

**Managing Change:
A Canadian Policy Study of
Self-Monitoring Blood Glucose**

by

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Abstract

Self-monitoring of blood glucose has long been a cornerstone of daily diabetes management. Though the clinical benefit of this practice is undisputed for diabetics treated with insulin, evidence to support the benefit of regular blood glucose testing for diabetics not treated with insulin is lacking. Yet provincial drug benefit programs—including the Ontario Public Drug Programs—have seen their blood glucose test strip expenditures grow exponentially among this patient group as a result of inefficient use. Using a qualitative research methodology, this study examines the barriers and facilitators to implementing policies that promote optimal use of blood glucose test strips in Canada. My research findings inform the development of policy options for Ontario, which are evaluated against a set of criteria. I find that a staged implementation of policies would be the best approach. I recommend that Ontario proceed with a targeted, multifaceted knowledge transfer initiative, and in the long term, implement careful restriction of reimbursement for blood glucose test strips.

Keywords: self-monitoring of blood glucose; type 2 diabetes; optimal use; value for money; evidence-based health policy; disinvestment

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Table of Contents

Approval.....	ii
Partial Copyright Licence	iii
Abstract.....	iv
Acknowledgements	v
Table of Contents.....	vi
List of Tables.....	viii
List of Acronyms.....	ix
Glossary.....	x
Executive Summary	xi
1. Introduction	1
2. Background	3
2.1. Diabetes mellitus	3
2.1.1. Types of diabetes.....	3
2.1.2. Managing diabetes.....	4
2.2. The burden and costs of diabetes in Canada.....	5
2.3. Self-monitoring blood glucose	6
2.3.1. Current clinical practice.....	7
2.3.2. BGTS utilization and expenditures in Canada	8
2.3.3. CADTH's optimal therapy recommendations.....	9
2.3.4. The controversy	10
2.4. Why should governments act on this evidence?	11
3. Policy Problem, Goals, and Objectives.....	12
3.1. Policy Problem	12
3.2. Health Policy Goals	13
3.3. Policy Objective.....	14
3.4. Project scope specifications	14
4. Methodology	16
4.1. Literature Review	17
4.2. Jurisdictional Review	17
4.3. Formal Interviews	18
5. Research Findings	19
5.1. Optimization and disinvestment.....	19
5.2. Canadian Jurisdictional Review Findings.....	20
5.2.1. Summary of key findings.....	21
5.3. International Findings	25
5.4. Barriers and facilitators to implementing disinvestment decisions.....	25
Barriers	25
Facilitators	27
5.5. Implementation strategies to promote optimal use.....	28
6. Policy Options	31
6.1. Status Quo Plus: Promote Knowledge Transfer.....	31

6.2. Restrict Annual BGTS Reimbursement.....	32
6.3. Promote Knowledge Transfer and Restrict Annual BGTS Reimbursement Using a Phased Approach.....	33
6.4. Partial Reimbursement.....	33
7. Criteria and Measures	34
7.1. Effectiveness.....	35
7.2. Stakeholder Acceptability	36
7.3. Administrative Operability.....	36
8. Evaluation of Policy Options	38
8.1. Status Quo Plus: Promote Knowledge Transfer.....	39
8.1.1. Effectiveness.....	39
8.1.2. Stakeholder Acceptability.....	40
8.1.3. Administrative Operability	41
8.1.4. Additional Considerations	42
8.2. Restrict Annual BGTS Reimbursement.....	42
8.2.1. Effectiveness.....	42
8.2.2. Stakeholder Acceptability.....	43
8.2.3. Administrative Operability	44
8.2.4. Additional Considerations	45
8.3. Promote Knowledge Transfer and Restrict Annual BGTS Reimbursement Using a Phased Approach.....	46
8.3.1. Effectiveness.....	46
8.3.2. Stakeholder Acceptability	47
8.3.3. Administrative Operability	47
8.3.4. Additional Considerations	48
8.4. Partial Reimbursement.....	48
8.4.1. Effectiveness.....	48
8.4.2. Stakeholder Acceptability.....	49
8.4.3. Administrative Operability	50
8.4.4. Additional Considerations	50
9. Recommendations and Conclusions	52
10. Limitations and Future Research	54
References.....	55
Appendix. Canadian Jurisdictional Review.....	62
Alberta.....	62
British Columbia.....	63
Manitoba	65
New Brunswick.....	66
Newfoundland and Labrador	66
Nova Scotia.....	67
Ontario	68
Prince Edward Island	69
Saskatchewan.....	69

List of Tables

Table 1.	Summary of CADTH's optimal therapy recommendations.....	10
Table 2.	Provincial Blood Glucose Test Strip Coverage.....	21
Table 3.	Suggested annual BGTS allowances	32
Table 4.	Criteria and measures for policy options	34
Table 5.	Summary of policy analysis.....	38

List of Acronyms

A1C	Glycated haemoglobin, also known as HbA _{1c}
BGTS	Blood glucose test strips
CADTH	Canadian Agency for Drugs and Technologies in Health
CCDSS	Canadian Chronic Disease Surveillance System
CDA	Canadian Diabetes Association
CERC	COMPUS Expert Review Committee
COMPUS	Canadian Optimal Medication Prescribing and Utilization Service
EAP	Exceptional Access Program
HTA	Health technology assessment
HTAi	Health Technology Assessment International
KT	Knowledge transfer
ODB	Ontario Drug Benefit program
OPDP	Ontario Public Drug Programs
PHAC	Public Health Agency of Canada
QALY	Quality-adjusted life-year
SMBG	Self-monitoring blood glucose
T1D	Type 1 diabetes
T2D	Type 2 diabetes

Glossary

A1C test	A blood test used to diagnose diabetes and monitor glycemic control. Test results reflect average blood glucose levels over the past two to three months.
Academic detailing	Traditionally involves an individual, face-to-face meeting between a prescriber and a trained health professional, such as a pharmacist, to discuss evidence-based prescribing
Blood glucose test strip (BGTS)	A small, disposable plastic strip used in conjunction with a glucometer for the purpose of monitoring blood glucose levels
Café Scientifique	CADTH-led “town hall” events held in cities across Canada with the purpose of reaching and engaging health care professionals and the public
Disinvestment	The process of fully or partially withdrawing resources from existing health technologies that offer little or no value
Glucometer	A monitoring device that reads blood glucose levels
Glycated haemoglobin	Glycated haemoglobin – also known as A1C or HbA _{1c} – is a hemoglobin molecule bound with glucose. Glycated haemoglobin is an indicator of blood glucose levels.
Hyperglycemia	A state of higher than normal blood glucose levels
Hypoglycemia	A state of lower than normal blood glucose levels
Insulin	A hormone produced by cells in the pancreas that plays an important role in regulating blood glucose (i.e. sugar) levels
Knowledge transfer	The transfer of information from researchers to end-users
Quality-adjusted life-year (QALY)	A quality-adjusted life-year (QALY) is a measure of the value of health outcomes. It is commonly used to compare the clinical effectiveness of health technologies and interventions.
Self-monitoring of blood glucose (SMBG)	The process of drawing a small drop of blood by puncturing the skin—typically on the fingertip—using a lancet device. The small blood drop sample is then applied to a BGTS and inserted into a glucometer.

Executive Summary

Inefficient blood glucose test strip (BGTS) use among non-insulin-dependent diabetics is imposing undue costs on provincial drug benefit programs. Over time, these programs have seen their BGTS expenditures grow exponentially among this patient group as a result of overuse. This is especially true for the province of Ontario, where BGTS represented the third largest expenditure by the Ontario Public Drug Programs (OPDP) in 2008—equivalent to over \$100 million or 3.3% of total drug expenditures. Approximately 63% of test strip expenditures were attributable to diabetics not treated with insulin. In 2011/2012 total BGTS expenditures reached \$140 million in Ontario. The purpose of this study is to examine the barriers and facilitators to restricting reimbursement as a means of reducing inefficient test strip use in Canada. Research findings serve to inform policy recommendations for Ontario. Though Ontario is the focus of the study, the recommendations may have relevance to other provinces.

Health care professionals have consistently prescribed routine use of test strips for all diabetic patients, regardless of their course of therapy. This is reflected in clinical practice, which has long emphasized self-monitoring of blood glucose (SMBG) as a cornerstone of daily diabetes management. SMBG involves taking a blood drop sample, placing it on a disposable BGTS, and then inserting the strip into a monitoring device that reads blood glucose levels. The purpose of SMBG is to improve glycemic control by enabling patients and their care providers to adjust lifestyle factors and treatment according to glucometer readings. Though the clinical benefit of this practice is undisputed for diabetics treated with insulin, evidence to support the benefit of regular blood glucose testing for diabetics not treated with insulin is lacking.

Accordingly, the provincial drug program in Nova Scotia—known as Pharmacare—planned to restrict reimbursement among this patient group in 2010; however, major opposition led the government to reverse their decision. Their experience suggests that significant barriers need to be overcome before reimbursement policy can be changed. Up to the present time, the OPDP has not made any overt attempts to effect change in utilization patterns or restrict reimbursement. However, extensive background work on this issue—including consultation with the Ontario Citizens' Council—has been done.

Using a qualitative methodology, I examined the barriers and facilitators to restricting reimbursement—otherwise known as disinvesting—in BGTS. My review of international academic and grey literature, as well as formal interviews, revealed that resistance to change and political sensitivities pose significant barriers to restricting reimbursement. This information and the sources of data obtained through my jurisdictional review informed the development of policy options available to promote optimal use of BGTS. Through this research, knowledge transfer was identified as an important component in promoting efficient test strip use. Research findings also revealed that a staged implementation of policies would be the best course of action.

Thus, I recommend that the Ontario Ministry of Health and Long-Term Care implement a targeted, multifaceted knowledge transfer initiative in the short term. In the long term, the OPDP should impose a quantity limit on test strips for non-insulin-dependent patients. This solution will free up substantial funds to reinvest in more effective interventions.

Continuing to engage the public and patients generally on the issue of disinvestment will be crucial to ensuring legitimacy and trust. The Ontario Citizens' Council is a valuable mechanism for meaningfully engaging citizens in important issues around formulary decision-making. Given the implications of formulary decisions, the province should explore additional ways to involve its citizens. Continuing to ensure transparency in the process of disinvestment is equally important.

1. Introduction

Routine self-monitoring of blood glucose (SMBG) has long been a cornerstone of daily diabetes management. Though the clinical benefit of this practice is undisputed for diabetics treated with insulin, evidence to support the benefit of routine testing for diabetics not treated with insulin is lacking (Cameron, Coyle, Ur, and Klarenbach, 2010a; Canadian Agency for Drugs and Technologies in Health [CADTH], 2009a). Moreover, some research findings indicate that SMBG may possibly lead to anxiety (Peel, Douglas, and Lawton, 2007). Despite the lack of clear evidence and some suggestion of harm, most provincial drug benefit programs offer coverage for blood glucose test strips (BGTS)¹ to this sub-group of diabetics, though to varying extents (Cameron et al., 2010a; Cameron et al., 2010b).

Over the past decade, provincial governments have seen their expenditures on BGTS grow substantially. An Ontario-based study by Gomes et al. found that BGTS use among patients over the age of 65 increased by 250% between 1997 and 2008 (2010). By 2008, Ontario BGTS expenditures had reached over \$100 million, making it the third largest expenditure of the Ontario Public Drug Programs (OPDP)—equivalent to 3.3% of total drug expenditures (Gomes et al., 2010, p.35). Approximately 63% of these expenditures were attributable to diabetics not treated with insulin. In 2011/2012, total BGTS expenditures by the Ontario Drug Benefit² (ODB) program reached \$140 million in Ontario (personal communication, 03/21/13). Rising costs in Ontario are largely related to increases in utilization, not increases in the prevalence of diabetes (Ontario Citizens' Council, 2011). This suggests that physicians are prescribing SMBG more frequently (Ontario Citizens' Council, 2011).

¹ I will refer to blood glucose test strips as “BGTS” and “test strips” interchangeably throughout this report.

² The ODB program is a component of the OPDP.

Although many provinces have experienced similar growth in utilization and spending, none that offer coverage for BGTS have restricted reimbursement to date (Henshall, Schuller, and Mardhani-Bayne, 2012). In 2010, the provincial drug program in Nova Scotia, Pharmacare, planned to restrict reimbursement; however, major opposition led the government to reverse its decision (Woo, 2010). That experience suggests a need to overcome significant barriers before changing reimbursement policy.

Using a qualitative research methodology, this study explores the following questions: What are the barriers and facilitators to implementing such policies? What policy options are available to provinces to promote optimal use of blood glucose test strips? And based on evidence currently accessible through this research, which option would best fulfill health, operational, and financial considerations in Ontario?

The next section provides background information. The third section provides overview of the policy problem, goals, and objectives, as well as further project scope specification. In the subsequent section, I detail the methodology used to address my research questions. Following this, I present the findings from my research, which informs my analysis of the policy problem and policy options presented in subsequent sections. I then present recommendations for reform of policies relating to BGTS by the Ontario Public Drug Program and suggestions for further research.

2. Background

Diabetes is a complex, chronic illness that affects millions of Canadians. This section provides a synopsis of the disease and how it is managed. I describe the scope and expense of blood glucose test strip (BGTS) usage for the purpose of self-monitoring blood glucose (SMBG). Then I summarize the latest evidence and the controversy surrounding SMBG and explore why this new evidence should be put into practice.

2.1. Diabetes mellitus

Diabetes mellitus—more simply known as diabetes—is a chronic disease that affects the body’s ability to produce or use insulin (Public Health Agency of Canada [PHAC], 2011). Insulin, a hormone produced by cells in the pancreas, plays an important role in regulating blood glucose (i.e. sugar) levels. Insulin regulates blood glucose levels by enabling cells in the body to absorb glucose from the bloodstream for energy or to store it for later use. This function is vital because unregulated blood glucose levels can lead to serious health complications and, if left untreated, can lead to death (PHAC, 2011).

Unregulated blood glucose typically results in a condition called hyperglycemia, which is characterized by persistently high blood glucose levels. Hyperglycemia damages the blood vessels and nerves over time, and ultimately affects the functioning organs like the heart, eyes, and kidneys (PHAC, 2011). Properly managing diabetes is essential to the prevention of these health complications.

2.1.1. *Types of diabetes*

Diabetes is classified into three main types. These types differ primarily by cause and treatment; however, differences also exist in the diagnostic process. Type 1 diabetes (T1D) occurs when the body’s immune system kills the pancreatic cells that

produce insulin. T1D is therefore accepted as an autoimmune disease. Since the onset of T1D commonly occurs during childhood, it is also known as “juvenile diabetes”; however, onset can also occur during adult years (PHAC, 2011). Researchers believe that genetic and environmental risk factors contribute to the onset of T1D, but they have not yet developed a full understanding of how these factors interact (PHAC, 2011).

In contrast, type 2 diabetes (T2D) is understood as a metabolic disease; that is, it develops when the pancreatic cells do not produce sufficient insulin or when the body does not effectively use the insulin produced. T2D onset is gradual, thus it tends to be diagnosed during adulthood. Though less common, it can also affect children and youth. The cause of T2D is related to behavioural, environmental, and genetic factors. People who are “overweight or obese, physically inactive and of certain ethnic populations” are at a higher risk for developing T2D (PHAC, 2011, p. 8). The Public Health Agency of Canada (PHAC) estimates that 90 to 95% of people diagnosed with diabetes have T2D, whereas 5 to 10% are diagnosed with T1D (2011, p.8).

The third type of diabetes, gestational diabetes, is characterized by hyperglycemia that develops during pregnancy. In most cases, this condition will disappear once a woman has given birth; however, these women may be at a higher risk for developing T2D (PHAC, 2011).

2.1.2. *Managing diabetes*

Proper management of diabetes is essential to the prevention of health complications associated with hyperglycemia. For people living with T1D—who are fully dependent on insulin therapy—proper management of their illness is a matter of life and death. Accordingly, a significant component of managing diabetes is focused on controlling blood glucose levels. Typically, this involves a combination of drug therapy (e.g. insulin injections or oral medications), lifestyle modifications (i.e. proper nutrition, etc.), and self-monitoring blood glucose levels (CADTH, 2009c).

Drug therapy varies both within and between diabetes types. Though insulin therapy, in some form (e.g. via injection, insulin pump, etc.), is necessary for people with T1D, people with T2D have greater variation in treatment. In part, this variation is

related to the gradual onset of T2D; that is, it may take years before symptoms present themselves and a diagnosis is reached (PHAC, 2011). Thus, partly depending on the point at which T2D is diagnosed, drug therapy may consist of oral anti-diabetic drugs, insulin, or may not require drug treatment at all. People with T2D who are either using oral anti-diabetic drugs or are not using drug treatment to manage their diabetes are categorized as “non-insulin-treated type 2 diabetics”³ in the literature. In Section 2.3, I briefly discuss the implications of drug treatment on managing blood glucose levels.

2.2. The burden and costs of diabetes in Canada

Findings from the PHAC 2011 report on diabetes in Canada reveal that it is a major public health issue. Diabetes one of the most prevalent chronic diseases in the country, and the rising prevalence rates are worrisome. According to the PHAC’s report, which uses 2008/2009 data from the Canadian Chronic Disease Surveillance System (CCCSS), approximately 2.4 million Canadians were living with diabetes in 2008/2009. This represents 6.8% of the Canadian population aged one year and older, the majority of which consists of people living with T2D (PHAC, 2011, p.13). Given the positive relationship between age and risk for developing T2D, it is not surprising that prevalence is highest among the 75 to 79 year age group. Nevertheless, the majority of the Canadian population living with a diagnosis are between the ages of 25 and 64 (PHAC, 2011, p.15).

Diabetes prevalence varies across Canada. Age-standardized data indicate that Newfoundland and Labrador, Nova Scotia, and Ontario have the highest prevalence rates of diagnosed diabetes in the country (PHAC, 2011, p.16). In these provinces, diabetes prevalence is greater than 6%. In contrast, Nunavut, Alberta, and Quebec have the lowest prevalence rates at roughly 5% or less.

Different factors contribute to the prevalence of diabetes in each province. Generally speaking, increases in prevalence are related to patients living longer with

³ Throughout this report I will refer to “non-insulin-treated type 2 diabetics” as “patients not treated with insulin” or as “non-insulin-dependent,” implying type 2 diabetes.

disease and increases in the incidence of disease (Hux and Tang, 2003). In the early 2000's, Hux and Tang found that the increasing prevalence rates in Ontario were more attributable to diabetics living longer than to new diagnoses (2003). According to a more recent report by the Canadian Diabetes Association (CDA), the high rates of obesity and greater concentration of high-risk populations may be contributing to the high diabetes prevalence rates experienced in Ontario (2011b). Ontario is home to many ethnic subpopulations that face higher risk of developing T2D, including people of South-Asian, Aboriginal, Hispanic-American, Chinese, and African descent (Canadian Diabetes Association [CDA], 2011b; PHAC, 2011). Similar to national findings, Hux and Tang found that older adults account for the largest proportion of people living with diabetes (2003).

Using data from the PHAC's Economic Burden of Illness in Canada data, the direct and indirect costs⁴ of diabetes were estimated to total \$2.5 billion nationwide in 2000 (PHAC, 2011, p.47). More recent numbers from the CDA, however, estimate the total cost of diabetes in Ontario alone to be in the order of \$4.9 billion per year (2011b, p.1). Despite the uncertainty around the exact figures, the costs of diabetes are substantial.

2.3. Self-monitoring blood glucose

Self-monitoring blood glucose (SMBG) is a cornerstone of daily self-management, especially for patients using insulin who rely on these tests to prevent hypoglycemia⁵. SMBG involves drawing a small drop of blood by puncturing the skin—typically on the fingertip—using a lancet device. The blood drop sample is then applied to a small, disposable plastic test strip and inserted into a glucometer, a monitoring device that reads the blood glucose levels. The purpose of SMBG is to help ensure normal blood glucose levels by enabling patients and their care providers to adjust

⁴ Direct costs included hospitalization, physician visits, and medication associated with diabetes and its complications. Indirect costs included premature death, and morbidity and disability (PHAC, 2011, p.47).

⁵ Hypoglycemia occurs when blood glucose levels become lower than normal. Insulin and some oral anti-diabetic drugs can trigger hypoglycemia.

lifestyle factors, and change pharmacotherapy or alter dosages according to glucometer readings. Over the long term, proper glycemic control can help prevent health complications. Test strips fit an accompanying glucometer and cannot be used interchangeably with other brands or models.

2.3.1. Current clinical practice

For decades, clinical practice guidelines have emphasized SMBG as a component of patient education and routine care. Accordingly, SMBG has been widely recommended to the majority of diabetics (CADTH, 2009b). Health care providers typically teach patients how to monitor their glucose levels using a glucometer following a diagnosis and encourage frequent testing. In recent years, a trend has developed among health care providers in which SMBG is also prescribed to patients diagnosed with prediabetes⁶ (Ontario Citizens' Council, 2011). Physicians report adjusting therapy according to SMBG glucometer readings and reviewing results with patients; however, patients report that physicians rely more heavily on AC1 test⁷ readings than glucometer readings (CADTH, 2009b).

To gain insight into the recommendations of health care professionals for adults not treated with insulin, Latter et al. (2011) conducted interviews with a range of health care professionals involved in diabetes care including physicians, diabetes educators, and pharmacists. The researchers found that SMBG was generally perceived to be valuable for this patient population across providers, despite some variation in recommendations made within and between provider groups. Providers perceived SMBG to be an empowering tool that provides valuable information both to patients and providers. Participants in this study also indicated that they used SMBG glucometer readings as supplemental information in decision-making over therapy. The study established that these provider groups trust clinical practice guidelines as a source of information about SMBG (Latter et al., 2011). This information demonstrates that SMBG

⁶ Prediabetes is condition in which some diagnostic criteria for diabetes are met, but not all those required to diagnose diabetes (PHAC, 2011).

⁷ The AC1 test is a blood test used to diagnose diabetes and monitor glycemic control. Test results reflect average blood glucose levels over the past two to three months.

has been, up until very recently, the standard practice recommended for patients not treated with insulin.

2.3.2. BGTS utilization and expenditures in Canada

Test strip utilization and expenditures in Canada are substantial. The costs of BGTS are borne both by publicly funded drug programs and private drug plans. Glucometers, in contrast, are typically provided to diabetics for free by pharmaceutical companies. Total public and private drug plan expenditures on BGTS exceeded \$330 million⁸ in 2006 and \$500 million in 2010 (CADTH, 2009e, p.5; CADTH, 2012d, p.1). The data indicate that nearly 60% of total spending on BGTS is accounted for by patients not treated with insulin (CADTH, 2009e, p.5; CADTH, 2012d, p.1). In 2006, total public expenditures in Canada on BGTS amounted to \$247 million (Cameron et al., 2010b, p.34).

Provincial drug program expenditures for BGTS vary across the country. In part, this variation is attributable to the differences in coverage offered through provincial drug programs, as well as the average price paid per test strip. Cameron et al. found that the average cost of BGTS across the country ranged from 72 cents to 89 cents per strip (2010b). In 2006, expenditures for BGTS ranged from \$5.7 million in Newfoundland and Labrador to \$109.3 million in Ontario (Cameron et al., 2010b, p.36). For many provinces, BGTS rank in the top five classes of drug expenditures (Cameron et al., 2010b). For example, BGTS represented the third largest expenditure of the Ontario Public Drug Programs in 2008, or 3.3% of total drug expenditures (Gomes et al., 2010, p.35).

Provinces have experienced an increase in BGTS expenditures as a result of increases in utilization. A study by Gomes et al. (2010, p.37) found that BGTS use among patients over the age of 65 increased by 250% between 1997 and 2008 in Ontario. Increases in test strip use were observed across therapy groups. Though patients using insulin claimed roughly twice as many test strips on average in 2008 (2.08

⁸ This value was estimated using the Brogan Inc. drug claims database. It is a conservative estimate because not all public and private drug plan data is submitted to Brogan.

strips per day), patients not using insulin accounted for 63% of total test strip use (0.75 to 1.16 strips per day) (Gomes et al., 2010, p.36-37).

2.3.3. CADTH's optimal therapy recommendations

In 2009, the COMPUS⁹ Expert Review Committee (CERC) at the Canadian Agency for Drugs and Technologies in Health (CADTH)¹⁰ published their “optimal therapy” recommendations for SMBG. Uncertainty around what constitutes the optimal daily frequency of SMBG—particularly for patients with T2D—prompted their systematic review and meta-analysis of international clinical studies and cost-effectiveness evidence. CERC’s main findings were that SMBG is associated with only modest improvement (-0.25%) in glycemic control among patients not using insulin (CADTH, 2009f, p.17).

The committee could not conclude with certainty that SMBG offers long-term benefits in terms of improved quality of life, health complications, or mortality, as the evidence was sparse and inconsistent. Thus, routine SMBG was deemed to be an inefficient use of health care resources for patients not using insulin. The incremental cost of a patient testing nine times per week—the reference case—was estimated to be \$113,643 per QALY¹¹ gained, relative to no testing (CADTH, 2009a, p.16). In comparison, testing four times per week carried a cost of \$46,445 per QALY gained and testing once per week cost \$6,322 per QALY gained (CADTH, 2009a, p.20). CERC found that periodic testing may be cost-effective and efficient, and noted that reducing the price per test strip would improve cost-effectiveness; for example, in order to reduce costs per QALY to \$31,101 per QALY for patients using nine test strips per week, costs per test strip would have to be reduced by 75% (CADTH, 2009a, p.20).

⁹ The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) is a program at CADTH, funded by Health Canada.

¹⁰ CADTH—a not-for-profit organization that is jointly funded by the federal, provincial, and territorial governments—conducts health technology assessments. It provides government decision-makers with evidence, analysis, and recommendations around medical devices and drugs.

¹¹ A quality-adjusted life-year (QALY) is a measure of the value of health outcomes. It is commonly used to compare the clinical effectiveness of health technologies and interventions.

CERC's recommendations were classified by diabetes type and course of treatment. The recommendations are summarized in Table 1.

Table 1. Summary of CADTH's optimal therapy recommendations

Therapy Group	Optimal Daily Frequency of SMBG
Adults and children with T1D	Individualized
Adults with T2D <i>using insulin</i> with or without oral anti-diabetic drugs	Individualized with a maximum frequency of 14 test strips per week
Adults with T2D using anti-diabetic drugs (<i>without insulin</i>) or no anti-diabetic drugs	Routine use of BGTS not recommended Periodic testing for select patients
Women with gestational diabetes not using anti-diabetic drugs	Individualized

These recommendations are contrary to current clinical practice; in particular, the advice for patients not using insulin is markedly different. CERC recommends that most adults treated with anti-diabetic drugs do not require routine SMBG. However, the committee notes that select patients may need periodic testing. Patients may require temporary testing under the following conditions: (1) unstable glucose levels; (2) acute illness; (3) changes to drug therapy; (4) risk of hypoglycemia; (5) pregnancy; and (6) jobs where hypoglycemia poses danger (CADTH, 2009d). Under these conditions, CERC advises that periodic testing should be linked to activities such as preventing hypoglycemia or adjusting drug dosage. Most adults controlling their diabetes only through their diet should not require routine SMBG, though women who are pregnant or considering pregnancy may benefit from periodic testing (CADTH, 2009d).

2.3.4. The controversy

CADTH's 2009 optimal therapy recommendations for SMBG received significant pushback from the diabetic community. In 2010, the CDA publicly opposed Nova Scotia's decision to restrict BGTS reimbursement based on CADTH optimal therapy recommendations, and that decision was subsequently reversed. Pushback was largely related to the fact that CADTH's recommendations are contrary to the clinical practice paradigm. A common criticism was that cost-effectiveness was weighted too heavily compared to clinical effectiveness in CADTH's optimal therapy recommendations. However, cost-effectiveness calculations are based on clinical effectiveness and cost.

Another common criticism was the need for more well-designed clinical trials. While the CDA recently changed their position on SMBG to be more in line with CADTH's, the CDA disagrees with the framing of SMBG as an intervention (Miller et al., 2011). The CDA believes that SMBG should be viewed as a tool to inform interventions. The fact remains, however, that SMBG is an expensive tool and patients not using insulin—especially those controlling their diabetes through diet only—are limited in their ability to use the information provided by the tool. The barriers to change are further explored in the findings section of this paper.

2.4. Why should governments act on this evidence?

The opportunity cost of the status quo is high. One study estimated that “if reimbursement policies do not change, the Ontario public drug plan will spend roughly \$500 million dollars over the next 5 years on SMBG test strips for patients ≥ 65 years of age” (Shah, Gomes, Juurlink, Paterson, and Mamdani, 2010, p.180). Substantial expenditures can similarly be expected in other jurisdictions. This could result in “policy steal”; that is, resources available for effective interventions are displaced by the costs of inefficient SMBG usage (Johnson et al., 2006, p.1250).

Of course, it is not always wise to act on the recommendations of a single study. In a discussion about what research messages should be transmitted to decision-makers, Lavis et al. (2003, p.223) rightly note, “not all research can or should have an impact.” The hierarchy of evidence is an important consideration in terms of what research is incorporated into decision-making. Yet, despite the need for more well-designed clinical trials, CERC’s systematic review and meta-analysis findings are the best available evidence. In addition, a recent Cochrane Collaboration review of the effects of SMBG in patients with type 2 diabetes mellitus who are not using insulin arrived at similar findings (Malanda, Welschen, Riphagen, Dekker, Nijpels, and Bot, 2012). The evidence suggests that more highly cost-effective interventions should be funded to improve this population’s health. Given the cost-ineffectiveness of routine SMBG for non-insulin treated diabetics, CADTH’s optimal therapy recommendations should inform the development of a policy strategy to address BGTS overuse in this patient group.

3. Policy Problem, Goals, and Objectives

In this section, I delineate the scope of my research project. I describe the policy problem and provide a justification for examining the problem from the perspective of the province of Ontario. The policy goal and objective are identified, and additional project scope specifications are noted.

3.1. Policy Problem

Despite lack of clear evidence and some suggestion of harm, self-monitoring of blood glucose (SMBG) continues to be a cornerstone of daily diabetes management for diabetics not treated with insulin. Health care providers still recommend SMBG because they perceive it to be beneficial to their patients and informative when making treatment adjustments (Latter et al., 2011). Furthermore, the 2008¹² Canadian Diabetes Association (CDA) clinical practice guidelines, which health care providers trust and have used to inform their recommendations to patients, advocate for SMBG (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, 2008; Latter et al., 2011). The 2008 CDA clinical practice guidelines affirm that SMBG is an essential element of self-management education and that it is beneficial to patients recently diagnosed, regardless of treatment with insulin. These guidelines note the limitations of the evidence, but suggest that most people can benefit from SMBG and recommend that frequency of testing be individualized (CDA Clinical Practice Guidelines Expert Committee, 2008; Miller et al., 2011). This information demonstrates significant practice and knowledge gaps regarding SMBG.

¹² The CDA's latest clinical practice guidelines were released in April 2013. Some discussion about these latest guidelines has been incorporated in Section 8.2.2 of this report.

Not surprisingly, the recommendations of health care providers are a major driver of BGTS utilization. In some provinces, health care providers act as a gateway to access BGTS coverage. With this in mind and given the fact that most provincial drug benefit programs offer some coverage for blood glucose test strips (BGTS) to diabetics not using insulin, the primary policy issue is defined as follows: Many diabetics not treated with insulin are using blood glucose test strips inefficiently, which is imposing *undue costs* on provincial drug benefit plans.

Given the differences in drug program structures across the provinces, I examine this policy problem from the perspective of Ontario. This focus of the report allows for more meaningful final recommendations. Ontario was selected because of the accessibility of information regarding test strip use and for contextual reasons, including their experience with substantial growth in BGTS expenditures. Additionally, up to the present time, the Ontario Public Drugs Program has not made any overt attempts to effect change in utilization patterns or restrict reimbursement. Extensive background work on the issue—including public consultation with the Ontario Citizens' Council—has been done (Ontario Citizens' Council, 2011; personal communication, 09/24/12). This framing of the issue shapes the analysis and recommendations presented in subsequent sections.

3.2. Health Policy Goals

Several overarching health policy goals apply to the policy problem defined above. One central goal is to ensure value for money; that is, to promote economy, efficiency, and effectiveness (Jackson, 2012). Given health care resource constraints, consideration for “what care is effective, for whom, and under what circumstances; and finding out whether that care actually has the desired effects” is of critical importance (Health Council of Canada, 2009, p.7). These considerations are central to the sustainability of the health care system. The proposed policy options aim to uphold these central goals.

3.3. Policy Objective

In order to achieve the policy goal of ensuring value for money, the following objective was established: to promote optimal use of BGTS among diabetics not using insulin, as defined¹³ by the CADTH. Though CADTH found that optimal use may vary between individuals depending on their health status, BGTS utilization data suggests that patients not treated with insulin should be reducing the frequency of SMBG. The policy objective can thus be further refined as reducing inefficient BGTS use.

3.4. Project scope specifications

Another way to achieve the policy goal of ensuring value for money may be to lower the price provinces pay for test strips. Researchers have noted that cost-effectiveness estimates are highly sensitive to changes in price. Cameron et al. undertook a sensitivity analysis in which they tested the effects of a 25%, 50%, and 75% price reduction in BGTS (2010a). Price reductions greater than 50% (equivalent to \$0.35 or less per test strip) increase the likelihood that regular SMBG among non-insulin treated diabetics is cost-effective (Cameron et al., 2010a).

While a tendering process or price negotiations with pharmaceutical companies may help achieve value for money, the feasibility of these options is unclear. Ontario appears to already pay the lowest average price per test strip in the country (Cameron et al., 2010b). A collaborative negotiation process involving the provinces and pharmaceutical companies could help achieve price reductions. For the very first time, the provinces recently announced that they will be jointly purchasing a selection of generic drugs (Gagnon, 2012). Examining these policy options is outside the scope of this project, as substantial barriers exist in accessing information related to such price negotiations.

Additionally, the scope of this project is focused on achieving reductions in inefficient test strip use by way of restricting reimbursement. While other policy levers

¹³ CADTH's optimal use recommendations are summarized in the background section of this paper.

could be used to encourage a reduction in inefficient test strip use, restricting reimbursement is the most direct mechanism and is an option available to all provincial government drug programs. As restricting reimbursement would inherently overcome the need to address other cost levers—such as negotiating lower test strip prices—and could achieve the most immediate cost savings, I chose to focus my research on restricting reimbursement.

4. Methodology

To answer the research questions outlined at the beginning of the study, I used a qualitative research methodology. A literature review and jurisdictional review serve as my primary methodologies. The abundance of literature and relevance of the policy issue led me to select these methodologies. My secondary methodology—formal interviews with key informants—supplement this research. Accordingly, the two sources of data used in this study are: (1) international academic and grey literature; and (2) semi-structured interviews with key informants. The study was approved by Simon Fraser University's Office of Research Ethics.

As a starting point, I conducted twelve informal scoping interviews with professionals who are knowledgeable about the policy issue. The purpose of the scoping interviews was to gain insight into the academic work on the topic and to identify sources of grey literature, rather than to solicit opinions. Scoping interviews also helped identify Canadian provinces that have implemented policies to promote optimal use of BGTS and potential key informants for formal interviews. Using a snowball sampling methodology, I conducted scoping interviews with provincial government administrators, employees of not-for-profit agencies, and leading health researchers from universities across Canada. They were interviewed in their professional capacity and were asked to provide references to publicly available information. Scoping interviews were conducted via e-mail, telephone, or in person, depending on the location and preference of the interviewee.

I also attended conference sessions¹⁴ relevant to SMBG at the 15th Annual CDA Conference in Vancouver, BC. This provided additional insight into academic and grey literature sources and helped identify Canadian provinces for the jurisdictional review.

4.1. Literature Review

To inform the development of policy options and evaluation criteria, I reviewed international academic and grey literature. After identifying key literature sources through scoping interviews and CDA conference sessions, I completed a literature review. Bibliographical searches guided my search for additional academic and grey literature. Academic literature was obtained through online databases and journals¹⁵ accessible via the SFU library and Google Scholar. Grey literature was obtained through Google searches, as well as directly from provincial Ministry of Health websites and the websites of organizations such as: the Canadian Agency for Drugs and Technologies in Health (CADTH); Health Technology Assessment International (HTAi); and the Canadian Diabetes Association (CDA). The literature sources used in this study were limited to English language publications and information available in the public domain. The review also helped identify barriers and facilitators to optimal use policies and informed the development of thematic areas for the analysis of key informant interviews.

4.2. Jurisdictional Review

Since CADTH's optimal therapy recommendations for SMBG are topical, I sought to identify provincial policies that have been implemented in Canada since 2009 by conducting a jurisdictional review. I chose 2009 as the year CADTH's optimal therapy recommendations were published. The interviews and CDA conference sessions helped

¹⁴ I attended a CDA conference session entitled "Self-monitoring of Blood Glucose: Monitoring with Meaning" among others relevant to my study.

¹⁵ Examples of databases and journals consulted included, but were not limited to the following: PubMed and Ovid Medline, as well as the *International Journal of Technology Assessment in Health Care* and *Diabetes Care*.

identify Canadian provinces that have implemented policies to promote optimal use of BGTS and thereby focused the scope of my search efforts. Grey literature was the main source of information included in the jurisdictional review. I searched provincial Ministry of Health websites, as well as the websites of organizations previously mentioned, for information about SMBG reimbursement policies and relevant policy initiatives.

4.3. Formal Interviews

To verify information obtained in the jurisdictional review and to fill gaps in the jurisdictional and literature reviews, I conducted formal, semi-structured interviews. These interviews also served to gain insight into the facilitators and barriers to implementing optimal use policies. A semi-structured interview guide was used to direct discussion. Using snowball sampling methodology, three key informants were recruited to participate in this study. Participants were recruited via e-mail, and interviews were conducted by telephone. Participants included one provincial government policy-maker in Nova Scotia and one in Alberta, as well as a health researcher at a Canadian university. Interviews were recorded, and key facts and themes were transcribed. A thematic analysis of interview findings served to identify patterns in barriers and facilitators. Key themes from the literature served as a basis for grouping themes identified in the interviews. To protect the anonymity of participants, their names are not used in this report.

5. Research Findings

Through my review of the literature, jurisdictional review, and formal interviews, I identify: (1) barriers and facilitators to promoting optimal use of BGTS; and (2) options available to governments in order to promote optimal use of BGTS. This section provides a synthesis of my research findings. Insights from formal interviews are integrated with my findings from the literature.

5.1. Optimization and disinvestment

Financial constraints and pressures on health systems are leading governments to rely increasingly on health technology assessment¹⁶ (HTA) for the evidence needed to support optimal funding decisions. Within the context of existing health technologies,¹⁷ “optimization” refers to improving access to technologies that are proven “effective, safe, and [offer] worth-while benefit” and minimizing the use of technologies that offer little or no value (Henshall et al., 2012, p.1; Porter, 2010). Disinvestment is the process of withdrawing resources from existing health technologies that offer little or no value, thus minimizing their use (Elshaug, Watt, Moss, and Hiller, 2009). Governments can approach disinvestment a number of ways; these strategies are discussed in Section 5.5.

Elshaug et al. (2009) clarify widespread misconceptions about disinvestment. Notably, disinvestment does not imply full withdrawal of a technology. Some patients may benefit more from a given drug than others, for example, because of their genetics or the characteristics of their medical condition. In such cases, governments will seek to optimize; that is, promote use among patients who benefit and discourage use among

¹⁶ Health technology assessment (HTA) is the systematic evaluation of a health technology or intervention in terms of clinical and cost-effectiveness.

¹⁷ The term “health technologies” refers to drugs, medical devices, and medical procedures.

those who do not benefit. Under such circumstances, partially withdrawing resources may be more appropriate for optimization. Another common misconception is that disinvestment implies a reduction in health care funding. The authors contend that disinvestment potentially entails a reallocation rather than a reduction of total resources. Disinvestment creates opportunities for investment in health technologies that offer better value for money. Elshaug et al. also draw an important distinction between disinvestment and rationing (2009). Whereas rationing entails withholding a beneficial technology for the purpose of preserving scarce resources, disinvestment restricts the use of inefficient technologies for the purpose of reallocation.

The best available evidence indicates that insulin-dependent patients benefit from routine SMBG, but it confers little clinical benefit to non-insulin-dependent patients. CADTH's optimal therapy recommendations for SMBG therefore exemplify a clear case for *optimization*; CADTH does not recommend withholding test strips from those who benefit, but instead offers evidence that routine SMBG for most non-insulin-dependent patients is inefficient. The gap between clinical practice and CADTH's recommendations suggests a need for disinvestment. This framing of the issue guided my search for barriers and facilitators to promoting optimal use as well as uncovering potential policy options.

5.2. Canadian Jurisdictional Review Findings

Here I provide a summary of my Canadian jurisdictional review findings. The purpose of the review was to identify provincial policies that have been implemented in Canada since the publication of CADTH's Optimal Therapy Report in 2009. I adopted a broad conception of the term "policy," thus the initiatives noted here are not limited to reimbursement levers. While government initiatives were the focus of the jurisdictional review, non-governmental initiatives were noted if identified. The following provinces were included in my review: Alberta, British Columbia (BC), Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Prince Edward Island (PEI), and Saskatchewan. Information obtained through scoping interviews and conference sessions identified these provinces as ones that have endeavoured to reduce inefficient BGTS use based on CADTH's optimal therapy recommendations. While scoping

interviews identified these jurisdictions as ones with relevant initiatives, detailed information about these initiatives was not always publicly available. For full provincial profiles, see the Appendix.

Table 2. Provincial Blood Glucose Test Strip Coverage

	Beneficiary Group			
	Social assistance recipients	Seniors	General (non-senior) population	Additional specifications
Alberta	✓	✓	✓	
British Columbia	✓	✓	✓	Must have a Certificate of Training from an approved Diabetes Education Centre.
Manitoba	✓	✓	✓	Cap of 4,000 strips per year. Over that amount, must apply using Part 3 Exception Drug Status.
New Brunswick	✓	✗	✗	Must qualify for health card for prescription drugs and have a request form completed by a physician, nurse practitioner, or Certified Diabetes Educator.
Newfoundland and Labrador	✓	✓	✓	Cap of 2,500 strips per year. Over that amount, requires special authorization.
Nova Scotia	✓	✓	✓	
Ontario	✓	✓	✓	Must have a prescription from a physician.
Prince Edward Island	✓	✓	✓	Must be registered with the Diabetes Control Program and be using insulin to be eligible for 100 strips every 30 days.
Saskatchewan	✓	✓	✓	

Source: Adapted from 2011 CDA Provincial/Territorial Financial Coverage Charts. Coverage may be conditional on income, age, or other provisions. To the extent possible, this information was verified with government officials.

5.2.1. Summary of key findings

Nearly all provinces offer some form of BGTS coverage to social assistance recipients, seniors, and the general (non-senior) population. A variety of strips are available across the provinces, most of which cost approximately 70 cents per strip. Some programs, including the program in Ontario, require that patients obtain a prescription from a physician to qualify for reimbursement. Patients in BC are referred by physicians to Diabetes Education Centres and required to obtain a Certificate of

Training to be eligible for coverage. In several provinces, once a patient qualifies for reimbursement, test strip eligibility is indefinite. However, coverage is not unlimited in all provinces. For example, Manitoba's program has a cap of 4,000 tests strips per year, which is equivalent to nearly 11 test strips per day; patients who require more must apply under their Exception Drug Status program. In Ontario, on the other hand, patients can obtain coverage for any amount prescribed by a physician.

With the exception of PEI and New Brunswick, none of the provinces that currently offer coverage restrict access to test strips by diabetes therapy type (i.e. insulin versus no insulin). PEI is a unique case in that prior to 2008 the province did not offer BGTS coverage. Test strip coverage has since been made available through their public drug program, but only to patients who have used insulin 150 days prior to submitting a claim. New Brunswick recently expanded test coverage to include non-insulin-dependent patients, applying annual restrictions that differ by therapy type. These reimbursement decisions were informed by CADTH's optimal therapy recommendations. These are not cases of disinvestment. Alberta technically poses a restriction on test strips in one of their five programs by offering a lower maximum annual coverage on diabetic supplies to non-insulin-dependent patients.

In spite of the evidence and the potential for significant savings, the provinces have been cautious in their approach to reducing inefficient BGTS use. To date, only Nova Scotia has attempted to reduce inefficient use by restricting the quantity of test strips accessible through their programs. Most other provincial initiatives consist exclusively of knowledge transfer to health care professionals, especially physicians, and patients. Knowledge transfer (KT) is the "one-way flow of knowledge" from researchers to end-users (Johnson, 2005). The intent of these initiatives is to reduce inefficient use of test strips by changing the understanding and practice of SMBG. With the exception of Manitoba, all of the provinces examined in this review were host to CADTH's Café Scientifique SMBG events—informal, "town hall" sessions in which experts and the public engage in discussion—early in 2010. These events can be considered a form of KT.

In February 2010, Nova Scotia was the first province to attempt reducing inefficient BGTS use. Their quantity limit on test strips for non-insulin-dependent

patients was met with significant opposition. Though they had started some educational initiatives at the time and planned for academic detailing¹⁸ on the topic of SMBG, these initiatives had not been in place long enough to take effect. Academic detailing is a form of KT, which involves individual, face-to-face meetings between a prescriber (typically a physician) and a trained health professional with clinical expertise to discuss evidence-based prescribing. Nova Scotia had developed an academic detailing program in order to influence prescribing practices. Proceeding too hastily with reimbursement restrictions worked to their disadvantage and resulted in a reversal of the decision. Currently, Nova Scotia has numerous educational resources available to patients and health care providers, as well as a decision-making tool to aid with prescribing. An academic detailing program is also in place. The Deputy Minister of Nova Scotia's Department of Health and Wellness has stated that the Department is considering BGTS restrictions again, though no official announcements have been made confirming such plans (Standing Committee on Public Accounts, 2011).

In July 2010, BC began KT initiatives to reduce inefficient test strip use. Though the province has not included SMBG as a topic in their academic detailing program, it has reached out to health care providers through the health authorities and research organizations. The province developed an information campaign called "Test with Purpose" to reach patients and health care providers. BC has also modified the provincial diabetes care clinical guidelines to include CADTH's recommendations. BC has not explicitly communicated any intention to restrict reimbursement for BGTS.

BC and Nova Scotia have taken the most comprehensive and multifaceted approach to KT. In contrast, Manitoba and Saskatchewan have opted for KT initiatives targeted at patients and health care practitioners in long-term care facilities. New Brunswick has incorporated CADTH's recommendations in their provincial diabetes strategies and recent test strip expansion¹⁹, which came into effect on April 1, 2013. Newfoundland and Labrador is working to incorporate CADTH's recommendations in

¹⁸ This type of knowledge transfer is discussed in greater detail in Section 5.5 of this report.

¹⁹ As I noted earlier, test strips were previously available to insulin dependent patients, but not non-insulin-dependent patients. The program expansion was informed by CADTH's report.

their provincial diabetes strategy. Very little publicly available information on these initiatives is accessible online.

Up to the present time, the Ontario Public Drugs Program has not made any overt attempts to effect change in utilization patterns or restrict reimbursement. Extensive background work on the issue—including public consultation with the Ontario Citizens' Council on managing of the drug formulary—has been done (Ontario Citizens' Council, 2011; personal communication, 09/24/12). The Council reviewed three case studies, including SMBG, in order offer advice on when the Executive Officer should consider delisting or restricting access to products on the formulary. In their report, members of the Ontario Citizens' Council stated that SMBG “can provide a sense of empowerment for the patient, and agreed that it is crucial to keep them on the Formulary while at the same time finding ways to appropriately limit their use” (2011, p.10). The Council stressed the importance of transparency in plans to delist or restrict access and recommended that these decisions “must be preceded by an appropriate notice period and adequate education of health professionals, patients and the general public” (2011, p.2). Though this report was published in 2011, it represents the most up-to-date, publicly available information on the current state of affairs in Ontario.

Given the recentness of these provincial initiatives, impact evaluation studies are only just beginning. Preliminary findings in BC and Nova Scotia indicate a downward trend in test strip usage. For example, NS has observed a “downward trend” in use since the beginning of their KT initiatives in 2010, as well as a 4% decline in total use since the release of the CADTH report; the nature of this evaluation to date has been a comparison of pre- and post-implementation expenditures (Interview, Participant 1; SECOR-KPMG, 2012, p. 43). In the coming years, ascertaining that downward trends are attributable to provincial KT programs may be challenging, because ongoing impact evaluation is costly.

The trend in provincial SMBG initiatives suggests that KT is an important component in promoting efficient test strip use. Furthermore, it suggests that KT should begin at an early stage and that reimbursement restrictions are unlikely to be successfully implemented as a first tactic. The literature supports these findings.

Ontario can learn from the KT initiatives undertaken in other provinces and adapt them to the local setting.

5.3. International Findings

A study by the SMBG International Working Group identified that national clinical guidelines across 14 countries recommend routine testing for patients not using insulin (2008). The Working Group found widespread SMBG usage among patients not using insulin, which suggests that physicians and patients support the practice. Nevertheless, several countries, including the UK, Sweden, and the Netherlands have come to similar conclusions as CADTH (Ur, 2011).

Indeed, some health departments abroad have restricted reimbursement. For example, test strips are fully reimbursed for patients using insulin in the Netherlands, but partially reimbursed for some patients not using insulin (SMBG International Working Group, 2008, p. e17). This is also true of the US Veterans Health Administration and Department of Defense (VHA/DoD), where test strip reimbursement was restricted prior to 2006 (Patel, Kharlamb, Reiter, and Lovly, 2008). The transferability of the American VHA/DoD experience is limited because prescribers are less autonomous than they are in Canada; effecting change in prescribing practices is thus more straightforward for the VHA/DoD.

These findings indicate that other countries have come to similar conclusions about optimal BGTS therapy, and some have taken steps to restrict reimbursement. This discovery strengthens the argument for developing a policy strategy to address BGTS overuse that is in accordance with CADTH's recommendations.

5.4. Barriers and facilitators to implementing disinvestment decisions

Barriers

Prompted by CADTH's optimal therapy recommendations, the Government of Nova Scotia announced plans to restrict BGTS reimbursement for non-insulin-dependent

patients in February 2010. The policy change was to impose a limit of 100 test strips per year for non-insulin-dependent patients. Concurrently, the Drug Evaluation Alliance of Nova Scotia (DEANS)²⁰ began to implement educational strategies to influence changes in prescribing and best practices among health professionals. Educational tools, including a decision-making tool for health care providers, and academic detailing were based on CADTH's SMBG recommendations. These strategies were not in place long enough to take effect, however. Soon after the policy plans were announced, the government reversed the decision because of strong pushback from the public, the CDA, and pharmaceutical companies (Interview, Participant 1; Standing Committee on Public Accounts, 2011; Woo, 2010). This experience indicates the substantial barriers to disinvestment.

Resistance to change is a key theme in the literature. Loss aversion is one manifestation of resistance to change and poses a significant barrier to disinvestment. Within this context, loss aversion is the tendency for people to perceive greater loss when access to existing health technologies is restricted compared to being denied access to something new (Henshall et al., 2012). Disinvestment decisions are often met with opposition because patients tend to develop a “sense of entitlement” to existing technologies (Henshall et al., 2012). Similarly, established clinical training and practice paradigms may entrench the use of a technology among health care professionals (Elshaug et al., 2009). This challenge has been classified as one relating to “professional and system inertia” (Henshall et al., 2012, p.3). Another related hurdle is the high degree of evidence about the absence of benefit demanded by stakeholders (Henshall et al., 2012). The standard of proof requested of governments has been likened to the standards of law—that is, “beyond reasonable doubt” (Elshaug et al., 2009, p.10).

Additionally, misconceptions about the implications of disinvestment previously described may also be a factor in stakeholder resistance. Those who benefit from a given health technology may misinterpret a complete disinvestment for that technology. But, in most cases, disinvestment does not mean a full withdrawal of resources from an

²⁰ The Drug Evaluation Alliance of Nova Scotia (DEANS) is a partnership between the Department of health and the University of Dalhousie College of Pharmacy and Continuing Medical Education.

existing health technology, rather partial withdrawal with remaining investments targeted to those who benefit (National Health Committee, 2012). In view of these barriers, it is not surprising that disinvestment poses substantial political challenges.

The experience in Nova Scotia corroborates the barriers to disinvestment identified in the literature. As one interviewee noted, CADTH's recommendations constitute a major change in practice for patients, not just physicians:

Some [people] have had diabetes for 20, 30 years and they've been told, 'You need to test, need to test, need to test,' and then suddenly somebody tells them, 'You don't need to test anymore.' It's a big change management issue. (Interview, Participant 1)

The reversal of the policy decision in Nova Scotia—following strong lobbying efforts by the CDA and pharmaceutical companies—clearly demonstrates that the issue was politically controversial. Political sensitivities and interests are major obstacles to disinvestment (Elshaug et al., 2009). Overcoming these barriers is possible, and the literature identifies facilitators that can help decision-makers successfully implement optimization and disinvestment decisions.

Facilitators

Stakeholder groups may hold strong views about access to health technologies. Actively involving stakeholders throughout the process of optimization decisions is thus crucial to successful implementation (Henshall et al., 2012; National Health Committee, 2012). Engaging stakeholders at an early stage can moderate concerns. This is especially true for patients and the public when the process is open and transparent. Furthermore, the public “can more readily accept disinvestment decisions or even become an ally” if they are actively engaged (Henshall et al., 2012, p.3). Similarly, consultation with health care providers is needed. Health care providers are inevitably partners in implementing optimization decisions and their support is vital (Henshall et al., 2012; National Health Committee, 2012). Indeed, British Columbia's experience with a multifaceted KT campaign aimed at patients and health care providers suggests that collaboration with stakeholders is the key to success (personal communication, 10/11/12).

Another facilitator to disinvestment is political support. Elshaug et al. assert that “success is dependent on politicians willing to lead from the front” (2009, p.10). In part, political readiness is a function of the extent to which stakeholders accept disinvestment decisions. With strategies in place to address pushback and lobbying, governments are better positioned for disinvestment. Politicians may also be more likely to take on disinvestment if communications strategies are in place. Furthermore, politicians may be more likely to disinvest if they have a strong evidence base to support the decision. As noted by one participant, it can take years to build a strong evidence base and for government to feel comfortable changing their policy or “stand on the evidence” in the face of political pushback (Interview, Participant 2).

To date, none of the provincial governments examined in this study have restricted coverage for test strips. Accordingly, there are no proven or tested facilitators to draw upon from the experiences of the provinces with SMBG. Despite this, a policy-maker from Nova Scotia suggested that there was a need to let the evidence percolate longer and devote more time to education (Interview, Participant 1). This was an important lesson learned.

Though there has been mention of plans to phase out test strip coverage for non-insulin-dependent patients in Alberta over time, this has not been implemented (ACHORD, 2012, p.2). Additionally, there are indications that Alberta is looking to harmonize their SMBG policies and use CADTH’s work to develop the messaging (SECOR-KPMG, 2012, p.42). Though the implications of harmonization are not explicit, one might speculate that this includes restricting coverage for non-insulin-dependent patients, as some of Alberta’s SMBG policies provide more restrictive test strip coverage than others. Nevertheless, there is no existing government plan to restrict test strip reimbursement (Interview, Participant 3).

5.5. Implementation strategies to promote optimal use

A range of implementation strategies are available to governments to promote optimal use through disinvestment. The National Health Committee offers a useful way of conceptualizing the types of strategies (2012). Broadly speaking, governments can

take implicit and explicit approaches to disinvestment. Implicit disinvestment strategies attempt to effect changes in clinical practice and public demand for access. Typically this is achieved through the provision of information to health care providers, patients, and the public and educational initiatives; it may also include other interventions aimed at promoting optimal prescribing.

In contrast, explicit strategies effect change through reimbursement levers, thus addressing the supply (National Health Committee, 2012). Formulary-related reimbursement levers include: (1) complete removal of the technology from the formulary; (2) partial reimbursement for use of the technology; and (3) restricting the technology to population sub-groups. In the case of SMBG, the third reimbursement lever is highly applicable given CADTH's optimal therapy recommendations, though partial reimbursement may also help achieve better cost-effectiveness for government. The literature documents many barriers to using explicit strategies as a first stage of disinvestment. Accordingly, the National Health Committee recommends employing implicit strategies first (2012).

Implicit disinvestment strategies attempt to effect changes in clinical practice and public demand for access, primarily through the provision of information. In the literature, the "one-way flow of knowledge" from researchers to end-users is referred to as knowledge transfer (KT) (Johnson, 2005). In the context of this policy issue, end-users include patients, the public, and health care providers. Research findings indicate that targeted KT is best (Lavis et al., 2003). This is because stakeholders groups respond differently to information and the messenger (Dolan, Hallsworth, Halpern, King, and Vlaev, 2010; Lavis et al., 2003). For example, detailed information about clinical outcomes would be appropriate for a physician, but likely not a patient or the general public. Similarly, a physician may be less receptive to clinical recommendations coming from a government organization, than from another health professional or clinical leader. Thus, the approach to KT will vary depending on the end-user, as audience-specific messages and messengers are needed (Lavis et al., 2003).

Research findings also suggest interactive KT approaches are more effective than passive approaches (i.e. provision of print material) regardless of the audience (Lavis et al., 2003). The literature on influencing prescribing practices suggests that this

is especially true for the provision of information to prescribers, who are typically physicians (Sketris et al., 2007). Academic detailing is an example of an interactive KT initiative that is effective in influencing prescribing habits (Lavis et al., 2003; Sketris et al., 2007). Academic detailing traditionally involves an individual, face-to-face meeting between a prescriber and a trained health professional, such as a pharmacist, to discuss evidence-based prescribing. Typically academic detailing is part of a larger initiative, since interactive KT approaches can be limited in reach (Maclure et al., 2006). Multifaceted KT approaches, which have active and passive components, are shown to be most effective (Sketris et al., 2007). Given that prescribers highly influence patient use of BGTS, effective methods of bridging knowledge gaps through KT is important to any disinvestment strategy.

KT is not without its challenges. For example, within the context of SMBG, Bélanger identifies the complexity of CADTH's recommendations as a challenge to the dissemination of the CADTH's recommendations (2011). Additionally, CADTH identifies the "perception that SMBG is synonymous with the management of diabetes" as a barrier to disseminating the message (2009, p.6). Nevertheless, KT plays an essential role in shifting clinical paradigms (Henshall et al., 2012).

Selecting an approach to disinvestment is highly context dependent. Both approaches inevitably require trade-offs that need consideration. Implicit strategies tend to encourage collaboration, especially with health care providers, which is a facilitator to disinvestment. On the other hand, approaching disinvestment through education and information provision poses challenges for measuring success; that is, it may be difficult to attribute any savings to the initiatives (National Health Committee, 2012). Explicit disinvestment can achieve measureable results, but this point is moot if opposition obligates decision-makers to reverse course. Generally speaking, it is advised that the first approach taken is an implicit one. This may help ensure compliance. New Zealand's National Health Committee affirms that starting with implicit approach helps build legitimacy, "as those subject to disinvestment will see it as fair and, accordingly, compliance with disinvestment decisions is more likely" (2012).

6. Policy Options

This section outlines the four policy options that emerged from my research findings. Knowledge transfer (KT), an implicit disinvestment strategy, was identified as an important component in promoting efficient test strip use. Hence, KT is a common component in two policy options. Though the research findings suggest that restricting reimbursement is unlikely to be successfully implemented as a first tactic, I have included this option to assess the feasibility within the context of Ontario. Additionally, I have included partial reimbursement as a potential lever for achieving better value for money.

6.1. Status Quo Plus: Promote Knowledge Transfer

Currently, the OPDP provides BGTS coverage to non-insulin-dependent patients through the Ontario Drug Benefit (ODB) program. This program offers coverage to seniors over the age of 65, individuals with high drug costs relative to income (i.e. the Trillium Drug Program²¹), people living in long-term care or home care facilities, and people receiving social assistance (MOHLTC, n.d.-a). A maximum price per test strip of 0.72 cents is reimbursed to eligible recipients who have a prescription from a physician (Ontario Public Drugs Programs, 2008). Under the ODB program, patients may pay a yearly deductible and co-payment per prescription filled.

To the present time, the OPDP has not made any overt attempts to effect change in BGTS utilization patterns. However, extensive background work on the issue—including public consultation with the Ontario Citizens' Council—has been done (Ontario Citizens' Council, 2011; personal communication, 09/24/12). This policy option consists

²¹ The Trillium Drug Program provides coverage to those under the age of 65 who do not have private insurance or full coverage under their private insurance plan (MOHLTC, n.d.-a).

of enhancing the status quo with a multifaceted KT initiative targeted at patients and health care providers involved in diabetes care. This policy option does not include a plan to restricting reimbursement in the short or long-term. Rather, the purpose of KT would be to disseminate CADTH’s optimal therapy recommendations with the intention of promoting efficient test strip use among patients and effecting a change in practice among health care providers.

This option is based on the comprehensive KT initiatives undertaken in British Columbia and Nova Scotia. These initiatives involved a multifaceted approach; that is, both passive (e.g. print materials) and interactive means (e.g. academic detailing) of transferring information were used to reach patients and health care providers. Given the vast number of patients and health care providers involved in diabetes care, a multifaceted approach to KT would ensure widespread reach of the message and promote a lasting change in practice. The Ministry of Health and Long-Term Care (MOHLTC) could tailor print materials produced by CADTH, including the Alternate Prescription Pad for patients—a card-sized handout highlighting CADTH’s recommendations. The Ministry could similarly adopt the decision-making tool created by the Diabetes Care Program of Nova Scotia for health care providers and create an academic detailing program on the topic of SMBG.

6.2. Restrict Annual BGTS Reimbursement

Restricting test strip reimbursement involves imposing a quantity limit on test strips for non-insulin-dependent patients. Using CADTH’s optimal therapy recommendations as a guide, the number of test strips could be restricted as follows:

Table 3. Suggested annual BGTS allowances

Patient Category	Annual Allowance
Newly diagnosed patients not receiving oral anti-diabetic drugs	One-time coverage for 50 strips
Patients receiving oral anti-diabetic drugs	100 strips

Note: The suggested annual allowances are based on a recent test strip program expansion in New Brunswick, which came into effect on April 1, 2013 (personal communication, 04/05/13). Previously, test strips were not available to non-insulin-dependent patients and the changes were informed by CADTH’s report.

This policy option thus promotes a message consistent with CADTH's recommendations and requires patients to use test strips more efficiently. Given that some patients may temporarily require more frequent testing (e.g. change in drug therapy), this option also allows for special requests from physicians or nurse practitioners in exceptional cases.

6.3. Promote Knowledge Transfer and Restrict Annual BGTS Reimbursement Using a Phased Approach

Using a phased, transparent approach, this policy option involves implementing a multifaceted KT initiative targeted at patients and health care providers in the short term, as previously described. In the longer term, it involves imposing a quantity limit on test strips for patients not treated with insulin. As described in the second policy option, test strips could be limited to 100 strips annually for patients receiving oral anti-diabetic drugs and to a one-time coverage for 50 strips for newly diagnosed patients not receiving oral anti-diabetic drugs.

6.4. Partial Reimbursement

Partial reimbursement consists of lowering the maximum price paid per strip by the ODB to that of the lowest-cost brand available on the formulary. By lowering the maximum price paid by the ODB from approximately 72 cents per strip to 40 cents per strip, this policy option would encourage patients to switch to the lowest-cost strips, which are more cost-effective (Ontario Public Drugs Programs, 2013). This option increases the out-of-pocket costs to patients who choose not to switch, which is likely to cause a reduction in test strip use.

7. Criteria and Measures

In this section, I present the three criteria that were used to evaluate the policy options: (1) effectiveness; (2) stakeholder acceptability; and (3) administrative operability. These criteria serve as a basis for differentiating between the policy options and highlighting the trade-offs. Table 4 provides a summary of the criteria and measures used in the analysis.

Table 4. Criteria and measures for policy options

Criterion	Definition	Measure	Index
Effectiveness	Extent to which the policy reduces inefficient BGTS use and the associated cost savings to government	67-100% reduction in inefficient use and associated cost savings to government	High 3
		34-66% reduction in inefficient use and associated cost savings to government	Medium 2
		0-33% reduction in inefficient use and associated cost savings to government	Low 1
Stakeholder acceptability	Degree to which patients, the public, health care providers, and pharmaceutical companies support the policy	Predominant support for the policy	High 3
		Mixed support for the policy	Medium 2
		Little to no support for the policy	Low 1
Administrative operability	Degree to which support and collaboration outside of the OPDP is needed to implement the policy	Substantial support and collaboration are needed	Low 1
		Some support and collaboration are needed	Medium 2
		Little to no support and collaboration is needed	High 3

7.1. Effectiveness

The effectiveness criterion aims to assess the degree to which a policy alternative reduces inefficient BGTS use and the associated cost-savings with this reduction. Specifically, effectiveness measures the expected percent reduction in inefficient BGTS use. A research study that examined annual BGTS claims data using the ODB database served as the basis for establishing benchmarks (Gomes et al., 2010). This study examined patterns in test strip use among patients aged 65 and older and estimated reductions in inefficient use using hypothetical quantity restrictions scenarios. Analysis was limited to patients aged 65 and older, because they are a stable beneficiary group of the ODB program (personal communication, 03/21/13). Trillium recipients, on the other hand, are a less stable beneficiary group because the eligibility is dependent on financial circumstances, which may fluctuate. Implicit in these estimates is the assumption that test strips claims are equivalent to use and that patients would not pay out-of-pocket to use additional strips.

Gomes et al. found that in 2008 63.3% of total BGTS utilization among diabetics aged 65 or older in Ontario was attributable to non-insulin-dependent patients (2010). Since the 65 and older patient group is a stable beneficiary group of the ODB program, a 63.3% reduction in total BGTS use provides a useful benchmark for potentially effective policies. While this is, admittedly, an imperfect benchmark—some patients may benefit from infrequent SMBG or temporarily require additional test strip use—it serves as a means to distinguish between high, medium, and low achievements. Accordingly, a high score is assigned to alternatives expected to realize a 67-100% reduction in excessive use (42.4-63.3% reduction in total use). Alternatives realizing a 34-66% (21.5-41.8% reduction in total use) and 0-33% (0-20.9% reduction in total use) reduction receive a medium and low score, respectively. I assess this criterion using information from a study by Gomes et al. (2010) and information presented at the 15th Annual CDA conference.

7.2. Stakeholder Acceptability

Research findings suggest that stakeholder acceptability is a necessary consideration when assessing the policy options. Stakeholder acceptability measures the degree to which key stakeholder groups support the policy. This criterion is assessed qualitatively using a scale of high, medium, and low. A score is assigned to each stakeholder group and then averaged, so as not to give higher importance to any particular group. A high rating indicates predominant support for the policy; medium indicates mixed support for a policy; and low signifies little to no support for the policy among stakeholders.

Key stakeholders identified include: patients, the general public, health care professionals, and pharmaceutical companies. Patient perspectives are evaluated separately from the perspectives of the public, as patients are “motivated primarily as consumers of health care and by what they perceive as the best interests of those with their condition” (Henshall et al., 2012, p.2). Consideration is thus given to the general public as “funders of health care” (Henshall et al., 2012).

The assessment for this criterion was informed by several sources of information, including a paper from the 2012 Health Technology Assessment International (HTAi) Policy Forum, which summarizes the perspectives of key stakeholders around issues of optimization (Henshall et al., 2012). To inform the assessment of patient perspectives, information from the CDA and survey results from the CADTH’s Café Scientifique events were consulted. Additionally, a report by the Ontario Citizens’ Council—an advisory body of 25 Ontarians—was used as a proxy for public opinions and values.

7.3. Administrative Operability

Administrative operability is defined as the ease with which a policy can be implemented. This criterion is a function of the need for support from and collaboration with other organizations or branches of the Ministry of Health and Long-Term Care (MOHLTC) to implement the policy. Need for support and collaboration is qualitatively assessed using a scale of high, medium, and low. High scores are assigned to

alternatives deemed to require little need for collaboration. Conversely, a policy expected to have a high need for collaboration is assigned a low score. This criterion is assessed using information obtained from both the literature review and jurisdictional review.

8. Evaluation of Policy Options

This section provides my analysis of the options based on the criteria and measures previously described. An overview of the analysis is presented in Table 5.

Table 5. Summary of policy analysis

Policy Options		Status Quo Plus KT	Annual Quantity Restriction	KT and Phased Annual Quantity Restriction	Partial Reimbursement (Lower Max)
Criteria					
Effectiveness	Percent reduction in inefficient BGTS use and associated cost savings to government	Low 1	High 3	Medium 2	High 3
Stakeholder acceptability	Patients	Medium 2	Low 1	Medium 2	Low 1
	General public	Low 1	High 3	Medium 2	High 3
	Health care providers	Medium 2	Medium 2	Medium 2	Medium 2
	Pharmaceutical companies	Low 1	Low 1	Low 1	Low 1
	Average score	1.5	1.75	1.75	1.75
Administrative operability	Low need for support and collaboration	Low 1	High 3	Low 1	?
Total score		3.75	7.75	4.75	>4.75 (?)

8.1. Status Quo Plus: Promote Knowledge Transfer

8.1.1. Effectiveness

Research findings indicate that KT is an important component in promoting efficient test strip use. Anticipating how effective a KT initiative will be in achieving the policy objective is extremely difficult. However, the literature does identify best practices and evidence to suggest that some strategies are more effective than others (Lavis et al., 2003; Sketris, Lummis, Langille and Ingram, 2007; Health Council of Canada, 2007). Examining the experiences of other provinces can help gauge the effectiveness of this option. Nova Scotia has seen a “trending down” in spending since their KT initiatives began (Interview, Participant 1). An evaluation report by SECOR-KPMG indicates that overall spending on test strips has declined by 4% in Nova Scotia since the release of the CADTH report in 2009 (SECOR-KPMG, 2012, p.43). Similarly, the Pharmaceutical Services Division (PSD) of British Columbia has observed a decline in total spending on BGTS among patients not using insulin between the year 2010 and 2011 (personal communication, 10/11/12). Since the release of the CADTH report, growth in test strip use in BC has slowed (SECOR-KPMG, 2012, p.43).

The extent to which the KT activities, including the “Test with Purpose”²² initiative, can be attributed to the decline in spending is difficult to estimate, but some competing explanatory factors can be ruled out. For example, British Columbia did not see a decline in prevalence between those years, and no additional restrictions on reimbursement were implemented during that period (CDA, 2011a). On the other hand, amendments were made to the BC Diabetes Care guidelines²³ in 2010, which may have independently affected physician prescribing patterns and thus the use of BGTS. The amendments summarize the controversy around the benefit of SMBG for diabetics not using insulin and outline CADTH’s findings. Nevertheless, it is unlikely that the KT

²² See the provincial profile for British Columbia in Appendix B for a description of the “Test with Purpose” campaign.

²³ The Diabetes Care clinical practice guidelines are developed by the Guidelines and Protocols Advisory Committee—a joint committee of the British Columbia Medical Association (BCMA) and the Ministry of Health. The guidelines are approved by the BCMA and adopted by the Medical Services Commission (BC Ministry of Health, n.d.).

initiatives mentioned above were totally without effect in changing BGTS use. Yet, because the KT initiatives in Nova Scotia and BC have only yielded modest reductions in inefficient use to date, this option received a low score.

8.1.2. Stakeholder Acceptability

While some patients may welcome a reduction in SMBG, others may find the new message confusing, especially without a corresponding change in policy. Accordingly, the acceptability of this option to patients received a medium score. Patients who have worked to include frequent testing as part of their regimen may initially be alarmed by the new recommendations; however, consistent guidelines may help patients become more comfortable with the changes (Diabetes Care Program of Nova Scotia, n.d.). Furthermore, by using a “clear, case-based, non-threatening approach with a message that makes sense”—as put forward in BC with the “Test with Purpose” campaign—patients may be more receptive to the KT initiatives (personal communication, 10/11/12). Implementing targeted KT initiatives provides the evidence to promote an overall reduction in BGTS—helping to create a new standard of care—while allowing health care providers and patients the autonomy to incorporate the information into their decision-making processes. This approach promotes individualized recommendations, which the CDA supports (Miller et al., 2011, p.319).

Consideration was given to the general public as “funders of health care” (Henshall et al., 2012). While some members of the general public may be supportive of this policy, others may feel it does not yield sufficient cost savings. The Ontario Citizens’ Council contended that changes to the listing status of test strips should be considered to encourage optimal use (Ontario Citizens’ Council, 2011). Accordingly, this option received a low score.

The perspectives of health care providers on this option are likely to be mixed, and thus it received a medium score. As noted by Henshall et al. (2012), health care providers tend to be motivated by their desire to “provide high quality care.” Given an appropriate choice of “messenger,” health care providers are expected to be amenable to KT initiatives. Some physicians, however, may dislike aspects of academic detailing, including visits during office hours and messages delivered by non-physicians (Maclure

et al., 2006). This could be mitigated by implementing an academic detailing program based on best practices.

Responses to the CADTH Café Scientifique evaluation survey suggest that patients, the public, and health care providers were “receptive” to the key messages communicated at the events (CADTH, n.d.-a, p.8). Though the survey results are not statistically representative of the population, they provide some additional insight into how these stakeholders might perceive this policy option.

Industry perspectives on this option are expected to differ from those of patients, the public, and health care providers. Pharmaceutical companies are unlikely to support the message, which is to reduce inefficient BGTS use, considering they spend an estimated \$500 million annually directly promoting their products to health care providers (Kondro, 2007). Given their capacity to influence health care providers through pharmaceutical detailing,²⁴ these companies are not likely to prevent government KT initiatives from developing, but rather seek to counter the messaging (Kondro, 2007).

8.1.3. Administrative Operability

This option received a low score for administrative operability. Both the time and resources needed upfront to develop and implement the initiatives make this option costly, especially given that Ontario does not currently have an academic detailing program in place. Academic detailing programs in Canada range from \$75,000 to \$500,000 per year (Kondro, 2007). Logistically, academic detailing is time intensive. According to the BC Provincial Academic Detailing (PAD) service, individual visits last between 15 to 30 minutes and small group sessions can last up to 60 minutes (British Columbia Ministry of Health, n.d.). In order to reach a large number of health care providers, “technology-enabled academic detailing” can help to support a program (British Columbia Ministry of Health, n.d.). Furthermore, collaboration with other divisions of the MOHLTC would be important to effectively implementing this option, as the Ontario Public Drugs Programs Division may not have the resources to implement KT initiatives.

²⁴ Visits by pharmaceutical company sales representatives to physicians (Maclure et al., 2006).

Despite the expenses of establishing an academic detailing program, some savings could be realized by adapting the resources and tools developed by CADTH. Many of their resources are readily available online. The Alternate Prescription Pad, for example, summarizes the CADTH recommendations for patients and identifies special circumstances in which they might test more frequently. This tool was adapted by the BC Ministry of Health and translated into several languages. Nevertheless, in the short-term this option is unlikely to generate the cost-savings needed to offset the costs of a multifaceted KT initiative.

8.1.4. *Additional Considerations*

How long it would take to observe a change in BGTS usage following a KT initiative is uncertain. In the future years, a more significant reduction may be realized. However, the opportunity cost of continuing to fund inefficient BGTS use is very high. Nevertheless, KT is an important measure in addressing the policy objective.

8.2. Restrict Annual BGTS Reimbursement

8.2.1. *Effectiveness*

This option guarantees a more substantial reduction in inefficient BGTS use in the short-term, as well as greater cost-savings. Accordingly, this option received a high score. Nevertheless, the effectiveness of restricting reimbursement in reducing inefficient BGTS use depends largely on the stringency of the policy change. Gomes et al. (2010) estimated an 8% reduction in total usage following a minimal restriction of 400 strips per year per person (2010). When restricting BGTS completely, they projected a 63.3% reduction in total use. Restricting reimbursement in accordance with CADTH's recommendations is likely to reduce total test strip use by nearly 50%. As previously stated, the assumption that patients would not pay out-of-pocket to use additional strips is implicit in these estimations.

8.2.2. Stakeholder Acceptability

Without KT, patients will be more likely to oppose this policy. This was the experience in Nova Scotia, where there was insufficient KT upfront. Accordingly, the acceptability of this option to patients received a low score. As a patient advocacy group, the CDA's position on test strip reimbursement provides some insight into what patients might consider an "appropriate" limit. According to Miller et al., the CDA is "prepared to suggest a minimum government reimbursement" of 15 strips per month for people deemed to have a low risk of hypoglycemia and 30 strips per month for those considered to be at high risk (2011, p.318-319). This amounts to 180 and 360 strips per year per person, respectively. The CDA proposes implementing a special authorization mechanism to ensure that exceptions are made when clinically necessary. In view of the CDA's mandate—"to advocate for and increase treatment options"—and the organization's major sponsors—pharmaceutical companies—their proposed restrictions should be considered with caution (Cassels, 2011; J. A. Johnson and Edwards, 2006; Laupacis, 2006). The general public, on the other hand, is likely to support this policy option because it is expected to yield high cost savings. Accordingly, this option received a high score for acceptability among the general public.

Additional information is required to adequately assess the acceptability of this option to health care providers. However, it is likely related to a clinician's understanding of the benefits of SMBG and their compliance with the policy. Clinicians are motivated to provide quality patient care and may also consider themselves patient advocates for access to treatments. To date, clinicians have routinely recommended SMBG and perceived there to be benefit. Without KT, many health care providers are likely to continue their practice as usual.

In the absence of KT, however, recent changes in the CDA's clinical practice guidelines regarding SMBG may help create some changes in practice (CDA Clinical Practice Guidelines Expert Committee, 2013). The recent changes suggest that frequency of testing should be individualized based on risk for hypoglycemia and level of glycemic control. Patients who are not at risk for hypoglycemia and who are meeting glycemic control targets may not need to test as frequently. These recent guidelines are more in line with CADTH's recommendations than the 2008 CDA clinical practice

guidelines. Some evidence suggests that health care providers consider the CDA's clinical practice guidelines to be a trustworthy source of SMBG information (Latter et al., 2011). Generally speaking, however, the effectiveness of clinical practice guidelines in changing clinicians' practices is unclear (Sketris et al., 2007). Given the likelihood of mixed knowledge about the minimal benefits of routine SMBG and compliance, this option received a medium score.

Pharmaceutical companies are expected to oppose this policy option because it restricts access to their product (Henshall et al., 2012). Accordingly, this option received a low score. In February 2010—following the announcement that coverage of test strips would be restricted—the Department of Health and Wellness of Nova Scotia received major opposition and lobbying from the industry, as evidenced by the Deputy Minister's remarks:

What ended up happening is we got out-manoeuvred by the drug company, to be quite honest, who used vulnerable patients and the Canadian Diabetes Association, who they fund heavily, to out-lobby us. [Test strips] is a multi-million dollar industry to the drug company. (Standing Committee on Public Accounts, 2011)

Though these interventions triggered a reversal of the policy decision in Nova Scotia, this level of opposition from the CDA may not arise in Ontario. As previously stated, the new 2013 CDA clinical practice guidelines are more in line with CADTH's recommendations on SMBG. Also, the CDA is prepared to see some reimbursement restrictions put in place—a significant departure from their position in 2010. This suggests the opening of a policy window. However, despite this, the restrictions considered acceptable to the CDA are substantially higher than what is consistent with CADTH's recommendations.

8.2.3. Administrative Operability

In terms of administrative operability, this option received a high score. Relatively little support from and collaboration with other organizations or branches of the MOHLTC is likely necessary to implement an evidence-based quantity restriction, or

Limited Use designation, under the ODB program. Providing notice of the change to health care providers is also unlikely to require much collaboration.

Nevertheless, developing optimal quantity restrictions and eligibility criteria involves a delicate balance. This in turn may have implications for administrative operability. Considerations for quantity restrictions and eligibility criteria are discussed below.

8.2.4. Additional Considerations

As a patient's health status changes, so too may their need for BGTS. Accordingly, a critical component of the effectiveness of this option is ensuring that patients who demonstrate clinical need are eligible for reimbursement. In other words, reimbursement policy should be restricted cautiously, so as not to preclude those who require and benefit from more frequent testing. Such outcomes are akin to a statistical "type I error" and could result in poor health consequences. On the other hand, a very limited restriction is likely to encourage the status quo—where patients who do not benefit from frequent testing have access to excessive strips. These cases exemplify statistical "type II errors," which raise program costs unnecessarily, as experienced in Ontario to date.

Both types of "errors" bring about considerable consequences; however, in this context, a less stringent policy would safeguard against denying a patient who has demonstrated need. Alternatively, safeguarding could be achieved by including BGTS in Ontario's Exceptional Access Program²⁵ (EAP). However, including test strips in the EAP could result in unintended consequences, including high take-up, especially if health care providers are reluctant to change their practices. Without KT, clinicians may be less likely to comply with the policy, and instead readily write requests for exceptional access. Furthermore, lack of clinician compliance with the policy could send mixed messages to patients and have implications for the acceptability of this option.

²⁵ The Exceptional Access Program (EAP) provides special access to products not covered on the formulary or for products not covered for particular patient subpopulations.

Despite the risk of high EAP take-up, ensuring that patients who demonstrate clinical need for additional test strips is important. This is especially true given the population that would be affected by the policy change. Currently, the ODB program covers groups deemed to be the most vulnerable in society, including seniors over the age of 65.

In addition to eligibility criteria considerations, it is important not to overlook the likelihood of stakeholder opposition to this policy. As previously stated, pushback resulted in the reversal of this policy decision in Nova Scotia in 2010. Given the lessons learned in Nova Scotia, a “change management” approach to quantity restriction is likely more favourable. Thus, a policy change that is not incremental may be more likely to generate pushback among patients and noncompliance among health care providers. As noted by Henshall et al., health care provider support for disinvestment decisions is crucial for successful implementation (2012).

In spite of the pushback generated by the CDA in 2010, this policy may not be met with such fierce opposition now. As previously stated the CDA has since changed their position and is willing to accept some quantity restrictions. However, the quantities acceptable are substantially higher than what is consistent with CADTH’s recommendations. Thus, opposition from this group is likely to centre on the stringency of the quantity restriction.

8.3. Promote Knowledge Transfer and Restrict Annual BGTS Reimbursement Using a Phased Approach

8.3.1. *Effectiveness*

This option guarantees a substantial reduction in inefficient BGTS usage and associated cost-savings in the long term. Since these outcomes are expected to be realized only in the long term, this option received a medium score. Again, the effectiveness of restricting reimbursement in reducing BGTS use depends largely on the stringency of the policy change. Restricting reimbursement in accordance with CADTH’s recommendations is likely to reduce total test strip use by nearly 50% (Gomes et al., 2010).

8.3.2. Stakeholder Acceptability

By actively involving patients from the start and ensuring an open and transparent process, patients can “more readily accept disinvestment decisions” (Henshall et al., 2012, p.3). Nevertheless, some opposition to this policy can likely be expected from patients since it limits access to test strips. As this option includes KT upfront, acceptability to the public received a medium score.

Members of the Ontario Citizens’ Council felt that SMBG “can provide a sense of empowerment for the patient, and agreed that it is crucial to keep them on the Formulary while at the same time finding ways to appropriately limit their use” (2011, p.10). While this reflects consideration for patient well-being, it also acknowledges efficient use of government resources. While this policy is expected to generate high cost savings, this outcome is only expected to be realized in the long term. Thus, in terms of acceptability to the general public, this option received a medium score. The assumption that people prefer savings in the near term is implicit in this assessment.

Again, additional information is required to adequately assess the acceptability of this option to health care providers. As previously stated, acceptability is likely tied to a clinician’s understanding of the benefits of SMBG and their compliance with the policy. KT is expected to help improve understanding of the current evidence on SMBG and thus improve compliance with the policy. Nevertheless, there may be some health care providers who oppose this option. Some clinicians may be opposed because they feel there is insufficient evidence to support the policy and it is counter to how they have been practicing for decades. Accordingly, this option received a medium score.

Much like in the second policy option, pharmaceutical companies are expected to oppose this policy option because it restricts access to their product (Henshall et al., 2012). Thus, this option received a low score.

8.3.3. Administrative Operability

The administrative operability of this option is rated as low. Relatively little support from and collaboration with other organizations or branches of the MOHLTC is likely necessary to implement an evidence-based quantity restriction under the ODB

program. However, implementing a multifaceted KT initiative will likely require substantial support and collaboration, in addition to requiring upfront expenses. Nevertheless, these expenses may be offset by cost savings associated with the policy in the future.

8.3.4. Additional Considerations

The considerations previously discussed related to determining the stringency of the quantity restriction and eligibility criteria also apply to this option. Though this option is expected to reduce inefficient test strip use and generate substantial cost-savings, realizing this outcome in the long-term bears an opportunity cost.

8.4. Partial Reimbursement

8.4.1. Effectiveness

Partial reimbursement would guarantee significant cost savings in the short-run. By lowering the maximum price paid by the ODB from approximately 72 cents per strip to 40 cents per strip, the program could expect to reduce expenditures on test strips by nearly half. This policy option would likely encourage some patients to switch to the lowest-cost strips on the formulary, making the practice of SMBG more cost-effective. It may also encourage newly diagnosed patients to choose the lower-cost strips.

Since this option increases the out-of-pocket costs to patients who choose not to switch, it is likely to cause a reduction in test strip use. Though the extent to which test strip usage would decrease is uncertain, a Cochrane Collaboration review provides evidence to suggest that direct cost-sharing policies can reduce drug use (Austvoll-Dahlgren et al., 2009). Though BGTS are considered a medical device by Health Canada, they are “functionally classified as drugs by the way they are listed and managed” on provincial drug formularies (Ontario Citizens’ Council, 2011, p.30). For this reason, similar results could probably be expected. Since this option ensures better value for money and high cost savings, it receives a high score for effectiveness.

8.4.2. Stakeholder Acceptability

This policy option is expected to receive strong opposition from patients and the pharmaceutical industry. In 2006, the average cost of BGTS in Ontario was approximately 72 cents per strip (Cameron et al., 2010). With this in mind—and given that the current maximum price is 72 cents per strip—most patients would likely have to pay out-of-pocket to continue using their accustomed brand. Since test strips cannot be used interchangeably, this option effectively constrains a patient’s choice of glucometer. Because patients are expected to oppose this policy option, it received a low score.

The acceptability of this option to the general public is unclear. The Citizens’ Council report does not offer any concrete insights on this type of policy change. However, on the basis that this option offers high cost-savings, this option would rank highly among taxpayers.

Similarly, the acceptability of this option to health care providers is unclear. However, some health care providers may consider themselves patient advocates for access to treatments “most appropriate to their needs” (Henshall et al., 2012, p.3). Some evidence suggests that health care providers consider patient financial circumstances and ability to monitor (e.g. manual dexterity), among other factors, when making SMBG recommendations (Latter et al., 2011). One might speculate that health care professionals would be more constrained in terms of the type of glucometer and test strips they prescribe to their patients. Thus, some providers may be opposed. Nevertheless, clinicians understand the need to efficiently manage health care resources (Henshall et al., 2012). Since it is unclear whether this would result in strong opposition to or support for the policy, this criterion is assessed as a medium score. Additional information is needed to more accurately assess the acceptability of this option to health care providers.

The pharmaceutical industry will strongly oppose this course of action because it increases patient cost for nearly all test strip brands currently available in the Canadian market. Accordingly, this option received a low score.

8.4.3. Administrative Operability

Additional information²⁶ is required to adequately assess this criterion. This option may require only a minor policy change to lower the maximum price paid per strip. However, it may require a legislative change to the *Ontario Drug Benefit Act* in terms of the maximum price paid and its relationship to the acquisition cost. A legislative change would likely require additional support and collaboration. For these reasons, the administrative operability of this option is assessed as unclear.

8.4.4. Additional Considerations

Some patients—especially seniors who tend to have low, fixed incomes—may be negatively affected by this change in the ODB program. Patients select particular glucometers for a variety of reasons, including for specific features. For example, a patient who has poor eyesight may select one with a larger display. Similarly, a patient with arthritis may choose a glucometer that is easier for them to operate. Some elderly patients may have become accustomed to using a particular glucometer and test strips over a period of many years at next to no cost. Selected members of this beneficiary group may choose to stop SMBG altogether as a result of increased cost-sharing, rather than learn to use a different product and receive full coverage. While a reduction in inefficient test strip use is the objective, a complete reduction in SMBG is not. Furthermore, without KT, patients may not fully understand this policy objective.

The introduction of new and relatively cheap test strips led CADTH to update an earlier review of the comparative cost-effectiveness of glucometers and test strips in Canada (CADTH, 2013). The initial review found no evidence to suggest that any one glucometer and test strips was more clinically effective and cost-effective than others (CADTH, 2011). CADTH's recent update included a review of five glucometers and test strips and found that three devices may have better diagnostic accuracy and performance than the other two (CADTH, 2013). However, CADTH indicated that the findings should be interpreted with caution because of the limited scope of the review

²⁶ My request for additional information regarding the feasibility of this option was not answered in time to include in this report.

and the limitations of the studies included. Furthermore, there was insufficient evidence upon which to draw conclusions on the comparative cost-effectiveness of these devices. These findings and any related updates should be kept in mind to ensure that the best available evidence is reflected in any policy decisions.

Retail pharmacies may also be opposed to this option because it limits patient access to the products they carry. This further consideration is important in assessing and preparing for stakeholder pushback, and thus the political feasibility of this option.

9. Recommendations and Conclusions

Both policy option two—an annual BGTS quantity restriction—and policy option four—partial reimbursement—stand out as high-ranking options. Despite the projected effectiveness of these options, however, the likelihood of strong pushback from patients and pharmaceutical companies requires careful consideration. Lessons learned from Nova Scotia, and the literature on disinvestment, indicate that KT is an important piece in the successful implementation of and compliance with these policies.

Thus, based on my research findings and analysis, I recommend that the Ontario Ministry of Health and Long-Term Care implement a multifaceted KT campaign targeted at patients and health care providers in the short term. Over the longer term, the Ontario Public Drugs Programs (OPDP) should impose a quantity limit on test strips for patients not treated with insulin. This solution will free up substantial funds to reinvest in more effective interventions. Firm commitments to reinvest savings may appease some patient pushback that could arise.

In the short term, continuing to engage the public and patients more generally on the issue of disinvestment will be crucial to ensuring legitimacy and trust. The Ontario Citizens' Council is a valuable mechanism for meaningfully engaging citizens in important issues around formulary decision-making. Given the implications of formulary decisions, the province should explore additional ways to involve citizens. Continuing to ensure transparency in the process of disinvestment is equally important.

Now that the CDA has released the 2013 clinical practice guidelines, the province should aim to develop and launch a multifaceted KT campaign. The CDA's guidelines, which are widely consulted by health care professionals, are now more in line with CADTH's recommendations on SMBG, thus ensuring more consistent messaging. The province should build on KT initiatives undertaken in other provinces and target patients and health care providers (particularly physicians and diabetes educators). The province should also consider establishing an academic detailing program to support

their KT transfer initiatives. Given the financial constraints facing the health care system, a program that encourages optimal prescribing and achieves results would be a valuable investment. Furthermore, the program could help disseminate future evidence-based recommendations.

In the long-term, the province should restrict reimbursement using a staged implementation approach. The OPDP should aim to restrict the quantity based on CADTH's optimal therapy recommendations. A tiered, therapy-based system, as proposed by the CDA, may be warranted, but the minimum quantity proposed should be critically reviewed. Ensuring sufficient administrative capacity to handle submissions and special exemptions is an important consideration in planning the stringency of the quantity restrictions and eligibility criteria.

10. Limitations and Future Research

The lack of publicly available information on stakeholder readiness to accept BGTS disinvestment in Ontario was a limitation in this research. For example, the CDA position on BGTS restrictions was used as a proxy for patient acceptability; this is an imperfect measure. Similarly, information from the Ontario Citizens' Council was used as a proxy for acceptance by the general public. The Council is likely better informed than the average citizen, thus their perspectives may also be considered an imperfect depiction of acceptability. Furthermore, this research could have been better informed about the perspectives of health care providers and through interviews. Interviews with decision-makers in Ontario would have also allowed for a more nuanced analysis of the administrative operability of these options.

In addition, the methodological approach taken to identify provinces in the jurisdictional review may have overlooked some SMBG initiatives. Notably, only English language literature was included, so that initiatives in Quebec were likely excluded.

Future research should explore potential processes for deliberative stakeholder engagement on the topic of disinvestment. Given the implications and complexity of formulary decision-making, stakeholder engagement is critical to understanding the values of citizens. Academic work in this area has already been undertaken (Watt et al., 2012). Further exploration of how genuine engagement can be achieved within the context of resource constraints is likely to be of interest to decision-makers. Future research should also include an investigation of policy options to improve the cost-effectiveness of test strips through mechanisms such as negotiated price reductions. An examination of the relationship between pharmacy rebates and test strip use and expenditures should also be explored.

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Appendix.

Canadian Jurisdictional Review

Alberta

Existing BGTS Coverage

Alberta Health sponsors 3 Blue Cross Plans: seniors (65 plus), non-group (under 65), and palliative care drug coverage plans. In February 2012, a \$600 maximum per client, per year was added to help cover the costs of diabetic supplies, including test strips, for insulin treated patients only.

Alberta Health also provides coverage for diabetic supplies through the AB Monitoring for Health program. This program is funded by Alberta Health and administered by the CDA. In February 2012, maximum benefits were increased from \$550 to \$600 for insulin treated diabetics. In addition, coverage was made available to patients with gestational diabetes. Coverage is also available to patients not treated with insulin; however, the maximum benefit is lower and these amounts did not change.

BGTS coverage is also available through Alberta Human Services. This plan covers income assistance clients. Test strips are available at no cost and there is no quantity limit (Interview, Participant 3).

Total Spending on BGTS

According to CADTH, Alberta's total spending on BGTS exceeded \$9.2 million in 2010. Approximately 60% of these expenditures were claimed by patients not using insulin. CADTH estimates that changes in practice could amount to \$9 million to \$23 million in savings between 2012 and 2015²⁷ (CADTH, 2012a).

SMBG Initiatives

No government initiatives were noted, apart from recent expansion of test strip coverage for the programs mentioned above. Non-governmental initiatives include: (1) the SMBG International Working Group and IHE conference 2006; (2) the Café Scientifique event held on October 26, 2010 in Edmonton, which reached 33 members of the public and 37 health care providers; (3) the Alberta Medical Association adapted CADTH's recommendations for elderly patients and published these recommendations in Drug Use in the Elderly Quarterly in April 2011 (CADTH, n.d.-a; Bélanger, 2011).

²⁷ These estimates are based on the following yearly quantity restrictions: 0, 100, 180, or 360 (CADTH, 2012a).

British Columbia

Existing BGTS Coverage

British Columbia covers BGTS for eligible patients through their provincial drug program known as PharmaCare. PharmaCare is comprised of a series of drug plans, which vary by “eligible population”. Coverage for BGTS is available through three PharmaCare benefit plans: Fair PharmaCare, Plan C (Income Assistance), and Plan F (At Home Program). Coverage is not offered through Plan B (Permanent Residents of Licensed Residential Care Facilities), as long-term care facilities offer medical supplies (including BGTS) to patients at no cost.

To be eligible for coverage, a patient must meet the following criteria: (a) SMBG must be deemed medically necessary; and (b) the patient must have a “Certificate of Training in Blood Glucose Monitoring” issued by a Diabetes Education Centre²⁸. Once a patient has acquired a Certificate of Training, they are required to submit it to PharmaCare. The certificate is then registered in PharmaNet—a provincial network that connects pharmacies— which qualifies patients for ongoing coverage (BC Ministry of Health Pharmaceutical Services Division, n.d.).

PharmaCare covers numerous BGTS brands, which affords patients choice in terms of the product they select. The program reimburses BGTS at the purchase price, up to a predetermined maximum for approved products. In addition, the dispensing fee is reimbursed up to a maximum allowable fee (BC Ministry of Health Pharmaceutical Services Division, n.d.).

Total Spending on BGTS

BC PharmaNet data reveals that the BC PharmaCare program spent roughly \$52.3 million on BGTS in 2010 and \$52.5 million in 2011 (CADTH, 2012b). Approximately \$23.8 million in expenditures were claimed by patients not treated with insulin in 2010. Roughly \$22.8 million was claimed by patients not treated with insulin in 2011 (personal communication, 10/11/12).

SMBG Initiatives

In July 2010, Education for Quality Improvement in Patient care (EQIP)²⁹ developed an educational portrait of BGTS use among diabetics not using insulin. The portrait, which includes a clinical vignette and provincial utilization and expenditure data, was sent to 4,833 family physicians and general practitioners in BC. EQIP notes that family physicians and general practitioners are “highly influential in helping patients [effectively] manage their diabetes” (EQIP, n.d.).

²⁸ Diabetes Education Centres are operated by Regional Health Authorities and service providers accredited by the Ministry of Health prior to April 1, 2003 (BC Ministry of Health Pharmaceutical Services Division, n.d.).

²⁹ EQIP is a joint initiative between the Pharmaceutical Services Division (PSD) of the BC Ministry of Health; the BC Medical Association (BCMA); and the University of British Columbia’s (UBC) Department of Anesthesiology, Pharmacology and Therapeutics, as well as the BC Chair in Patient Safety. The purpose of EQIP is to provide physicians with tools to support better prescribing practices (EQIP, n.d.).

In September 2010, the existing provincial Diabetes Care guidelines³⁰ were released. These guidelines incorporate evidence from the CADTH's 2009 SMBG report (Guidelines and Protocols Advisory Committee, 2010).

Following EQIP's initiative and the revision of the provincial Diabetes Care guidelines, the Drug Use Optimization (DUO) branch of the Ministry's Pharmaceutical Services Division (PSD) implemented a multifaceted provincial knowledge translation campaign in March 2011 called "Test with Purpose", which targeted patients and health care professionals. In keeping with the DUO's mandate, the campaign was designed to educate and engage the health care professionals, patients, and the public on the optimal use of BGTS in order to "achieve improved health outcomes in a fiscally responsible manner" (personal communication, 10/11/12).

Materials developed for the Ministry's campaign were based on resources created by CADTH. As a partner in the campaign, CADTH assisted at several stages, including the planning, implementation, and follow-up. The following list of tools and resources, which was presented at the 15th Annual CDA conference in Vancouver, BC, provides a snapshot of the activities undertaken by DUO:

- Optimal Therapy Prescribing Newsletter
- BC adapted alternate prescription pad (available on-line in multiple languages)
- Presentation to health authority executives and staff
- Presentation to and networking with diabetes education centers
- Café Scientifique³¹
- Posters
- Letters to care providers
- Articles, e-blasts
- Existing educational initiatives
- Networking with HealthLink BC, home care, and residential care nurses
- Displays at health fairs

In addition, DUO worked with CADTH to develop an educational pamphlet, which was adapted for those living in residential care and aimed at informing their family members and caregivers (CADTH, n.d.-b).

PSD has started evaluating the "Test with Purpose" campaign; however, the results have not yet been made publicly available. In a presentation at the 15th Annual CDA conference in Vancouver, BC, DUO representatives cited preliminary findings from their

³⁰ Guidelines are developed by the BCMA, the BC Ministry of Health, and the Guidelines and Protocols Advisory Committee.

³¹ Café Scientifique events were held in Vancouver, BC on October 28, 2010 and in Surrey, BC on February 28, 2011. The events reached 91 members of the public and 70 health care providers (CADTH, n.d.-a).

evaluation. Based on PharmaNet claims data, they estimated a 4% decline in total spending on BGTS among patients not using insulin between the year 2010 and 2011.

Lessons Learned

DUO cited several barriers, facilitators, and lessons learned in their presentation 15th Annual CDA conference in Vancouver, BC. Some lessons learned from working with the Diabetes Education Centres include: (1) provide education to the circle of care and update it regularly; (2) use clear, case-based, non-threatening approach with a message that makes sense: “test with purpose”; (3) provide tools to facilitate change and minimize resistance to change. In addition, they cited the following barriers and facilitators: timing, communication, details, clear messages, and relationships. Establishing a plan for evaluation was also noted as a lesson learned.

Manitoba

Existing BGTS Coverage

Manitoba offers BGTS coverage through its provincial drug program, PharmaCare. PharmaCare is an income-based program; that is, the annual deductible is determined on the basis of adjusted family income³² (CDA, 2011e). Once the deductible is reached, PharmaCare covers 100% of BGTS acquisition costs, plus a dispensing fee for a maximum of 4,000 test strips per benefit year. Patients requiring more than 4,000 test strips per year may apply for additional coverage through the Part 3 Exception Drug Status (EDS) program. First dollar coverage is available to those qualifying for social assistance³³ (CDA, 2011e).

To be eligible for BGTS coverage a patient must obtain a prescription from a physician (personal communication, 03/28/13).

Total Spending on BGTS

In 2010, the Manitoba PharmaCare Program spent in excess of \$7.8 million on BGTS. Over 60% of these expenditures were claimed by patients not using insulin. CADTH estimates that changes in practice could amount to \$7 million to \$19 million in savings between 2012 and 2015³⁴ (CADTH, 2012c).

SMBG Initiatives

In collaboration with CADTH, the government developed an educational pamphlet, which was adapted for those living in residential care and aimed at informing their family members and caregivers (CADTH, n.d.-b). In terms of non-governmental initiatives, the Manitoba Centre for Health Policy identified SMBG as an opportunity to promote optimal use, citing CADTH's recommendations; however, there is no publicly available information to suggest that other SMBG initiatives are underway (Ur, 2011).

³² Total family income minus \$3,000 for spouse and each dependent under 18 (CDA, 2011e).

³³ Employment & Income Assistance (EIA) program.

³⁴ These estimates are based on the following yearly quantity restrictions: 0, 100, 180, or 360 (CADTH, 2012c).

New Brunswick

Existing BGTS Coverage

Coverage for BGTS is available to clients receiving social assistance from the Department of Social Development and low-income patients who are not eligible for social assistance, but have high drug costs. Effective April 1, 2013, coverage was expanded to include non-insulin-dependent patients. The program expansion was informed by CADTH's optimal therapy recommendations. To be eligible, patients must obtain a request form from a physician, nurse practitioner, or Certified Diabetes Educator (CDE). Newly diagnosed patients who are not receiving drug therapy are eligible to receive a one-time supply of 50 test strips. Patients receiving oral anti-diabetic drugs are eligible to receive 100 test strips annually. Under exceptional circumstances, a physician or nurse practitioner can make a special written request for additional strips based on need (personal communication, 04/05/13).

SMBG Initiatives

The NB Department of Health used CADTH's recommendations to inform their comprehensive diabetes strategy (New Brunswick Department of Health, 2011). The strategy cites improving access to necessary diabetic supplies in accordance with CADTH's recommendations as a key deliverable. This includes covering a limited number of test strips for people not using insulin and a one time, limited supply of test strips for those recently diagnosed with diabetes for the purpose of learning SMBG. As previously stated, these changes were implemented on April 1, 2013.

Non-governmental initiatives include: (1) the Café Scientifique event on September 23, 2010 in Moncton. The event reached 10 members of the public and 31 health care providers (CADTH, n.d.-a); (2) the Horizon Health Network has used the evidence to inform a decision about the need for home care nurses to have glucose meters available (Ur, 2011).

Newfoundland and Labrador

Existing BGTS Coverage

BGTS coverage is available through all of the Prescription Drug Program plans (CDA, 2011). To be eligible, a patient must have a drug card and prescription from a physician. Coverage is limited to 2,500 strips annually. Special authorization is required to obtain coverage for strips in excess of 2,500 annually. Special authorization is also required for patients not receiving drug therapy to be eligible for BGTS coverage (personal communication, 03/28/13).

Total Spending on BGTS

In 2006, total spending on BGTS was approximately 5.7 million (Cameron et al., 2010b).

SMBG Initiatives

Non-governmental initiatives include: (1) the Café Scientifique event on March 8, 2011 in St. John's. The event reached 44 members of the public and 13 health care providers (CADTH, n.d.-a); (2) an accredited Continuing Medical Education presentation on SMBG for people with type 2 diabetes at Memorial University (Bélanger, 2011).

Nova Scotia

Existing BGTS Coverage

Test strips are accessible to any Seniors' Pharmacare and Family Pharmacare beneficiaries (Interview, Participant 1; CDA, 2011). In 2004, the maximum reimbursement price per test strip was 0.74 cents for the Seniors' Pharmacare (Sanyal et al., 2008).

Total Spending on BGTS

In 2006, total spending on BGTS was approximately \$6.3 million (Cameron et al., 2010b).

SMBG Initiatives

Café Scientifique events were held on February 17-18, 2010 in Halifax. The events reached 20 members of the public and 40 health care providers (CADTH, n.d.-a).

Prompted by CADTH's optimal therapy recommendations, the Government of Nova Scotia announced plans to restrict BGTS reimbursement for non-insulin-dependent patients in February 2010. The policy change was to impose a quality limit of 100 test strips per year for non-insulin-dependent patients. Concurrently, the Drug Evaluation Alliance of Nova Scotia (DEANS)³⁵ began to implement educational strategies to influence changes in prescribing and best practices among health professionals. Educational tools, including a decision-making tool for health care providers, and academic detailing³⁶ were based on CADTH's SMBG recommendations. These strategies were not in place long enough to take effect; however, and soon after the policy plans were announcement, the government reversed the decision because of strong pushback from the public, the Canadian Diabetes Association (CDA), and pharmaceutical companies (Interview, Participant 1; Standing Committee on Public Accounts, 2011; Woo, 2010).

Currently, Nova Scotia has numerous educational resources available to patients and health care providers, as well as a decision-making tool to aid with prescribing. An academic detailing program is also in place. The Deputy Minister of Nova Scotia's Department of Health and Wellness has stated that the Department is considering BGTS restrictions again, though no official announcements have been made confirming such plans (Standing Committee on Public Accounts, 2011).

Lessons Learned

The biggest lesson learned was that SMBG is a big change management issue. Other key findings that emerged from the interview was that there was a need to "let the evidence percolate" and focus more on education before pursuing such a dramatic change in practice (Interview, Participant 1).

³⁵ The Drug Evaluation Alliance of Nova Scotia (DEANS) is a partnership between the Department of health and the University of Dalhousie College of Pharmacy and Continuing Medical Education.

³⁶ Academic detailing traditionally involves an individual, face-to-face meeting between a prescriber and a trained health professional, such as a pharmacist, to discuss evidence-based prescribing.

Ontario

Existing BGTS Coverage

The Ontario Public Drugs Programs (OPDP) provides coverage for BGTS through the Ontario Drug Benefit (ODB) program. The ODB program offers coverage for seniors over the age of 65, individuals with high drug costs relative to income (Trillium Program³⁷), and people living in long-term care or home care facilities, and people receiving social assistance (MOHLTC, n.d.-a). A maximum price per test strip of 0.72 cents is reimbursed to eligible recipients who have a prescription from a physician (Ontario Public Drugs Programs, 2008). Under the ODB program, patients may pay a yearly deductible and co-payment per prescription filled.

Coverage for diabetic supplies is also available through the Ontario Monitoring for Health program. This program is funded by the Ministry of Health and Long-term Care and administered by the CDA. This program offers financial assistance for patients who are insulin-dependent or have gestational diabetes. Program recipients receive a 75% reimbursement up to a maximum of \$820 per year for BGTS and lancets (CDA, n.d.).

Total Spending on BGTS

The most current, publicly available BGTS expenditure data is for the year 2008. In 2008, BGTS represented the third largest expenditure of the Ontario Public Drug Programs—equivalent to 3.3% of total drug expenditures (Gomes et al., 2010). More than 60% of these expenditures were attributable to patients not using insulin. One study estimated that “if reimbursement policies do not change, the Ontario public drug plan will spend roughly \$500 million dollars over the next 5 years on SMBG test strips for patients ≥65 years of age” (Shah, 2010, p.180).

SMBG Initiatives

Up to the present time, the Ontario Public Drugs Program has not made any overt attempts to effect change in utilization patterns or restrict reimbursement. Extensive background work on the issue—including public consultation with the Ontario Citizens’ Council—has been done (Ontario Citizens’ Council, 2011; personal communication, 09/24/12). This report by the Ontario Citizens’ Council is the most up-to-date, publicly available information on the current state of affairs. The Council reviewed three case studies, including SMBG, in order offer advice on when the Executive Officer should consider delisting or restricting access to products on the formulary. Members of the Ontario Citizens’ Council felt that SMBG “can provide a sense of empowerment for the patient, and agreed that it is crucial to keep them on the Formulary while at the same time finding ways to appropriately limit their use” (2011, p.10). The Council stressed the importance of transparency in plans to delist or restrict access and recommended that these decisions “must be preceded by an appropriate notice period and adequate education of health professionals, patients and the general public” (2011, p.2).

³⁷ The Trillium Program, which is part of the ODB program, offers coverage to those who are under the age of 65 and do not have private insurance or full coverage under their private insurance plan (MOHLTC, n.d.-b).

In addition, Café Scientifique events were held in Ottawa on November 30th, 2010 and in Toronto on December 1st, 2010. The events reached 75 members of the public and 59 health care providers.

Prince Edward Island

Existing BGTS Coverage

In 2008, Prince Edward Island began offering BGTS coverage for eligible patients through their provincial drug program known as Diabetes Control Program. The existing policy states that the patients “must have had a prescription for insulin filled in the last 150 days to be eligible for blood glucose strip coverage, and be registered under the Diabetes Program” (Health PEI, 2011, p.6).

SMBG Initiatives

In addition to establishing BGTS coverage based on CADTH’s evidence, there have been some non-governmental initiatives including: (1) the Café Scientifique event on September 21, 2010 in Charlottetown. The event reached 12 members of the public and 24 health care providers (CADTH, n.d.-a); (2) some long-term care facilities have changed their policies and practice around the frequency of testing for residents (Bélanger, 2011).

Saskatchewan

Existing BGTS Coverage

Coverage for BGTS is available through all government drug and extended benefit plans (CDA, 2011k). Any Saskatchewan Health beneficiary is eligible to receive BGTS. Patients are required to pay according to their deductible and/or co-pay, as they are with other eligible drug plan expenses. A prescription is not required to be eligible for coverage; however, patients generally present a prescription to the pharmacy (personal communication, 03/20/13).

Total Spending on BGTS

In 2006, total spending on BGTS was approximately \$10.2 million (Cameron et al., 2010b).

SMBG Initiatives

In collaboration with CADTH, the government developed an educational pamphlet, which was adapted for those living in residential care and aimed at informing their family members and caregivers (CADTH, n.d.-b). Non-governmental initiatives include: (1) the Café Scientifique events on March 2-3, 2010 in Regina. The events reached 19 members of the public and 55 health care providers (CADTH, n.d.); (2) use of CADTH’s alternate Rx pad as part of the standardized material given to patients in the Saskatoon Community Clinic (Ur, 2011); (3) uptake of the CADTH’s messages from Assiniboine RHA Diabetes and Heart Health Program (Bélanger, 2011).; (4) RxFiles, an academic detailing program, created a prescribing aid for practitioners based on CADTH’s evidence (Bélanger, 2011).