keep it quiet?
- I: do you feel LU codes and section 8 forms limit your prescribing abilities as a physician, earlier you said yes, but what about with the LU codes, you mentioned section 8 limits, but what about LU codes?
- P: well LU also limits, due to the criteria you need to use. I think you know, the step up approach – that's why I say evidenced base and the formulary doesn't keep – there is a bit of a disconnect between them. If you look at asthma, asthma treatment as a step up, it doesn't feel that it is as easy to prescribe the medication for asthma prevention in a patient that fails his initial treatment. I might be wrong but it feels to me – and even if you have a patient with COPD or an exacerbation, a prescription with a cortisone, it is very difficult to argue from the criteria we have at the moment. So definitely some conditions where you would use medications with a clear conscious and evidence base behind it, as the appropriate drug and my feeling again is the formulary is not timely reviewed, it doesn't keep a base with newer guidelines, newer guidelines for hypertension, newer guidelines for asthma, newer guidelines for diabetes, again, the more vulnerable population is deprived of the most recent drug treatments.
- So they should keep up with guidelines, because guidelines are reviewed, if you look at hypertension, it is reviewed, possibly every 5 years, some medications are changed, medications are taken out, well if they can do it on a timely basis every 5 years, they could keep up with all these other guidelines. And I mean I understand the cost containment is a major, major factor, but, it could become so cumbersome – this is the whole idea behind evidence based medicine, if you do treat, you treat your target, you want to achieve something with the medication, you want to do something with the medication and if you have to treat patients with a medication that is not as effective anymore and there is more efficacious medication available, you are going to end load that whole process because you are not going to achieve your target, you are going to have the complications down the road, so you may save money right now but 20 years down the line maybe not.
- So it is wise for them to invest time and effort in reviewing it and keeping

up with the guidelines, and still go for the generic cheaper drugs, and still have guidelines in place, you know, I have no problem with it, because as physicians we can be wasteful, you know, I can't speak for everyone, but we can be wasteful, so I don't mind the guidelines, its two sides to the coin, they have to keep to their part of the bargain as well – keep it timely and keep to the guidelines.

- Lack of evidence based, and lack of timely review. We do not get any notice of reviews, doctors are not aware of it.
- Be very transparent of the criteria for how medications get approved. So that the medical community - I mean they probably are and I don't spend enough time to research it but just ensure that we have medications available to us that are widely recognized by evidence to be effective.
- P: you know they do send updates all the time on what medications have been added to the formulary, what medications have been removed, it might be worthwhile to put a little sheet that serves as a basic reminder of what basic policy is with the ODB, in other words, how do they select medications to stay, how do they select medications to be removed, why the policy, why the necessity of a LU code and a section 8 strategy. Like I said when we get these regular handouts telling us what's changed it might be a useful piece of information upfront.
- Umm, no, just that if they can find a way to update me with the new medications and the ones they have taken out of the program, that would be beautiful. Because you write a prescription and you think I know this is covered by ODB and they tell you it is not, I'm thinking but I thought I wrote this two years ago for someone, so if they find a way to – if its sending something saying this is no more covered or this is covered, so you know. That would be perfect for me.
- No, just inform me.
- I want to believe they have members of the public, pharmacists, few physicians when they make their decisions because – and the reason I say members of the public is because as a physician, I want every medication to be on ODB but that is not realistic, if everybody is on the boat, then everybody can make a decision on which one should be and which one shouldn't be. But if every medication is there that would be beautiful so I don't need to think about it when I write the prescription. I think it is a very good program. I have practiced a bit in the UK and they kind of have something like this but not as good. I didn't think it was this good and the UK is the best out of Europe. I noticed that most of the medications, you had to go through a lot of hoops like the LU code is not monitored here, you pu LU code for everybody, but in the UK, most of them you have to go through different hoops before they approve it. And I think what's the big deal, if it is million dollar medication maybe, but here you just put the LU code and pharmacy gives the medication. So it is easy, I am not trying to say that they are loose, but they are easy and easy for physician as well as patient and pharmacists. I just don't like the section 8 – like the patient I told you about – maybe they have certain cases that they have to approve

within 24 hours, but it took quite a while and they came back and said no. I'm sure they have a budget, but I don't like section 8.

- The website I find it's not the easiest website to navigate, although I think there have been some improvements made. Actually I think the website is better than the paper binders that - they used to mail out paper binders like these huge things of paper that we had to then put in to different sections in a binder and it would come with every update because it was with the new LU codes and the new section 8's but they have stopped that which is a good thing, because it was a waste of paper and a lot of the doctors - that would just go into the blue box or the garbage. I think just enhancing accessibility of their website. Probably doing more active education or doing more education about evidence based medicine but - I mean one example of that - I don't know if you have seen the orange book at the clinic called The Guide to Antibiotic Prescribing - this is actually an evidence based prescribing for antibiotics, it is Ontario based, and they go through sort of the choice of antibiotics you should use, the cost per day as per the ODB, but that is the information doctors need so it is handy and because of that initiative, I have seen prescribing patterns changing I think if you just have ongoing education with physicians about appropriate prescribing practices we could probably save the ODB program some money. I guess the trillium program - a lot of patients - people don't seem to be aware of it and there seems to be a lot off paper work, there seems to be a lot of hoops to jump through to apply for it, people have to reveal their income tax returns and then they are paying upfront so it just seems to be a clunky cumbersome program that isn't well promoted and not much known. And even then, if people do qualify, I have had some patients that have to pay their first \$800 upfront, or their first \$1000 or \$1500 in medications upfront and that is often a barrier to them so I don't know if there is a better way that that could be spread out over the year.
- I guess another interesting thing - getting back to painkiller so chronic pain - the oxycontin issue is that people that actually qualify for the ODB program usually are the ones that don't have any access to physiotherapy or massage therapy or can't afford a gym membership or have so much going on in their life so there are other ways to manage their pain that aren't available to them because of financial reasons so as physicians we are almost forced to prescribe them narcotic medications so they can keep functioning so it would be great if there was access to physiotherapy or other pain management resources.
- The limited availability of physiotherapy directly ties in to the amount and type of drugs that we have to prescribe to people. And other things like you know cardiac rehab programs, we can go even farther that the people on welfare - you have probably heard of the welfare diet? You know high in carbohydrates, because they can't afford fresh fruits and vegetables and then you have issues with obesity, high blood pressure diabetes, that I think it would be better to deal with those issues and do the preventative care through nutrition and diet and teaching people how to shop, how to

	<p>cook...</p> <ul style="list-style-type: none"> <li>- I: so this ties into primary prevention and basically the healthcare system in Canada is trying to turn towards as opposed to the traditional secondary or tertiary prevention means</li> <li>- P: Right, right now we are paying huge amounts of drugs, but you have to ask can this money be spent elsewhere and I think the government has got that and I think they have started focusing on that. The focus on diabetes is certainly out there and the focus on – I don't know if you know last week the OMA put out a paper on childhood obesity.</li> <li>- I: so you are saying expanding the ODB to not only drugs?</li> <li>- P: Ya or, just saying look, we have this limited amount of money to spend, why are we spending it all on drugs? But at the same time I would hate if I had a patient with diabetes that came in and needed the medication and the ODB would say that we don't cover diabetes medication anymore because that is a lifestyle, that is the patient's fault, so they would have to pay for it, you also don't want that type of society. If people need drugs, they should have access to them.</li> <li>- As a physician, I will be happy to be more informed about policies of ODB either by sending me quarterly info on changes for example.</li> <li>- I would also be happy to get information on any new drug – that is a LU drug. For example, we are usually informed through pharmaceutical companies and not ODB themselves – I would rather hear from ODB. Need more communication between ODB and physicians</li> <li>- I'm happy making patients happy by knowing more information and being more educated</li> <li>- I think ODB and physicians should communicate more.</li> <li>- I would like to see ODB cover as much as they can and I want to see more drugs covered for my patients since they are my primary goal and making them healthy</li> <li>- Everything we do is for the patient we are here for them so by me collecting more correct information, I can better deliver care to patients.</li> <li>- In general I am very thankful for ODB covering meds especially when comparing to other countries.</li> </ul>
<p><b>Suggestions from physicians</b></p>	<ul style="list-style-type: none"> <li>- I know in some provinces, when you start a new prescription, or you give a new prescription to a patient, that they say that the provincial program will only pay for a 14 day supply initially in case the patient has an allergy or an adverse reaction or can't tolerate the medication and I actually think that is not a bad idea because right now, we can write like a full three month prescription and then the patient will come in a week later and say I can't take this medication and so then all of a sudden you have 90 pills that have been wasted. So that is one thing – having for any new initial prescription for chronic – I'm thinking about chronic diabetic pills, blood pressure pills, heart pills, anything like that, maybe a limited quantity for the first prescription would be a good idea.</li> <li>- I would like to see more drugs covered under ODB like the new ones on the market</li> </ul>

	<ul style="list-style-type: none"> <li>- I wish the ODB would consider covering for more medications and provide less limitations specifically for medications most often used or prescribed.</li> <li>- Ex: Ciprofloxacin 500mg is for the elderly but only under LU code and most of those patients have chronic UTI's and require Ciprofloxacin but if they do not qualify, then they have to pay for it.</li> <li>- 1. The MOHLTC should talk to primary care providers and see their concerns with prescribing meds</li> <li>- 2. Designing simpler forms to fill out to save physician time and at the same time still providing all the important information to receive approval for coverage</li> <li>- 3. Involve pharmacists' views in ODB development/improvement of ODB so they have a good idea from the front line staff using and following the ODB program</li> </ul>
<b>Primary prevention</b>	<ul style="list-style-type: none"> <li>- (when asked about primary prevention and how primary prevention is halted if the diabetic medication is not covered) It is a bit too late to try to prevent something that has turned into an epidemic. Possibly – although I don't think for patients it is the lack of equipment that prevented them from checking their blood sugars, I wish it was that simple, but it is a little more complicated looking after patients' health, it is more than providing them access to healthcare, or medications or even to equipment, screenings, or checking, it's trying to change their – not so much their attitudes it is their behaviour which falls outside the program.</li> <li>- The trouble with primary prevention is the benefits have to far outweigh the risks, that's the problem. Because people who are in primary prevention, don't have any symptoms and so don't feel anything bad. So when you are giving them an intervention, it must have a dramatic benefit compared to the risks and so if it has any side effects, they won't take them and that's the trouble and with those kinds of medications, it is not easy to get the data for, to say it has that kind of benefit and it becomes expensive to get that data and in turn the medication becomes expensive. They will look at things that cost as little as can be in order to get the most benefit and the drugs that do that are the secondary medications and tertiary medications are the medications that are the ones that sadly, ODB will cover, and the primary prevention ones won't be. By not treating certain primary prevention things, absolutely, you will have patients who progress on to having the disease – so for example, one of the things that we have been dealing with most recently is the shingles vaccine which is not covered by ODB at this point, it is not a perfect vaccine, it covers and reduces the risk of shingles by about 50% percent, it reduces that risk for the post shingles pain which is a terrible debilitating pain that patients can get by about 50%, so it is not perfect but it's the only thing we have that prevents. There are medications that you can give once the patient has shingles in order to treat the shingles and prevent the actual onset of this</li> </ul>

	<p>post shingles pain, and there has never been a study that tells you how much it reduces the risk of post shingles pain, but the government is not paying for prevention, but they are paying for the treatment of the shingles and the pain control that is required when you get the post shingles pain. So that is a very black and white thing we see now, that if the government does pay for the shingles vaccine, it needs, I think, about 1000 patients or 350 patients or something like that to prevent post shingles pain, so the numbers are high, but that case, if you are the one out of that number, you want to have that shingles vaccine, you know what I mean?</p> <ul style="list-style-type: none"> <li>- As policy makers they need to balance the value which is the benefit of that particular intervention with the cost – which is not just the side effects, but actually monetary cost and right now it is a black box, I don't know how they make that decision.</li> </ul>
<p><b>Requirements of ODB</b></p> <ul style="list-style-type: none"> <li>- <b>Section 8/Exceptional Access Program (EAP)</b></li> </ul>	<ul style="list-style-type: none"> <li>- There are certain medications where you need to get a specific permission under the EAP which takes up time, and sometimes makes you think twice about prescribing those medications to patients – which is not necessarily a good thing. I don't see the point for us requesting special access for medications we think are best for our patients.</li> <li>- “I would wish that the section 8 – there would be some form of reminder or a letter sent to the patient saying that it will run out, and if you require further medication, please contact your doctor because it should be the patients' onus to tell the doctor to renew it.</li> <li>- “In terms of my experience and interaction with the actual government agency, I don't have a face to the government agency, they are usually forms that I fill out, that get faxed and I get back, and responses from certain adjudicators based on the information I submitted, I remember for a while, the EAP or section 8 process took a long time often times it takes months before the return of a notice whether it is supported or rejected, so I guess with those things, it has given me less interest in pursuing those kinds of submissions and it has made it more and more painful to try and make a submissions, so, to be very honest, the things that I do, often times, try to circumnavigate having to go through those kinds of processes.”</li> <li>- The EAP form takes a few weeks before it comes back. I imagine you also – I mean, with the program, you have to have some framework for providing medications, with a set budget, and I imagine if brand names are so much more expensive than generic medications, 25% compared to 100%, then they have to make some kind of rule, and it is reasonable for them to expect us to provide further information, which is often embellished.</li> <li>- They need to remove section 8.</li> <li>- I don't think they should be de-listing drugs patients need unless they show studies that show they are not as effective as other meds etc... they</li> </ul>

<p>- <b>Limited use codes (LU codes)</b></p>	<p>should allow doctors to use discretion in prescribing meds. We are cautious when it comes to cost and if they don't think so, then they can education us about cost effectiveness.</p> <ul style="list-style-type: none"> <li>- Remove section 8</li> <li>- Not de-listing drugs unless deemed unsafe or not efficacious</li> <li>- Removing deductible each year</li> <li>- (when asked about Section 8 forms): I don't think after I have done it properly and dotted the I's and crossed the T's, I have ever had one refused. They are very, very good about that. If you do the paperwork, they are probably going to give it to you. And for that reason, I think that if you think there is an Exceptional Use – I think, philosophically they don't want to deny a person to have the chance to have the drug that is best for them and they are letting me and the patient decide what that best is. They are not getting involved in the therapeutic contract between me and the patient, but they are going to give me guidelines about what we should probably try first before we end up breaking the bank and again that's their mandate and I don't have a problem with it.</li> <li>- Many many, many things are covered by the ODB, you can certainly practice a lot of medicine just on a list of drugs on the ODB, you don't have to be an outlier, you can be a doctor that says I 'm not giving anything that is off the ODB and you would still have lots of patients. So its those exceptional cases- I don't think I do very many EAP forms do I do a year – I doubt 6. The LU codes I certainly do a few a month obviously.</li> <li>- I am ok with section 8 forms if I know ahead of time to fill it – it takes time for approval and that is not good for patient sometimes if they need meds immediately.</li> <li>- I usually like to tell patients to be on time with the request in order to not run out of medication because it takes time for approval.</li> <li>- I don't have experience with section 8 request being rejected – I am lucky so far.</li> </ul> <p>- YES! Definitely, it is quite a pain, because I don't remember all the codes – it is quite a pain to look through them every time you want to use it. I mean, by now, we know most of the criteria, but some of the way that you are asked to use it, may not necessarily be most beneficial to the patient so certain drug of choice that I would put on, with a certain condition, I couldn't do it because the LU code doesn't allow for that condition to be used, especially for antibiotics, well then you can't use it. You either have to ask patient to pay for it, which most patients will not, and they would basically ask you well prescribe something else then. With the section 8, again, it takes an approval process, the approval process takes time, and it's not in a matter of a day you get approved, it's usually weeks, so my experience is that one patient that required a certain type of pain medication that is in section 8 only, she was in quite a bit of discomfort and other choices were not able to help with it and only that particular</p>
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medication was one of the ones that have been tried and it worked but we couldn't prescribe it until we had section 8 approval and we waited 8 weeks and that is a long time, so she was in pain while waiting for it, so it is a little bit difficult in that regard. But the other thing, is that it relies on – the onus is on the physician and patient to remember to renew the section 8 forms. Which means, 8 weeks in advance, at least I try to do that, I give myself a reminder so that I would write a letter on behalf saying this needs to be renewed and you need to give an update on the patient's behalf, write an update on their health, why you continue to need it and what medication has been tried and you need to do that every year. Unless you remember, you won't know. Some of the pharmacies are good in saying it is running out but the majority of them they don't tell you so it is up to us to remember to renew it, otherwise there will be a gap. There are certainly, I remember, there weren't any rejections (from section 8 requests) they didn't really outright reject it, I think the reason this patient took so long, (the above patient), as far as I can remember correctly, I think was happened, was there was a letter sent back to me asking me for more information before they approve it, but so far, I don't think I ever had an experience where it was rejected, maybe once but I can't remember exactly.

- My wish list is that there is easier ways of not having to go through the book for the limited use codes, because every time we do that, we spend more time with the patient so with all the letters we have to write and different things like that..."
- Yes and no, yes in that my opinion is not as big as some who may have a majority of third party payers within their practice, or patients who have third party payers, so often times I will look at any class, or any particular indications that are required that have a list of classes of drugs to treat that indication and because ODB only covers certain things, I will limit myself to being very conversed and remember those particular drugs. A good example is a drug called Celebrex, which requires an LU code in order for you to use it, for good reasons, an requires three particular different anti inflammatories before actual use for it to be covered under LU code, so what happens is I make myself very familiar with three different types of anti inflammatories and pretty much, I don't think about any other anti inflammatories, and if I need something else, I'll go to Celebrex for example. In a sense, I have limited what is functional to me, I feel like I need to know certain things in order to jump through certain criteria with the ODB benefits and therefore I have limited myself to knowing those things. No in a sense that I am still open to using medications that are not part of the ODB, there is a number of different diseases that don't have good treatment in ODB and so medications for IBS, or fibromyalgia, chronic fatigue syndrome, even though there is now new medications being listed under ODB, so certain treatments for those types of disease that ODB doesn't have coverage already, I'm free to pick whatever I want to pick, but oftentimes, the indications that do have coverage under ODB,



<p>- <b>LU and Section 8/EAP experiences together</b></p>	<p>I would limit my functional knowledge to what is covered by ODB, and then supplement that, so oftentimes I would end up saying ok these are the things that I treat regularly, I get very familiar with them and those things that I don't are often ones that are not ODB covered.</p> <ul style="list-style-type: none"> <li>- I think what's frustrating is that the ODB has different levels of benefit, which requires different levels of process in order to get the benefit and that is frustrating, I'd like to see – if something is covered by ODB, then cover it, don't give me different hoops to jump through to get it covered based on whatever criteria that ODB uses. I think – they have, from their point of view, treatments get more and more expensive as new things come out so in order to contain cost, newer treatments have to go through a process of these different – whether it be EAP process or LU process, before they getting general listing and to some level, that makes sense, but others, it doesn't. and it is not a transparent process, I don't know what criteria they use to evaluate; ok so the cost of the drug is this, and we will put it on the LU code because of efficacy, cost etc... - I don't know what criteria they use to decide upon that, one of the things I'd like to see given that they do regular testing particularly on the new agents that come through, is having a monthly or quarterly review of things that they have investigated – so they do studies all the time about the efficacy of certain drugs that have come out, it would be great if we can get as clinicians, what ODB has done in terms of the research and how they came to the decision; it doesn't have to be so lengthy that we get bored of it, a synopsis of the decision making – a little bit more transparency about it. I guess the bad thing would be, they would get complaints because whatever they decide, people will complain, so if they are not transparent about it, they don't have to answer to us, but if they are then they have to be accountable for what they did.</li> <li>- The LU code which I don't honestly see the point of, I'm sure other physicians feel the same way, really doesn't inhibit me from prescribing medications because you are always able to find an indication which may not necessarily be the total honest way of doing it but if you feel the patient needs it you will circumvent that to get the medication</li> <li>- No, I think the only thing that would limit me is the list of medications on the formulary. Sometimes I may forget to write the LU code and the pharmacist usually just asks for one and doesn't query the code I put in, so that doesn't limit me.</li> <li>- It is a weakness, I'm not sure of their motif for putting it in, it might be a prompt or reminder to physicians that it is only approved for certain conditions, but I'm sure most physicians do not follow that rule strictly</li> <li>- It is good to help people who have given service to the country and are now retired.</li> <li>- I do. I feel that you know, I don't know how well it is evidence based and whether it is reviewed on a timely basis – that is my biggest concern.</li> <li>- There are examples where the benefit book has stayed the same for many</li> </ul>
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years, as far as I know, I could be wrong.

- And that you know, some patients, especially our vulnerable elderly population do not always benefit from newer evidence based medicines so I do feel it limits us.
- My experience is that if you used a section 8, I don't know how much it is used, we know that medicine is not a "cookie cutter" it is individual based, and despite formulating a great argument for use of a medicine for a specific patient, I have never had an experience where they have actually okayed it and said I could use it. My experience with section 8 is terrible. They have an approach that is very rigid and with little discernment and very little discretion, I think they have strict guidelines that they keep by them and I don't know if the detail you always provide them with is valued. That is my experience with section 8.
- Limited Use (LU), my experience with LU where I can name the negative is for instance the older population using medications for insomnia because sleep is an important function you need to sleep, it is as important as eating. At times you have to prescribe sleep medication, we know some meds are less addictive as others and we don't have the privilege of using them and they have been generic for several years now; that is one concern.
- Another example is a patient that had a recent angio – had stenting done, and because the Plavix didn't fulfill the specific code, they didn't prescribe it to the patient, and fortunately it did not block up his stent again, that would have been disastrous for him. So it does put patients at risk at times.
- (when asked about perspectives on genericized drugs) Imovane is now Zopiclone, and we all prescribe Zopiclone as a treatment for insomnia because we all understand from the evidence available that it is less addictive than the diazepam, but we don't have the privilege of using them because they are not on the formulary, they have to use Tomazepam and there is a greater risk of getting addicted to the sleep medication. While Imovane which is not generic – Zopiclone, should be quite cheap and it is still not on the formulary. So my concern is how do they review all their codes, and how often do they review the medications, do they keep up to date, is everything evidence based.
- Whether they are as effective as the original? I don't know if there are any big trials done that indicate the generic are not as effective as the original. I think in a country like Canada, I'm sure the standards are safe, and where it is produced, and they have to keep to a certain standard and the active ingredient is the same, I trust that. Individuals will sometimes come and tell you that some medications work better than the others, is that just an individual metabolic issue, or a placebo effect, you never know. In a case like that, I would just say no generic, only original to be given and they benefit.
- No. most of us have figured out ways to wiggle off the hook if we want to and I'm sure most of the other physicians have told you the same thing –

not that I'm going to tell you any names!

- If you really wanted a person to get a specific drug, if you dot the I's and cross the T's on the paperwork, they are going to get it. It is very seldom have I – but I will say this, because the suggestions have been made that ODB will pay for X,Y and Z, I do think about costs for particular individuals and I will say well we haven't tried this yet, so let's go with it first, I will do that. But many, many times, when you want a particular drug that you have to do a Section 8 for your patient has already tried 3 or 4 different things because of drug samples. And we can give somebody who doesn't have any money to pay for a particular prescription, you try them on the sample, you say give this stuff a shot and come back and let me know how it works in a month or so. They come back and say well it doesn't work, so you try something else – well it doesn't work. Then you go to ODB, and going without the common things that they will let you prescribe and then you have to go to the section 8 to say they actually need this particular drug because the others didn't work. But sometimes, you can't do all of that and you know that the drugs are particularly better. I think the thing is the ODB lists of medicines might not quite be as up to speed as what the physician in the community wants to use. There is a lag there, there definitely is. And you will have physicians in the community doing off label use of stuff that ODB won't pay for so then you have to make up nonsense so they can end up getting the drug that they want. So most of us will do that without too much of a problem. But that's because the ODB committee – I don't know how often they meet – do they meet once a month or something and say should we put this on the ODB list or not? And that's the one thing that we would probably find fault with – is the drugs that are commonly used by us, for example chronic pain management, around here, that is a big problem, and certain medications that are going to be used for chronic pain managements comes right out of the books and journals that we read are not covered by ODB under their set of guidelines so the only thing we can do is make up the person to have that problem so they can fit the guidelines to get the medicine that they need. And like I said, most of us would probably jiggle the box because we are more up to speed on things as frontline physicians perhaps, than the ODB committee who says we have to dot the I's and cross the T's and watch the bottom line. Most physicians that I would work with very seldom worry about bottom line costs and it is simply because we deal with the microcosm. We are dealing with one patient or 2, sitting in an office across from us, and I can't worry about the entire cost of medical therapy for the province of Ontario when I have a patient sick in front of me. And that's because that's the nature of the business so the ODB committee really has to look at things from the entire province's point of view, otherwise we go broke so we need them and I appreciate them and I wouldn't want their job. But in terms of the rest of us, if I have a particular drug I have to give someone, I will jump through hoops to make sure that they get it. But I certainly will take the guidelines and pick the cheapest

because one of the things that I have found is that there sometimes isn't a great deal of difference between any of them.

- I have often wondered if the government should get into the business of making their own drugs. That is a creative solution but they don't want to be in business but I can tell you right now that very few drug companies are going out of business and they all post a profit and if Ontario is picking up the tab for that then those companies are making a lot of money off our back. To me it is a bit Ludacris, that you are going to pay for doctors therapy, people in the hospital, but 60-80% of everything we do involves pharmaceuticals that the government doesn't pick up the tab for and that's the therapy, that's why people get better. The drugs that you give schizophrenics is why they don't end up in Emerg down on Queen St. in Toronto, the drugs you give those heart patients when they are 45 and can't afford them, that is what keeps them out of hospital. So having the ODB is very very good for business. And if it is an expensive program then maybe the government should figure out ways of making it cheaper for themselves.
- I: Actually, let's go back to this, you mentioned earlier that you will do whatever you need in order to get a patient the medication that they need, so going back to the LU codes, you say certain LU codes will be used even if they don't qualify?
- P: in who's strict of sense? One of the LU codes says you can use this drug if they have been on 2 or 3 prior drugs of similar nature that have failed. Well ok, sometimes it may not be three, it may be 2 so ya officially the criteria wouldn't be met. And that of course is creative accounting on the part of the physician. But remember the physician doesn't get anything out of this, why is the physician doing this? Because he's got a patient he thinks he's got a better drug for and doesn't want to wait 6 months it's going to take to try three different drugs when he has one in front of him that he knows will do the job today. So in terms of delaying what a patient gets you're right. If I'm going to have a wait on my hands that I think is unreasonable, I think a lot of physicians will fudge things and you can't quote me on that one!
- I: and do you want to see changes with the LU codes?
- P: for the time it takes for me as a physician now that I'm using a computer, to fire in an LU code, after they have given me the five or six different ones that I can choose, I don't have a problem doing that at all. I mean it takes more time on my part but I don't have a problem doing it. I mean some people might bark at the fact that the ODB should be every single drug out there, and I would disagree with that, I think the ODB has to be put in place because there has to be checks and balances, this is not an enormously expanding, never ending open ended pie that just keeps getting bigger. We have this much to deal with and we have to divvy it up appropriately so having checks and balances on the system, I'm quite comfortable with. And for the time it takes me to put an LU code in that I know is probably going to work, I fire in a couple of codes, the person

gets the drug they need and we are home free. So I don't have a problem with it, the system works pretty well, I think so. I think the only thing would be is that if the current standard of practice is that a certain drug is used for specific type of syndromes, then it would be nice not to have to jump through hoops to get somebody the drug in a timely fashion. And I think that's the thing, timely fashion has got to be one of those things that the patient and I decide, it shouldn't be decided in a committee someplace else. Because there are going to be people that are going to be failing rather quickly and if you have to wait x amount of weeks or months to try alternative therapies before things start going south on you, you are going to feel bad that you weren't able to help that person upfront so you want to be able to get stuff on board fairly rapidly but firing in an LU code it always comes, they say fine and pick it up.

- To a small extent. The LU codes can be an issue at times when the code doesn't automatically match my need for a pretty good medications so for example low molecular weight heparin in people who are anti-coagulated, some people who are anti-coagulated have to go for a short period of time back on their heparin such as pre-operatively and post operatively but the codes don't allow you to do that so then you either have to, basically fraudulently use an incorrect code, or make the patient pay but I would say that is less frequent. The only thing with the LU code, is that they add an extra wrinkle when it comes to prescribing and I'm not really sure that the system benefits from that strategy. So LU codes while a bit of a nuisance aren't an overwhelming obstacle. Section 8 I find a big nuisance. So you know, I think if ODB wants to be more straight forward then they should be evidence based in their approach to our use of medication, support the use of medication for which there is sufficient solid evidence be reluctant on others. So section 8 is too time consuming in a busy practitioner's day.
- I guess – that wasn't already mentioned – I mean it is accessible, the fact that I believe patients can go to different pharmacies I mean it is available throughout the province, if someone is away on holidays, you know they can still get their drugs covered. In general I think they try to practice evidence based medicine so they are not putting the newest drug on the list just because the pharmaceutical company thinks it is a good idea, you know, I believe that they make an effort to put drugs that are both cost effective and most beneficial to the patient. I think in – I'm trying to think of some specific examples, for the most part, drugs that I want to prescribe are covered by it.
- I think it is a good thing that when the people come to the ER department, that they are able to access, if the person is on ODB, the ER is able to access the medication records, that is a very valuable service. They can go into the database – registration at ER is authorized to look up a record. So then you have elderly people who do not have a copy of their medication list or didn't bring their pills with them and they are able to access it, so that is a huge improvement, it has been around for 8 or 10 years.
- my overall experience with ODB is good – it covers many drugs that

people need and who can't afford or do not have any source of income to pay

- my experience as a family physician is good
- I would not say limiting, I'd rather say it takes longer to find LU code, and sometimes I forget to put LU code or I don't know it is covered, patients comes back for the code – it happens rarely but when it does it takes up clinical time.
- Sometimes I wish I could choose another medication for patient but if it is not covered by ODB, then patient can't pay 0 I wish ODB would cover more and more medications
- For the most part no.
- Most drugs we use with an LU and it goes through fine – but section 8 – they deny everything. I don't use expensive drugs, but when they don't work, we have to go to section 8. I don't like section 8 very much but ODB in general is good. It helps patients get their medications. It is not VERY restrictive, but the problem I have is they take meds off the list and then I have to turn to old medications that don't work, or don't work as well.
- LU is ok, for most seniors. Once patient is able to get medication that they need, then I'm fine. The only concern I have is removing meds from the list sending you back to ancient meds. I do not like section 8 at all 0 most times they decline you. It is a waste of time, what is the point?
- P: section 8 yes – I have had a bad experience once and I have not been desperate enough to use section 8. If a medication – there is a pain medication that at the end of the year I have to do section 8 after one year, what I have actually done is to switch patients to a different pain medication so I don't do section 8. for the LU codes, no I have not have problems with that. Maybe because I just put the code. Once in a while I have had to read ok this patient does not qualify for this code and I will tell them, most of the choose to pay for it, if I have samples, I give it to them, but I would say that would be like 1% of my practice so there hasn't been any problems with limitations with LU codes.
- Nobody really likes LU codes, it is something I have learned to live with during my career as a family physician. It sort of struck home to me because I teach family medicine residents and they said how do you learn about LU codes? And I realized like there is no real rhyme or reason – there is no logic to it because my residents will write prescriptions and there is no flag within – like there is no warning that something is LU until you get a call from the pharmacy back. And I mean no one is – I can't tell my residents to go and read the LU website and memorize them, it is just something you have to learn to do by experience. So myself personally, I guess I have the drugs I prescribe most often, I have the LU codes memorized and so it is just a matter of doing the prescription and putting the LU code in. I see it as a bit of a game, because I am always trying to avoid the pharmacy calls and trying to do the best for my patients to try and prescribe something that is covered for them.

- The section 8 forms, we have fewer of those to do than we used to, it was always frustrating when you get a notice that your section 8 approval for your patient was going to run out in 4 weeks or whatever, it just seemed like an exercise in useless paper work because it was almost always approved I'd complete the form, I'd fax it off and at some point there was like long, long wait lists for getting these requests back so I had the sense that I was doing the work and then it was just sitting in a pile somewhere at the ministry and someone with no medical knowledge was just basically giving it a stamp and approving it so it was creating a barrier for me and also the patient If they didn't get their approval in time.
- I: but in general when you do submit the section 8 forms, they do come back approved?
- P: yes because I believe I take care to choose the patients appropriately and I try to choose the patients who qualify for it.
- I would be happy to see the LU codes and section 8 forms – just get rid of them. At some point in the program either just say this drug is either covered or it is not and if it is covered, these are the patients it is appropriate for. But sometimes I think it would just be easier to say just cover the stupid drug and pay for it! And there is less administrative work for the government's end and less work for pharmacists and physicians and hopefully for the patients' benefit.
- (when asked if any rejections of section 8 requests) Oh all the time, the section 8 forms often come back and say we need such and such data to further assess the situation and oftentimes the data - they want to see evidence that the medication made a difference with hemoglobin A1C for example, when I think certain drugs were on EAP before, but patients can't try it if they don't have coverage and we don't have samples to give them so we don't have that data to give them and then there is no point, the process stops, you can't ask further for ODB to cover it! And some of it are flat out rejections, - we reviewed the data about this medication, we found this medication is of no clinical benefit compared to the existing medications that are on ODB benefit and because the cost difference is so dramatic, we feel that, we are listing only these drugs as opposed to the ones you are requesting. And that's fine, there is some of that too but again, why do I need to write a letter, three months later get a response to tell me no, if we do the education ahead of time, you save me all that energy and wait for that patient and I could be trying something else for that patient. What happens is patients wait and then they get a no, and they put all their hopes on this medication when they could have been tried on something else.
- I hardly even do it now, if the medications are not easily covered on ODB, or LU, I probably avoid it, you know, I do do some in extenuating circumstances, but I seem to tend to avoid it. And I can't say that I've done any homework recently in how ODB and how they develop their criteria in what's covered straight up, what's covered by LU and what's covered by section 8.

	<ul style="list-style-type: none"> <li>- I: and did they approve it?</li> <li>- P: no I guess that was a bad experience after all the wait, I can't remember the excuse they gave, it was almost four years ago, but at the time it made sense, there was no reason to say no to the request so since then I have not done section 8 I either swap or look for samples.</li> </ul>
<p><b>Prescribing habits</b></p>	<ul style="list-style-type: none"> <li>- I think for GPs, depending on your practice preference, there are certain GPs who will prescribe newer medications once they come out on the market, others will take a few months once they see their colleagues are using them and others will wait even longer to see if there are guidelines that recommend certain medications.</li> <li>- If you are one of the physicians who wants to prescribe new medications as they become available, then it is a problem with getting it approved, especially if there are alternate medications - Alternative medications that are probably older and not as effective and possibly, usually, if I did choose a newer medication is because the patient tried an older one and it wasn't effective</li> <li>- I think the rationale for them choosing medications that they prescribe – maybe that they have not found acceptance into really strict treatment guidelines before they are approved</li> <li>- Maybe the time for medications to enter the formulary is probably too long for certain medications that are shown to be effective quite quickly after started in use. I think probably the oncologist would feel that way for medications that are known to work but don't have approval.</li> <li>- I don't mind trying new medications for patients who have failed older medications, I'm just left giving them samples to see if it does work but it is a problem if it does work and they don't have the finances, or they are not in the program, or the program doesn't accept coverage.</li> <li>- Sometimes they cover something but only if you write it a specific way</li> <li>- It should be covered without writing the prescription in a specific way <ul style="list-style-type: none"> <li>- Example: I ordered a steroid with lidocaine and the patient had to pay for it. However, if I ordered the steroid and lidocaine separately, and mixed it myself, it is covered. Patient had to pay for it because I didn't know, but now I ask for it separately and mix it myself.</li> </ul> </li> <li>- I: you mentioned when you started that there are some drugs that you are used to prescribing that are not covered. What did you have to do – did you submit a section 8 request or write a whole new prescription?</li> <li>- P: I completely changed – I have never, I did a section 8 once when I was training and I didn't like it. The fact that I had to fill out that form and wait for them, I have never done it since then. So what I do is change he prescription or I look for samples and give the patients samples. And I hope the pharmaceutical companies continue to bring the samples because if they don't – I did the section 8 once and it was more like a teaching thing from my preceptor and we were waiting and waiting and oh my goodness. So I've never really done it again, I don't really do section 8.</li> </ul>



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