Negotiated Contracts for Funding Pharmaceuticals: A National Survey of Canadian Public Drug Payers

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EXECUTIVE SUMMARY

Introduction and Objectives

This report has been prepared for Dr. Morgan of the UBC Centre for Health Services and Policy Research. It provides a literature review, an analysis of interviews conducted with provincial decision makers, and recommendations for provincial policy makers.

Faced with challenges such as rising drug costs and uncertainty at the time of listing, public drug payers have increasingly begun using product listing agreements (PLAs) to reduce various kinds of uncertainty, to secure better prices, and/or to improve the cost-effectiveness of new medicines. PLAs are defined as any negotiated agreement between a manufacturer and a public drug payer with terms that affect the final price paid for a new medicine. Due in part to their confidential nature, there is currently little publicly available information on PLAs, particularly in the Canadian context.

Therefore, this report uses interview data from key informant interviews to document and explore the use of PLAs as a new tool in the Canadian context. The report focuses on two primary research objectives: 1) to report baseline information on PLA use and to describe the goals, benefits, downsides, and challenges in PLA use as perceived by policy makers across Canadian provinces; and 2) to analyze policymakers' perceptions on the potential benefits, disadvantages, and obstacles to the establishment of a joint negotiation mechanism for Canadian provinces.

Methods

A literature review of relevant grey and academic literature on PLAs in both Canadian and international jurisdictions was conducted to identify gaps, refine the research questions, and inform the development of the interview script. Key informant interviews with provincial drug plan managers were conducted to solicit information and decision makers' views on the use of PLAs in Canada. Participants were identified using purposive sampling and were invited to participate in 45 minute telephone interviews. Nine of the ten provinces participated. All interviews were audio recorded and professionally transcribed. Interview transcripts were analyzed using open coding and thematic analysis.

Findings

PLAs appear to be a new norm in Canada. Eight of the nine provinces interviewed have used at least one PLA in the past year; however, PLAs use was rare before 2005. Several factors have contributed to the recent increase in PLA use, including recent changes in the language of the Common Drug Review recommendations and increasing payer uncertainty about the value of new medicines. Payers also reported feeling pressure to provide access to medicines while staying within their budgets, and in some cases, they reported pressure from manufacturers to use a PLA. Additionally, it appears that there is no alternative for payers, as manufacturers will not provide a transparent discount by reducing the list price.

Provincial payers generally agreed upon similar goals in their use of PLAs, mainly providing access to new medicines while managing the budget impact of listing decisions and making new medicines more affordable. Reflecting these articulated goals, this study found that provinces are primarily using financial and utilization-based agreements, with PLAs based on health outcomes being very rare.

All provinces noted challenges or downsides to using PLAs, such as the time and resource burden in negotiating and administering PLAs, challenges surrounding the asymmetry of information between the payer and the manufacturer, and the lack of transparency which causes challenges in a multi-payer environment. In particular, a Canadian-specific challenge called 'whipsawing' was identified, in which manufacturers offer one province a good deal on a new medicine, which, once listed in the initial province, then puts pressure on other provinces to cover the drug for not as good of a deal. Canadian inequities in access and price were also described as being exacerbated by the provincial variation in the capacity to negotiate and use PLAs. Discussions of power inequities between payers and manufacturers were a common theme identified. Inequities across provinces (in the individual bargaining power, capacity to negotiate, and the final price paid for medicines) were also identified as a significant and reoccurring theme.

Building on some existing calls for increased provincial cooperation, this study found that there is general support for provincial cooperation in the form of joint negotiations. Most participants described potential benefits such as increased bargaining power resulting in lower prices and improved interprovincial equity in access and price. However, there are significant barriers to achieving joint negotiations surrounding overcoming significant differences in existing provincial institutions, the reluctance to cede provincial autonomy, the resources likely required for joint negotiations, and the political will necessary to move towards a collective process. There is still significant uncertainty as to what joint negotiations would look like in practice, which body would conduct the joint negotiations, and how the process would operate.

Recommendations

Three broad recommendations for provincial drug plan managers emerged from the literature review and analysis of interview data. Gven that there is little information on PLAs in Canada and uncertainty about the use and value of PLAs as a tool, provinces using PLAs should engage in some formal internal evaluation of PLAs. The second recommendation is for provinces to collaborate on the development of guidelines or best practices to help guide independent provincial use of PLAs. Finally, it is recommended that provinces begin to work together to establish a joint negotiation mechanism to reduce interprovincial disparities and increase collective bargaining power to secure better deals. Future research could focus on the mechanism to facilitate interprovincial cooperation on the negotiation of PLAs.

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INTRODUCTION

Developed countries are facing challenges due to rising health costs and limited budgets. In Canada, health spending as a percentage of GDP has risen from 7% of GDP in 1980 to 11.3% in 2009 (Organization for Economic Co-operation and Development, 2011). Pharmaceuticals make up an increasingly significant portion of this health spending; total expenditure on pharmaceuticals and medical non-durables as a percentage of total expenditure on health has risen from 8.5% in 1980 to 17% in 2009 (Organization for Economic Co-operation and Development, 2011). Therefore, public payers are looking for ways to provide health services, including access to pharmaceuticals, to their citizens while finding cost-savings measures in order to stay within their budgets.

Within this context of rising costs, drug plan managers are further challenged to make decisions about whether or not to list new medicines, often without sufficient information on their cost-effectiveness or efficacy (Carlson, Garrison, & Sullivan, 2009, p. 683). Product Listing Agreements (PLAs), defined in this report as any negotiated agreement between a pharmaceutical manufacturer and a payer with contract terms that affect the final price paid for the drug, have emerged in international jurisdictions as a new and potentially useful tool in managing various types of uncertainty faced by payers at the time of listing.

PLAs have been found to be an increasingly important input into the decision-making process of listing decisions (Nason & Sproule, 2011, p. 13). However, given the confidential nature of these agreements (Carlson, Sullivan, Garrison, Neumann, & Veenstra, 2010) and perhaps their relative novelty, there is little information available on PLAs. There has been some documented use of various types of PLAs in international jurisdictions (Carlson, et al., 2010, pp. 181-182) but no comprehensive study on their use in Canada. Little is known about their use in Canadian provinces (Nason & Sproule, 2011, p. 10); therefore, provincial payers must make decisions on PLA use with little Canada-specific information available.

While health is under provincial jurisdiction and provinces are each responsible for listing drugs and negotiating PLAs with manufacturers, there is potential for increased collaboration. Provinces could establish a joint PLA negotiation body or other cooperative mechanism in order to increase their bargaining power, potentially securing better deals for pharmaceuticals (Laupacis, 2005, pp. II-18) and reducing interprovincial inequities (Husereau & Cameron, 2011, p. 25). While some coordination has been tried through a recent pan-Canadian purchasing alliance, little progress has occurred to date.

To address the knowledge gaps on PLA use in Canada and the potential for a joint negotiation mechanism, this report focuses on two research objectives. The first objective is to report baseline information on PLA use and to describe the goals, benefits, downsides, and challenges as perceived by policy makers across Canadian provinces. The second objective is to analyze policymakers' perceptions on the potential benefits, disadvantages, and obstacles to the establishment of a joint negotiation mechanism for Canadian provinces. To address these objectives, this report uses data from semi-structured key informant interviews with provincial representatives involved in drug plan management in their jurisdiction.

Structure of Report

The report begins with a brief background describing the increasing cost and importance of pharmaceuticals in healthcare, the recent introduction of PLAs as a new tool, and the potential for interprovincial cooperation on the negotiation of PLAs. A literature review then provides some brief information on what is already known about the objectives, advantages, disadvantages, and challenges in using PLAs. The results are presented in two sections: the first focusing on PLA use and the second on the potential for joint negotiations. The discussion will then describe some of the themes that emerged from the analysis relating to current use of PLAs in provinces and the potential for increasing provincial cooperation. Finally, three recommendations are presented for provincial governments to consider in this area. The first is that provinces engage in some formal evaluation of PLAs, especially before moving towards more complex health outcomes-based PLAs. The second recommendation is for provinces to collaborate and hold a meeting where provincial policymakers meet to discuss best practices, lessons learned, and other cross-jurisdictional policy lessons to produce a joint guideline or statement on PLA use. The third recommendation, to be accomplished in the longer term, is for provinces to establish a joint negotiation mechanism for the listing of most or all new medicines, which could greatly increase provincial bargaining power, reduce duplication and inefficiency, and reduce jurisdictional disparities in access and price.

Client Background

The client for this report is Dr. Steve Morgan, Associate Director of the Centre for Health Services and Policy Research (CHSPR). One of Dr. Morgan's current research interests is the use of PLAs in Europe, North America, Australia, and New Zealand. Dr. Morgan is currently researching PLAs because they are a new, relatively unexplored component of the listing decision process.

This project will contribute to the production of academic research papers and a potential report for provincial policy makers which may include policy recommendations. Upon completion, the papers and report will also provide information on the potential for interprovincial policy learning and help inform the dialogue about PLAs in Canada.

BACKGROUND

All aspects of healthcare, including administration and delivery of health services, fall under provincial jurisdiction. While the Canada Health Act (1984) requires provinces to provide certain health services (e.g., emergency care) to all citizens under universal public coverage, pharmaceuticals are not covered under the Act. Therefore, provinces have been left to develop their own public drug coverage insurance systems, which can vary significantly in access, price, coverage, and structure (Daw & Morgan, 2012, p. 19).

In 2004, over nine million Canadians received drug coverage under provincial plans (Competition Bureau of Canada, 2007, p. 36). Provincial public drug plans typically cover only a portion of the population, which differs depending on the province (Daw & Morgan, 2012, p. 19). Certain groups, such as seniors, recipients of social assistance and individuals with "catastrophic" drug costs are typically provided with some drug coverage, but this eligibility and the level of coverage varies across provinces (Daw & Morgan, 2012, p. 19). In fact, Canada's drug coverage system has been described as a "patchwork" of programs (McMahon, Morgan, & Mitton, 2006, p. 340). While two-thirds of Canadians have some drug insurance coverage through their employer (Paris & Docteur, 2006, p. 4), private insurers have been excluded from the scope of this report, which focuses only on provincial public drug plans.

Public payers are facing a challenging policy context, as pharmaceuticals make up an increasingly large share of public health expenditures in Canada. Pharmaceuticals "are one of the fastest growing cost components of modern health care systems" (McMahon, et al., 2006, p. 339), with drug costs rising significantly in the last several years (Paris & Docteur, 2006, p. 4). Given trends in increasing cost and use of pharmaceuticals, public drug spending has risen from 3.8% of public-sector health expenditure in 1985 to 9.4% in 2008 (Canadian Institutes for Health Information, 2011a, p. 31). In 1988 provincial and territorial governments spent $1.6 billion on prescription drugs but by 2010, this number had risen to $10.5 billion (Canadian Institutes for Health Information, 2011a, p. 13). After hospitals and physician services, pharmaceuticals are the third most significant component of health expenditure in Canada (Blackwell, 2012, para. 7).

While drug costs are rising, public payers are also facing uncertainty and risk at the time of listing. Despite formal health technology assessment and cost-effectiveness evaluative processes, decision makers are often faced with insufficient evidence on the safety or effectiveness of a drug to justify its inclusion on the formulary (Canadian Institutes for Health Information, 2011b, para. 1). Other new medicines may not meet traditional cost-effectiveness thresholds and may be considered unaffordable.

Therefore, product listing agreements have recently been recognized as potentially useful instruments for reimbursement decision-making under these conditions of cost pressure and uncertainty or risk. (Carlson, et al., 2010, p. 180; Neumann, Chambers, Simon, & Meckley, 2011, p. 1; Trueman, Grainger, & Downs, 2010, pp. 79-80). PLAs come in a variety of forms, from rebates and discounts to contracts in which reimbursement prices will be affected by the volume, appropriateness, and/or outcomes of medicine use. These confidential agreements are intended to help payers manage costs; secure lower

prices for pharmaceuticals; and/or manage other areas of risk relating to utilization, appropriate promotion, or health outcomes.

Internationally, PLAs have been referred to by many terms, including reimbursement schemes, patient access schemes, utilization management agreements, managed entry, value-based pricing, risk-sharing schemes, supply contracts, and product listing agreements. This report will use the term Product Listing Agreement (PLA), a term used by the provincial drug plan managers in the interviews conducted. For the purposes of this report, PLAs are defined as any negotiated agreement between a manufacturer and a public drug payer that affects the price paid for a new medicine. PLAs have also been described as "formal agreements by product or defined group of products, between individual companies and payors to address uncertainty or risk around appropriate use, budget impact, or outcomes associated with the reimbursement and associated use of pharmaceutical products" (Nason & Sproule, 2011, p. 3). Recent reports have noted that PLAs are becoming both more common and important; however, there is little information available and "they are poorly understood" (Nason & Sproule, 2011, p. 2).

PLAs have been used in many jurisdictions, including Australia, the United States, and Europe (Carlson, et al., 2010, pp. 187-188); however, Canada is unique in that provincial governments, not the federal government, is responsible for health policy. Therefore in Canada, provinces negotiate PLAs and make final listing decisions (Nason & Sproule, 2011, p. 9), based in part on the recommendations provided to all provinces (except Quebec) by the Common Drug Review. In contrast to other countries which are single-payer systems, Canada has ten provincial drug plans, three territorial drug plans, and six federally-run drug plans for aboriginal peoples, veterans and other groups. The fragmented multi-payer system can cause both inefficiencies, as provinces are each negotiating on the same drug independently of each other, and inequities, as provinces receive different deals from manufacturers (Husereau & Cameron, 2011, p. 24). It is likely that provinces could experience greater bargaining power and lower prices if they cooperated to jointly negotiate PLAs (Husereau & Cameron, 2011, pp. 24-25). It has been suggested that provinces are currently failing to realize potential savings that could be gained from collective action, and industry is able to continue charging higher prices in this "fragmented market" where each provincial drug plan acts independently (Federal/Provincial/Territorial Ministerial Task Force on the National Pharmaceuticals Strategy, 2006, June, p. 39).

The alternative to the current system is the establishment of a mechanism to facilitate cooperation and collective action. Countries which use their national buying power to negotiate directly with manufacturers (and also employ other formulary-based cost-savings strategies) realize significant savings (Morgan, Hanley, McMahon, & Barer, 2007, p. 5 and 13). Additionally, group purchasing has already been used by hospitals in Canada and other countries as a cost-saving procurement strategy for pharmaceuticals and other health products (Health Council of Canada, 2011, p. 11; Mayerovitch, 2003, para. 10; Nollet & Beaulieu, 2003, p. 5 and 7) and has been demonstrated to significantly reduce the price of drugs (Lynas, 2010, p. 264).

This potential for generating savings through provincial collective action has been previously noted. A 2006 Progress Report written by the Ministerial Task Force of the National Pharmaceuticals Strategy reiterated that "there is a strong case for a collaborative national approach to achieve the Pricing and

Purchasing mandate" (Federal/Provincial/Territorial Ministerial Task Force on the National Pharmaceuticals Strategy, 2006, June, p. 39). A recent report also discussed the potential for a national procurement strategy for pharmaceuticals to coordinate provincial drug plan efforts and reduce costs (Health Council of Canada, 2011, p. 11).

There has been some response to these calls for interprovincial cooperation, but no significant broad-based change. In August 2010, an agreement was reached between the premiers to pursue the development of a pan-Canadian purchasing alliance for pharmaceuticals and other medical products (Lynas, 2010, p. 264). The alliance was proposed as voluntary for provinces to opt-into (Smith, 2010, para. 12) and was to be led by Ontario and B.C. (Lynas, 2010, p. 264). It was established in the belief that provinces would increase their purchasing power by acting collectively, and would benefit by having lower prices available to all participating provinces (Laupacis, 2005, pp. II-18). As pharmaceuticals are a significant component of healthcare spending, even a small reduction in prices could have a significant impact on provincial budgets. In addition, patient access organizations have contributed to the calls for "some harmonization in listing decisions" (Nason & Sproule, 2011, p. 9) which could potentially be achieved through a joint negotiation mechanism.

There have been two examples of successful joint provincial negotiations. In 2011, Provinces negotiated a PLA on Soliris (eculizumab), "the world's most expensive medicine" which is used to treat a very rare disease (Blackwell, 2012, para. 8-9). After the initial success of Soliris, a second joint negotiation process (2012) was completed for the blood thinner Pradax (dabigatran etexilate), while a third joint PLA is in progress for an undisclosed drug (Blackwell, 2012, para. 11).

However, it appears there is still no agreement amongst stakeholders on what the true benefits of joint negotiations are, given the institutional and jurisdictional challenges that provinces would have to overcome (Lynas, 2010, p. 264). Perhaps this is part of the reason that actual progress on the pan-Canadian purchasing alliance has been slow. In contrast to stalled progress on joint purchasing of pharmaceuticals, collaboration has already been established at other points of the drug review process. In 2003, the national Common Drug Review was established with a mandate to provide all provinces (excluding Quebec) with recommendations on which new drugs should be listed and under what conditions (McMahon, et al., 2006, p. 340).

It is unclear why levels of cooperation in drug purchasing and PLA negotiation remain very low (with only three drugs negotiated to date), despite the potential benefits to cooperation, the apparent political support of the pan-Canadian purchasing alliance, and the precedent set by consolidation of the drug review process in the Common Drug Review.

LITERATURE REVIEW: PRODUCT LISTING AGREEMENTS

Before any interviews were conducted, a search for academic literature was conducted in Google Scholar and Academic Search Complete, which searches many databases, including MEDLINE/PubMed. The UBC library website search engine Summon was also used. Grey literature was searched for using Google to retrieve reports or other documents available from research centres and government websites. The aim of the literature review was used to provide some brief background on a new policy tool and to answer two questions: 1) what information is already known about the use and design of PLAs, and 2) how are contracts perceived or described in the literature? The answers to these questions helped refine the study's research questions and inform the semi-structured interview questions. The gaps identified in the literature review also helped focus the research questions.

The search yielded very limited results; the most salient sources found included a few systematic reviews, case studies, and jurisdictional scans that amalgamate examples of PLA use from international jurisdictions. About half of the literature used for this project was opinion or commentary pieces in academic journals (with a few academic research studies on PLAs), while the remainder included news articles and reports. Most articles were published between 2006 and 2011, and focused primarily on PLA use in the United States, Europe, and Australia. Given the lack of Canada-specific information available on PLAs (Husereau & Cameron, 2011, p. iii), the literature review draws on work describing various kinds of PLAs in an international context.

The relative lack of information on PLAs could be attributed to several factors. First of all, PLAs are a relatively new tool, with the majority of documented cases occurring since 2005 (Carlson, et al., 2010, p. 189). Second, there are low levels of transparency due to confidentiality agreements and high levels of secrecy surrounding the use of contracts or price negotiations (Nason & Sproule, 2011, p. 9). Third, there are few published examples of PLA use (Cook, Vernon, & Manning, 2008, p. 555), especially when the scope is narrowed to a search of only one country, such as Canada. This may soon change, however, as some authors have noted a recent major increase in both interest and use of risk-sharing schemes (Carlson, et al., 2009, p. 683; Nason & Sproule, 2011, p. 13). Last of all, the lack of formal evaluation to date has likely contributed to the lack of information on PLA use. Various authors have noted the lack of evaluation of PLAs (Carlson, et al., 2010, p. 187; McCabe, Stafinski, Edlin, & Menon, 2010, p. 143) and lack of available results on use (Breckenridge & Walley, 2008, p. 667). This is a challenge for policy makers who are trying to determine if, when, and how to use PLAs, given that there is "little if any literature providing guidance on their design or evaluation" (Menon, McCabe, Stafinski, & Edlin, 2010, p. 109).

Context

The literature on PLAs describes the challenges and policy context that led to their first use as a new tool. Drug plan managers face difficult decisions about whether to list a drug or not. Decision makers are often faced with competing interests that they must balance in order to satisfy their stakeholders and the public. While they are pressured to keep costs low they must also ensure they create a supportive environment conducive to research and development for pharmaceutical companies (Pomey, Forest,

Palley, & Martin, 2007, p. 470). They must balance the goal of providing access to the newest and best drugs against the uncertainty inherent in drug listing decisions, as often there is incomplete information about the cost-effectiveness of a drug at the time of the listing decision (Carlson, et al., 2009, p. 683).

Under conditions of uncertainty, risk, cost pressures, and budget constraints, drug plan managers are increasingly negotiating agreements with drug manufacturers at the time of listing (Carlson, et al., 2009, p. 683; Carlson, et al., 2010). This trend has been spurred in part by public pressure on governments to cover new and expensive drugs, and likely also pharmaceutical companies who may view it as a source of revenue to compensate for losses from the expiry of patents. (Adamski et al., 2010, p. 2). In response, payers are looking for ways to provide access to patients "while (at least partially) protecting the principles of their reimbursement decision-making processes" (McCabe, et al., 2010, p. 143).

There are several other factors cited as contributing to the rise in performance-based schemes, a particular type of PLA which is the focus of much of the literature in this area:

> (a) a limited evidence base and associated uncertainty for pharmaceuticals and other medical products at the time of market introduction owing, in part, to accelerated drug approval;
>
> (b) increasing cost pressures from those who fund and pay for health care;
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> (c) the increased use of external reference pricing globally; and
>
> (d) an increased emphasis on policies to control new technologies such as health technology assessment programs (Carlson, et al., 2009, p. 683)

McCabe et al. elaborate on the "limited evidence base" (bullet (a) above), describing an "inevitable tension" between goals surrounding access and "robust reimbursement processes", which must sometimes take place with limited or uncertain information about efficiency or cost-effectiveness (McCabe, et al., 2010, p. 151). While clinical trials provide evidence on efficacy, the true effectiveness of the medicine is not entirely understood until it is put into practice and observed in the broader patient population (Carlson, et al., 2009, p. 683). In addition, lack of certainty about patient groups, such as how many patients will use the drug and how much each patient will require (Carlson, et al., 2009, p. 683) can further complicate cost and cost-effectiveness calculations.

PLAs can therefore be used when payers are uncomfortable with the level of risk in listing a new drug, particularly for relatively expensive products (Zaric & O'Brien, 2005, p. 800). Cook, Vernon and Manning describe these negotiated agreements as essentially being warranties which "can be used to signal high quality when product quality is not fully observable" (2008, p. 551). Before the use of contracts, payers generally assumed the risk of listing a new drugs (Stafinski, McCabe, & Menon, 2010, pp. 114-115), or sometimes managed certain aspects of risk through post-marketing studies (de Pouvourville, 2006, p. 156). However, the recent trend towards PLA use is modifying the risk profile of listing decisions. In essence, a PLA can shift some of the risk from a payer to a manufacturer (Garber & McClellan, 2007, p. 2). Cook et al. describe how PLAs "essentially call upon the pharmaceutical manufacturer to put the price of the drug at risk" (2008, p. 554). For example, in some types of PLAs, the manufacturer stands to

lose revenue if the drug is not as effective as anticipated, while in other types of PLAs with terms relating to utilization, the manufacturer may receive a lower price or no money at all if use exceeds pre-agreed upon thresholds.

Types of PLAs

There are numerous types of PLAs. Carlson et al. provide a thorough systematic review of health outcomes-based PLAs in international jurisdictions from 2000 to 2010, and propose a taxonomy to define and classify different types of contracts (2010, p. 183). The taxonomy offers a method of classifying the various kinds of PLAs, dividing them into two main categories: 1) non-outcomes-based contracts, such as price-volume agreements and utilization caps; and 2) health outcomes-based or performance-based contracts, such as conditional treatment continuation, coverage with evidence development, and outcomes guarantees (Carlson, et al., 2010, p. 183).

As most of the literature focuses on forms of health outcomes-based PLAs, there is less detail available on non-outcomes-based PLAs. However, after conducting the lit review and analyzing the interview transcripts, this report will further divide non-outcomes-based PLAs into two categories: 1) PLAs that are based on simple terms such as a pure price negotiation or discounts, and 2) more complex agreements that have terms related to population or patient utilization and/or volume of the drug used.

Therefore, three kinds categories were used to describe and analyze PLA use in Canadian provinces. The first category is simple price negotiations, which include negotiated discounts and rebates. Agreements in this category could be based on uncertainty relating to the manufacturers' claims of the drug, the value for money, or other forms of uncertainty. The final price is not dependent on anything, but is simply negotiated down before the final listing decision is made. The literature review revealed almost no information on this type of PLA, given that the final price negotiated is confidential.

The second category is utilization-based PLAs where the final price is affected by patient or population utilization or volume of drugs sold. These can be used by payers to "limit total expenditures and budget impact" (Carlson, et al., 2009, p. 684). For the purposes of this report, this category will include price-volume agreements, utilization caps, and expenditure caps.

The third category used in this report is health outcomes-based PLAs, also referred to as "pay by results" or "pay for performance", in which the final price is affected by the real-world outcomes of the drug. This category encompasses a wide variety of PLAs, including coverage with evidence development, conditional treatment continuation, and performance-linked reimbursement such as outcomes guarantees (Carlson, et al., 2010, p. 183).

Carlson et al. recommend that health-outcomes based PLAs are most useful in a few select situations (2010, p. 189). There must be a clear method to measure the effects of the treatment and the outcome of the pharmaceutical must be evident (Carlson, et al., 2010, p. 188). Otherwise, the PLA will be unable to reduce uncertainty and risk. Health outcomes-based PLA are less easy to implement and perhaps unsuitable in cases where the time period is long and/or the outcome is difficult to measure (Breckenridge & Walley, 2008, p. 667). Thus, health outcomes-based PLA are more useful for certain

kinds of drugs and in certain situations (de Pouvourville, 2006, p. 157). An overwhelming majority of the literature on PLAs focuses on international use of access with evidence development, coverage with evidence development, and other health outcomes-based PLAs. However, given that this kind of PLA is very rare in Canada, this report will not go into further detail describing the particulars of health outcomes-based PLAs.

Objectives for Use

There is little available information on the specific motivations or particular objectives of using PLAs. Most of the information available is speculation on the goals of payers, although some authors have also written about hypothesized motivations of manufacturers.

Payers are motivated to use PLAs in part due to external public pressure to provide access to new and expensive medicines. External pressure has included media campaigns aimed at pressuring policy makers to include specific new drugs on their formularies (Robertson, Walkom, & Henry, 2009, p. 193). A recent study of stakeholder perceptions of PLAs found that "patient access" was the most frequently cited primary goal in PLA use (Nason & Sproule, 2011, p. 13). The increasing cost of new drugs, such as targeted cancer therapies, also strains policymakers to stay within their budgets (Robertson, et al., 2009), while still meeting the needs of citizens by providing access to new therapies.

Payers are also looking to manage uncertainty related to health outcomes and effectiveness. For example, in coverage with evidence development schemes, the payer is motivated in part by the potential to collect additional data on new drugs after listing (de Pouvourville, 2006, p. 157). Given that payers do not always have all the information they want at the time of the listing decision, they may use PLAs "as a tool for managing the information asymmetry that exists between payers and drug manufacturers" (Zaric & O'Brien, 2005, p. 794).

Another primary goal noted in the literature is that payers may look to manage financial uncertainty, sometimes simply referred to as "risk". Payers can not anticipate the exact number of people who will take the drug or in what quantity, therefore they do not know the exact volume and are unable predict the exact budget impact of a listing decision. Consequently, "payers face considerable financial risk if demand is much greater than expected at the time of listing" (Zaric & O'Brien, 2005, p. 793).

Payers may prefer to use PLAs for high volume pharmaceuticals that are expected to have a significant impact on their budget (Carlson, et al., 2010, p. 188) or are particularly high-cost (Carlson, et al., 2009, p. 685). Therefore, drugs in some areas, such as oncology, may be more suitable to health-outcomes based schemes as they fit the above criteria. Indeed, it appears that in some cases, medications from certain disease groups are more likely to be associated with PLA use; in an international review of access with evidence development PLAs involving outcomes guarantees, one study found that 17 of the 25 PLAs involving pharmaceuticals were for cancer drugs (Stafinski, et al., 2010, p. 128).

Some authors have speculated on manufacturers' motivations for engaging in PLAs. De Pouvourville suggests that a pharmaceutical company engages in a health outcomes-based PLA when it "has sufficient confidence in its claims of either effectiveness or efficiency that it is ready to accept a reward

or a penalty depending on the observed performance of its product" (de Pouvourville, 2006, p. 156). In this case a PLA could be beneficial to both the payer (who manages financial risk) and the manufacturer (who may have a greater chance of having their drug listed). Additionally, the structured terms of PLAs can give manufacturers some "predictability" (de Pouvourville, 2006, p. 157). These potential benefits may motivate manufacturers to engage in PLAs but can also have drawbacks for manufacturers. For example, manufacturers may feel more compelled to ensure that the evidence is high quality as their revenue will depend on the real outcomes of the drug (de Pouvourville, 2006, p. 157).

Garber and McClellan point out due to the high fixed cost of a developing a drug compared to the marginal cost of drug production, pharmaceutical manufacturers can have a strong incentive to seek out pay-for-performance schemes when the alternative is not having the drug covered at all (2007, pp. 2-3). If the drug is deemed not cost-effective, then the company loses out on all the potential revenue from that drug in that particular jurisdiction (Garber & McClellan, 2007, p. 2). Therefore, it is sometimes preferable for manufacturers to offer a discount or risk-sharing agreement than to not have the drug listed at all. Additionally, manufacturers may use PLAs as a tool to keep prices confidential (Zaric & O'Brien, 2005, p. 800) so that discounts negotiated in one jurisdiction do not set a precedent in another due to global reference pricing. Indeed, it has been noted that manufacturers are reluctant to use transparent discounts in the list price due to the global reference price system, where list prices in one country are used to inform prices in others (Morgan, et al., 2007, p. 5).

Advantages and Benefits of Use

Some authors assert that PLAs can have significant benefits for policy makers, the public, and even pharmaceutical companies. Some have asserted that health outcomes-based agreements can contribute important evidence and result in data collection that might otherwise not have occurred (Carlson, et al., 2009, p. 683), protect payers from unwanted risk when listing a new drug (Cook, et al., 2008, p. 555), and reward innovative manufacturers for producing effective new drugs (Cook, et al., 2008, p. 555). Laupacis discusses conditional listing (a type of health outcome-based PLA) as a potentially useful tool that can have many benefits: "more rapid access to effective drugs, less rigid regulation of prescribing, and a decrease in the incentives for excessive marketing of the drug" (2005, pp. II-18). Laupacis favors the use of conditional listing PLAs and in 2005 he argued that these should be increasingly used by policy makers (pp. II-18).

Some authors take a more neutral or cautious position on the benefits of PLAs, arguing that they can be useful tools under certain conditions (Cook, et al., 2008, p. 552), while others take an even more critical view, citing numerous objections to their use and arguing that PLAs are beneficial in very few situations (Adamski, et al., 2010, p. 12). While Robertson, Walkom, and Henry are critical of the negotiation process and in particular the lack of transparency associated with PLAs, they agree that PLAs can be acceptable if they result in lower prices and these benefits are passed onto consumers (2009, p. 197). This can be challenging as citizens who are covered by drug plans often still pay a portion of their drug costs through copayments, deductibles, and/or coinsurance (Paris & Docteur, 2006, p. 4), which is calculated on the transparent (non-discounted) list price.

Disadvantages and Challenges of Use

Given the secretive nature of many PLAs (Laupacis, 2005, pp. II-18), some have criticized the listing decision process as being not transparent enough, arguing that opacity is a disadvantage of PLAs, and suggesting that the trend is moving towards less publicly available information (Robertson, et al., 2009, p. 195). Laupacis argues that while there are several advantages to using PLAs, the details of use are not clear (2005, pp. II-18). He questions the ability of policy makers to effectively measure outcomes and evaluate whether the drug met the conditions of the PLA or not; for example, data may simply not be available to provide sufficient evidence either way (Laupacis, 2005, pp. II-18).

There are also many challenges discussed in implementing PLAs. In a study of PLAs in the United States the authors argue that "[r]isk sharing for pharmaceuticals is appealing in theory but hard in practice" (Neumann, et al., 2011, p. 2333) and PLAs "are proving hard to implement" (p. 2329). Carlson, Garrison, and Sullivan (2009, p. 685) have noted several barriers to implementation of health outcomes-based agreements:

(a) the associated transaction and administration costs;

(b) the limitations of current information systems in terms of tracking performance;

(c) agreeing on the scheme details (e.g., the appropriate outcome measure of the financial adjudication process);

(d) physician push-back;

(e) the 'free-rider' problem – other manufacturer or payer competitors may benefit from the information or schemes developed; and

(f) a lack of trust between payers and developers.

The "physician push-back" challenge (bullet (d) above) refers to the fact that the administration of health outcomes-based agreements can place a burden on physicians to collect data and monitor outcomes. More generally, the use of any type of PLA requires resources, time, and information; therefore, some have noted that PLAs can be expensive (Nason & Sproule, 2011, p. 1). The complicated nature of some types of contracts, such as health outcomes-based PLAs, can contribute to significant challenges in their use and implementation. Tracking outcomes can also pose a challenge to payers (Carlson, et al., 2009, p. 685), while payers and manufacturers may not agree on the monitoring mechanism or the "appropriate level of proof" required (de Pouvourville, 2006, p. 157). It can be a challenge to get both the manufacturer and the payer to agree on the details of the scheme (Carlson, et al., 2009, p. 686), especially when PLAs become more complicated or outcomes are difficult to measure.

Some authors describe the challenges to the implementation of health outcomes-based PLAs, primarily surrounding measurement and monitoring of outcomes (Garber & McClellan, 2007, p. 3; Nason & Sproule, 2011, p. 13). Outcomes-based PLAs can require a clear objective for them to be effective (McCabe, et al., 2010, p. 144), and require management, monitoring, and data collection and validation

(McCabe, et al., 2010, p. 147). There are also "difficulties associated with monitoring costs and with reaching agreement on the relevant thresholds" (Cook, et al., 2008, p. 555). In short, some types of PLAs can be expensive, challenging to implement, and difficult to monitor (Nason & Sproule, 2011, p. 12).

Canadian Use

The literature review revealed that little information is available on Canadian PLA use and Canada-specific challenges and benefits to PLA use; in fact, a recent report concluded that there is a significant literature gap on PLA use in Canada (Nason & Sproule, 2011, p. 10). Confidential negotiated contracts for funding pharmaceuticals are a relatively new phenomenon in Canada, and as such, there is limited information on their use. Since Ontario's first trial use of performance-based contracts in 1998 (Paris & Docteur, 2006, p. 30), few examples have been documented in Canada. Little is currently known about the extent of use and practical application of PLA negotiations in Canadian provinces (Nason & Sproule, 2011, p. 10).

In 2005, it was reported that the Ontario Drug Benefit Plan (ODBP) was engaging in "virtually no [price] negotiation" with drug manufacturers (Laupacis, 2005, pp. II-18). By 2009, the Executive Officer of the Ontario Public Drug Plan, asserted that most provinces were engaging in some form of negotiation relating to price with manufacturers (Silversides, 2009, p. E81). Manitoba began negotiating with manufacturers by 2007, mostly with financial-based PLAs such as price-volume agreements and caps (Silversides, 2009, p. E81).

A scan of provincial government websites for all ten provinces revealed that publicly available and accessible information on PLA use is limited. Information on when provinces may have used PLAs for specific drugs is only available for two provinces. In Ontario, the Executive Officer Decisions and Committee to Evaluate Drugs Recommendations note when a PLA was used. For example, a recent Executive Officer decision to approve Januvia (sitagliptin) in March 2012 notes that a "cost and utilization agreement with the manufacturer" was signed (Commitee to Evaluate Drugs, 2012, p. 1). No further detail is provided on the details of the agreement. The other province to give some indication of when a PLA is used is British Columbia, which notes when a complex review has been completed. The timeline for a complex review is twelve months (compared to the nine months for a standard review). This additional three months could be allocated for several reasons: "the need to develop clinical coverage criteria, to develop a Special Authority form, to complete a Product Listing Agreement, or to complete other implementations steps as required" (Pharmaceutical Services Division, 2011, p. 2). For example, the Review Results webpage for Abilify (aripiprazole) notes that "this review was moved to complex review based on mutual agreement with the manufacturer" (Ministry of Health Services, 2011). However, it is not possible to determine whether this was because of PLA negotiations or one of the other potential reasons that can cause the timeline to be extended.

In the academic literature, there is minimal information on a select few examples of PLAs (primarily health outcome-based PLAs) in Canada, including: an agreement where the manufacturer agreed to reimburse the provincial funder the cost of the drug for patients who did not meet specific health targets; another where the manufacturer would reimburse the cost of the drug for patients who

discontinued use; and an agreement where the manufacturer would cover the full cost of the medicine for patients who required surgery despite taking the drug (Adamski, et al., 2010, p. 8). Another review found that in 2005, the Ontario Health Authority negotiated conditional treatment continuation (a form of performance-based scheme) with three manufacturers for Alzheimer's drugs (Carlson, et al., 2010, p. 184).

Overall, it was clear from the literature review that there is little information available on which provinces are engaging in PLAs, what types of PLAs were being used, what are the primary motivations and challenges in using PLAs, and how this new tool is perceived by provincial decision makers.

METHODS

The objective of this qualitative study was primarily to describe a relatively unexplored phenomenon. The study is therefore descriptive and exploratory. No special software was used to complete the analysis, other than Excel and Word. Qualitative coding strategies were developed based on the work of Miles and Huberman (1994), while the thematic analysis was modeled based on the six step process outlined by Braun and Clark (2006).

I completed a literature review of PLAs, both in an international and Canadian context. Findings from the literature review were used to identify gaps to be filled by this study using key informant interviews. The literature review helped to shape the objectives and purpose of the interviews. The literature also established what was known about PLA use and identified gaps to inform the development of the interview questions.

In February, 2012, a series of semi-structured interviews was conducted with Canadian provincial government representatives who are drug plan managers. Respondents were high-level policy makers solicited for elite interviews to provide insight into the use of PLAs in their jurisdiction and their personal perceptions on this use or non-use.

Interview candidates for this study were selected by Dr. Morgan using purposive sampling and were identified through online government directories. As the purpose of the study was exploratory and the analysis was qualitative, a representative sample was not required. Candidates who declined to participate due to lack of knowledge or experience in PLA negotiation were asked if they would consider proposing an alternate candidate from their organization who would be more suitable. One representative from each of the 10 provinces was identified, and nine chose to participate in this study (response rate 90%). Interviews were approximately 45 minutes, were conducted on the telephone, and were audio recorded. The audio recordings were sent to a private transcription firm in Vancouver, B.C.

Interviewees were asked to provide information to answer three primary questions (a full interview script is available in Appendix A):

- What is the extent of use of different types of contracts made between public drug funders and drug manufacturers across provinces?
- What are the articulated objectives and perceived benefits and challenges for use of contracts made between public drug funders and drug manufacturers across provinces?
- What do policymakers perceive as the potential for joint negotiations of pharmaceuticals in Canada?

To analyze the data, I began by reading all the transcripts, immersing myself in the data, and keeping detailed notes. I then developed a draft list of codes for certain baseline information that could be quantified through a coding system in Excel and codes that could help identify emerging themes.

I met with my CHSPR research team (led by Steve Morgan). We each brought notes and lists of codes that we felt emerged from the data. At the meeting, we amalgamated and created new codes to come to a final list, thereby increasing the validity of the codes.

I independently drafted a list of themes and sub-themes that emerged from the data and coding exercises. I then met with the team and we discussed the themes we had each identified to come to a final commonly agreed upon list of themes.

Once the codes and themes had been finalized, I reread and coded all nine Canadian transcripts for the baseline information. (A second coder then coded the transcripts to ensure validity of the results). I then reread and tagged coded quotes that illustrated each theme and subtheme. At the end of my analysis, I reviewed the quotes pulled under each theme and sub-theme in order to develop the narrative for the report. (Full coding results are available in Appendix B.)

This project was approved by the University of British Columbia's Behavioural Research Ethics Board (Appendix C) under an application submitted by Dr. Steve Morgan. It was also approved by the University of Victoria's Human Research Ethics Board (Appendix D).

RESULTS

This section provides insight into the use of PLAs in Canada and the perceptions of provincial decision makers on questions related to PLAs, including factors that have led to their increased use, goals, the nature of use, challenges and downsides of use, and the value of PLAs as a new policy tool.

PLA Use

Eight of the nine provinces have at some point in the last 12 months used a PLA. Half of respondents said they use contracts *sometimes*, while three provinces *always* use them and one *never* uses them. PLAs are a relatively new phenomenon; all respondents who use contracts indicated that they began using them regularly after 2005. Some provinces did note that they had experimented with ad hoc use as early as the late 1990s or early 2000s but that these early experiments were rare. Half of the respondents noted that PLA use is on the rise in recent years.

Factors that Have Led to Increased Use

It appears that there are several factors that have led provinces to begin considering PLAs as a policy tool and to begin using them routinely. When asked about these external factors leading to the increased use of PLAs, the majority of respondents named a recent trend in Common Drug Review (CDR) recommendations, in which the CDR is increasingly including language in its recommendations about the need for price reductions to make new medicines more cost-effective. One respondent noted this trend in CDR recommendations as contributing to the increased use of PLAs: “we were following the recommendation, and by getting rebates, the price was lower” (Interviewee #1).

Half of respondents described uncertainty surrounding the incremental value of new medicines as a primary factor leading to increased use of PLAs. Provinces described the challenge of covering new medicines, some of which are not deemed to be cost-effective, either due to their high cost or uncertainty surrounding their cost-effectiveness or both. Provinces noted challenges in determining the incremental value of adding a new drug to the formulary, particularly when the drug has a similar purpose or outcome to potentially less expensive drugs that are already listed. One respondent described it like this: “What we tend to use these agreements for is if there is potentially increased cost associated with the product and not necessarily – we don’t see that there is an additive clinical benefit” (Interviewee #6). Another respondent described new drugs as being “premium priced” even if they were very similar to drugs that are already on the market.

Another factor leading to increase use is the pressure that drug plan managers experience from multiple sources. The first is political pressure, which often takes the form of pressure to cover drugs that are listed in other provinces. This pressure can come from the political sphere, as politicians are under pressure from interest groups to cover drugs. One respondent emphasized the importance of politics: “is there unmet clinical therapies out there that in other jurisdictions – that we don’t cover? That’s politically horrendous. And unfortunately, the political element, obviously, rules the day often” (Interviewee #3). Some respondents described how patient groups, interest groups, and clinicians advocate for more access, often framing their demands around equity and Canadian values: “Because

you have patient groups, you know, that are making the point, and rightly so, that we're all Canadian and this drug is now accessible in Ontario, BC and Quebec but not in smaller jurisdictions" (Interviewee #2). These groups rely on comparing coverage across jurisdictions to lobby for coverage of particular new drugs in their own province. Therefore, some of the pressure payers experience is created by the precedent set by other provinces in their listing decisions.

This precedent is no accident, as some provinces described this process as a deliberate strategy used by manufacturers. Manufacturers will approach one province to list a drug (often enticed by a low price or discount) knowing that this will put increased pressure on other jurisdictions to cover the drug, often at a higher price. This "whipsawing" strategy creates significant pressure that can affect the final decision by forcing some provinces into coverage decisions or PLAs that they would not normally have signed**:**

> And I felt that it—we just couldn't withstand the pressure because, you know, eight out of ten provinces had already listed them. And I thought, well, I can list and pay full price, or I can list and hold my nose and sign a PLA. So we did. (Interviewee #1).

Another factor that has contributed to the use of PLAs is that payers have no other way to make medicines more affordable or cost-effective, as manufacturers will not decrease the list price. This is a global phenomenon due to reference pricing; the precedent set by a low price in one jurisdiction means that manufacturers are reluctant to change the public list price (Husereau & Cameron, 2011, p. 19), so the only option left for payers is to negotiate a confidential agreement. According to interviewees, manufacturers have clearly communicated this to payers. One province reported: "one of the things we hear because, you know, we're talking to these companies, and they always bring the global, you know, they can't do anything about price – they can't decrease list price because of the global economy" (Interviewee #2).

The last factor that has led to increase use, as reported by interview participants, is that manufacturers are actually seeking out payers to propose PLAs. Manufacturers have clearly identified PLAs as a desirable tool and they are approaching provinces individually on specific drugs: "Last couple of years, usually they're contacting us to say, you know, 'Can I meet to tell you what I can do for you?' And in most cases, it's a PLA" (Interviewee #1).

It is important to note that many respondents emphasized that PLAs were not used when there was uncertainty or lack of evidence surrounding safety and effectiveness:

> We definitely do not look at doing listing agreements if there are significant clinical concerns, or if there are gaps in therapy that might suggest there is either a safety issue or there is a lot of concerns around the clinical use of a particular drug. (Interviewee #6)

Goals

Most provinces described their primary motivations for using PLAs as financial goals relating to managing the budget impact of new drugs or reducing other aspects of financial risk. These goals relate to uncertainty regarding utilization, for example where the volume of use of a new drug is difficult to

predict prior to listing. One type of PLA that would be used to achieve this goal of managing financial risk relating to utilization uncertainty is a cap, an agreement that the manufacturer will pay a certain amount of the cost of a drug beyond a pre-determined volume or expenditure threshold. This helps the province manage its budget, as it can be assured that it will not have to spend beyond a certain amount on a particular drug, even if demand or utilization exceed expected levels. One province described this financial goal in terms of budget and sustainability: "if it's a drug that we want to provide and is needed, and we need to provide, then it's making it more affordable and making our drug plan more affordable and sustainable" (Interviewee #2).

A second financial goal also mentioned by a majority of provinces was securing low prices on drugs. Some provinces aimed to negotiate discounts on drugs, to make their price more "acceptable" and make them more "cost-effective". For example, a simple discount could be used to achieve this goal. Another described their primary goals as being "just to achieve better value for public funds spent on drugs" (Interviewee #9).

The last major goal was providing access to new medicines for the public covered under the provincial drug plan. Half of all respondents cited "increasing access" or "maximizing formulary" as a goal in using PLAs. Some respondents described PLAs as a tool that allowed them to list drugs that they would otherwise have had to say no to.

While provinces described access as an objective in and of itself, they were also skeptical of increasing access for the sake of increasing access, and were skeptical about the true benefit or value of some new drugs that they felt pressured to list. Some didn't accept the "more access is always better" narrative:

> I don't buy the notion of increased access is always good. […] what benefit are we getting out of each of these drugs? We just keep dumping drugs onto a formulary. […] All I know is I'm going to get – take an incremental hit to our budget. (Interviewee #3)

Despite uncertainty about the value of access in some cases, respondents felt pressure to provide access due to clinicians, the public, and patient groups advocating for particular drugs: "So when the public is demanding access, you also have physicians and patient advocacy groups that are almost exclusively of the opinion that more access is always good by definition" (Interviewee #3).

The final set of goals that were described by respondents relate to managing clinical uncertainty. Respondents were eager to clarify that they never use PLAs to manage uncertainty related to safety or effectiveness, asserting that it is not about listing "bad drugs" for less money. This was described as a challenge when manufacturers approach provinces offering PLAs on drugs that don't add value:

> They come with the PLA saying, 'If we give you a rebate, will you list us anyway?' So I guess my first reaction is, well, why—if it's a crappy drug, why do I want to list it for any price? (Interviewee #1)

Some provinces noted that other jurisdictions including some countries in Europe are using schemes to address uncertainty related to health outcomes. Respondents expressed interest in pursuing PLAs to

achieve outcomes-based goals, but also expressed uncertainty about their implementation, administration, and monitoring:

> They would be very difficult for us to accurately calculate what the end measurement is that [manufacturers are] proposing. It would also be very difficult to attribute the reimbursement of a drug to a particular cost effect—or clinical effect, or those clinical effects could be years down the road. (Interviewee #6)

Nature of Use

The most common type of PLA used by provinces in the last year is volume or utilization-based agreements, such as utilizations caps, expenditure caps, and price volume agreements. In the past 12 months, most provinces have used at least one financial PLA which had terms relating to volume sold or expenditure on a particular drug. However, one province focused almost exclusively on utilization-based PLAs, asserting that adherence, appropriate utilization, and perhaps marketing, are essential to a successful agreement:

> The real losses occur at the compliance and the failure rates, which is the risk-sharing. […] if it's a wonderful product and it's not reaching the patients, it's not much good. If it's not a great product and it's reaching the whole population, that's also not good because you've got failure rates. (Interviewee #5)

Other provinces were wary of utilization-based PLAs which require collecting data on use or adherence: "we have no way of actually measuring that or harvesting those savings, we don't really consider them to be an adequate value proposition" (Interviewee #8). The methods used to monitor utilization-based PLAs were not clear in the interviews, but more research could be done to understand the implementation, enforcement, and/or evaluation of these types of contracts.

The second most common type of PLA used was simple rebates or discounts. However, while a majority of provinces had used either simple rebates, discounts, volume- or utilization-based agreements, only one province has had experience with health outcomes-based PLAs. No province reported using outcomes-based PLAs regularly. Some described perceived challenges with their potential use relating to high levels of complexity of the contracts or the need for significant resources for implementation and monitoring: "it's going to be very resource intensive to do that and a lot of obstacles" (Interviewee #2). However, a few provinces mentioned that they would like to move towards using outcomes-based PLAs, despite the associated challenges and barriers: "I would love to see an agreement that talks about things like coverage with evidence. I'd love to move a little bit beyond just the pricing piece" (Interviewee #6).

One province described a unique process that was not seen in other jurisdictions, the RFPLA (request for product listing agreement). RFPLAs are generated for therapeutic categories and manufacturers can submit proposals to compete for coverage. This was described as being a potentially useful tool for decision-makers in negotiating agreements with manufacturers.

Challenges and Downsides

All jurisdictions described challenges (either experienced or perceived) with using contracts. Many of the issues noted by respondents were related to the perceived complexity of PLAs. Respondents noted that even "simple" PLAs structured around financial goals had associated challenges with either negotiation or implementation. One respondent described the challenge of complexity as follows: "I'll say there's more levels than you might think or more issues to consider. Sort of like an onion, every time you peel one layer there's another, or at least it seems that way" (Interviewee #7). Many respondents described similar perceptions of complexity, calling PLAs "challenging", "onerous", "complex", and both time- and resource-intensive. This complexity contributes to the difficulty in administering and implementing the terms of the PLA: "so the more complicated they get, the more operationally onerous they are" (Interviewee #3).

Once a provincial drug plan begins using PLAs, they may feel pressure to continue using the tool, either from the political sphere, manufacturers, or indirectly from the public (whose demand for more access can push provinces into PLA use). This precedent contributes to challenges in finding sufficient resources to administer the PLA: "now there's this expectation that we're going to use the PLA on almost every new submission that comes along that's viewed positively by the Drug Benefit Council, and that requires a lot of time and human resources and things like that" (Interviewee #8).

The time-intensive and resource-intensive nature of PLAs was clearly described by respondents. It was noted that contract negotiations are complex and time consuming and that they require specialized business, legal, and evaluative resources. In particular, managing PLAs requires resources particularly for annual reporting, evaluation, and monitoring:

> The downside is the management of it. Some of the terms of them require that you're embedding another layer of operational hassle because there's utilization and there's every single year […] each of those [PLAs] has terms in it that have to be met" (Interviewee #3).

Some provinces suggested that the asymmetry of information due to the confidential nature of PLAs is a significant challenge: "The major difficulty with PLAs is we don't know what's in there. The only one who does know is the manufacturer. They can compare" (Interviewee #4). In other words, provinces have significantly less information available to them at the negotiation stage than the manufacturer. Provincial payers don't have access to information on the price or terms of PLAs that other provinces were offered. Therefore, the manufacturer could be described as having an advantage in the negotiation of PLAs due to this asymmetry of information. One province described how manufacturers use this asymmetry of information to their advantage:

> Large jurisdictions who are first adopters get lower prices to convince other jurisdictions that this is a lovely product, but they can't share that information. So the company, which holds all the cards in that instance, gets to know who – basically, does profit maximization by giving away a small discount to some players, but keeping all the other decision makers in the dark about

> how good of a deal they have in relation to others. And therefore, they have the profit maximized because none of the buyers can share that information. (Interviewee #5)

Another downside of PLAs is the delay associated with their use. It was noted that negotiations can delay listing decisions because of time required to structure PLAs and to arrive at an agreement:

> Delay. I mean, it just—it holds everything up. In some way you might say, oh, well, that means your budget's kind of more controlled, but it's just a pain when you have—you know, you start working on a file, and you know, six months later, you're still working on the file. (Interviewee #1)

Some provinces also described challenges at the renegotiation stage. Interview data indicate that PLAs are generally signed for a three-year period, but at the end of the three year term the province is at a significant disadvantage for renegotiation. Once a provincial payer has set a precedent in their jurisdiction that a drug will be covered, it is much more difficult to revoke coverage by delisting a drug. So a PLA that saves money initially can actually end up costing the province more in the long-run if they are forced into signing a less advantageous deal at the renegotiation stage.

Various Canadian-specific downsides were also discussed, such as the perception that PLAs can generate or exacerbate provincial inequity with regards to price (and perhaps even access). This theme of inequity was present in many of the interviews, ranging from concerns about varying provincial capacity to negotiate to the inequities in outcomes from PLAs across provinces.

Some respondents also described challenges in using PLAs because PLAs negotiated by the provincial drug plans only provide the negotiated deal to the public payer. Private insurers and uninsured citizens pay based on the list price. Even citizens covered by the public plan (which varies by province, but can include those on social assistance and seniors) pay their co-insurance based on the list price, and therefore do not benefit from the confidential negotiated discount.

Value of PLAs as a Tool

There was no consensus on the true value of PLAs as a policy tool. Some provinces felt they were not actually generating significant savings by using PLAs. Some appeared to perceive PLAs as having a low value, especially given that they require resources to administer. One province reported that overall "the value that we can get is pretty marginal" (Interviewee #8). Another felt that some provinces were mistaken in thinking they were deriving significant value from using PLAs: "They're all out there negotiating—and I used that word loosely, because frankly, there isn't much negotiation on price. It—the companies know what they have to play with, and that's it" (Interviewee #1).

Other provinces had a more positive view of PLAs, noting that they perceived receiving a high value or good return when PLAs were used. They felt that were saving money and negotiating meaningful discounts: "we were actually surprised how well we could negotiate even though there was pressure to list" (Interviewee #3). One province reported that after they began using PLAs, they moved away from

being “price takers” with little power to negotiate, saying “the pendulum has swung more towards – more in favour of the reimburser or the payer” (Interviewee #3).

Support for Joint Negotiations

Given that provinces are currently negotiating PLAs independently, but there have been some calls for increased provincial cooperation in this area, interview participants were asked to describe their perceptions of the idea of joint negotiations of PLAs in Canada.

Overall, the interviews concluded with a general sense of will to move forward on increased cooperation. When asked about joint negotiations, all provinces expressed a moderate to high level of support in principle, although responses differed on how feasible or realistic joint negotiations would be in practice. Many interviews had a tone of uncertainty, with study participants describing many challenges and barriers to the implementation of joint negotiations.

Participants articulated several benefits associated with joint negotiations. The most commonly mentioned benefit was that joint negotiations would increase bargaining power, particularly for smaller provinces, and that this increased bargaining power could lead to reductions in the price of medicines. Many participants believed that joint negotiations could increase cost savings for provinces that could not be achieved if each province continued to act independently.

Half of participants identified provincial equity in price and provincial equity in access as potential benefits of joint negotiations. For some this was a major motivator in supporting the idea of increased collaboration. This sentiment was expressed by both large and small provinces**.** One respondent described the potential to reduce interprovincial equity as follows:

> Well, I think the main benefit [of joint negotiations] is consistency. I think it’s also that the provinces are working together, and hopefully you can break down a little bit of the barriers of, you know, depending on where you live, you may have different access to different medications—or to the same medication (Interviewee #6).

Some respondents described the potential for increased delay for time-to-listing due to a lengthy negotiation process as a significant downside of joint negotiations. Others expressed concern that given the current challenges with negotiating a PLA in one province, negotiating contracts with many other provinces would simply be too onerous, complex, or challenging: “It is, from my understanding, labour-intensive in one jurisdiction. Imagine if you have to do that for a lot of jurisdictions” (Interviewee #4). Rather than describe improvements to administrative efficiency through joint negotiations, some provinces anticipated that administrative challenges would increase in a joint negotiation process.

Structure of a Joint Negotiation Mechanism

When asked about the suggested structure of a joint negotiation mechanism, no respondent had a clear vision of mechanism that could be used to facilitate joint negotiations. There was support for the idea of cooperation more generally, but uncertainty about the actual structure, design or method that would be

the ideal mechanism for increased cooperation. In fact, almost half of interviewees indicated that they did not know or were unclear as to what joint negotiations would look like in practice. The other half of respondents used relatively vague terms such as "body of individuals" to describe the potential structure. The most commonly suggested structure for joint negotiations was for a centralized, third party, or arms-length organization. Some believed that this other body would need to have the mandate to negotiate the PLAs on behalf of most or all provinces. However, there was skepticism about the feasibility of implementation of an arms-length organization:

> "Ideally, we'd have some sort of infrastructure sort of like a CADTH[1] that could do that, but I don't know if that, you know, that's costly, and I don't know if that's realistic. [….] I think ideally an arm's length organization is the way to go, but I don't think that realistically we could get there." (Interviewee #2)

Barriers to Establishing Joint Negotiations

When asked about obstacles and barriers to joint negotiations, most respondents cited multiple barriers and were generally not optimistic that the barriers could be overcome without significant investments and institutional changes. Barriers discussed by respondents can be grouped into four categories: institutions, autonomy, resources, and political will.

Institutions

The majority of respondents described at least one institutional barrier. Some asserted that a primary barrier to joint negotiations is the fundamental design of the health care system. Jurisdictional responsibility for health lies with the provinces and pharmaceuticals do not fall under the Canada Health Act. Others noted that each province has its own decision making process surrounding drug listing decisions. Therefore, provinces would not be able to all agree on a contract with the same terms, because they have different institutional requirements and processes:

> "…we all have different frameworks for funding drugs. Some of us use legislation, some use regulation, some use policy, some use—you know, it could be Minister decisions, some have to go to cabinet. Everybody has a very different process around listing drugs. So how do you align those processes so that you're not creating a lot of unintended barriers as you're trying to move forward with an agreement?" (Interviewee #6)

Other provinces expressed similar concerns about the need to align different steps in the process, including "the evaluation, the decision, the negotiation" (Interviewee #4). One province described institutional differences between provinces as not only a barrier to interprovincial cooperation, but as a barrier to coming to an agreement on a pan-Canadian PLA with a manufacturer who "will want terms fairly consistent" in each province (Interviewee #2). However, respondents also noted that provinces may be unable to agree to consistent terms due to legislative and structural variation. Some

[1] Canadian Agency for Drugs and Technologies in Health

respondents even went as far to say that all provinces would need to have the same reimbursement system for joint negotiations to work. One respondent described this by saying there "needs to be some consistency across the program with respect to how products are reimbursed and the criteria for that reimbursement" (Interviewee #6). Another respondent suggested that joint negotiations are unlikely to happen before all provinces essentially have the same drug benefit plan.

Autonomy

The next barrier category, autonomy, includes responses about provinces being unable and unwilling to cede authority for negotiations and listing decisions to another province or a joint negotiation body. While provinces recognized that ceding authority to some degree is likely a precondition to joint negotiations, they were skeptical about the practicality of doing so*:*

> So somehow, you'd have to streamline, you know, you'd give one group authority that would make the decision that would be binding on all provinces, which isn't going to happen, have one level of legal so that one agreement that's signed off doesn't have to be vetted through every jurisdiction. (Interviewee #7)

Some provinces expressed reluctance to cede their authority as a drug that is negotiated on a pan-Canadian basis could have a different budgetary impact in each province based on the patient population, the degree of coverage, and the size of the drug plan. Therefore, it may be more difficult for provinces to cede authority for PLA negotiation when the authority making the decision (e.g., an arms-length organization) is not focused on the impact on or interests of any particular province. The expenditure on – and therefore budget impact – of a particular drug can vary depending on the characteristics of the jurisdiction, also leading to increased complexity for a central authority in negotiating a joint PLA.

Provinces also have varying prescribing contexts, diverse patient populations (with differences in factors related to demand for drugs, such as age or prevalence of chronic disease), and consequently, different priorities for which drugs to reimburse. Given that a central authority could not cover *all* new medicines, it is unclear how priorities would be set. One province described this as a political challenge: "politicians have different pressures at different pressures at different times for listings" (Interviewee #3). With provinces facing different priorities and political contexts, a joint negotiation mechanism could cause conflict, unless provinces were to agree on a priority-setting process.

The decision made by a joint mechanism would have challenges for political acceptability. Although a joint mechanism could potentially produce cost savings for provinces, thereby increasing access to more medicines, it could also result in delay for each decision given the need to coordinate multiple actors:

> So when individual jurisdictions are being pressured to deal with some access issues, and you've got a process that's going to add more time into the—into a final funding decision, that's probably the biggest barrier. (Interviewee #6)

This political trade-off of access and delay could be challenging for politicians who are looking to meet the needs of their constituents. In addition, some provinces were wary of losing autonomy as a joint negotiation mechanism has the potential to force them into PLAs: “you get into deals that you wouldn’t have signed on your own” (Interviewee #3).

Resources

Technical and administrative resources were also perceived as being significant barriers to increased cooperation. Some provinces described frustration at the lack of resources currently available for independent provincial PLA negotiation and for coordination through the pan-Canadian purchasing alliance. One respondents described the current lack of resources it by saying “we are doing that off the corner of our desk”, with “no dedicated resources, we just plug it into our already crazy days” (Interviewee #1). Respondents generally agreed that without a significant investment of resources, joint negotiations will be unlikely to succeed.

Political will

Lastly, half of respondents cited provincial or federal political will as a barrier to joint negotiations. A few respondents noted that provinces currently negotiating PLAs successfully may lack the will to participate in joint negotiations because they would not have incentive to do so. One province summed up this concern by saying “the people that have the least to gain are the most important part of it” (Interviewee #3).

It is important to note that the provinces described by some as having little incentive to participate (large provinces and those with systems in place to negotiate PLAs on many medicines) did not express a concern that they would not benefit from a joint negotiation process. In fact, they still expressed support for the idea of increased cooperation through joint negotiations.

Overall, the interviews concluded with a general sense of will to move forward on increased cooperation, but with doubts as to how the barriers to implementation of joint negotiations could be overcome.

DISCUSSION

Provincial PLA Use

Several themes emerged from the interviews and analysis of transcripts. These themes, in combination with the results and a few major literature review findings, will form the basis for three recommendations presented to provincial policymakers in the Recommendations section.

Power

One of the major themes that surfaced from the interviews was power. Specifically, there were conflicting reports about whether drug manufacturers or provincial payers are in control in the use and negotiation of PLAs. Some respondents perceived having high levels of power, describing cases where they were successful in pressuring manufacturers to give them better deals. They described their success in part due to an approach that helped them maintain power by taking a tough stance. This 'tough' approach was described through anecdotes. For example, one province described a situation where they refused a better deal submitted by a manufacturer, because the official process had already concluded. They refused to allow the manufacturer to come back to the table after they had submitted a final PLA proposal. Also in support of payers being in control, some described some select cases where they had demanded or *required* PLAs from manufacturers.

While a few respondents felt that they were in control, the majority described a perceived lack of power, often described as a feeling of being gamed by manufacturers. This gaming or power theme related to several perceptions: that PLAs are on manufacturers' terms, that manufacturers are using PLAs as a tool to circumvent formal processes, that manufacturers are in control of critical information not available to payers, and that provinces are in reality received limited savings from the use of PLAs. As previously described, manufacturers have access to more information and there is therefore an asymmetry of information that disadvantages the provincial payer in PLA negotiations.

This power theme was present in situations where the manufacturer was described as pushing the use of a PLA. These respondents perceived that PLAs were of less value and some admitted that they did not believe that they were getting beneficial deals. The power narrative was also evident in discussions of how patient groups and clinicians are always advocating for more access. In some cases, respondents described these interest groups as holding some significant power exercised through public and political pressure.

These contrasting power narratives could be the result of several factors. There is still much uncertainty surrounding PLA use, and therefore payers may be unable to determine the true value of the PLAs they are signing. With the lack of evaluation and information available on the value of PLAs, payers may not be able to make the cost-benefit assessments required for evidence-informed policy. In addition, the secretive nature prevents provinces from sharing information, which puts power in the hands of the manufacturer. One respondent described this power balance of asymmetry of information as the manufacturer "holding all the cards" in a card game.

Inequities

Many interviewees had concerns relating to the theme of inequity. One of the most significant was the provincial inequities in capacity that cause challenges for provinces in negotiating contracts. Canadian provinces are varied in size (population), technical capacity (expertise required to negotiate), and resources (financial, time, and other). These variations cause inequities in negotiation, implementation, administration, and monitoring capacity. Provincial inequities in capacity to negotiate was also identified in the literature (Nason & Sproule, 2011, p. 13). In addition, manufacturers are aware of these inequities; therefore, provinces perceive that they are being offered different deals. (Of course, this cannot be confirmed since the price and terms of the agreement are confidential.) Some of this difference of opinion on the value of PLAs as a tool (described above) may be a result of the variation in capacity and current inequities across provinces.

Another inequity sub-theme identified relates to the differentials in access and price of drugs, specifically relating to how this affects citizens of various provinces. The current system of provinces negotiating independently could potentially exacerbate existing access and price differentials if provinces are correct in asserting that large provinces receive more favourable terms or prices due to their advantageous bargaining power. Indeed, the current interprovincial inequity is seen as a justification for the need for joint negotiations (Husereau & Cameron, 2011, p. 15).

The last sub-theme related to inequity is that the price negotiated by a public payer is not available to private payers, including uninsured citizens who pay for drugs out of pocket and private insurance firms. Several participants noted that confidential deals may create price inequity across payers. For example, within a province, rebates to government may put private payers in a situation where they pay inflated artificial list prices (including co-insurance calculated as a percentage of the transparent list price). One province noted that this payer inequity was a challenge in using PLAs:

> However, our clients, our customers, our patients, or whatever you want to call them, are paying on the list price, so they're not paying on this nontransparent price. So they're not getting the benefit, other than in this kind of roundabout way, of a decrease in price. (Interviewee #2)

Whipsawing

Whipsawing was a theme that emerged, tangentially related to themes of power and inequity, but was significant enough to merit its own discussion. The term "whipsawing" was used to describe what was perceived to be a deliberate strategy by manufacturers to either pressure a jurisdiction into covering a drug, pressure a jurisdiction to accept a higher price or less favourable contract terms, or both.

For example, some respondents expressed concerns that manufacturers strike early deals with select provinces in order to place greater pressure to list on the remaining ones. This whipsawing theme was described by one respondent as follows:

> The drug company will try and do the conquer and divide thing, and they'll go to Ontario, Quebec and BC, offer a better price, and then we have no negotiating power because we're so small." […] "BC and Ontario get a better price than the rest of us, and it kind of evens out for the drug company […] it puts pressure on the rest of the jurisdictions to cover […] Without a deal or with not as sweet a deal." (Interviewee #2)

This respondent continued on to say that once the manufacturer had got the drug listed in one or more initial provinces at a very low price, "they whipsaw the other ones into high prices" (Interviewee #2), and those provinces are forced to list the drugs due to the precedent set by the first jurisdiction. This whipsawing process increases price disparities, as the first jursidiction to sign a PLA receives the best price. Whipsawing can put pressure on provinces to list drugs they wouldn't normally list, or to list them at a higher price than they would normally accept. As previously described, provinces lose bargaining power when a manufacturer knows patient groups will lobby to cause sufficient political pressure to list drugs that are listed in other provinces, even if there is little real benefit to doing so.

This was also noted in a recent Canadian report on PLAs, where the whipsawing process was described as contributing to the access differentials (Husereau & Cameron, 2011, p. iii) and the price differentials (p. 24) experienced by provinces. Smaller provinces, which already have less capacity to negotiate individually, are the primary losers in this whipsawing process. Husereau and Cameron note that it is the smaller provinces who may be pressured to pay more (2011, p. 24). In short, "[c]urrent pricing and reimbursement policies and practices in some provinces undermine the efforts of others to negotiate lower prices, resulting in higher prices for everyone" (Husereau & Cameron, 2011, p. iii).

No Alternative

While not a major theme, it is important to note that no province described an alternative tool to PLAs. Both the academic literature and interview respondents noted that policymakers need new tools to make medicines affordable and manage uncertainty, and it appears PLAs are the only viable option. Manufacturers don't offer alternatives to secret PLAs, as they are cognizant of the impact that transparent agreements or price discounts would have on the prices of pharmaceuticals in other countries due to the global reference pricing system. Instead, they prefer confidential PLAs or other agreements that do not affect the global reference price (and their profits) in other countries (Morgan, et al., 2007, p. 5).

Potential for Joint Negotiations

Lack of political will was not found to be a significant barrier to establishing joint negotiations. Politicians have demonstrated support for cooperation which is evident by the Premiers collaborating on a pan-Canadian purchasing alliance. However, there some respondents perceived barriers surrounding political will regarding consensus of direction for joint negotiations: "And I don't know […] whether or not there is consensus around all the jurisdictions that that's the way they want to go" (Interviewee #8). Establishing a joint negotiation mechanism would likely require an agreement on mutual goals, reached by all or at least the majority of the provinces. Having one or more provinces refuse to participate would decrease the potential bargaining power and may delegitimize the joint mechanism.

Design of a Joint Mechanism

Due to competing demands, lack of resources and uncertainty about the potential mechanism for joint negotiations, the provincial vision for forward movement is unclear. Therefore, a brief discussion of potential design considerations and structure may be of value for exploring the potential for establishing joint negotiations.

There are two primary modes of cooperation in federal systems: horizontal and vertical cooperation. Horizontal cooperation occurs across governments at the same level (e.g., interprovincial cooperation), while vertical cooperation occurs between governments of two levels (e.g., federal-provincial cooperation). In Canada, healthcare is primarily dominated by vertical relations (Cameron & McCrea-Logie, 2004), in which the federal government sets standards or provides funding through transfer payments, while provinces administer their own healthcare programs. Most conflict occurs vertically, due to monetary and political disputes (Cameron & McCrea-Logie, 2004, pp. 112-113).

A search for examples of purely provincial horizontal cooperation on policy yielded limited results, leading to the conclusion that there is limited precedent for purely horizontal cooperation in Canada, not only in health but in any sector. Even with the will to cooperate, provinces are unlikely to cooperate successfully through informal mechanisms or existing institutions. As seen through the pan-Canadian alliance, only minimal success has been realized. Further, the interview data suggests that provinces are hesitant to rely on a single province to negotiate on behalf of others.

Therefore, for joint negotiations to be successful the establishment of an independent body to conduct negotiations on behalf of the provinces is likely needed. This is substantiated by calls from the provinces that "we need somebody to do it" (Interviewee #1), preferably an arms-length, third-party organization acting on behalf of the provinces.

Implementation

For joint negotiations through an arms-length third-party mechanism to succeed, there would likely need to be an enforcement mechanism to ensure that a joint decision to not list a drug would not result in provinces defecting and signing their own PLAs with manufacturers to list in their own jurisdictions. This concern that provinces could defect and circumvent the collective process was mentioned in the interviews during discussions of the pan-Canadian Purchasing Alliance. It appeared to be a serious concern for some interviewees: "if the Pan-Canadian Purchasing Alliance can't come to an agreement and won't accept their, you know, whatever they're offering, then there'll be pressure on the individual provinces to cover these products" (Interviewee #7). Another province noted that that cherry-picking, where each province chooses to adhere to only a few jointly negotiated PLAs when it is in their individual best interest, could be threat to the success of a joint negotiation mechanism, as manufacturers would not have the stability or certainty they need in joint PLAs. Public pressure to list a drug rejected by the joint negotiation mechanism and political acceptability of the decision are also significant concerns which would need to be addressed.

Regardless of the design of a joint negotiating mechanism, cooperation will fail if there are high levels of conflict and governments focus on political games such as winning political credit and avoiding blame for decisions (Cameron & McCrea-Logie, 2004, p. 92). Other factors that contribute to increased levels of conflict can include: different or competing ideologies (e.g., different perspectives on the role of government); challenges to a region's or government's status or identity; the presence of regional or linguistic considerations; and power struggles between federal and provincial governments (a lack of willingness for one level to defer to the other) (Cameron & McCrea-Logie, 2004, pp. 84-85). The characteristics of the issue at hand do not entail these challenges or considerations, so conflict in establishing joint negotiations is likely to be focused on jurisdictional issues and provincial concern for autonomy and self-interest.

While respondents generally expressed support for a joint negotiation mechanism, there are significant barriers to overcome. The biggest obstacles to cooperation are institutional and related to autonomy; the problem is not lack of a will to cooperate, but lack of a way. Respondents were unclear on what cooperation or a joint mechanism for negotiations would look like. As it was not the focus of this report to study the structure itself, it's unclear whether joint negotiations are more likely to be successful through a federally-led (vertical), more purely inter-provincial (horizontal) mechanism, or a multilateral (federal and all provinces) or bilateral/regional (e.g., two provinces) approach. Further research could examine these specific design and structure questions in more detail.

RECOMMENDATIONS

While the purpose of the report was exploratory and did not require the development of recommendations for action, three key recommendations emerged from the findings. The following recommendations section is intended for provincial decision makers. Recommendations are presented sequentially and in order of anticipated complexity. While it is recommended that joint negotiations be a long-term goal, it is anticipated that given the barriers described it may take some time to establish. Therefore, there are two other recommendations that should be implemented in the short-term to address some of the current challenges identified with individual provincial PLA use.

Evaluation of PLAs as a Policy Tool

In order to address the uncertainties related to the value of PLAs and the asymmetry or lack of information, those provinces using PLAs should begin planning for a formal provincial evaluation of PLAs. The results of the internal evaluation would likely remain partially or primarily confidential as the PLAs themselves are confidential and provinces are prohibited from sharing information. However, the evaluation would serve as a starting point for individual provinces in creating future policies around PLA use and forming a clearer understanding of when PLAs are useful (e.g., under what conditions, for what drugs, and with what contract terms). This was also an area identified in the literature as a gap, as there is no formal or informal evaluation of PLAs available in either an international or Canadian context. As noted in the literature review, many have noted the lack of evaluation of PLAs.

In addition, some provinces noted in the interviews that they were interested in moving toward health outcomes- or performance-based PLAs. However, both the literature and interview data revealed that these types of PLAs are even harder to implement, administer, and measure than PLAs such as discounts or price-volume agreements. One study on health outcomes-based PLAs found that “enthusiasm for it has been premature” (Neumann, et al., 2011, p. 2335), especially given the lack of evaluation of this tool. Therefore, this report recommends an evaluation of PLAs currently in use in provinces (which are primarily financial, and volume/utilization-based) before progressing toward more challenging and harder to measure agreements based on health outcomes. Any province considering moving into health outcomes-based PLAs should conduct an analysis or projection of how health outcomes-based agreements would be implemented, monitored, and administered in the province, and what value they are anticipated to produce.

Collaboration on Guidelines

One of the conclusions from the literature review was there is no current practical set of guidelines for use. The interviews confirmed that policymakers are still experiencing significant uncertainty on how to use PLAs, when, under what circumstances, for what drugs, and with what anticipated benefit or measurable results. A recent Institute of Health Economics report identifies the need for more information and evaluation by finding that “[t]here is a need for better understanding of when and where particular categories of formal ‘innovative’ product agreements can add value to the health system(s) in Canada and reduce uncertainty for payors and industry” (Nason & Sproule, 2011, p. 1). It

also notes that PLAs are likely more suitable sometimes, in some situations or for some drugs (Nason & Sproule, 2011, p. 1). But policymakers in the interviews expressed some uncertainty about the best situations or conditions for use.

While conducting the literature review, it was observed that there have been a few international meetings of policymakers, who have collaborated to explore the use of PLAs by sharing information on their best practices, concerns, and successes with PLAs (McCabe, et al., 2010; Menon, et al., 2010). One such meeting was found in Canada, where international government representatives met in Banff, Alberta to discuss principles of use for Access with Evidence Development (AED), a particular kind of outcomes-based agreement in which a payer will provide access to a pharmaceutical on the condition that additional information and evidence is collected from this conditional access, and this evidence is used to inform longer-term coverage decisions (McCabe, et al., 2010).

Given the uncertainty around the use of PLAs and the lack of guidelines on when and how they should be used, this report recommends that representatives from all provinces currently using or considering using PLAs in the future hold a meeting during which they establish basic guidelines for use and best or smart practices on PLA use. The guidelines would be focused on the most common types of PLAs used, primarily financial and utilization/volume-based, as described in this report. While policymakers can not reveal the specific terms of their contracts with manufacturers, they can share information about general lessons learned to promote cross-jurisdictional policy learning and the development of best practices. Indeed, one report recently called for "[a] set of defined characteristics for innovative' agreement components in provinces or even nationally" (Nason & Sproule, 2011, p. 15).

The report or outcomes from this proposed meeting could be modeled on the key success factors identified for use in health outcomes-based PLAs (see Appendix E) or the access with evidence development guidelines produced by the Banff summit, which can be found in Appendix F.

Cooperation on Joint Negotiations

The third and most important recommendation is the most challenging, resource-intensive, and complex recommendation. It is therefore a longer-term recommendation to take place over the next several years. Given the whipsawing currently taking place, the concern for inter-provincial inequities in access and price, the articulated equity concerns, and the will to increase collective bargaining power through greater cooperation, this report recommends that provinces begin work to establish a joint negotiations mechanism for most if not all new medicines.

Provinces expressed significant will to participate, citing several benefits (and few downsides) to joint negotiations. In general, most provinces did not believe that they are currently receiving the best possible deal by negotiating alone. This perception was validated by the literature which suggested that a joint mechanism would likely improve interprovincial equity, reduced provincial disparities in access, and promote savings through deals negotiated with collective bargaining power.

It has been shown that actors often fail to cooperate, even when they would realize benefits from collaboration (Fuller & Vu, 2011). Therefore, sometime actors require a formal mechanism to facilitate

cooperation. In this case, it has been suggested that there needs to be an arms-length organization with the "legislated authority to negotiate price on behalf of other provinces (and federal) jurisdictions and to keep prices confidential" (Husereau & Cameron, 2011, p. iv).

The results from the interviews suggest that there is significant uncertainty in most provinces about what the mechanism or structure would look like. It is possible that joint negotiations could take place through an existing body, such as the Patented Medicine Prices Review Board (PMPRB), a national "quasi-judicial body" which regulates the maximum prices for patented pharmaceuticals in Canada (Patented Medicines Review Board, 2011, para. 1-2). While the PMPRB currently regulates maximum prices, the maximum prices do not take into account the confidential negotiated discounts, contracts, and PLAs negotiated between provincial payers and manufacturers. Therefore in order for the PMPRB to play a role in increased provincial cooperation and perhaps negotiate a discounted price which would be available to all provinces, there would need to be significant changes to their mandate and legislation. Another option, as proposed by one respondent, is to set up a new organization, perhaps similar to the Canadian Agency for Drugs and Technologies in Health (CADTH).

There are many other options of structures or mechanisms to facilitate cooperation; further study is needed on the potential body through which to conduct joint negotiations. However, it is clear that any joint mechanism would require buy-in from most of the provinces, an enforcement mechanism, resources, and would need to overcome the barriers noted by the provinces. Therefore, it is recommended that the provinces begin discussions of ways to overcome the institutional and authority-related barriers identified as primary obstacles to joint negotiations.

FUTURE RESEARCH

Given the findings of the literature review and the results of the interviews, it is clear that there is a need for more research on PLAs in a Canada-specific context. In particular, studies which conclude with best practices or policy recommendations and studies of results (for the purposes of evaluation) appear to be two areas with unmet information needs. In addition, more studies on direct price negotiation (including discounts and rebates) would be useful, to understand how provincial capacity to negotiate affects final price. However, such studies are unlikely to happen given that final negotiated prices are kept confidential. Studies that look at the confidentiality and lack of transparency surrounding the use of PLAs could also be useful. Given that various international jurisdictions provide more information on their use PLAs than most Canadian provinces do, it may be worthwhile to study why Canadian provinces have such relatively low levels of transparency and public disclosure.

There is also a need for future research on the potential for a joint negotiation mechanism. Specifically, future research should explore the design possibilities and implementation considerations in order to provide useful policy advice to provincial governments who have a collective will to move forward on joint negotiations, but are unable to progress given the articulated barriers.

In addition, some study could be done on the current pan-Canadian purchasing alliance as currently, there is very little information available on the alliance. This study did not focus on policymakers' perceptions of the alliance and the two (soon to be three) joint PLAs negotiated to date as this was not a focus of the research project. However, future studies could explore how these joint PLAs were negotiated, how the alliance operates and how effective the alliance has been in negotiating deals with manufacturers. Studies aimed at answering these questions could provide insight into lessons learned for moving forward with a similar project in establishing joint negotiations through a new arms-length body to negotiate jointly on all or most new medicines.

CONCLUSION

While PLAs are used in many international jurisdictions, little information is available on their use in Canada. Additionally, little is known about the potential for interprovincial cooperation through a joint negotiation mechanism. PLAs are a relatively new policy tool but their use has been increasing in recent years. It is anticipated that they will continue to be used increasingly to help policymakers address financial goals and manage various aspects of risk at the time of listing new medicines. A literature review identified some issues and potential concerns with using PLAs but also some potential benefits. The literature review was primarily used to identify gaps and gain an understanding of what was and was not known about PLA use in Canada.

Semi-structured interviews with drug plan managers from nine of the ten provinces provided data for analysis, revealing information on both PLA use and the potential for interprovincial cooperation. Study participants identified benefits, downsides, and challenges, as well as describing some factors that have led to the recent increase in use of PLAs. In addition, results from the interviews suggest that there are power inequities between payers, manufacturers, and provinces. Results also indicate that provinces are currently independently negotiating PLAs, causing inter-provincial inequities in price and access, due to various factors such as differing provincial capacity and bargaining power.

Interview results indicate that provinces are overall supportive of joint negotiations while also perceiving significant barriers to establishing joint negotiations. Primary barriers noted were institutional and related to difficulties in ceding provincial autonomy.

However, given some of the problems in the current context of provinces independently negotiating contracts (which are described through the themes of power, inequities, whipsawing), there is a clear impetus for provinces to move towards inter-provincial cooperation through a joint negotiation mechanism. However, given the barriers described by respondents, together with the lack of a clear vision on the design of a joint mechanism, there are significant challenges in implementing a joint negotiation mechanism.

Therefore, three recommendations are provided to provincial decision makers. In the short-term, provinces should begin an internal evaluation of PLA use in their individual jurisdictions, especially before progressing towards using more complex and challenging PLAs. Secondly, provinces are encouraged to host a collaborative meeting to develop guidelines on the use of PLAs, thereby encouraging interprovincial policy learning. Third and most importantly, provinces should consider beginning the process of designing and establishing a joint negotiation mechanism in an arms-length organization with the authority to negotiate PLAs on behalf of provinces.

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APPENDIX A: INTERVIEW SCRIPT

Our research project is focused on the extent of and issues related to the use of supply contracts (also called product listing agreements or reimbursement schemes) between drug manufacturers and organizations that fund prescription drug purchases in several countries around the world. Contracts we are interested in include any negotiated agreement that affects the net price paid for a medicine, including agreements regarding how prices will be affected by utilization levels, utilization patterns, or health outcomes.

1) We are aware that drug coverage decision-making processes often involve several stages, ranging from technical assessment through to price determination and final coverage decisions. To start our discussion today, could you briefly describe the stages of drug coverage decision making in your jurisdiction and who is responsible for each stage of that process?

2) Thinking about listing decisions made for new drugs (not generics) in your jurisdiction over the last 12 months, approximately how often were supply contracts, product listing agreements or reimbursement schemes used? (Perhaps estimate this as a share of the total number of listing decisions made.)

This section is directed to those that use contracts:

3) Could you tell me approximately when contracts/agreements/schemes were first introduced in your jurisdiction?

4) Broadly speaking, what would you say are the overarching motivations and objectives for using contracts/agreements/schemes in your jurisdiction? Have these objectives changed over time?

5) We recognized that a variety of types of contracts/agreements/schemes are in use around the world. What types have been used in your jurisdiction over the last 12 months? What type is most common?

6) Thinking about contracting decisions made in your jurisdiction over the past 12 months, what are the critical factors that influence the decision to use a contract/agreement/scheme?

7) Thinking again about contracting decisions made in your jurisdiction over the past 12 months, what factors were likely to result in a decision <u>not</u> to use a contract/agreement/scheme?

8) What do you perceive to be the pros and cons of contracts/agreements/schemes?

This section is directed to those not using contracts:

9) We recognized that contracts/agreements/schemes are not used everywhere and would like to better understand the rationale for not using them in some jurisdictions. Could you please describe the reason (or reasons) that such contracts/agreements/schemes are not used in your jurisdiction?

10) Recognizing that contracts/agreements/schemes are not used in your jurisdiction, what do you perceive to be the pros and cons of contracts as used in other jurisdictions?

This section is for all respondents:

In recent years, it has been proposed that Canadian provinces co-operate (either independently or with the federal government) to establish a joint purchasing mechanism for prescription drugs.

11) What would a joint purchasing mechanism look like in your view?

12) What do you see as the potential benefits of a joint purchasing mechanism?

13) What do you see as the potential downsides of a joint purchasing mechanism?

14) *To date, there has been limited action towards establishing a joint purchasing mechanism for prescription drugs.* What are the key obstacles to establishing such a mechanism?

15) What do you think it would take for such a joint purchasing mechanism to be implemented and applied broadly (e.g., for purchases of many if not all medicines)?

APPENDIX B: CODING RESULTS

The interviews were analyzed using two methods: coding for baseline information and a thematic analysis. The results of both the coding and thematic analysis are presented under the "Results" heading in the main body of the report. For additional information, the results of the baseline coding for quantifiable information is presented below.

Variables: PLA Use	Sum
Frequency of use (in the last 12 months)	
Never	1
Sometimes	5
Almost always	3
Unclear/don't know/other	0
Beginning of regular use of contracts	
Before 2000	0
Between 2000 and 2005	0
After 2005	8
N/A jurisdiction doesn't use contracts	1
Unclear/don't know/other	0
Frequency of use in recent years	
Increased	5
Decreased	0
No change	0
N/A jurisdiction doesn't use contracts	1
Unclear/don't know/other	3
External factors that led to trend of increasing use of contracts	
HTA recommends price negotiation (e.g., CDR Recommendations "no based on price")	6
Trend toward specialization (personalized medicine)	0
Uncertainty of incremental value of new medicines	5
Increase in list prices/harmonization of list prices (e.g., as a starting point for negotiations)	2
Manufacturer pressure/manufacturer proposing contract	3
Public/political pressure to list specific drugs	3
Precedent set by other jurisdictions who are using contracts	3
None, jurisdiction doesn't use them	1
Unclear/don't know/other	0
Internal goals (motivations/objectives) for using contracts	
Securing low prices (financial)	5
Managing budget impact/financial risk (uncertainty related to utilization)	8
Uncertainty related to effectiveness	3
Increasing access (maximizing formulary)	5
Ensuring stability of supply (e.g., dealing with drug shortages)	0

Regulating promotion of drugs (by manufacturers)	2
None, jurisdiction doesn't use them	1
Unclear/don't know/other	0
Types of contracts used in last 12 months	
Simple rebate/price only (rebates, discounts)	6
Volume or utilization based (utilization caps, expenditure caps, price volume agreements)	7
Health outcomes based (including CED/AED)	2
None, jurisdiction doesn't use them	1
Unclear/don't know/other	0
Cons of contracts	
Feeling of being gamed (contracts are on manufacturers' terms, manufacturers are using contracts as a tool to circumvent formal processes, manufacturers are in control of critical information e.g. price, asymmetry of information, limited savings)	6
Difficult to enforce	6
Resource-intensive	7
Delay/lengthy process (in negotiation of contracts)	3
Lack of transparency	4
Difficult to renegotiate	3
Administrative inefficiency/duplication of effort	1
Generates provincial inequity	2
Generates inequity between public and private payers	2
Unclear/don't know/other	0
Reasons for not using contracts	
None, jurisdiction uses them	8
Lack of technical and/or administrative capacity	0
Institutions/policies do not permit use	1
Not transparent/other ethical opposition to contracts	1
Unclear/don't know/other	0

Variables: Joint Purchasing Mechanism	**Sum**
Suggested structure of joint purchasing mechanism	
Centralized, 3rd party, arms-length organization	4
One provinces takes the lead	2
Federal involvement/lead	2
Unclear/don't know/other	4
Potential benefits of a joint purchasing mechanism	
Administrative efficiency	2
Provincial equity in price	5
Provincial equity in access	5
Increased bargaining power (reduction in price/cost savings)	7
Increased access (can fund more drugs)	1
Unclear/don't know/other	1
Potential downsides of a joint purchasing mechanism	
Reduction in provincial autonomy	4
Savings may be lost for large provinces	2
Resource-intensive	2

Delay/length of process	5
Decreased access in some jurisdictions	1
Unclear/don't know/other	2
Obstacles to establishing a joint purchasing mechanism	
Resources (technical and administrative)	5
Bureaucratic will	1
Political will (provincial and/or federal)	6
Political acceptability of the decision (will no really mean no/will yes really mean yes)	4
Differences in budget constraints (affordability of listing decision differs)	3
Differences in the structure of provincial drug benefit programs (e.g., age-based vs. income-based)	5
Differences in institutions/policies/legislation governing listing decision	6
Differences in prescribing context (prescribers, patient populations etc)	3
Unclear/don't know/other	0

APPENDIX C: UNIVERSITY OF BRITISH COLUMBIA ETHICS CERTIFICATES

The University of British Columbia
Office of Research Services
Behavioural Research Ethics Board
Suite 102, 6190 Agronomy Road, Vancouver, B.C. V6T 1Z3

CERTIFICATE OF APPROVAL - MINIMAL RISK

PRINCIPAL INVESTIGATOR:	INSTITUTION / DEPARTMENT:	UBC BREB NUMBER:
Steven G. Morgan	UBC/Medicine, Faculty of/School of Population and Public Health/Centre for Health Services and Policy Research	H11-03390

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:

Institution	Site
UBC	Vancouver (excludes UBC Hospital)

CO-INVESTIGATOR(S):
Jamie Daw
Paige Thomson
Melissa Friesen

SPONSORING AGENCIES:
Canadian Institutes of Health Research (CIHR) - "CIHR/Health Canada team in policies for equitable access to medications"

PROJECT TITLE:
Negotiated contracts for funding pharmaceuticals: a national survey of Canadian public drug payers

CERTIFICATE EXPIRY DATE: January 9, 2013

DOCUMENTS INCLUDED IN THIS APPROVAL:		DATE APPROVED: January 9, 2012
Document Name	Version	Date
Protocol:		
Research Protocol	N/A	December 13, 2011
Consent Forms:		
Consent Form	N/A	December 13, 2011
Questionnaire, Questionnaire Cover Letter, Tests:		
Interview Schedule	N/A	December 14, 2011
Letter of Initial Contact:		
Contact Letter	N/A	December 13, 2011

The application for ethical review and the document(s) listed above have been reviewed and the procedures were found to be acceptable on ethical grounds for research involving human subjects.

This study has been approved either by the full Behavioural REB or by an authorized delegated reviewer

The University of British Columbia
Office of Research Services
Behavioural Research Ethics Board
Suite 102, 6190 Agronomy Road, Vancouver, B.C. V6T 1Z3

CERTIFICATE OF APPROVAL - MINIMAL RISK AMENDMENT

PRINCIPAL INVESTIGATOR:	DEPARTMENT:	UBC BREB NUMBER:
Steven G. Morgan	UBC/Medicine, Faculty of/School of Population and Public Health/Centre for Health Services and Policy Research	H11-03390

INSTITUTION(S) WHERE RESEARCH WILL BE CARRIED OUT:

Institution	Site
UBC	Vancouver (excludes UBC Hospital)

CO-INVESTIGATOR(S):
Jamie Daw
Paige Thomson
Melissa Friesen

SPONSORING AGENCIES:
Canadian Institutes of Health Research (CIHR) - "CIHR/Health Canada team in policies for equitable access to medications"

PROJECT TITLE:
Negotiated contracts for funding pharmaceuticals: a national survey of Canadian public drug payers

Expiry Date - Approval of an amendment does not change the expiry date on the current UBC BREB approval of this study. An application for renewal is required on or before: January 9, 2013

AMENDMENT(S):		AMENDMENT APPROVAL DATE: January 24, 2012
Document Name	Version	Date
Consent Forms:		
Consent Form	N/A	January 17, 2012
Letter of Initial Contact:		
Contact Letter	N/A	January 17, 2012

The amendment(s) and the document(s) listed above have been reviewed and the procedures were found to be acceptable on ethical grounds for research involving human subjects.

This study has been approved either by the full Behavioural REB or by an authorized delegated reviewer

APPENDIX E: KEY SUCCESS FACTORS

The following is a table from a paper (Neumann, et al., 2011, p. 2335) on health outcomes-based PLAs. The authors found that the use of health outcomes-based PLAs had associated challenges. Therefore, as part of their study of health outcomes-based PLAs (or "risk-sharing agreements"), they provided a table that outlines the key success factors for use, with a particular focus on breaking down the factors by stakeholder group.

A similar table could be developed by provincial policymakers, but regarding the types of PLAs most used by provinces (such as rebates, price discounts, price volume agreements, or utilization-based agreements). Such an exercise would encourage inter-provincial policy learning, information-sharing, and the potential for jointly developing best practices and guidelines for PLA use that fit within the Canadian context.

EXHIBIT 2

Key Success Factors For Risk-Sharing Agreements

Stakeholder	Factor
Manufacturers	Ability to measure outcomes in short time frame, with clear indicator (biomarker) Undeveloped evidence base, opportunity to gather real-world evidence Product with clinical advantage over lower-cost competitors Few comorbid conditions, limited size of target patient population Availability of multiyear clinical data (mid–life cycle rather than newly launched products) IT infrastructure to track and audit data and manage patient registries
Payers	IT infrastructure to track outcomes and switched patients, simple audit systems Clear payment or reimbursement mechanism (free initial therapy preferable to later rebates if outcomes are not reached) Unequivocal outcome measure (for example, valid biomarker) Clear outcome-reporting flow from physicians
Physicians	Objective outcomes measures (for example, MRI or biomarkers) Opportunity to standardize dosing requirements and minimize overuse through physician training Small patient population, few comorbid conditions, system to monitor adherence
Patients	Rapid enrollment process, simple data-release authorization Clear clinical advantage of product, lack of alternatives Participation in outcome reporting Opportunity to improve adherence

SOURCE Authors' analysis. **NOTES** IT is information technology. MRI is magnetic resonance imaging.

APPENDIX F: PRINCIPLES OF DESIGN

The following is an excerpt from a consensus statement (Menon, et al., 2010, pp. 109-111), the outcome of a 2009 meeting in Alberta of international experts in access with evidence development (a type of health outcome-based PLA). The Banff Summit produced this consensus document after the meeting, which included presentations by various country representatives, a review of findings from the literature on access with evidence development (AED), and open discussion on policy lessons and best practices.

Five principles of design for AED PLAs were identified:

- Principle 1: The design problem that the AED is designed to address should be clearly specified;
- Principle 2: The objective(s) of the AED should be stated;
- Principle 3: The objectives of the AED should inform the design of the study;
- Principle 4: The design of the AED should reflect the organizational characteristics and objectives of the healthcare system in which it operates; and
- Principle 5: The AEDs governance should ensure the independence of the scheme from any parties with a vested interest in its outcomes.