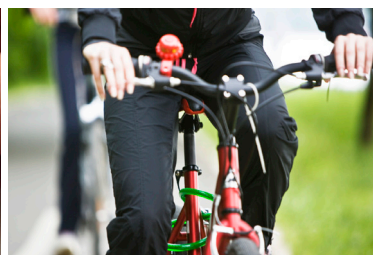
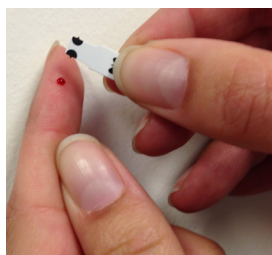




UBC CENTRE FOR
HEALTH SERVICES AND
POLICY RESEARCH

Utilization Patterns and Reimbursement Options for Diabetes Test Strips in British Columbia

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*Utilization Patterns and Reimbursement Options for Diabetes
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About CHSPR

The Centre for Health Services and Policy Research (CHSPR) is an independent research centre based in the School of Population and Public Health of the University of British Columbia. Our mission is to stimulate scientific enquiry into health system performance, equity and sustainability.

Our faculty are among Canada's leading experts in primary health care, health care funding, variations in health services utilization, health human resources, and pharmaceutical policy. We promote interdisciplinarity in our research, training, and knowledge translation activities because contemporary problems in health care systems transcend traditional academic boundaries.

We are active participants in various policy-making forums and are regularly called upon to provide policy advice in British Columbia, Canada, and abroad.

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For more information about CHSPR, please visit www.chspr.ubc.ca.

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List of Acronyms

A1C	Glycated haemoglobin, also known as HbA1c
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
DUO	Drug Use Optimization
EQIP	Education for Quality Improvement in Patient Care
GPAC	Guidelines and Protocols Advisory Committee
OTC	Over-the-counter
PHAC	Public Health Agency of Canada
PHARMAC	Pharmaceutical management Agency of New Zealand
PSD	Pharmaceutical Services Division
QALY	Quality-adjusted life-year
SMBG	Self-monitoring blood glucose
T1D	Type 1 diabetes
T2D	Type 2 diabetes

Introduction

Diabetes and Glycemic Control

Diabetes is a complex, chronic illness affecting approximately 400,000 British Columbians—roughly 8% of the total population.¹ Fewer than 10% of diabetics are estimated to have type 1 diabetes (T1D), while the remainder have type 2 diabetes (T2D).^{1,2} As diabetes disrupts the body's ability to regulate blood glucose levels, management regimens aim to stabilize blood glucose by maintaining it at a healthy level.³ Typically, this involves a combination of drug therapy (e.g. insulin injections or oral medications), lifestyle modifications (i.e. proper nutrition, etc.), and the self-monitoring of blood glucose levels.⁴ Properly managing diabetes is essential to preventing possible health complications that arise from elevated blood glucose levels.

Management regimens vary depending on both the type and severity of diabetes. While people with T1D depend on insulin therapy, people with T2D may be treated with oral glucose-lowering pills and/or insulin. Not all diabetics with T2D need drug therapy to manage blood glucose levels; some people achieve glycemic control by increasing exercise and modifying their diet. To assist in optimizing treatment, health care providers usually monitor a patient's glycemic control using HbA1c tests. Patients are also commonly instructed to self-monitor their blood glucose levels regularly as an important part of managing their diabetes.⁵

Self-Monitoring Blood Glucose: Rethinking Current Practice

Routine self-monitoring blood glucose (SMBG) has long been a cornerstone of daily self-management.⁵ This is especially true for diabetics using insulin, who may rely on SMBG to prevent hypoglycemia

and accurately dose insulin boluses. SMBG involves several components, including lancets, disposable test strips, and a glucometer. Glucometer readings enable patients and their care providers to make informed decisions about changing drug therapy or altering dosages, as well as adjusting lifestyle factors. Over the long term, accurate glycemic control can help prevent health complications. Generally, test strips fit only their accompanying glucometers and have very limited interchangeability with other models. Test strips cannot be used with other brands of glucometers.

Though the clinical benefit of SMBG is undisputed for diabetics treated with insulin, evidence to support the benefit of routine testing for diabetics not treated with insulin is lacking.^{4,6,7} Moreover, some research findings indicate that routine SMBG among non-insulin treated type 2 diabetics may be associated with higher levels of anxiety.^{8,9} Despite the lack of clear evidence and some suggestion of harm, several Canadian public drug benefit programs—including BC Pharmacare—currently offer unrestricted coverage for blood glucose test strips (BGTS) to all diabetic populations.

Public Coverage for Test Strips in BC

Test strips are listed as a benefit under three PharmaCare plans: Fair PharmaCare, Plan C (Income Assistance), and Plan F (At Home Program). To be eligible for coverage under these public plans, an individual must meet two criteria. First, SMBG must be deemed medically necessary.¹⁰ A prescription is not required for this criterion to be met; rather, individuals are referred to a Diabetes Education centre if SMBG is deemed clinically beneficial. Once this has been established, the individual must obtain a Certificate of Training in Blood Glucose Monitoring issued



by a Diabetes Education Centre.¹⁰ After the certificate has been registered in the PharmaNet system an individual qualifies for ongoing coverage.

PharmaCare currently covers over 50 BGTS products. The public program reimburses the pharmacy's actual acquisition cost, up to a predetermined maximum price per test strip for each approved product.¹⁰ The maximum price paid is based on the manufacturer's list price plus a 7% mark-up.¹¹ Test strip prices on the formulary range from \$0.45 to \$0.93 per individual strip. A dispensing fee is also reimbursed up to a maximum allowable fee of \$10.00.¹² Glucometers, in contrast, are not covered by Pharmacare. These devices are available over-the-counter (OTC) and cost \$80 on average. As test strips fit an accompanying glucometer and are not compatible with other brands, manufacturers generally provide glucometers for free with the purchase of test strips to entice shoppers to use their products.

Cost Trends for Public Drug Programs

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 aged 65 and over increased by 250% between 1997 and 2008.¹³ By 2008, BGTS expenditures in Ontario 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.¹³ Approximately 63% of these expenditures were attributable to diabetics not treated with insulin.¹³ Similarly, in British Columbia (BC), test strips were Pharmacare's third highest expenditure in 2012.¹⁴ It is estimated that Pharmacare spends nearly \$1 million per month in test strips for patients not treated with insulin.¹⁴

The anticipated future cost of these coverage policies is high. For example, researchers at the Institute for Clinical Evaluative Sciences (ICES) estimated in 2010 that if the Ontario public drug plan did not change its reimbursement policies, the program would spend roughly \$500 million dollars on test strips over the following five year period.¹⁵ Substantial test strip expenditures could conceivably be expected in other jurisdictions, like BC, that have unrestrictive policies. This in turn could lead to a "policy steal"; that is, resources available for more effective interventions or tools get displaced by the costs of comparatively lower-value SMBG test strip utilization.¹⁶

Research Objectives

Given the high cost of SMBG test strip use, this study examined potential policy options that achieve reductions in test strip use and costs. These policy options were designed to ensure coverage for the British Columbians who benefit most from SMBG test strip use. More specifically, the objectives of the research study were:

1. To examine the trends in test strip use among BC PharmaCare beneficiaries between 2004 and 2012, including variations in use by different groups of diabetics.
2. To simulate the impacts and potential cost-savings of implementing quantity restrictions on test strip coverage in line with the Ontario Public Drug Programs' (OPDP) quantity restrictions that became effective in August 2013.

Background

Overview of Current Evidence

Uncertainty around the benefits of SMBG—particularly for patients with T2D not treated with insulin—prompted the Canadian Agency for Drugs and Technologies in Health (CADTH) to conduct a systematic review, meta-analysis, and cost-effectiveness evaluation that was published in 2009.¹⁷ As part of this study, the COMPUS Expert Review Committee (CERC) reviewed the results of seven randomized control trials that compared SMBG use to non-use among diabetics not treated with insulin. This analysis concluded that SMBG is associated with a modest improvement (decrease of 0.25% in HbA1c) in glycemic control among patients not treated with insulin.¹⁷ Although this improvement was found to be statistically significant, it was deemed not to be clinically meaningful. 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.¹⁷

Recent systematic reviews and meta-analyses—including a study by Malanda et al. of the Cochrane Collaboration—corroborate CADTH's findings.^{6,7} Researchers sought to update an earlier Cochrane review published in 2005 and synthesize the clinical evidence. Six new randomized control trials that investigated the effects of SMBG use versus non-use among non-insulin-treated type 2 diabetics were added to the original review. Their analysis demonstrated that the benefits of SMBG compared to no SMBG for patients who have been living with type 2 diabetes for at least one year are statistically significant, but minimal; testing conferred an improvement in glycemic control (decrease of 0.3% in HbA1c) for up to six months, which ceased after 12 months.⁶

In terms of cost-effectiveness, CERC estimated that the incremental cost of routine SMBG—testing nine times per week—was \$113,643 per QALY gained relative to no testing.¹⁸ Sensitivity analysis revealed that testing four times per week cost \$46,445 per QALY gained and testing once per week cost \$6,322 per QALY gained.¹⁸ The committee found that a reduction in testing frequency would likely improve cost-effectiveness, as would reducing the price per test strip. For example, at utilization rates of nine test strips per week, reducing the price per strip by 75% would reduce costs to \$31,101 per QALY gained.¹⁸ CERC concluded that at current prices, routine SMBG among non-insulin treated patients is unlikely to be an efficient use of health care resources.

Subsequent to CADTH's study, ICES published findings from an investigation of test strip use and costs among diabetic patients over the age of 65 Ontario.¹⁹ ICES researchers examined trends across four diabetes therapy groups and found that test strip use increased substantially in all groups; the total number of test strips paid for between 1997 and 2008 increased almost five-fold: from 24.9 million strips to 117.6 million strips.¹⁹ They also formulated five policy scenarios that would restrict the number of test strip dispensed to different groups of patients and estimated the potential cost reductions. The first two scenarios were guided by CADTH's optimal therapy recommendations, both of which allow unlimited test strip use among insulin-users and limit test strip payment to a maximum of 100 strips per year among all other therapy groups. The other three scenarios permitted unlimited use among insulin-users and users of hypoglycemia-inducing oral drugs, with reimbursement maximums ranging from 100, 200, and 400 strips per year among patients at low risk of hypoglycemia, respectively. ICES estimated that cost



reductions ranging from 8% to 63% could be achieved depending on the stringency of the reimbursement criteria.¹⁹

A recent report by the Patented Medicines Pricing Review Board (PMPRB) examined test strip use and cost in Saskatchewan, Manitoba, and Nova Scotia using data from 2008.²⁰ Utilization data for three distinct therapy groups (i.e. insulin-only users, insulin and oral anti-diabetic drugs users, and non-users of insulin) were compared to test strip frequency recommendations made by CADTH in 2009, and the CDA in 2008 and 2011. Based on this comparison, PMPRB found that the majority of non-users of insulin (59% to 81%) tested in line with the CDA's 2011 minimum government reimbursement recommendations of between 15 and 30 strips per month.²⁰ PMPRB also compared the formulary prices of test strips between the provinces and three comparator countries, using the US Federal Supply Schedule (US FSS), and the United Kingdom and French formularies. Findings indicate that the three Canadian provinces pay significantly more than comparator countries for test strips (\$0.73-\$0.79 CAD).²⁰ The provinces pay nearly twice as much as the average price listed on the US FSS (\$0.39 CAD), and the substantially more than the average formulary prices in the UK and France (\$0.56 CAD and \$0.49 CAD, respectively).²⁰

Optimal Therapy Recommendations and Clinical Practice Guidelines

The optimal therapy recommendations that emerged from CADTH's study are classified by diabetes type and course of treatment. These recommendations are summarized below in Table 1.

At the time of publication, CERC's recommendations were contrary to the prevailing clinical paradigm and existing practice guidelines; in particular, the guidance for patients not treated with insulin. Specifically, CERC recommended that most adults using anti-diabetic drugs without insulin do not require routine SMBG. The committee noted, however, that select patients may need periodic testing. Patients might require more frequent 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.⁴ Under these conditions, CERC advised that testing should be linked to activities such as preventing hypoglycemia or adjusting drug dosage. The committee recommended that most adults controlling their diabetes through diet do not require routine SMBG, noting that women who are pregnant or considering pregnancy may benefit from periodic testing.⁴

Table 1. Summary of CERC optimal therapy recommendations

Diabetes Therapy Group	Optimal Frequency of SMBG
Adults and children with T1D	CERC recommends individualized SMBG
Adults with T2D using insulin with or without oral anti-diabetic drugs	CERC suggests a max frequency of 14 tests per week
Adults with T2D using anti-diabetic drugs (without insulin) or no anti-diabetic drugs	Routine SMBG is not recommended Periodic testing for select patients
Women with gestational diabetes not using anti-diabetic drugs	CERC recommends individualized SMBG

The CDA’s 2013 Clinical Practice Guidelines are more in line with CADTH’s optimal therapy recommendations than the previous 2008 guidelines. For example, the new guidelines indicate that infrequent SMBG is appropriate for some patients not treated with insulin.³ Table 2 below provides an overview of the CDA Clinical Practice Guideline Expert Committee’s recommendations on the frequency of SMBG. A major difference between CADTH’s recommendations and the CDA’s guidelines is the distinction made between oral anti-diabetic drugs that pose risk of hypoglycemia versus those that do not. The Expert Committee suggested that increased frequency of SMBG may be required if a patient is treated with hypoglycemia-inducing anti-diabetic drugs, among other conditions summarized in the CDA’s Recommendation Tool for Healthcare Providers.²¹

In terms of international guidelines, a recent post-market review by the Australian Department of Health and Ageing and the University of South Australia found that most guidelines by major international professional organizations and health

technology assessment bodies note the lack of evidence to support routine SMBG by diabetics not treated with insulin.²²

SMBG: The Controversy

The research findings outlined above have challenged the prior clinical paradigm on SMBG. The conclusions drawn from these studies have been met with substantial criticism. One major criticism has been that some randomized clinical trials included in the systematic reviews treat SMBG as an “unvarying medication or treatment”; that is, some studies divide participants into treatment and non-treatment groups without specifying the frequency of SMBG and use of glucometer readings.²³ Critics have argued that SMBG is not inherently a uniform intervention. Rather, it is a tool that requires sufficient education and training for both patients and health care providers to be effective.²³ They highlight the need for well-designed clinical trials that involve structured SMBG, including a streamlined method of recording glucometer data and analyzing trends.

Table 2. Summary of the CDA’s 2013 Clinical Practice Guidelines

Diabetes Therapy Group	SMBG Recommendation
Individuals with T1D using insulin more than once a day	The Expert Committee recommends SMBG at least 3 times per day.
Individuals with T2D using insulin once a day in addition to oral anti-diabetic drugs	The Expert Committee recommends SMBG at least once a day at variable times. The Expert Committee recommends individualized SMBG based on type of oral anti-diabetic drugs, level of glycemic control, and risk of hypoglycemia.
Individuals with T2D <i>not using insulin</i>	When glycemic targets are not being met, SMBG should be introduced and should include periodic pre- and postprandial measurements, as well as training on how to modify meds and lifestyle according to glucometer readings. When glycemic targets are being met or anti-diabetic drugs do not pose risk of hypoglycemia, infrequent SMBG is appropriate.



Within the Canadian context, CERC's 2009 optimal therapy recommendations for SMBG were initially met with major pushback from the diabetic community. In 2010, the CDA publicly opposed Nova Scotia's policy decision to restrict BGTS reimbursement based on CERC's optimal therapy recommendations.²⁴ One key criticism by the CDA was that cost-effectiveness was weighted too heavily compared to clinical effectiveness in CERC's optimal therapy recommendations.²⁵ Another criticism was that the recommendations did not differentiate between oral glucose-lowering drugs that pose a higher risk for developing hypoglycemia. While the CDA has since revised its clinical practice guidelines, the organization disagrees with the framing of SMBG as an intervention.^{3,25} Rather, the CDA believes that SMBG should be viewed as a tool to inform the use of other interventions.

Jurisdictional Overview: Existing Public Coverage Policies

Canadian Patient Eligibility Criteria and Benefits

All Canadian provinces offer some level of public coverage for test strips. However, individual patient eligibility criteria, benefits, and the approved products for coverage differ considerably, as shown in Table 3. Although prescriptions are a common requirement to obtain test strip coverage, some variations exist in terms of which health care providers are authorized to prescribe test strips. Prescriptions are not required to obtain test strip coverage in BC or Saskatchewan. However, a Certificate of Training from an approved Diabetes Education Centre is required for coverage in BC.

Nearly all provinces offer some level of public coverage to non-insulin treated diabetics. One notable exception is the drug program in PEI. When test strip coverage was first introduced in PEI in 2008, it was made available only to patients treated with insulin. Of the nine provincial programs that cover test strips for non-insulin treated diabetics, BC, Nova Scotia, Quebec, and Saskatchewan offer unrestricted benefits. Manitoba and Newfoundland and Labrador cap yearly benefits uniformly across diabetes therapy regimens, whereas yearly caps in Alberta, New Brunswick, and Ontario vary based on diabetes therapy regimen.

Table 3. Summary of patient eligibility criteria and yearly benefits

Province	Patient Eligibility Criteria		Benefit (per year)
	Prescription Required	Other	
Alberta	Yes	Varies between plans	Varies between plans; AMFH program caps benefit at \$100, \$250, \$600 per year depending on diabetes therapy regimen
British Columbia	No	SMBG must be deemed medically necessary and have a Certificate of Training from an approved Diabetes Education Centre	Ongoing coverage
Manitoba	Yes	N/A	4,000 strips per year
New Brunswick	Yes	Must qualify for a health card issued by the Department of Social Development and obtain a pharmacy estimate	50, 100, or individualized number of strips per year depending on diabetes therapy regimen
Newfoundland and Labrador	Yes	Providers must obtain special authorization from the Department of Health and Community Services if there is no history of insulin or oral diabetic medications	2,500 strips per year
Nova Scotia	Yes	N/A	Limited to the amount prescribed
Ontario	Yes	N/A	200, 400, or 3,000 strips per year depending on diabetes therapy regimen
Prince Edward Island	Yes	Must be eligible for the Diabetes Program and using insulin within the last 150 days	1,200 strips per year*
Quebec	Yes	N/A	Limited to the amount prescribed
Saskatchewan	No	N/A	Ongoing coverage

* Maximum of 100 test strips per 30 days



Benefit Prices and Dispensing Fees

Considerable variations exist in terms of the benefit price—or maximum reimbursement amount—paid by each of the provincial drug programs for approved products. These differences are summarized below in Table 4. BC, Newfoundland and Labrador, Prince Edward Island, and Quebec reimburse the manufacturer's list price plus a maximum allowable mark-up, which ranges from 6.5% to 10%. Ontario reimburses the manufacturer's list price plus a maximum mark-up of 8% up to the Maximum Allowable Reimbursement (MAR) price of 0.7290 cents per strip. Nova Scotia reimburses the Pharmacare Reimbursement Price (PRP), which is based on the manufacturer's list price, up to 0.7400 cents per strip plus a 6% mark-up. Test strip reimbursement in Saskatchewan is based on total cost, which includes the manufacturer's list

price, an 8.5% wholesale mark-up, a tiered pharmacy mark-up, and the dispensing fee. Alberta reimburses the retail price claimed up to the maximum yearly benefit amount of \$100, \$250, or \$600 per year. New Brunswick's Department of Social Development does not have an explicit pricing policy, but does require a pharmacy price quote; case managers are guided by what is informally considered “usual and customary” pharmacy prices for test strips.

Dispensing fees apply to test strips in most provinces and are covered by the public programs up to a maximum fee. As described in Table 4, maximum dispensing fees vary to a great extent, ranging from \$8.62 to \$22.55 per prescription filled. The public programs in Alberta, New Brunswick, and Prince Edward Island do not cover dispensing fees for test strips, as the fees do not apply.

Table 4. Summary of provincial test strip reimbursement

Province	Benefit Price (Max Reimbursement)	Ingredient Price (cents per strip)	Dispensing Fee	Max Dispensing Fee
Alberta	Retail price claimed	N/A	No	N/A
British Columbia	MLP + 8% mark-up	\$0.41-\$0.86	Yes	\$10.00
Manitoba	Acquisition cost through wholesaler (McKesson Canada)	N/A	Yes	No cap; usual and customary applies
New Brunswick	Individual pharmacy price quotes approved by Dept. of Social Development	N/A	No	N/A
Newfoundland and Labrador	MLP + 8.5% mark-up	\$0.38-\$0.94	Yes	\$11.05 for drug costs up to \$49, \$22.55 for drug costs between \$50 and \$249.99
Nova Scotia	Pharmacare Reimbursement Price (PRP) up to 0.7400 cents per strips + 6% mark-up	\$0.39-\$0.74	Yes	\$12.10
Ontario	MLP + 8% mark-up up to 0.7290 cents per strip	\$0.37-\$0.68	Yes	\$8.62
Prince Edward Island	MLP + 10% mark-up	N/A	No	N/A
Quebec	MLP + 6.5% mark-up	\$0.40-\$0.73	Yes	New prescription: \$9.16; repeat: \$8.78
Saskatchewan	Based on total cost (MLP + 8.5% mark-up + tiered pharmacy mark-up + dispensing fee)	\$0.42-\$0.82	Yes	\$10.75

MLP: Manufacturer list price

International Context

Patient Eligibility Criteria and Benefits

Reimbursement policies for test strips vary to a great extent between countries, as well between regions within countries.²⁶ We examined test strip public coverage policies in the following six countries: the United States, the United Kingdom, Sweden, the Netherlands, Australia, and New Zealand. Much like in Canada, prescriptions are commonly required to obtain test strip coverage and variation exists in terms of which health care professionals are authorized to prescribe test strips between countries.

Table 5 outlines additional eligibility criteria and test strip benefits in each country. All countries examined offer some level of public coverage to non-insulin treated diabetics. Benefits vary between countries and between regions within countries, namely in the UK, the Netherlands, and for US Veterans Affairs. Unrestricted benefits are available non-insulin treated patients in Sweden and to patients registered with Australia's National Diabetes Services Scheme (NDSS).²² Australia's Pharmaceutical Benefits Scheme (PBS) caps benefits uniformly across diabetes therapy regimens, but imposes distinct limits for patients receiving treatment under a GP Management Plan or Team Care Arrangement.²² The US Centres for Medicare and Medicaid Services and the New Zealand restrict the quantity of test strips based on diabetes therapy regimen.^{27,28}

Benefit Prices and Dispensing Fees

Considerable variations exist in terms of benefit price paid by each country for approved products. Table 6 summarizes these differences. New Zealand, and the UK reimburse the manufacturer's list price. Australia and Sweden reimburse the manufacturer's list price, plus allowable mark-ups. US Veterans Affairs negotiates prices in the same way as other pharmaceutical products. The price reimbursed by the US Centres for Medicare and Medicaid Services was achieved through a competitive bidding process.²⁹ Dispensing fees apply to test strips in all but two programs: US Veterans Affairs and US Centres for Medicare and Medicaid Services. The maximum dispensing fees vary by region or contractor in New Zealand and the UK, respectively.



Table 5. Summary of patient eligibility criteria and yearly benefits

Country and Program	Patient Eligibility Criteria		Benefit
	Prescription Required	Other	
US Veterans Affairs	Yes	Varies by Veterans Integrated Service Network (VISN)	Varies by Veterans Integrated Service Network (VISN)
US Centres for Medicare and Medicaid Services	Yes	Prescription must containing the following information: (1) Whether the beneficiary has diabetes; (2) What kind of blood sugar monitor the beneficiary needs and why they need it (e.g. if special monitor is needed because of vision problems, the doctor must explain it.); (3) Whether the beneficiary uses insulin; (4) How often the beneficiary should test their blood sugar; (5) How many test strips and lancets the beneficiary needs for one month.	1,200 strips per year for insulin-users and 400 strips per year for non-insulin-users
New Zealand	Yes	Only the CareSens meters and test strips are reimbursed, with the following exceptions, which require special authorization: (1) Patients using an Accu-Chek Performa meter with an Accu-Chek Combo insulin pump before 1 June 2012. (2) Patients using a Freestyle Optium meter and receiving prescriptions for both blood glucose and ketone testing before 1 June 2012. (3) Visually impaired patients are eligible for the SensoCard Plus Talking Blood Glucose Meter.	Maximum quantity of 50 strips per prescription. Additional strips are available with a prescription to the following groups: (1) Patients prescribed insulin or a sulphonylurea; (2) Pregnant women with diabetes; (3) Patients on home TPN at risk of hypoglycemia or hyperglycemia; (4) Patients with a genetic or an acquired disorder of glucose homeostasis excluding type 1 or type 2 diabetes and metabolic syndrome.
Netherlands	Yes		Reimbursement limits vary between health insurance providers, which set their own policies, but typically a maximum of 30 strips per month are reimbursed to individuals treated with oral anti-diabetic drugs. Insulin-treated individuals receive ongoing coverage for strips.
UK	Yes		Clinical Commissioning Groups (CCG) may put local restrictions on test strips
Australia: Pharmaceutical Benefits Scheme	Yes	To access more than the standard five repeats, patients must be treated under a GP Management Plan or Team Care Arrangement. Accu-Chek Mobile test strips are only available to patients treated with insulin.	Maximum quantity of one pack of 100 test strips plus five repeats per prescription. People receiving treatment under a GP Management Plan or Team Care Arrangement are eligible to receive a maximum quantity of one pack plus 11 repeats.
Australia: National Diabetes Services Scheme (NDSS)	No	Registration under the scheme	Ongoing coverage
Sweden	Yes	N/A	Ongoing coverage

Table 6. Summary of international test strip reimbursement

Country and Program	Benefit Price (Max Reimbursement)	Ingredient Price (\$CAD per strip)	Dispensing Fee	Max Dispensing Fee
US Veterans Affairs	Federal Supply Schedule negotiated prices	\$0.15-\$0.45	No	N/A
US Centres for Medicare and Medicaid Services	\$10.41 per package of 50 strips	\$0.22	No	N/A
New Zealand	MLP	\$0.17-\$0.47	Yes	Varies by region
UK	MLP	\$0.23-\$0.53	Yes	Varies by contractor
Australia	PBS price = (MLP + 7.52% wholesaler mark-up) + \$4.50 (AUD) pharmacy mark-up + \$6.63 (AUD) dispensing fee	\$0.37-\$0.74	Yes/No	\$6.63 (AUD)
Sweden	AUP plus VAT	\$0.29-\$0.51	Yes	Varies

MLP: Manufacturer's list price

AUP: Apotekets utförsäljningspris

VAT: Value added tax



Data Sources and Methodology

Study Design

We used a retrospective serial cross-sectional study design and examined administrative data between 2004 and 2012.³⁰

Data Sources

We used PharmaNet data to examine the current level of test strip use and coverage in BC, and to simulate the impact of different potential policy changes. The PharmaNet³⁰ database contains comprehensive information about all prescriptions dispensed in BC. Three key components of the database were used in this study: (1) drug product data; (2) patient, prescriber, and pharmacy profile information; and (3) cost-related data. Data were used to define diabetes treatment groups, distributions, maximum reimbursement levels, means and quintiles, and identify dispensing fees and costs to both public and private payers.

To conduct an international comparison of test strip prices, we assembled publicly available price information obtained through several online sources. As a starting point, we sought price information for the United States and the United Kingdom, as these countries were included in a recent study by the Patented Medicine Prices Review Board (PMPRB) that examined international test strip prices in 2008. As the French data source used by the PMPRB was no longer

available at the time of our study, we were not able to include these prices in our comparative analysis. Price information for the US and UK was obtained from the United States Federal Supply Schedule and the United Kingdom Formulary through www.mims.co.uk. We also examined prices in New Zealand, Australia, Sweden, and the US Centre for Medicare and Medicaid, using data from the Pharmac Schedule, the Pharmaceutical Benefits Scheme (PBS), the Tandvårdsoch läkemedelsförmånsverket (TLV) formulary, and the DMEPOS Competitive Bidding Program's National Mail-Order single payment amount, respectively. All prices were retrieved in August 2013.

Study Population and Diabetes Therapy Groups

We studied BC PharmaCare beneficiaries over the age of 18 who received at least one prescription for blood glucose test strips between January 1, 2004 and December 31, 2012. Individuals prescribed test strips were assigned to one of four mutually exclusive diabetes therapy groups based on their medication use in each year. The diabetes therapy groups (Table 7) mirror those used in the ICES study in 2009 and those in CDA's recommendations, which differentiate between hypoglycemic inducing and non-hypoglycemic inducing oral drugs.^{19,25} Individuals who received at least one prescription for oral glucose-lowering drugs, but not prescribed insulin, were

Table 7. Diabetes therapy groups

Treatment Group	Description
1 – Insulin only	One or more prescriptions for insulin
2 – Hypoglycemia-inducing oral drugs	One or more prescriptions for an oral glucose-lowering drug with a higher risk of hypoglycemia in year, no insulin
3 – Non-hypoglycemia inducing oral drugs	One or more prescriptions for an oral glucose-lowering drug with a lower risk of hypoglycemia in year, no insulin
4 – No glucose-lowering drug treatment	No prescriptions for either insulin or oral diabetes drugs

stratified into either Groups 2 or 3, based on the risk of drug-induced hypoglycemia (list of drugs available in Appendix 2). Group 4 consisted of individuals who received at least one prescription for test strips, but who did not received a prescription for oral glucose-lowering drugs or insulin. Descriptive statistics for each diabetes therapy group, including the number of patients, total number of test strips dispensed and total cost, formed the basis of the scenario simulations.

Test Strip Utilization and Cost

To determine the overall level of test strip utilization, we calculated the number of test strips dispensed per calendar year of the study period, both overall and stratified by diabetes therapy group. We also calculated the total Pharmacare costs paid for test strips per year, which includes the drug (or product) costs paid plus professional (dispensing) fees.

Reimbursement Restriction Scenario

Using the Ontario Public Drugs Programs' 2013 test strip quantity limits, we developed a test strip quantity restriction scenario to compare to the status quo. The scenario, outlined in Table 8, was used to simulate the cost-savings of adopting different quantity restrictions per benefit year.

For this simulation, we calculated the overall reduction in test strip utilization and associated cost-savings per year from 2004 to 2012. Reductions in test strip use were estimated by applying limits to the amount of test strips dispensed per patient per year. In cases where patients had been dispensed fewer test strips than the limit in a given year, the dispensing amount remained unchanged. Total public costs were calculated by adding both the product cost and dispensing cost paid by PharmaCare.

International Price Comparisons

The top ten test strip brands were determined by analyzing the volume of strips dispensed in 2012. The price per strip of the ten most commonly used brands were then compared against prices for the same brand in the formularies for six drug programs in five countries—Australia, New Zealand, Sweden, UK, US CMS, and US VA.

Table 8. Test strip quantity restriction scenario by diabetes therapy group

Ontario Recommendations	Model Quantity Limit
Insulin users: 3000 strips annually	3000 strips annually (30 Rxs)
Hypoglycemia-inducing oral glucose-lowering drug users: 400 strips annually	400 strips annually (4 Rxs)
All other patients: 200 strips annually	200 strips annually (2 Rxs)



Results

Test Strip Utilization and Cost

Overall, during the study period, test strip use has increased in BC. Within the BC PharmaCare program, the total number of SMBG test strips dispensed to individuals 18 and older between 2004 and 2012 increased by 28%, from 26.4 million to 33.7 million (Figure 1). However, since 2010, SMBG utilization has shown been decreasing. After reaching a peak of 36.2 million strips dispensed in that year, the total number has decreased by approximately 4% each year since. Similarly, the annual cost of SMBG test strips paid for by PharmaCare increased by 22% over the study period, from \$18.4 million to \$22.6 million. In 2012 this represented \$21.2 million in product costs and \$1.4 million in dispensing fee costs.

SMBG Use by Diabetes Therapy Groups

We analysed test strip utilization within four different therapy groups; (1) insulin users, (2) patients taking hypoglycemia-inducing oral glucose-lowering drugs,

(3) patients taking non- hypoglycemia-inducing oral glucose-lowering drugs, and (4) patients treating with no glucose-lowering drug. Across all therapy groups, the number of patients aged 18 years or older using SMBG test strips that were recorded in PharmaNet increased by 36%, from 100,576 patients in 2004 to 136,659 patients in 2012.

In 2012, 85% (N=44,256 of 51,885) of the included patients taking insulin received test strips. 61% (N=30,851 of 50,434) of those taking hypoglycemia-inducing oral glucose-lowering drugs, and 54% (N=35,066 of 64,866) of the patients taking non-hypoglycemia-inducing oral glucose-lowering drugs received SMBG test strips, in the same year (Figure 2). Note that it is not possible to include individuals treating their diabetes without a glucose-lowering drug in this figure, as it was not possible to identify these patients based on diabetes pharmacotherapy.

Figure 1. Annual number and total cost of blood glucose test strips dispensed to patients aged 18 years and older covered by the PharmaCare program in BC, 2004 to 2012

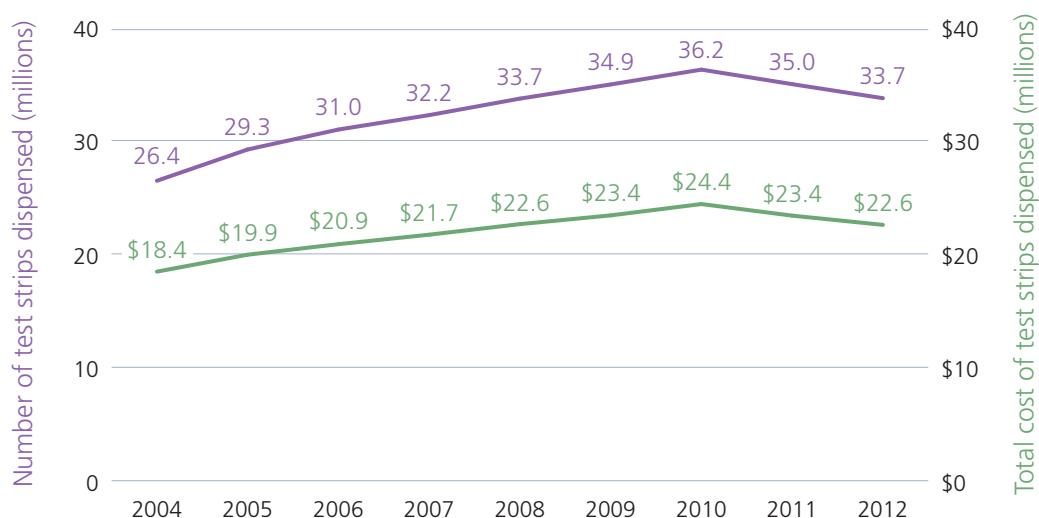


Figure 2. Proportion of patients aged 18 and older with diabetes using blood glucose test strips, by diabetes therapy group, in BC, 2004 to 2012

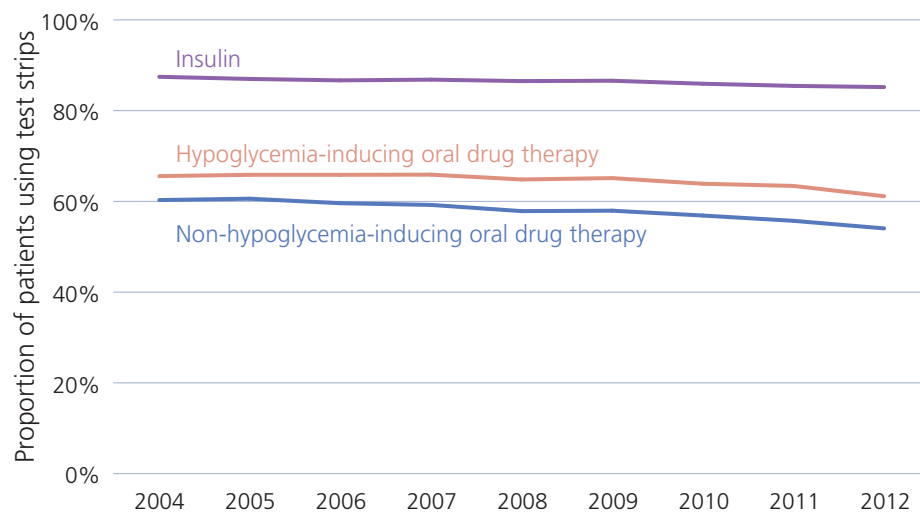
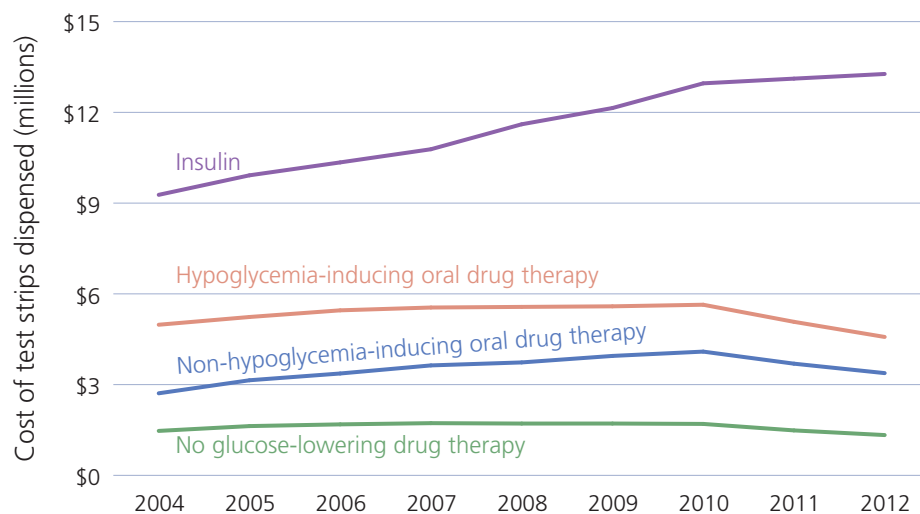


Figure 3. Annual PharmaCare cost of blood glucose test strips dispensed to patients aged 18 and older with diabetes, by diabetes therapy group, in BC, 2004 to 2012





SMBG Cost by Diabetes Therapy Groups

As shown in Figure 3 and Table 9, the largest increase in total PharmaCare SMBG costs occurred among patients using insulin (43% increase, from \$9.3 million in 2004 to \$13.3 million in 2012), followed by non-hypoglycemia-inducing oral glucose-lowering drugs (25% increase, from \$2.7 million in 2004 to \$3.4 million in 2012). PharmaCare SMBG costs decreased over the study period among patients using hypoglycemia-inducing oral glucose-lowering drugs (8% decrease, from \$5.0 million in 2004 to \$4.6 million in 2012), and those with no glucose-lowering therapy (9% decrease, from \$1.5 to \$1.3 million).

Reimbursement Restriction Scenario

We modeled a quantity limit scenario based on the Ontario 2013 Policy (described above). We found that the Ontario Policy would impact 12% of the SMBG testing population (see Table 10).

The potential cost reduction from quantity limits based on 2012 utilization was \$4.4 million when we applied the Ontario Policy (see Table 11). In this scenario, patients in the non- hypoglycemia-inducing oral drug and hypoglycemia-inducing oral drug therapy groups would have been impacted more than those on insulin or not on a glucose-lowering therapy at all.

Table 9. Blood glucose test strip utilization and costs, for patients aged 18 years and older, for the BC PharmaCare program, calendar year 2012

N (%) Patients	N (%) SMBG Claims	N (%) SMBG Strips Dispensed	N (%) SMBG Strips Pharmacare Paid	Total Cost of SMBG Strips		
				Total Cost of Strips	Product Cost	Dispensing Cost
Insulin						
44,256 (32%)	228,582(53%)	34,791,488 (57%)	20,517,199 (61%)	\$13,269,422	\$12,495,981	\$773,441
Hypoglycemia-inducing oral glucose-lowering drugs						
30,851 (23%)	80,893 (19%)	10,574,559 (17%)	6,438,663 (19%)	\$4,575,495	\$4,268,052	\$307,443
Non-hypoglycemia-inducing oral glucose-lowering drugs						
35,066 (26%)	77,796 (18%)	9,645,968 (16%)	4,823,943 (14%)	\$3,379,675	\$3,148,549	\$231,126
No glucose-lowering drug therapy						
26,486 (19%)	47,684 (11%)	5,708,886 (9%)	1,943,321(6%)	\$1,331,770	\$1,243,224	\$88,547

Table 10. Number of patients impacted by the Ontario scenario, based on diabetes therapy group, in 2012

Therapy Group	Current	Ontario
	Number of Patients	Number Impacted
Insulin	44,256	549
Hypoglycemia-inducing oral glucose-lowering drugs	30,851	5,484
Non-hypoglycemia-inducing oral glucose-lowering drugs	35,066	7,424
No drug therapy	26,486	2,781
Total	136,659	16,238
% of Patients Impacted	–	12%

Table 11. Reduction in utilization and cost associated with the Ontario policy scenario related to testing frequency, for patients aged 18 years and older, in BC, calendar year 2012

Calendar Year 2012			Ontario Policy		
No. Patients	No. Strips	Total Cost	No. Patients Impacted	No. Strips	Total Cost
Insulin					
44,256	20,517,199	\$13,269,422	549	20,105,800	\$13,023,783
Hypoglycemia-inducing oral glucose-lowering drugs					
30,851	6,438,664	\$4,575,495	5,484	4,121,011	\$2,919,917
Non-hypoglycemia-inducing oral glucose-lowering drugs					
35,066	4,823,943	\$3,379,675	7,424	2,249,630	\$1,573,067
No glucose-lowering drug therapy					
26,486	1,943,321	\$1,331,770	2,781	987,552	\$676,662
Total					
136,659	33,723,127	\$22,556,363	16,238	27,463,993	\$18,193,430
Total Reduction					
–	–	–	–	6,259,133	\$4,362,933

Table 12. Estimates on test strip limits for insulin users, for patients aged 18 years and older, in BC, in 2012

Test Strip Limit for Insulin Users	Number of Patients Impacted in BC in 2012	Estimated Total Cost	Total Savings
2,000	2,075	\$12,497,693.46	\$771,728.98
3,000	549	\$13,023,783.27	\$245,639.17
4,000	169	\$13,178,618.11	\$90,804.34
5,000	70	\$13,234,979.11	\$34,443.33
6,000	24	\$13,256,620.31	\$12,802.13

If BC were to implement SMBG test strip limits for insulin users, the savings increase as the limit is lowered. The Ontario Policy allows for 3,000 strips per year (over 8 strips per day) and in 2012 would only have impacted 549 British Columbians using insulin, and resulted in \$245,639 in savings. Other programs have instituted more strict guidelines. For example, the Non-Insured Health Benefits (NIHB) program has adopted a policy that more closely reflects the CERC Recommendations and limits SMBG test strip use

for insulin users to 1,825 strips per year (five strips per day).³¹ Table 12 shows the number of patients impacted and savings from different test strip limits for insulin users. Limiting BC reimbursement to 2,000 strips per year (an average of 5.5 strips per day) would have impacted 2,075 British Columbians in 2012 and saved \$771,728. Increasing the limit to 4,000 strips per year would significantly lower the number of patients impacted to 169, but would also decrease the savings.



Potential Impacts of Quantity Limits

Quantity limits would produce savings in terms of both products costs and dispensing fees, as some patients would qualify for fewer refills (see Figure 4). Applying the Ontario Policy to 2012 test strip utilization would have produced over \$4 million in product cost savings, and \$200,000 in dispensing cost savings.

If current testing patterns continue, we project that the total cost of SMBG will exceed \$120 million dollars over the next five years (see Figure 5). Our projections based on current trends in utilization estimate that the Ontario 2013 Policy would reduce the costs for SMBG test strips by at least \$23 million in BC over the next five years.

Figure 4. Costs of blood glucose test strips associated with the Ontario scenario related to testing frequency, in patients aged 18 years and older, in BC, calendar year 2012

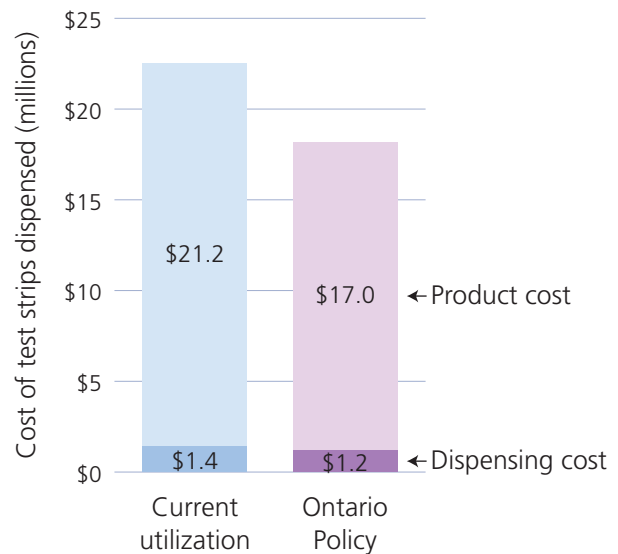
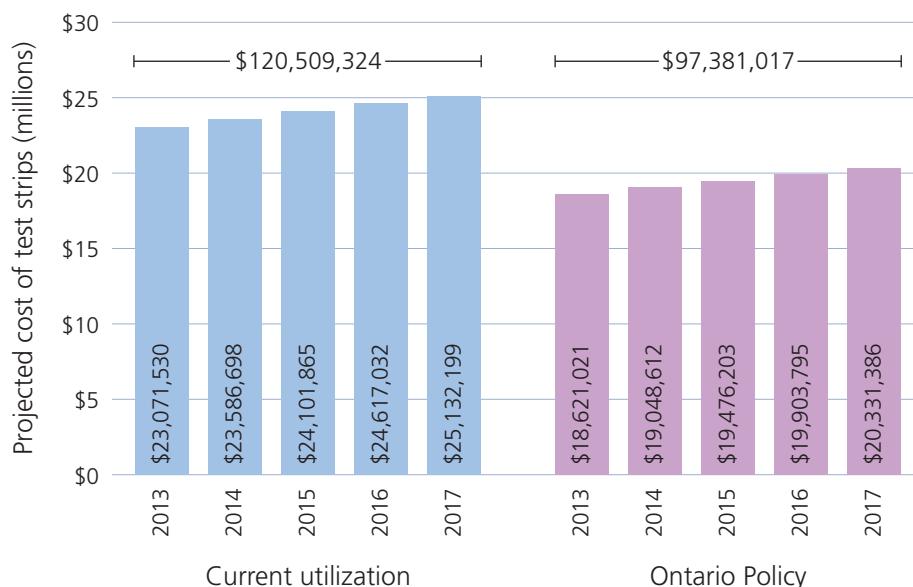


Figure 5. Projected total costs of blood glucose test strips associated with the Ontario scenario related to testing frequency, in patients aged 18 years and older, in BC, calendar years 2013 to 2017



International Price Comparisons

As shown in Table 13, we found that international prices were substantially lower for the top ten most commonly used brands of test strips in BC. For example, One Touch Ultra test strips—which account for over one third of all test strips used in BC—are

reimbursed at rates 68% lower in public insurance programs in the United States. Further, nine out of the top ten strips were sold in other countries, and in every instance they were available at lower costs than in BC.

Table 13. Comparison of international prices for top ten test strip brands in BC, by utilization, January 2014 prices

Brand name	BC PharmaCare	Min Int'l (\$CAD)	Program	% Difference
One Touch Ultra	\$0.67	\$0.22	US CMS	- 68%
Ascensia Contour	\$0.68	\$0.22	US CMS	- 68%
Accu-Chek Aviva	\$0.69	\$0.22	US CMS	- 69%
Accu-Chek Compact	\$0.71	\$0.51	UK	- 28%
Freestyle Lite	\$0.67	\$0.19	US VA	- 71%
Ascensia Microfill	\$0.73	-	-	-
Ascensia Breeze 2	\$0.69	\$0.22	US CMS	- 68%
One Touch Verio	\$0.68	\$0.48	UK	- 29%
Bayer Contour Next	\$0.69	\$0.36	SWE	- 48%
One Touch	\$0.68	\$0.47	UK	- 31%



Discussion

Policy Implications

At the current utilization rate, we found that the costs of blood glucose test strips will likely exceed \$120 million to the BC PharmaCare program over the next five years. Implementing quantity limits similar to those implemented in Ontario in 2013 could stem these costs by more than \$23 million over the same time frame. As this policy was only implemented by Ontario in August of 2013, it will also be important to monitor and consider the evidence on implications for both patient care and costs of this policy change.

Further, using international price comparisons, we found that BC is currently paying more for diabetes test strips than other jurisdictions.

Any policy change for blood glucose test strip coverage will require engagement with stakeholder groups, and in particular clear communication and doctors and pharmacists who will be prescribing and dispensing strips to patients. A change in coverage will no doubt elicit questions and concerns from patients, so medical professionals will need to be prepared and supported to adequately respond.

Challenges and Opportunities

Many Canadian provinces have implemented new policies surrounding blood glucose test strip use in recent years, meeting varied responses from the public. Nova Scotia attempted to implement new quantity restrictions that reflected the CERC recommendations; however, there was no consultation with stakeholder groups before the policy was announced. The proposed policy was quickly rescinded and no subsequent policies to limit test strip utilization have been implemented.³² The CERC recommendations may have been seen as too restrictive, but the CDA guidelines have been met with more openness. When

Ontario introduced their quantity restriction policy in August 2013, they did not encounter the same resistance as Nova Scotia. This could be credited partly to their policies consistencies with CDA guidelines.

Price negotiations in other jurisdictions have involved the use of exclusive listing agreements in order to achieve large cost reductions. For example, in 2012 the Pharmaceutical Management Agency (PHARMAC) in New Zealand, announced the sole listing of Care-Sens blood glucose meters and test strips.³³ The move to sole sourcing was estimated to save \$10 million NZD, annually—nearly half of the \$22 million NZD in subsidies that PHARMAC was paying for diabetes test strips.³⁴

Limitations

There are two key limitations to this study. First of all, the number of test strips dispensed does not necessarily equal the number of test strips used. It is possible that patients could stockpile or sell test strips, or give them to others who do not have pharmaceutical prescription coverage. However, it is important to note that such activities would not change the results of our simulations in terms of the impact on cost and quantity of test strips reimbursed. The second limitation is that the scenarios calculated do not account for exceptions that would likely be made a component of any policy change. Such exceptions, of course, would both cost resources to process and lead to higher utilization than calculated above.

Conclusions

The current coverage regime for diabetes test strips offers an opportunity to reduce costs while maintaining consistency with existing clinical practice recommendations. The scale of the savings from such changes will be critically dependent on the restrictiveness of the reimbursement policy. Further, BC should consider engaging in negotiations with manufacturers to achieve further savings through formulary price reductions for test strips. Implementing policy changes including both quantity limits and negotiated price reductions would likely result in more appropriate blood glucose testing and better value for money in the BC PharmaCare Program.



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Appendix 1: Oral Anti-Diabetic Medications

Table 14. Pharmacotherapy treatments by risk of hypoglycemia

Pharmacotherapy with a higher risk of hypoglycemia

Sulfonylureas (e.g. acetohexamide, chlorpropamide, glibenclamide, gliclazide, glimepiride, glyburide, tolbutamide)

Meglitinides (e.g. nateglinide, repaglinide)

Pharmacotherapy with a lower risk of hypoglycemia

Metformin

Acarbose

Thiazolidinediones (e.g. pioglitazone, rosiglitazone)

DPP-4 inhibitors (e.g. saxagliptin, sitagliptin)

GLP-1 agonists (e.g. exenatide, liraglutide)

Adapted from: http://www.health.gov.on.ca/en/pro/programs/drugs/teststrips/docs/pro_faq.pdf



Appendix 2: Test Strip Brand Names

Table 15. Test strip products eligible for coverage

BC PIN	Brand Name	BC PIN	Brand Name
44123035	Sidekick Bg Test Strip	44123030	Bd Blood Glucose Test Strip
44123036	True Track Bg Test Strip	44123043	Nova Max Blood Glucose Test Strips
44123041	Life Brand Portable Blood Glucose Test Strips	44123044	Ez Health Oracle Blood Glucose Test Strips
44123052	Medi+Sure Blood Glucose Test Strips	44123011	One Touch Bg Test Strip
44123039	Life Brand Blood Glucose Test Strips	44123012	Surestep Bg Test Strip
44123023	Novo-Glucose Bg Test Strip	44123040	Freestyle Lite Blood Glucose Test Strips
44123045	Truetest Blood Glucose Test Strips	44123014	Exactech Bg Test Strip (Discontinued)
44123048	Rightest Gs100 Blood Glucose Test Strips	44123017	Fast Take Bg Test Strip
44123029	Prestige Blood Glucose Test Strips	44123042	On-Call Plus Blood Glucose Test Strips
44123054	Myglucohealth Test Strips	44123024	Precision Extra Bg Test Strip
44123004	Glucofilm Bg Test Strip	44123025	One Touch Ultra Bg Test Strip
44123005	Glucostix Bg Test Strip	44123027	Sof-Tact Blood Glucose Test Strip
44123034	Ittest Blood Glucose Test Strip	44123031	Precision Easy Bg Test Strip
44123018	Smart Strip Bg Test Strip	44123049	Onetouch Verio Blood Glucose Test Strips
44123010	Tracer Bg Test Strip (Discontinued)	44123028	Freestyle Bg Test Strip
44123003	Encore Bg Test Strip	44123008	Advantage Bg Test Strip (Discontinued)
44123047	Bgstar Blood Blood Glucose Test Strips	44123021	Advantage Comfort Bg Test Strip
44123013	Companion li Bg Test Strip (Discontinued)	44123037	Ascensia Contour Bg Test Strips
44123020	Chemstrip Bg Test Strip Visual - Discontinued	44123033	Accu-Chek Aviva Bg Test Strips
44123053	Freestyle Precision Blood Glucose Test Strips	44123046	Accu-Chek Mobile Blood Glucose Test Strip
44123051	Bayer Contour Next Blood Glucose Test Strips	44123026	Accu-Chek Compact Bg Test Strip
44123050	Novo Nordisk Blood Glucose Test Strips	44123002	Ascensia Elite Bg Test Strip
44123001	Dextrostix Bg Test Strip (Discontinued)	44123019	Ascensia Autodisc Bg Test Strip
44123022	Checkmate Plus Bg Test Strip	44123032	Ascensia Microfill Bg Test Strip
44123007	Accu-Chek Easy Bg Test Strip (Discontinued)	44123038	Ascensia Breeze 2 Blood Glucose Test Strips
44123009	Chemstrip Bg Test Strip - Discontinued	44123015	Sensor Electrodes Plus / Precision Bg Test Strip
		44123016	Bg Test Strips (Offline Use Only)
		44123006	Accutrend Bg Test Strip

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