Economic analysis of insulin initiation by pharmacists in a Canadian setting: The RxING study

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ABSTRACT

Background: Conducted in Alberta, the RxING study examined the effect of a community pharmacist prescribing intervention on glycemic control in patients with uncontrolled type 2 diabetes mellitus (T2DM) using insulin glargine. The objective of this study was to assess the cost-effectiveness of pharmacists' prescribing of insulin glargine as an early intervention in uncontrolled patients with T2DM vs usual clinical practice.

Methods: The IMS CORE diabetes Markov model was used to project long-term clinical outcomes, costs and cost-effectiveness of interventions. The efficacy of insulin glargine, in terms of hemoglobin A1c reduction and hypoglycemia rates, was obtained from the RxING study. Health utility and cost data were found in Canadian publications.

The base-case analyses examined the economic and clinical effects of having pharmacists initiate insulin therapy in patients with uncontrolled T2DM in comparison to a physician initiate it up to 3 years later.

Results: Insulin initiation by pharmacists with uncontrolled T2DM patients is cost-effective. Having pharmacists prescribe insulin 1 year earlier than usual clinical practice resulted in an incremental cost savings of \$805 (CDN\$) and a gain of 0.048 QALYs per patient. Pharmacists prescribing insulin 2 years earlier resulted in an incremental cost savings of \$624 (CDN\$) per year and a gain of 0.075 quality-adjusted life-years (QALYs). Prescribing 3 years earlier allowed for a minor increase of \$26 and a gain of 0.086 QALYs.

Conclusion: Earlier initiation of insulin by pharmacists in uncontrolled T2DM patients, resulted in cost savings and delays in the development of diabetes-related complications, leading to an improved quality of life and increased survival rates. *Can Pharm J (Ott)* 2016;149:130-137.

Introduction

Type 2 diabetes mellitus (T2DM) is a progressive disease with at least 50% loss in insulin-producing capacity at the time of diagnosis, with an average loss of 5% annually thereafter.¹ As such, many patients with T2DM will require insulin in order to maintain acceptable glycated hemoglobin (HbA1c) levels. Despite evidence from the Canadian INSIGHT study and the recommendations

of the Canadian Diabetes Association guidelines,² which demonstrate that initiating insulin glargine results in improved glycemic control, some physicians seem hesitant to prescribe it.

Pharmacists are frontline health care professionals who see patients with T2DM frequently and so could help patients achieve their targets by intervening in a timely manner. In Alberta, pharmacists can prescribe insulin and order

laboratory tests. This advanced practice provides an opportunity for early identification and intervention in patients with uncontrolled T2DM. Recently, a Canadian study (the RxING study) aimed to determine the effect of a community pharmacist prescribing intervention on glycemic control in patients with poorly controlled T2DM.³ The RxING study showed pharmacists can help patients to significantly reduce patients' HbA1c by initiating basal insulin with insulin glargine. The RxING study reported that a community pharmacist prescribing intervention improved glycemic control in patients with uncontrolled T2DM. HbA1c was reduced from 9.1% (SD 1) at baseline to 7.3% (SD 0.9) at 26 weeks, whereas fasting plasma glucose (FPG) was reduced from 11 mmol/L (SD 3.3) at baseline to 6.6 mmol/L (SD 1.8) at 26 weeks.

The objective of this study was to evaluate the cost-effectiveness of pharmacists' prescribing of insulin glargine as an early intervention in patients with uncontrolled T2DM in comparison to waiting for later insulin initiation, as is often seen in usual diabetes care. This economic study was designed in order to understand and examine the impact and benefits of early initiation of insulin glargine (Lantus, Sanofi, Quebec, Canada) therapy via an economic evaluation based on data from the RxING study.

Methods

This cost-effectiveness analysis compared 2 groups of patients with uncontrolled T2DM with similar characteristics: one group was the RxING study cohort, while the other one was a hypothetical cohort followed by a physician. We assumed the 2 groups had the same baseline characteristics. The group followed by pharmacists was switched immediately to insulin and was assumed to continue on this treatment regimen. In the hypothetical delayed cohort, described below, patients were switched to insulin 1 to 5 years later, upon consulting the physician, reflecting the current clinical inertia reported in recent studies.^{4,5}

Model overview

Cost-utility analysis combines the incremental cost of the addition of insulin glargine to oral antidiabetic drugs (OADs) with the benefit it can bring in terms of quality and quantity of life, expressed as quality-adjusted life-years (QALYs). In addition, the model considers

different costs and disutilities for future diabetes-related complications. The IMS CORE Diabetes Model was used to evaluate the cost-effectiveness. Details of this model are described elsewhere.⁶ Simulations measured the costs and utilities associated with pharmacists' initiating insulin 2 years earlier than did the physician. It was assumed that patients would receive care from the same health care professional for the duration of the analysis.

A 50-year time horizon was considered to capture future diabetes complications during the patient's lifetime. We used a 5% discount rate. Only direct health care costs were considered in the model.

Direct medical costs, including treatment costs, pharmacy costs and medical costs related to the complications of having T2DM, were considered, as the perspective of this analysis was based on the Canadian health care system.

Patients

The IMS CORE Diabetes Model was populated based on the patients' characteristics from the RxING study.³ Default values from the IMS CORE Diabetes Model were retained if no data were available from the RxING study.

Characteristics that were not collected during the trial were taken from a previous study⁷ that economically evaluated third-line therapies in patients uncontrolled on the metformin-sulfonylurea combination. In this study, patients' mean age was 64 years, and they had diabetes for 9.2 years, HbA1c of 9.1%, body mass index of 29.4 kg/m² and a clinical diagnosis of T2DM for ≥ 6 months (Table 1).³ The model also took into account the rates of major and minor hypoglycemic episodes, which were 0.623% and 17.245%, respectively.

Clinical efficacy

As reported in the RxING study, pharmacists' initiation of insulin in patients with poorly controlled T2DM resulted in a 1.8% (95% confidence interval [CI], 1.4–2; $p < 0.001$) absolute reduction in HbA1c levels, as well as a 4.1 mmol/L (95% CI, 3.3–5; $p = 0.007$) absolute reduction in FPG.³

Resource use and cost data

Drug-related costs. The costs of OADs, insulin, needles, self-monitored blood glucose test strips and lancets were based on Canadian prices and are described in Table 2. A markup of 10% was

TABLE 1 Patient characteristics

Patient demographics			
Parameters	Mean	Unit	Reference
Start age	64	Years	RxING study ³
Duration of diabetes	10.2	Years	RxING study ³
Male	58	%	
Baseline risk factors			
HbA1c	9.1	%	RxING study ³
SBP	149	mmHg	IMS CORE ⁶
T-CHOL	234	mg/dL	IMS CORE ⁶
HDL	46	mg/dL	IMS CORE ⁶
LDL	157	mg/dL	IMS CORE ⁶
TRIG	162	mg/dL	IMS CORE ⁶
BMI	31.6	kg/m ²	RxING study ³
% smoker	22	%	RxING study ³
Cigarettes/day	2	—	IMS CORE ⁶
Alcohol consumption	2	oz/wk	RxING study ³
Racial characteristics (%)			
White	89	%	RxING study ³
Black	5	%	RxING study ³
Hispanic	0	%	RxING study ³
Native American	1	%	RxING study ³
Asian/Pacific Islander	5	%	RxING study ³

BMI, body mass index; HbA1c, hemoglobin A1c; HDL, high-density lipoprotein; LDL, low-density lipoprotein; SBP, systolic blood pressure, T-CHOL, total cholesterol; TRIG, triglyceride.

applied to the lowest available price, which also includes a \$7.00 pharmacy fee per 90-day supply.⁷ Eligible patients remained on OADs, which included metformin (2000 mg) and glyburide (10 mg), until a switch occurred to insulin glargine. It was assumed that patients were receiving the maximum daily dose of metformin when switched to insulin glargine.⁸ Doses of glyburide were based on the defined daily dose (DDD) published by the World Health Organization Collaborating Centre for Drug Statistics Methodology.⁹ The daily dose of insulin glargine (31.1 units) used in the model was based on the RxING study. It was assumed that there would be no changes to the doses of insulin glargine (once titrated) and oral

hypoglycemic agents. The use of lancets and test strips was also considered in the model. Patients using hypoglycemic agents, like insulin, typically test their blood glucose frequently; therefore, they use more test strips when compared to those on oral hypoglycemic agents. We assumed that patients on insulin would require 2.08 tests per day, whereas patients on oral hypoglycemic agents would require 1.16 tests per day.¹⁰

Costs due to diabetes complications. The costs of diabetes-related complications were obtained from various sources (Table 3) and expressed in 2014 Canadian dollars. All costs were inflated to 2014 using the health care component of the Canadian Consumer Price Index.⁸

TABLE 2 Insulin and glycemic test costs

Item	Cost (\$CAN)	Reference
Insulin glargine (vial)	\$60.52	Alberta cost ¹¹
Insulin glargine (cartridge, 1500 IU)	\$91.39	Alberta cost ¹¹
Syringes (per unit)	\$0.22	Harris et al. (2007) ¹²
Glyburide (10 mg/day)	\$0.11	Alberta cost ¹¹
Metformin (2000 mg/day)	\$0.23	Alberta cost ¹¹
Dispensing fee	\$7.00	Canadian Agency for Drugs and Technologies in Health report ⁷
Lancets (BD Ultra-Fine II Lancets)	\$0.06	Diabetes Depot (www.diabetesdepot.ca)
Test strips	\$0.80	Canadian Agency for Drugs and Technologies in Health report ⁷

Costs due to hypoglycemic episodes. It was assumed that mild/moderate hypoglycemic events required no health care resource use and as such had no associated costs.⁸ The cost of a severe hypoglycemia event was based on the 2013 CADTH report on optimal use of third-line therapies. The cost of a severe event was estimated at \$2030.91 (\$CAN 2012).⁸

Utility data

Patients with T2DM who had no complications were assumed to have a utility value of 0.80.¹¹ Disutilities for diabetes-related complications were obtained from the literature (Table 4).

Sensitivity analysis

In the sensitivity analysis, insulin initiation time by the physician varied (up to 5 years after the pharmacist), with the assumption that patients are initially followed by their pharmacist for the 1st year and by their physician thereafter.

Results

Pharmacists initiating insulin 2 years earlier than usual clinical practice resulted in a cost-saving intervention in patients with uncontrolled T2DM on OADs. The resulting improvement in glycemic control triggered savings in preventing long-term complications, despite the increase in treatment cost. It resulted in cost savings of \$624 (CDN\$) and a gain of 0.075 QALYs and 0.090 life-years, making the early pharmacist intervention dominant over usual clinical practice. Initiation at 1 year earlier also resulted in greater savings (\$805) and an improvement of 0.048 QALYs.

When looking at longer time intervals (3–5 years earlier), we noticed that the results became

cost-effective rather than cost-saving. At a 3-year interval, the cost difference was \$26 more for the pharmacist intervention, but the QALY gained remained higher than usual clinical practice (0.086 QALY gained), reaching an incremental cost-effectiveness ratio (ICER) of \$244/QALY. The trend was the same up to 5 years, with an increase in cost difference up to \$766, but also an increase in incremental QALY up to 0.101. At year 5, the ICER increased to \$7613/QALY (Table 5). Although the ICER increased, it remained well under the \$50,000 threshold that is often used in Canada.¹⁹

Discussion

The RxING study demonstrated that a pharmacist's prescribing of basal insulin in uncontrolled T2DM patients resulted in a 1.8% decrease in HbA1c. The findings of the RxING study are consistent with the findings of the Canadian INSIGHT study, which reported an absolute reduction of 1.55% in HbA1c when insulin was initiated by family physicians.²⁰ Considering this finding, one would wonder about the impact on the ability of pharmacists to provide savings to the health care system. This economic analysis shows that for the first 2 years, having pharmacists initiate insulin earlier is a cost-saving intervention where benefits (mostly preventing diabetes-related long-term complications) offset the additional cost of insulin glargine.

The expectations were that the longer the delay in initiating basal insulin, the greater the clinical benefits and savings would be. This rang true regarding the clinical benefits, as more complications were avoided while improving the QALYs and life-years gained; however, it was

TABLE 3 Complication costs related to type 2 diabetes mellitus

Description of event or state	Costs (\$CAN 2012)		Reference
	Year 1	Year ≥2	
Nonstandard ulcer treatment	\$180.33	—	Guillermin et al. (2011) ¹³
Myocardial infarction	\$19,103.93	\$2987.26	O'Reilly et al. (2006) ¹⁴
Angina	\$4099.68	\$1912.67	O'Reilly et al. (2006) ¹⁴
Congestive heart failure	\$17,476.22	\$4899.52	O'Reilly et al. (2006) ¹⁴
Stroke	\$26,021.11	\$3610.24	O'Reilly et al. (2006) ¹⁴
Fatal stroke	\$8123.33	—	O'Reilly et al. (2006) ¹⁴
Peripheral vascular disease	\$6168.53	—	Alberta Health and Wellness (2006) ¹⁵
Hemodialysis	\$78,545.59	\$78,545.59	Manns et al. (2003) ¹⁶
Peritoneal dialysis	\$55,632.22	\$55,632.22	Manns et al. (2003) ¹⁶
Renal transplant	\$100,042.42	\$42,067.72	Guillermin et al. (2011) ¹³
Major hypoglycemic event	\$142.97	—	O'Brien et al. (2003) ¹⁷
Lactic acidosis event	\$10,919.63	—	Ontario Case Costing Initiative (2010) ¹⁸
Edema onset	\$3590.92	—	Guillermin et al. (2011) ¹³
Retinal photocoagulation	\$637.56	—	O'Brien et al. (2003) ¹⁷
Cataract extraction	\$4226.19	\$2660.54	O'Reilly et al. (2006) ¹⁴
Severe vision loss/blindness	\$3196.87	\$2277.62	O'Reilly et al. (2006) ¹⁴
Neuropathy, onset	\$190.62	—	O'Brien et al. (2003) ¹⁷
Amputation, year of event	\$40,364.87	\$5528.36	O'Reilly et al. (2006) ¹⁴
Gangrene	\$10,048.91	—	O'Brien et al. (2003) ¹⁷
Infected ulcer	\$2811.69	—	O'Brien et al. (2003) ¹⁷
Uninfected ulcer	\$1342.09	—	O'Brien et al. (2003) ¹⁷

a different case when looking at costs. Results show that the intervention is cost-saving on a horizon of up to 2 years, while it becomes cost-effective thereafter. The fact that it becomes cost-effective instead of remaining cost-saving with an increasing delay is due to the fact that delaying insulin initiation reduces treatment costs but also maintains a suboptimal glycemic control in patients.

Increasing the delay in insulin therapy initiation is detrimental to glycemic control, increases the risk of long-term complications (while decreasing patients' quality of life) and goes against the main objective of the medical community, improving people's health. Moreover, relying on such a strategy to limit health

care spending goes against the basis of patients' well-being and optimal diabetes treatment. Despite this, however, our results still show that insulin initiation by pharmacists is a desirable intervention, as it is either cost-saving or well within the proposed cost-effective threshold of \$50,000/QALY. The annual cost difference, even at a 5-year delay, remains marginal in light of the clinical benefits this can bring to patients in avoiding late insulin initiation.

This model, although robust, took into account some simplified assumptions regarding the treatment and care of patients with uncontrolled T2DM. For example, at insulin initiation, OAD treatment was not the same across all patients, as it was not an inclusion criterion;

TABLE 4 Utilities and disutilities associated with type 2 diabetes complications

Utility or disutility	1st year/per event	Subsequent years	Reference
Utility for T2DM without complications	0.80	—	Cameron and Bennett (2009) ⁸
Myocardial infarction event (disutility per event)	−0.0409	−0.0120	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰
Angina	−0.0412	−0.0240	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰
Congestive heart failure	−0.0635	−0.0180	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰
Stroke event (disutility per event)	−0.0524	−0.0400	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰
Peripheral vascular disease	−0.0210	—	Cameron and Bennett (2009) ⁸
Microalbuminuria	−0.012	—	Cameron and Bennett (2009) ⁸
Gross proteinuria	−0.017	—	Cameron and Bennett (2009) ⁸
Dialysis	−0.160	—	Cameron and Bennett (2009) ⁸
Renal transplant	−0.030	—	Cameron and Bennett (2009) ⁸
Diabetic retinopathy	−0.0156	—	Cameron and Bennett (2009) ⁸
Macular edema	−0.0171	—	Cameron and Bennett (2009) ⁸
Severe vision loss/blindness	−0.0498	—	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰
Cataract	−0.0171	—	Cameron and Bennett (2009) ⁸
Neuropathy	−0.0243	—	Cameron and Bennett (2009) ⁸
Active ulcer (infected)	−0.1400	—	Cameron and Bennett (2009) ⁸
Active ulcer (uninfected)	−0.090	—	Cameron and Bennett (2009) ⁸
Amputation (disutility per event)	−0.280	−0.280	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰
Severe hypoglycemia (disutility per event)	−0.01	—	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰
Minor hypoglycemia (disutility per event)	−4.77E-06	—	Canadian Agency for Drugs and Technologies in Health (2013) ¹⁰

however, we do not expect this to have an impact on the economic results, as those agents were assumed to be the same for both comparative groups. We also assumed that patients were followed by either a pharmacist or a physician for diabetes management, while in reality, patients are usually managed by a health care team. The impact of having a 1st-year follow-up by pharmacists, and then carrying over to a physician, was assessed. Results were marginally affected

due to the difference in professional fees for management plans and follow-up visits.

In the analysis, we did not account for potential OAD intensification in the delayed insulin initiation group. That would have a direct impact on costs (increasing costs in the usual care group) and glycemic control (increasing benefits or reduced complications in the usual care group). Similarly, in the model, we assumed no insulin dose adjustments once the 6-month

TABLE 5 Cost-effectiveness of pharmacists' prescribing of insulin glargine as an early intervention in uncontrolled patients with type 2 diabetes mellitus vs usual clinical practice

Scenario (patient switching to insulin after x years)	Δ Cost	Δ QALYs	Δ LYs	Incremental cost/QALY	Incremental cost/LY
1 year	−\$805.00	0.048	0.061	Dominant	Dominant
2 years	−\$624.00	0.075	0.090	Dominant	Dominant
3 years	\$26.00	0.086	0.104	\$297	\$244
4 years	\$677.00	0.094	0.111	\$7240	\$6100
5 years	\$766.00	0.101	0.116	\$7613	\$6614

LY, life-year; QALY, quality-adjusted life-year.

titration was completed. This may have increased the cost of therapy but also may have improved the efficacy in the pharmacist group.

Conclusion

The findings of this analysis demonstrated the vital role that pharmacists can play in improving glycemic control in patients with uncontrolled

T2DM. Pharmacists' intervention for glycemic control in patients with uncontrolled T2DM being clinically beneficial in improving glycemic control projects reduced long-term complications while providing savings to the health care system. This could be an attractive approach considering current treatment gaps and the shortage of family physicians in certain areas in Canada. ■

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