

# Canadian Journal of Diabetes

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## DIABETES AND SOCIETY

# Diabetes in the Elderly

### INTRODUCTION

Diabetes is common in the elderly (1-3). At least 20% of elderly Caucasians have type 2 diabetes mellitus, and more than half of these individuals are not aware they have this disease. There is a substantially higher prevalence in other ethnic groups, most especially First Nations and East Asian populations.

### PATHOGENESIS

There is clearly a strong genetic predisposition to type 2 diabetes in the elderly, although the actual genes involved have not been clearly defined (1-3). However, there are multiple other factors that contribute to the high prevalence of diabetes in this age group. Normal aging is characterized by progressive alterations in insulin secretion and insulin action. Many older individuals are inactive or obese or have a diet that is low in complex carbohydrates and high in fat. Older patients frequently have diseases characterized by inflammation and higher levels of inflammatory cytokines. Finally, older people often take multiple drugs and have multiple comorbid conditions that can alter glucose metabolism. Thus genetic, physiologic and environmental factors work in concert to result in a high prevalence of diabetes in the elderly.

Most middle-aged patients with type 2 diabetes have increased fasting hepatic glucose production, impaired glucose-induced insulin secretion and resistance to insulin-mediated glucose disposal (4). Diabetes in the elderly is metabolically distinct (5-8). Fasting hepatic glucose production is not increased. Lean older subjects with type 2 diabetes have a marked impairment in insulin secretion but relatively normal insulin action, whereas obese older subjects have relatively normal insulin secretion but marked resistance to insulin-mediated glucose disposal. These metabolic abnormalities suggest that the therapeutic approach should be different in older people. Lean patients should be treated initially with either an insulin secretagogue or insulin since the principal defect is an impairment in glucose-induced insulin secretion. In contrast, obese patients should be treated with agents that enhance insulin sensitivity.

There is evidence that autoimmune phenomena may play a role in the pathogenesis of type 2 diabetes in some lean older patients (1). It is possible in the future that measurements of autoimmune parameters such as anti-glutamic acid decarboxylase or islet cell antibodies will be performed

at diagnosis in lean older patients with diabetes to predict which patients are more likely to require insulin therapy early in the course of their condition.

### PRESENTATION AND CLINICAL FEATURES

Because the renal threshold for glucose increases with age, older people do not develop glucosuria until the plasma glucose level is extremely elevated. In addition, older people have impaired thirst mechanisms so that even when they develop hyperglycemia, they often do not develop thirst (1-3). For this reason, the classic symptoms of diabetes are usually not present in this age group, and the diagnosis is made when the patient goes for routine health screening or is admitted to hospital for an intercurrent illness. If symptoms are present, they tend to be nonspecific.

### COMPLICATIONS

Although diabetes is listed as the sixth-leading cause of death among the aged, it is actually a much more common cause of death because it contributes to many cardiovascular events (1-3). Older patients with diabetes have double the mortality of age-matched controls without the disease, and the principal reason for death is macrovascular events. Diabetes is one of the strongest predictors of functional decline in older people (9). Older people with diabetes have a poorer quality of life and use substantially more healthcare resources.

#### Vascular complications

There is clearly an increased risk for microvascular and macrovascular complications as well as heart failure in older people with diabetes, and the risk of these complications increases with the age of the patient, the duration of the diabetes and glycated hemoglobin (A1C) values. This suggests that improved glycemic control may reduce the risk of complications. There is some evidence that improving glycemic control reduces the risk of microvascular complications in these patients, but the effect on macrovascular complications is far from certain. It is abundantly clear, however, that modification of other risk factors, such as hypertension and hyperlipidemia, has a beneficial effect on the risk for macrovascular events in these patients.

#### Hypoglycemia

Older people have an increased risk of severe or fatal hypoglycemia when treated with insulin or certain oral agents (1-3,10,11). This is due to impaired secretion of counterreg-

ulatory hormones, particularly glucagon, reduced awareness of autonomic warning symptoms of hypoglycemia, and lack of education about the symptoms of hypoglycemia (12,13). The only way to prevent this complication in the elderly is through better education of older people about the symptoms of and treatment for hypoglycemia, and to use oral agents or insulin that are associated with lower frequency of hypoglycemia.

### Cognitive function

It is clear that the risk for vascular dementia and Alzheimer's disease increases in older people with diabetes, but it is not known at this stage if improved glycemic control or control of risk factors will reduce the risk of dementia in this age group (1-3). Older people with diabetes also have a higher incidence of depression, and some data suggest that improved glycemic control improves affective function (14,15).

### PREVENTION OF DIABETES

While 20 to 25% of older people have diabetes, another 20 to 25% have impaired glucose tolerance (1-3). The Diabetes Prevention Program suggested that while metformin is not a particularly effective intervention to reduce the risk of diabetes in the elderly, lifestyle interventions are very effective (16). The Study to Prevent Non-Insulin-Dependent Diabetes Mellitus demonstrated that alpha-glucosidase inhibitors reduced the frequency of diabetes in this age group and also decreased the incidence of macrovascular events (17). It has also been shown that thiazolidinediones can effectively prevent diabetes (18) in the elderly, but there is concern about the use of these medications because of an increased incidence of side effects.

### DIAGNOSIS AND MONITORING

Given that diabetes is so common in the elderly, it has been suggested that there should be widespread screening for diabetes on the assumption that earlier intervention will reduce the risk of complications. Fasting glucose is not a particularly robust screening test in the elderly because a substantial number of cases of diabetes in this age group will be missed using this test. Recently, various organizations around the world have recommended that standardized measurement of A1C may be a reliable screening tool in people with diabetes of all age groups. Further data is needed to validate this as a screening test for diabetes in the elderly.

### TREATMENT GOALS

Currently, there is substantial controversy about the benefits of improved glycemic control in patients with diabetes (19-22). The consensus of opinion seems to be that tight glycemic control appears to be beneficial if it is instituted

early in the course of the condition, before complications develop. In addition, tight control may reduce the risk of microvascular events in patients whose condition is of longer duration. Unfortunately, since there is a lack of data from randomized controlled trials in patients over 70, it is difficult to set treatment goals. However, it is worth keeping in mind that the average 80-year-old woman with diabetes in North America has a life expectancy of approximately 9 years, but can expect to spend the vast majority of that time with a major disability. In patients with diabetes, the main cause of disability is vascular disease. Anything that can reduce the risk of these complications will improve function and quality of life in the elderly. Although the benefits of tight glycemic control are controversial, data from randomized controlled trials demonstrate that control of blood pressure and lipids will have a substantial impact on the risk of complications and quality of life in this age (23-28).

The European Geriatrics Society and the International Diabetes Federation have developed guidelines for the control of diabetes and associated risk factors in older people (see Tables 1 and 2) (29). These guidelines must be individualized based on comorbidity and functional status.

**Table 1. Glycemic targets in older patients with diabetes**

	<i>Healthy</i>	<i>Frail</i>
Fasting blood glucose	<7.0 mmol/L	<10.0 mmol/L
2-h postmeal glucose	<10.0 mmol/L	<14.0 mmol/L
A1c	<7.0%	<8.5%

A1c = glycated hemoglobin

**Table 2. Blood pressure and lipid targets in older people with diabetes**

	<i>Healthy</i>	<i>Frail</i>
Blood pressure	<140/80 mm Hg	<150/90 mm Hg
LDL-C	<3.0 mM	—
TG	<2.3 mM	—

LDL = low-density lipoprotein cholesterol

TG = Triglyceride

### THERAPEUTIC OPTIONS

It is difficult to treat older people with diabetes because of their complex social situations, polypharmacy and multiple illnesses. Therefore, a team approach to management is essential. Multidisciplinary programs for older patients have been shown to result in better compliance with therapy and improved glycemic control (30-32). The involvement of family members in the management plan is absolutely essential. For elderly patients with diabetes, risk-factor modification is essential. Calcium channel blockers, diuretics, angiotensin-receptor blockers and angiotensin-converting enzyme inhibitors are all effective antihypertensive agents and reduce the

risk of cardiovascular events. Beta-blockers are not particularly effective antihypertensive drugs in this age group. Several randomized control trials suggest that treatment with statins reduces the risk of cardiovascular events and overall mortality in older people with diabetes (23-25).

### Diet and exercise

Several groups have recommended dietary guidelines for diabetes in older patients, but there is little objective data to support these recommendations. Older patients appear to benefit from weight loss, but rigorous diets for people with diabetes do not appear to result in marked improvements in glycemic control in older patients who reside in nursing homes (33). Older patients with diabetes may be deficient in trace elements, and several small short-term studies suggest that supplementation with magnesium, zinc and antioxidant Vitamins C and E may improve glycemic control (1-3).

Exercise has been evaluated in a number of small randomized control trials (34-36). These studies have found that strength training may significantly improve glycemic control in these patients, but aerobic exercise has a limited impact.

### Medication management

Although it has never been evaluated in randomized control trials in this age group, metformin appears to be safe and relatively effective in older people with diabetes. Acarbose is a modestly effective drug in the elderly (37). Most patients are able to tolerate the gastrointestinal side effects of this drug if it is titrated carefully. Thiazolidinediones are very effective drugs in the elderly, but there is concern about their use (38,39). The risk for fluid retention triples in these patients, and there are also concerns about the effects on bone density. Issues regarding the potential cardiovascular toxicity of rosiglitazone have yet to be fully resolved.

The risk of severe or fatal hypoglycemia with glyburide increases exponentially in the elderly (1-3,10,11). This risk appears to be less with gliclazide and glimepiride, and these agents are the preferred sulfonylureas in the elderly (40-42). Repaglinide and nateglinide are rapidly acting insulin secretagogues that result in a lower frequency of hypoglycemia than glyburide in the elderly and may be particularly useful for older people who eat erratically.

There are no studies as yet evaluating the use of exenatide and liraglutide in this age group. Several short-term studies suggest dipeptidyl peptidase-4 inhibitors are effective agents in the elderly (43,44). Long-term efficacy and potential side effects in this age group have not been evaluated.

Because older people frequently make errors when they try to mix insulins, premixed insulins result in improved accuracy (45,46). Insulin pens also result in more accurate dosing of insulin in this age group. Insulin glargine and

detemir are associated with a lower frequency of hypoglycemia in older people with diabetes than conventional insulin regimens (47,48).

## SUMMARY

We are approaching an epidemic of diabetes in the elderly. Diabetes can be prevented in a large number of elderly patients with appropriate intervention. Because diabetes is metabolically distinct, the approach to therapy should differ in older patients. Further studies are clearly needed to define the most therapeutic interventions in this age group.

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## Thank you to the world class experts in diabetes management and education!

National Volunteer Week (April 10–16th) is approaching and is a time to recognize healthcare professionals who volunteer with the Canadian Diabetes Association. Your contributions to the Association are invaluable and you are helping us to deliver our mission by translating research into practical applications. Thank you for being leaders in the fight against diabetes.

## RESEARCH UPDATE

# Dr. David Cherney, Canadian Diabetes Association–KRESCENT Joint New Investigator Awardee

In 2010, Dr. David Cherney (Figure 1), a clinician–scientist at the University Health Network in Toronto, was awarded both a Canadian Diabetes Association Clinician–Scientist Award and a Kidney Research Scientist Core Education and National Training (KRESCENT) program New Investigator Award. The Canadian Diabetes Association (CDA), Canadian Society of Nephrology (CSN) and the Kidney Foundation of Canada (KFOC) recognized that this provided a unique opportunity to support an up-and-coming researcher to a greater extent than any of the organizations could do individually. Thus, the 3 organizations entered into a pledge agreement to support Dr. Cherney with the CDA–KRESCENT Joint New Investigator Award. This award consists of 3 years of joint funding (half from the CDA and half jointly from the CSN and KFOC) followed by 2 years of funding from the CDA alone.

The Canadian Diabetes Association Clinician–Scientist Award supports the development and retention of highly qualified clinician–scientists in the early stages of their careers in diabetes research in Canada. Clinician–scientists are pursuing careers that include both patient care and research, and play a critical role in shaping research projects that respond to hypotheses and questions arising in practice settings, and also in translating the findings of research into clinical practice. The KRESCENT program New Investigator Award is given to individuals who have clearly demonstrated excellence during their pre- and post-doctoral training in kidney disease. The purpose of this award is to assist such individuals to become established as fully independent investigators in the field of kidney disease.

Diabetes continues to be the most frequent primary cause of end-stage renal disease in Canada, accounting for 35% of Canadian patients (1). Dr. Cherney believes that prevention of kidney disease early in the natural history of diabetes is therefore of utmost importance. In order to further his knowledge of diabetes and kidney disease, and to find ways of preventing kidney damage, Dr. Cherney's long-term aim is to establish a premiere human renal physiology laboratory in Canada. His research focuses on 2 areas of study: the nitric oxide system and the renin-angiotensin system (RAS). In each of these areas, Dr. Cherney will combine physiological assessments of blood vessel function with measures of molecular markers.

Dr. Cherney is recognized for having made a significant contribution to the understanding of human kidney function, particularly kidney disease associated with diabetes.



Figure 1. Dr. David Cherney

He has identified gender differences in kidney function in healthy people (2) as well as in people with type 1 diabetes (3). Dr. Cherney realized that it would be important to understand how vasodilatory systems impact kidney hemodynamic function. He found that angiotensin-converting enzyme (ACE) inhibition results in an incomplete reduction in kidney hyperfiltration, which may account for the partial kidney protection that results from ACE inhibitors (4), and that blocking the effects of cyclooxygenase-2 results in partially reduced hyperfiltration, similar to ACE inhibition (5).

Kidney damage from diabetes is, in part, mediated by activation of the RAS by high blood glucose (6). Blocking the RAS with ACE inhibitors and type 1 angiotensin II receptor blockers will slow the damage but will not stop the progression of kidney disease (7-10). More recently, a new class of RAS blockers, called direct renin inhibitors (DRIs), has become available. DRIs have a better effect on blood flow than previous medications and may have advantages over ACE inhibitors (11,12).

Dr. Cherney's current research focuses on the effects of two drugs, ACE inhibitors and DRIs (alone and in combi-

nation) on blood vessel function and on the proteins that promote kidney injury in people with type 1 diabetes. In this study, people with type 1 diabetes will be treated with a DRI for 4 weeks, followed by treatment with a DRI and ACE inhibitor for an additional 4 weeks. Dr. Cherney and his team will measure kidney and artery function at each step and will relate this to levels of kidney injury proteins found in the urine.

The aim of Dr. Cherney's project is to better understand how diabetes affects kidney and blood vessel function, and to find new approaches to manage diabetes.

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## EDITORIAL COMMENTARY

## Self-Monitoring of Blood Glucose Levels in Persons with Type 2 Diabetes Not Requiring Insulin: Routine Use Is Not Recommended

The time has come to question the benefit of one of our routine clinical practices in diabetes education and care. Are we guilty of “treatment creep” in teaching people with type 2 diabetes who do not require insulin about self-monitoring of blood glucose (SMBG)? Why is SMBG perceived by health professionals as a valuable tool of empowerment for persons with type 2 diabetes who are not using insulin? Is this practice reinforced by the prominence of SMBG equipment in the diabetes displays of most pharmacies in Canada?

In this issue of the *Canadian Journal of Diabetes*, Latter and colleagues review the practices of health professionals in making SMBG recommendations for adults with type 2 diabetes treated with lifestyle (with or without oral drugs) in Nova Scotia during the winter months of 2007–2008 (1) prior to publication of the *Canadian Diabetes Association 2008 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada* (the 2008 clinical practice guidelines) (2). The 2003 clinical practice guidelines published 5 years earlier recommended that “all people with diabetes, who are able, should be taught how to self-manage their diabetes, including SMBG” (3). The evidence that was used to make that recommendation was a systematic review of comprehensive self-management training in type 2 diabetes published in 2001 (4). The 2003 clinical practice guidelines recommended that the frequency of SMBG should be based on the treatment prescribed, the type of diabetes and the individual’s ability to use the results to modify behaviours or adjust medication. In the current study by Latter and colleagues, the health professionals were guided by those 2003 recommendations. It was common practice at that time to recommend SMBG several times per week at different times of the day to provide information to patients and providers on the variability of blood glucose levels in response to carbohydrate intake, mixed meals and exercise. The authors interviewed a small, self-selected group of 21 volunteer physicians, diabetes educators and pharmacists (1). All participants recommended some form of SMBG for adults with type 2 diabetes treated with lifestyle modification (with or without oral drugs). The healthcare providers were reluctant at that time to rely solely on glycated hemoglobin (A1C) for surveillance of glycemic control in this group of patients. The difference in responses between the 3 professional groups related only to the recommended frequency of SMBG testing.

Since publication of the 2003 and 2008 clinical practice guidelines, diabetes practice has evolved in Canada, but have we evaluated our individual beliefs, biases and local policies on SMBG for persons with type 2 diabetes who do not require insulin? As these authors indicate in the discussion section of the paper, the current 2008 CDA recommendations are open to broad interpretation because it is not clearly stated that SMBG is ineffective in improving glycemic control in this group of patients but rather that the “frequency of SMBG should be individualized” (2). The Cochrane review of this topic is not helpful because it has not been updated since 2005 (5); the conclusions are similar to the 2003 CDA guidelines. A recent 2010 systematic review conducted by the Aberdeen Health Technology Assessment Group in Europe (6) and another recent comprehensive review of 14 published randomized controlled trials (7) concluded that SMBG is of limited value in adults with type 2 diabetes who are not using insulin. A similar conclusion was reached by the Canadian Optimal Medication and Prescribing Service of the Canadian Agency for Drugs and Technologies in Health (8).

The role of SMBG is particularly perplexing in adolescents with type 2 diabetes who do not require insulin. Pediatric diabetes teams routinely teach the use of SMBG upon diagnosis of type 1 diabetes. Perhaps it is most difficult for these teams to switch gears for youth with type 2 diabetes. However, factors mitigating this challenge are the dramatic differences in the education and counselling of youth with type 2 diabetes about self-management and the lack of any evidence of a role for SMBG in type 2 diabetes in this age group. A randomized controlled trial of the impact of SMBG on glycemic control and the potential negative emotional effect in the adolescent population with type 2 diabetes is desperately needed. Alternatively, perhaps we need better health information systems to ensure that patients of all ages have access to their personal A1C results, better tools that are age- and culturally appropriate to help them interpret their A1C, and better strategies to internalize and track their A1C level over time (9).

Recognition of the need for highly selective and limited use of SMBG in adolescents and in adults with type 2 diabetes who are not using insulin is important for a number of reasons. Most important is consistent and simple messages in the rapidly evolving world of inter-professional chronic

disease management, which are vital for achieving improved population health. The recommendation for SMBG must be the same in primary and specialty care, within and between health professionals, and in both small, isolated and large, urban settings. We must also convince leaders in healthcare settings to abandon the use of SMBG as a measure of quality in clinical care so that professionals will believe they will not be judged on the number of patients who successfully implement SMBG. Lastly, we hope the savings in public funding for strips can be diverted to human resources to encourage behaviour modification in order to achieve optimum glycaemic control.

The new version of the clinical practice guidelines will be available in 2013. The evidence is mounting quickly that health professionals working with people with type 2 diabetes who do not require insulin must use SMBG in more selective and limited circumstances (7).

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Look for the notification in your inbox or mailbox of the Regional Annual Meeting in your community this spring or go to <http://www.diabetes.ca/get-involved/community> to find the Regional Award Nomination Forms.

## EDITORIAL COMMENTARY

## Diabetes Self-Management Education: More is Better

There has been a growing understanding about the benefits of diabetes self-management education (DSME) in recent years. One of the key findings guiding the most recent research and intervention efforts in this field is the growing evidence of the sustainability of improvements and behavioural changes made during DSME. We now understand that improvements made during education tend to fade after 6 months (1-3). While some might view this as evidence that DSME is ineffective, in reality the contrary is true. Education works and does what could be expected as a short-term intervention. But diabetes is complex, progressive and lasts a lifetime. As a result, ongoing information and support is needed for people with all types of diabetes so they can manage effectively as their health, psychosocial and life circumstances change. Based on this evidence, the current international and United States DSME Standards recommend ongoing diabetes self-management support (DSMS) following diabetes education (4-5).

One of the issues with recommendations for ongoing DSMS is how to provide this type and level of support within existing healthcare systems that allow only limited educational benefits. A proposed option is to increase the number of trained peer leaders and community health workers who can provide behavioural and emotional support at a lower cost and in more convenient community locations (6). The article by McGowan and colleagues provides an excellent example of this type of model. Using lay health workers within the community (trained in a previously developed and tested program) is more cost-efficient than creating a new program delivered by diabetes educators. It also maximizes the skills of both diabetes educators and lay leaders so everyone can do what they do best. Based on the reported outcomes, program participants clearly benefited. But there are benefits for the healthcare system as well; better outcomes translate into fewer complications and lower costs in the future.

But this type of approach represents a change in how we practice, and health professionals struggle with change just as much as patients. Our messages about diabetes education now need to reflect this new understanding. One of the issues faced by McGowan was that fewer than one-fourth of the patients wanted to participate in the ongoing DSMS program, citing time as a barrier to “additional” education. Clearly, we need to help patients understand that diabetes requires lifelong learning and support, and that ongoing education is not additional to education but an integral component. Diabetes educators also need to help other

health professionals understand that continuing support is essential for improved outcomes. The message also needs to convey that this is not a negative reflection on the educator or the education program, but a reflection of the self-management burden imposed by diabetes.

New messages are needed for funding providers and government leaders about what is needed in diabetes care, as well. In many ways, this is analogous to the early days of diabetes education when pioneers in the field fought hard for recognition of the importance of education and for coverage. It is now time to make a similar effort for ongoing DSMS. Although some might argue that the economic climate is not right to ask for something new, in reality this is the ideal time. Assisting patients to maintain improved outcomes has the potential to reduce both the personal and healthcare system costs of diabetes. Using lay and peer leaders within communities can provide a more economical way to accomplish this goal.

As the number of people with diabetes continues to rise, all of us who work in this field must become more creative about how we provide education and care. McGowan implemented and tested one effective model. We now need to develop and test this model in other populations and settings and evaluate other models and approaches. When it comes to education, more is better. And our patients deserve the best.

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## ORIGINAL RESEARCH

# Lifestyle and Care Indicators in Individuals with Major, Minor and No Depression: A Community-Based Diabetes Study in Quebec

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## ABSTRACT

**OBJECTIVE:** To investigate the association between depression status (major, minor, no depression) and lifestyle and care indicators in adults with diabetes in Quebec.

**METHODS:** A random-digit-dial telephone survey was conducted. Depression status was evaluated using the Patient Health Questionnaire (PHQ-9). Self-reported lifestyle and care indicators, along with perceptions related to these indicators, were measured. Logistic regression was used to assess the independent associations between depression status and lifestyle/care/perception indicators.

**RESULTS:** Among the 2003 respondents, 8.7 and 10.9% had major and minor depression, respectively. Of those with major depression, 53.4% had 2 or 3 unhealthy lifestyle indicators (smoking, inactivity, obesity), compared with 33% of those who had minor depression and 21% of those who had no depression. Results of logistic regression analyses indicated that subjects with depression were more likely to be female, less educated, not married, inactive, smokers and to perceive their diabetes control to be poor ( $p < 0.05$ ). Depression was not associated with obesity, but was associated with the perception of not being able to control the amount of food eaten ( $p < 0.05$ ). Depression was also associated with more frequent blood glucose testing ( $p < 0.05$ ).

**CONCLUSION:** Management of diabetes for individuals with depression should not focus solely on lifestyle or care indicators; it should also take perception indicators into account.

**KEYWORDS:** behaviours, care, depression, diabetes, lifestyle behaviours

## RÉSUMÉ

**OBJECTIF :** Étudier le lien entre le statut dépressif (dépression majeure, dépression mineure, pas de dépression) et les indicateurs du mode de vie et des soins chez des adultes atteints de diabète au Québec.

**MÉTHODES :** Un sondage téléphonique a été mené au moyen d'un système d'appel aléatoire. Le statut dépressif a été évalué à l'aide du questionnaire sur la santé du patient (PHQ-9). Les paramètres évalués étaient les indicateurs du mode de vie et des soins selon la personne interrogée et les perceptions relatives à ces indicateurs. On a procédé par régression logistique pour évaluer les liens indépendants entre le statut dépressif et les indicateurs du mode de vie, des soins et des perceptions.

**RÉSULTATS :** Parmi les 2003 répondants, 8,7 % souffraient de dépression majeure et 10,9 % de dépression mineure. Il y avait deux ou trois indicateurs de mode de vie malsain (tabagisme, sédentarité, obésité) chez 53,4 % des personnes souffrant de dépression majeure, par rapport à 33 % de celles souffrant de dépression mineure et à 21 % de celles ne souffrant pas de dépression. Les résultats des analyses de régression logistique ont révélé que les sujets dépressifs étaient plus susceptibles d'être de sexe féminin, d'être moins instruits, de ne pas être mariés, d'être sédentaires, d'être fumeurs et de percevoir comme médiocre leur maîtrise du diabète ( $p < 0,05$ ). La dépression n'était pas liée à l'obésité,

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mais plutôt à la perception de ne pas pouvoir maîtriser la quantité de nourriture ingérée ( $p < 0,05$ ). La dépression était aussi liée à une plus grande fréquence de mesures de la glycémie ( $p < 0,05$ ).

**CONCLUSION :** La prise en charge du diabète chez les personnes dépressives ne doit pas mettre l'accent uniquement sur les indicateurs du mode de vie ou des soins, mais doit aussi tenir compte indicateurs des perceptions.

**MOTS CLÉS :** comportements, soins, dépression, diabète, mode de vie

## INTRODUCTION

Rates of depression in Canada range from 4.8 to 8.2% (1-3) and are at least twice as high among individuals with diabetes (4-8). The presence of depression has important implications for diabetes management and adherence to treatment (4) and has been found to be associated with increased healthcare expenditure (5) and higher risk of complications (9). Depression has also been associated with perceived lack of control of diabetes (10) and poorer care behaviours, such as fewer ambulatory care visits (11) and less frequent blood glucose testing (12). It is also well documented that depression is associated with poorer lifestyle behaviours (8,12-18). However, few studies have examined the association between severity of depression and these behaviours (8,16,18).

Surveys among individuals with diabetes have consistently shown that tobacco use is twice as frequent among those with major depression (14-16). Indeed, the results of one study showed that the severity of depression was associated with tobacco use: 26% of those with major depression smoked, compared to 20% and 12% with minor and no depression, respectively (16). Lower physical activity levels have also been found to be associated with depression status (12,14). In a study exploring diabetes and lifestyle, 44% of those with major depression engaged in physical activity less than twice a week, compared to 27% without major depression (14). In type 2 diabetes, those with major depression exercised less frequently (mean of 1.96 days/week) compared to those without major depression (2.81 days/week) [12]. As well, those with major depression were also more likely to have consumed fewer fruits and vegetables and more high-fat foods (12,14,17). When lifestyle behaviours (smoking status, physical activity, and fruit and vegetable intake) were clustered, there was an inverse association between mental distress and unhealthy lifestyle behaviours (18). In fact, only 12% of adults with diabetes reported having 3 healthy lifestyle behaviours (non-smoking;  $\geq 30$  minutes of physical activity  $\geq 5$  days/week; and at least 5 daily servings of fruits and vegetables). Similarly, another study reported

that poorer adherence to treatment (meal plan, exercise and medications) was associated with depression (19).

In diabetes, depression and obesity have also been linked, although not consistently. While one study found that severity of depression was associated with obesity (67% of those with major depression were obese, compared to 55% with minor depression and 47% with no depression) (8), others have found no association between body mass index (BMI) categories (underweight, normal weight, overweight, obese) and major depression in diabetes (15,17). In a sample of individuals with type 2 diabetes, those with major depression had a higher mean BMI ( $34.2 \pm 6.2$  kg/m<sup>2</sup>) than those without major depression ( $30.7 \pm 6.2$  kg/m<sup>2</sup>) (12). In contrast, in a prediabetes population participating in the Diabetes Prevention Program, no association between BMI and depression status was observed (20). Among adults with type 2 diabetes, perceptions have been reported to mediate the relationship between depression and lifestyle indicators. In fact, self-efficacy has been found to mediate the relationship between BMI and depression, as well as between treatment adherence and depression (21-22).

The severity of depression in relation to lifestyle/care indicators in people with diabetes has not been extensively examined, nor has the association with perceptions related to these indicators. Furthermore, as shown above, the evidence for an association between obesity, BMI and depression is, at best, equivocal. Therefore, the primary objective of this study was to describe lifestyle/care/perception indicators associated with major, minor and no depression in a community-based sample of adults with diabetes in Quebec. We hypothesized that individuals with diabetes and major or minor depression would be more likely to have poorer lifestyle/care/perception indicators than those without depression. Our secondary objective was to examine the contribution of lifestyle/care/perception indicators to depression status. The results of this study will inform health professionals planning treatment programs for individuals with diabetes and depression.

## METHODS

The Montreal Diabetes Health and Well-Being Study is a population-based longitudinal study designed to examine the association between depression and disability in adults with diabetes in Quebec. As previously described (23), participants were recruited between January and April 2008 using a random-digit-dial method. Telephone interviews, 30 minutes in duration on average, were conducted at baseline and 1 year later. Adults, 18 to 80 years of age, with a physician diagnosis of diabetes, were eligible to participate; subjects also needed to be able to respond to questions in French or English. Participants received \$20 for each completed interview. The protocol was approved by the

Research Ethics Committee of the Douglas Mental Health University Institute, McGill University, Montreal, Quebec, Canada. Informed consent was obtained from each participant. This manuscript presents the results of baseline data.

## **Variables**

### ***Depression status***

Depression status was assessed with the Patient Health Questionnaire (PHQ-9), which was used to classify subjects into 3 categories: major, minor and no depression (24). For major depression, individuals must have reported 5 or more depressive symptoms for more than half of the days, 2 weeks prior to the interview, with at least 1 of these symptoms being either depressed mood or anhedonia. For minor depression, individuals must have had 2 to 4 symptoms, with at least 1 of the symptoms being either depressed mood or anhedonia (24). The PHQ-9 has high sensitivity (75%) and specificity (90%) compared to structured psychiatric interviews (24).

### ***Diabetes***

The presence of diabetes was based on self-report. Individuals who reported a diagnosis of diabetes before 30 years of age and insulin treatment at the time of diagnosis were classified epidemiologically as having type 1 diabetes (25). Individuals were classified as having type 2 diabetes if they were not currently treated with insulin therapy; if they were diagnosed with diabetes at or after 30 years of age; or if they were diagnosed before 30 years of age, but were not treated with insulin at diagnosis.

### ***Sociodemographic indicators***

The sociodemographic characteristics of the sample were determined using questions adapted from the Canadian Community Health Survey, 3.1 (26).

### ***Lifestyle indicators***

Tobacco use included 2 groups: current smokers and non-smokers (never smoked or smoked formerly). Physical activity was evaluated using the following question: On how many days did you exercise or participate in sports activity for at least 15 minutes in the last month? Responses were provided in number of activity sessions per day, per week or per month and categorized into 3 groups: inactive (0 times per month); somewhat active (1 to 12 times per month); moderately active (>12 times per month). BMI was calculated based on self-reported weight and height (body weight in kg/[height in m]<sup>2</sup>).

### ***Care indicators***

Subjects were asked whether they had visited a physician for diabetes treatment in the past year (yes/no) and how

frequently they tested their blood glucose levels (number of tests per day, per week or per month and categorized into 2 groups: <1 time per day and ≥1 time per day). Sub-analyses were also conducted for those with type 1 and type 2 diabetes. Since subjects with type 1 diabetes tested their blood glucose levels more than once a day, their responses were categorized as testing <3 times per day and testing ≥3 times per day, taking into account the blood glucose monitoring recommendations in the Canadian Diabetes Association 2008 clinical practice guidelines (4).

### ***Perception indicators***

Subjects were also questioned about their perceptions of diabetes control (In the past month, would you say that the control of your diabetes was: excellent, very good, good, fair, poor?); blood glucose control (In the past month, would you say your blood glucose levels were: excellent, very good, good, fair, poor?); ability to control body weight (In general, how confident do you feel that you can control your weight: not at all, a little, moderately, very much?); and ability to control the amount of food eaten (In general, how confident do you feel that you can control the amount of food you eat: not at all, a little, moderately, very much?).

### ***Complications***

Complications of diabetes were assessed using the Diabetes Complications Index (DCI), a self-report measure (27). This questionnaire consists of 17 questions used to identify 6 complications: coronary artery disease (5 questions), cerebrovascular disease (3 questions), peripheral vascular disease (2 questions), neuropathy (2 questions), foot problems (3 questions) and eye problems (2 questions). When a complication was present, a score of 1 was assigned; when it was not present, a score of 0 was assigned. Scores were summed and could range from 0 to 6.

### ***Lifestyle behaviour clustering***

Lifestyle behaviours were clustered into 4 profiles: 3 unhealthy lifestyle indicators (smoker, physically inactive and obese); 2 unhealthy lifestyle indicators; 1 unhealthy lifestyle indicator; and 3 healthy lifestyle indicators (non-smoker, somewhat or moderately active and not obese).

### ***Statistical analysis***

Data were analyzed using the SPSS statistical software package version 17.0 (SPSS Inc., Chicago, Illinois). Chi-square analyses were conducted to describe the characteristics of subjects with major, minor and no depression for socio-demographic, lifestyle, care and perception indicators.

A series of logistic regression analyses were then conducted to determine factors that predicted depression status. For these analyses, depression status was regrouped as major/

minor vs. no depression and entered as the dependent variable. First, logistic regression analyses were conducted with each indicator. Second, stepwise logistic regression analyses (backward method) were conducted for each group of the indicators (sociodemographic: sex, age, education and marital status; lifestyle: smoking, physical activity and obesity; care: frequency of blood glucose testing and visits to a physician; and perception: diabetes control, blood glucose control, body weight control and eating control). Indicators that remained significant in each group were then included in the final regression model. The level of significance was set at  $p < 0.05$ .

## RESULTS

A total of 2003 adults with diabetes participated in this study: 86 486 phone calls were made, 62 439 persons were reached, 54 930 agreed to be interviewed, 3221 reported having diabetes and were eligible to participate, and 2003 completed the baseline interview. The response rate among those eligible was 62%. Among the 2003 participants, 54.4% were female, 42.8% had less than a high school education and 61.6% were married. The mean age ( $\pm$ SD) was 59 (12.4) years, with 64.5% being under 65 years of age. Ninety-three percent were classified as having type 2 diabetes.

The prevalence of major depression was 8.7% and of minor depression was 10.9%. Depression status was found to be associated with sociodemographic indicators (Table 1): those with major or minor depression were more likely to be female, have less education and be married ( $p < 0.05$ ). Subjects 50 to 64 years of age were more likely to have major depression than those aged 18 to 49 or  $\geq 65$  years ( $p < 0.05$ ). Depression status, however, was not found to be associated with type of diabetes or number of complications as assessed by the DCI.

Table 1 presents lifestyle/care/perception indicators among study participants with diabetes, according to depression status. Among those with major depression, 42.5% smoked, compared to 21.2% and 19.0% among those with minor and no depression, respectively. In terms of physical activity, 52.9% of those with major depression were physically inactive, compared to 43.2% with minor depression and 25.5% with no depression. In addition, 48.1 and 46.4% of those with major and minor depression were obese, respectively, compared to 40.9% of those with no depression.

Of those with major depression, 53.4% had 2 or more unhealthy lifestyle indicators, compared to 32.8% with minor depression and 20.9% with no depression (Figure 1). Furthermore, logistic regression analysis showed that 2 or 3 unhealthy lifestyle indicators had an independent and strong association with depression status (OR 2.71, 95% CI 1.91–3.86; and OR 4.49, 95% CI 2.24–9.01,  $p < 0.001$ ,

respectively), whereas 1 unhealthy lifestyle indicator was not significantly associated with depression when controlling for sociodemographic, care and perception indicators.

For care indicators (Table 1), individuals with major depression were more likely to test their blood glucose levels more than 1 time per day (77.7%) than those with minor (72.3%) and no (66.7%) depression. In subgroup analyses for type 1 and 2 diabetes, blood glucose testing was significantly associated with depression status in the type 2 diabetes group, but not in the type 1 diabetes group. In contrast, those with major depression were less likely to visit a physician for diabetes treatment (79.3, 82.9 and 86.1% with major, minor and no depression, respectively).

For perceptions, a substantial proportion of those with major depression perceived that their diabetes and blood glucose control were poor to fair (43.4 and 41.3%, respectively), and that they had little ability to control their body weight (43.4%).

Table 2 contains the results of univariate logistic regression analyses. Odds ratios related to depression status (major/minor vs. no depression) for each sociodemographic, lifestyle, care and perception indicator are presented. All variables were significantly associated with depression, except for age.

Table 3 presents the results of the stepwise logistic regression analyses conducted for each of the following groups of variables: sociodemographic, lifestyle, care and perception indicators. Obesity was not significantly associated with depression among the lifestyle indicators, and perception of blood glucose control was not significantly associated with depression among the perception indicators; these variables were not included in the final regression model.

Table 4 shows the results of the final model of the stepwise regression analyses. Individuals with depression were more than twice as likely to be physically inactive (OR 2.20, 95% CI 1.69–2.85,  $p < 0.001$ ) and perceive their diabetes control to be poor or fair (OR 2.22, CI 1.70–2.89,  $p < 0.001$ ). Those with depression were also more likely to smoke, perceive not being able to control the amount of food eaten, have a high school education or less, test their blood glucose levels daily, be female and not be married.

## DISCUSSION

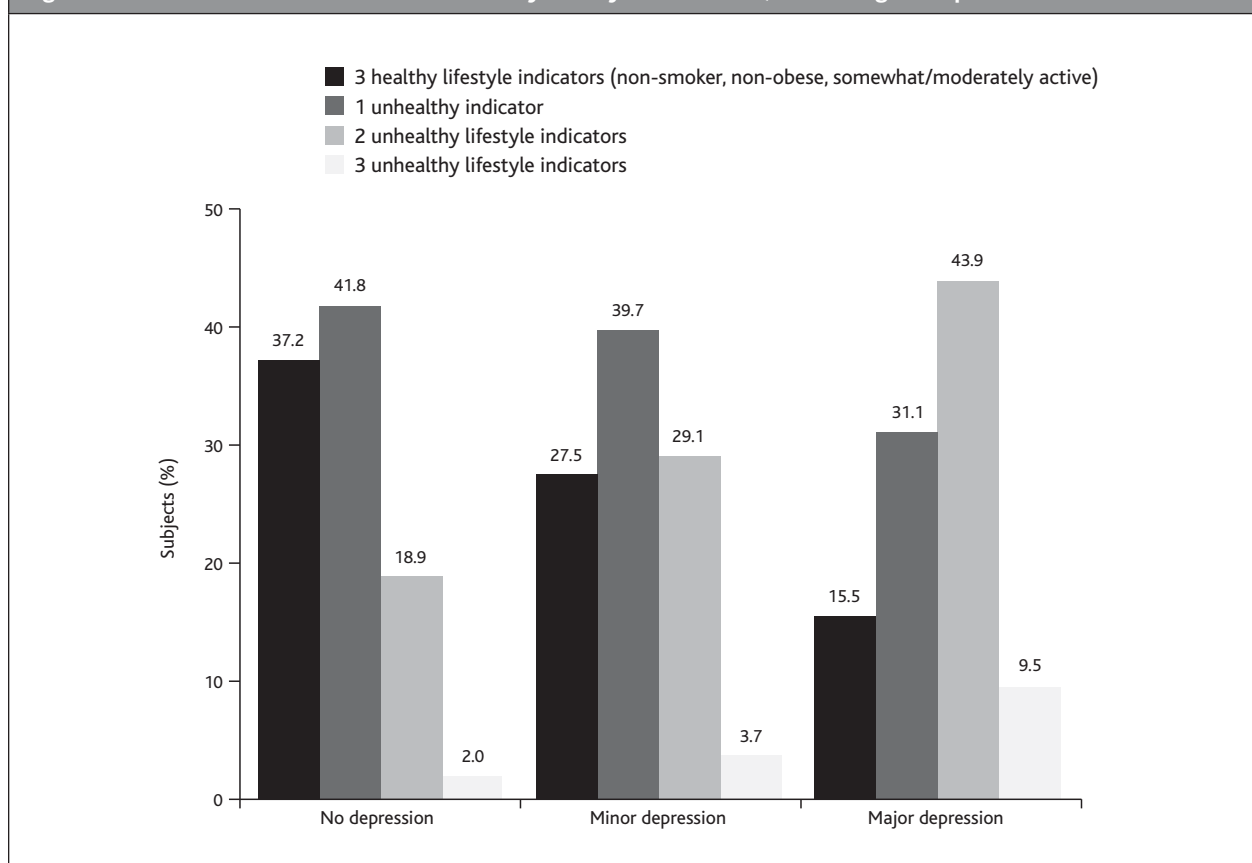
In our large community-based Quebec sample of over 2000 individuals with diabetes, the prevalence of major depression was 8.7% and that of minor depression was 10.9%. These results are in line with those of Katon and colleagues (8), who found a prevalence of 12 and 8.5% for major and minor depression, respectively, among over 4000 primary care clinic patients with diabetes. Similarly, Li and colleagues (28) reported a rate of 8.3% of major depression among individuals with diabetes in the Behavioral Risk

**Table 1. Study participants' characteristics according to depression status**

<b>Variables</b>	<b>Total sample n (%)</b>	<b>No depression n (%)</b>	<b>Minor depression n (%)</b>	<b>Major depression n (%)</b>	<b>p value*</b>
<b>Sociodemographic indicators</b>					
Sex					
Female	1084 (54.4)	837 (52.3)	139 (64.1)	108 (62.1)	<0.001
Male	908 (45.6)	764 (47.7)	78 (35.9)	66 (37.9)	
Age, years					
18–49	422 (21.2)	332 (20.7)	47 (21.7)	43 (24.7)	0.013
50–64	863 (43.3)	691 (43.2)	83 (38.2)	89 (51.1)	
65–80	707 (35.5)	578 (36.1)	87 (40.1)	42 (24.1)	
Level of education					
Less than high school	841 (42.8)	639 (40.5)	111 (51.6)	91 (52.6)	<0.001
High school	559 (28.5)	452 (28.7)	54 (25.1)	53 (30.6)	
More than high school	564 (28.7)	485 (30.8)	50 (23.3)	29 (16.8)	
Marital status					
Married/partner	1224 (61.6)	1023 (64.1)	115 (53.2)	86 (49.4)	<0.001
Widowed/divorced/separated	503 (25.3)	376 (23.5)	72 (33.3)	55 (31.6)	
Single	260 (13.1)	198 (12.4)	29 (13.4)	33 (19.0)	
<b>Lifestyle indicators</b>					
Smoking status					
Non-smoker	1566 (78.7)	1295 (81.0)	171 (78.8)	100 (57.5)	<0.001
Current smoker	423 (21.3)	303 (19.0)	46 (21.2)	74 (42.5)	
Physical activity level					
Inactive (0x/month)	580 (29.9)	398 (25.5)	92 (43.2)	90 (52.9)	<0.001
Moderately active (1–12x/month)	706 (36.4)	601 (38.6)	64 (30.0)	41 (24.1)	
Very active (>12x/month)	655 (33.7)	559 (35.9)	57 (26.8)	39 (22.9)	
Body mass index, kg/m <sup>2</sup>					
Underweight ( $\leq 18.4$ )	21 (1.2)	13 (0.9)	2 (1.0)	6 (3.8)	0.006
Normal weight (18.5–24.9)	389 (21.4)	318 (21.7)	44 (22.7)	27 (17.3)	
Overweight (25–29.9)	643 (35.4)	537 (36.6)	58 (29.9)	48 (30.8)	
Obese ( $\geq 30$ )	765 (42.1)	600 (40.9)	90 (46.4)	75 (48.1)	
<b>Care indicators</b>					
BG testing: all subjects					
$\geq 1$ x/day	1285 (68.2)	1017 (66.7)	146 (72.3)	122 (77.7)	0.008
<1x/day	599 (31.8)	508 (33.3)	56 (27.7)	35 (22.3)	
BG testing: type 2 diabetes					
$\geq 1$ x/day	1170 (66.5)	920 (64.7)	136 (71.6)	114 (77.0)	0.003
<1x/day	589 (33.5)	501 (35.3)	54 (28.4)	34 (23.0)	
BG testing: type 1 diabetes					
$\geq 3$ x/day	100 (80.0)	84 (80.8)	8 (66.7)	8 (88.9)	0.403
<3x/day	25 (20.0)	20 (19.2)	4 (33.3)	1 (11.1)	
Physician visit for diabetes treatment in past year					
Yes	1695 (85.1)	1377 (86.1)	180 (82.9)	138 (79.3)	0.037
No	296 (14.9)	223 (13.9)	37 (17.1)	36 (20.7)	
<b>Perception indicators</b>					
Perception of diabetes control					
Excellent/very good	858 (43.5)	746 (47.1)	69 (31.9)	43 (24.9)	<0.001
Good	650 (33.0)	522 (33.0)	73 (33.8)	55 (31.8)	
Fair/poor	464 (23.5)	315 (19.9)	74 (34.3)	75 (43.4)	
Perception of BG control					
Excellent/very good	727 (37.9)	621 (40.4)	73 (34.3)	33 (19.8)	<0.001
Good	738 (38.5)	602 (39.2)	71 (33.3)	65 (38.9)	
Fair/poor	452 (23.6)	314 (20.4)	69 (32.4)	69 (41.3)	
Perception of ability to control body weight					
Very much	624 (31.7)	522 (33.1)	58 (27.0)	44 (25.4)	0.002
Moderately	701 (35.6)	574 (36.4)	73 (34.0)	54 (31.2)	
Not at all/a little	642 (32.6)	483 (30.6)	84 (39.1)	75 (43.4)	
Perception of ability to control amount of food eaten					
Very much	721 (36.5)	603 (38.0)	68 (31.3)	50 (29.4)	<0.001
Moderately	810 (41.0)	658 (41.5)	91 (41.9)	61 (35.9)	
Not at all/a little	443 (22.4)	326 (20.5)	58 (26.7)	59 (34.7)	

\*Statistically significant at  $p < 0.05$ 

BG = blood glucose

**Figure 1. Distribution of number of unhealthy lifestyle indicators, according to depression status**

Factors Surveillance System in the United States. When rates of major and minor depression are combined in the present study (19.6%), they are similar to those reported in a meta-analysis of diabetes community-based studies (19%) (6), but higher than rates in non-diabetes community-based studies (12.7%) (6). Comparison of rates of major depression between our study population and the Canadian adult population is difficult, since different reporting measures for depression status are used. One study found that the lifetime prevalence of major depression in Canadian adults was 12.2%—4.8% for a past-year episode of depression, and 1.8% for a past-month episode (2).

Our study sample consisted primarily of older adults, in keeping with the age of individuals with diabetes in the Montreal area (29). However, the rate of obesity in our study sample (42%) was higher than that of the Canadian diabetes population (22%) (30).

Overall, depression was associated with poorer lifestyle indicators, in agreement with previous studies (8,14,16,18). The prevalence of smoking among those with major depression was 42%, similar to the findings of a population-based study in diabetes (15). The prevalence of smoking among those with minor or no depression was 21% and 19%, respectively, similar to smoking rates among the general population of Canada (18%) and Quebec (19%) (31).

Our results indicate that physical inactivity was associated with the presence of depression, as well as its severity. However, rates of inactivity in the present study (30%) were lower than those in Canada and Quebec (55% and 58%, respectively) (32), a discrepancy likely due to differences in the definition of physical inactivity (<15 minutes in the last month in the present study compared to <30 minutes per day in the national study).

In terms of the association between depression and BMI categories, major depression was slightly higher among both underweight and obese subjects ( $p < 0.01$ ). Furthermore, 48 and 46% of those with major and minor depression were obese, respectively, compared to 41% with no depression. However, when including smoking and physical activity in the regression analyses, the obese BMI category did not remain significantly associated with depression, as reported in some studies (15,17,20). The lack of an independent association between depression and obesity can first be explained by the fact that over 40% of the sample was obese. Second, obesity may not be directly associated with depression. In fact, in the present study, inactivity and poorer perceived control of amount of food eaten were both independent risk factors for depression. It is possible that the relation between obesity and depression could be mediated by these factors and explain, in part, the lack of a direct association.

**Table 2. Factors associated with major/minor depression: univariate analyses**

Variables	OR	95% CI	p value
Sex			
Male	0.64	0.51–0.80	<0.001
Female	1.00		
Age, years	0.99	0.98–1.003	0.19
Level of education			
High school or less	1.60	1.27–1.99	<0.001
More than high school	1.00		
Marital status			
Not married	1.68	1.34–2.09	<0.001
Married/partner	1.00		
Smoking status			
Current smoker	1.89	1.48–2.43	<0.001
Non-smoker	1.00		
Physical activity			
Not active (0–1x/month)	2.60	2.10–3.33	<0.001
Active (>1x/month)	1.00		
BMI, kg/m <sup>2</sup>			
Obese (≥30)	1.29	1.02–1.63	0.033
Non-obese (<30)	1.00		
Daily BG testing			
<1x/day	0.68	0.52–0.88	0.004
≥1x/day	1.00		
Physician visit for diabetes treatment in past year			
No	1.42	1.06–1.90	0.019
Yes	1.00		
Perception of diabetes control			
Fair/poor	2.50	1.97–3.17	<0.001
Excellent/very good/good	1.00		
Perception of BG control			
Fair/poor	2.22	1.74–2.83	<0.001
Excellent/very good/good	1.00		
Perception of ability to control body weight			
Not at all/a little	1.58	1.25–1.98	<0.001
Moderately/very much	1.00		
Perception of ability to control amount of food eaten			
Not at all/a little	1.67	1.31–2.15	<0.001
Moderately/very much	1.00		

BG = blood glucose

Also, it has been suggested that subjects who are obese for a long time might undergo an adaptation process that allows them to cope better with the psychological distress linked to the stigma of obesity (33). Overall, our results indicate that neither BMI nor confidence in being able to control body weight was associated with depression, although there was an association with confidence in being able to control the amount of food eaten. Further study exploring patients' perceived links between BMI, diabetes control, body weight, eating behaviours and physical activity is warranted.

When lifestyle behaviours were clustered into profiles, 86% of those with 2 or 3 unhealthy lifestyle indicators

**Table 3. Factors associated with major/minor depression: relations within groups of variables (sociodemographics, lifestyle behaviours, care behaviours and perceptions)**

Variables	OR	95% CI	p value
<b>Sociodemographic indicators</b>			
Sex			
Male	0.68	0.53–0.85	0.001
Female	1.00		
Age, years	0.99	0.98–0.99	0.025
Level of education			
High school or less	1.59	1.26–1.99	<0.001
More than high school	1.00		
Marital status			
Not married	1.55	1.23–1.94	<0.001
Married/partner	1.00		
<b>Lifestyle indicators</b>			
Smoking status			
Current smoker	1.82	1.39–2.39	<0.001
Non-smoker	1.00		
Physical activity level			
Not active	2.44	1.90–3.12	<0.001
Active	1.00		
Body mass index, kg/m <sup>2</sup>			
Obese (≥30)	1.23	0.96–1.57	0.098
Non-obese (<30)	1.00		
<b>Care indicators</b>			
Daily BG testing			
<1x/day	0.66	0.51–0.86	0.002
≥1x/day	1.00		
Physician visit for diabetes treatment during past year			
No	1.50	1.10–2.04	0.011
Yes	1.00		
<b>Perception indicators</b>			
Perception of diabetes control			
Fair/poor	2.49	1.94–3.19	<0.001
Excellent/very good/good	1.00		
Perception of ability to control body weight			
Not at all/a little	1.35	1.03–1.76	0.028
Moderately/very much	1.00		
Perception of ability to control amount of food eaten			
Not at all/a little	1.35	1.01–1.80	0.043
Moderately/very much	1.00		

BG = blood glucose

were more likely to have major or minor depression, in line with Li and colleagues (18). A combination of 2 or 3 unhealthy lifestyle indicators appeared to have a stronger association with depression than 1 unhealthy lifestyle indicator. It may be that health professionals should assist individuals with diabetes and depression—particularly women—in modifying all unhealthy lifestyle indicators (e.g. increasing physical activity, reducing tobacco use and

**Table 4. Final logistic regression model for factors associated with major/minor depression**

Variables	Adjusted OR	95% CI	p value
Age, years	0.99	0.98–1.002	0.094
Sex			
Male	0.68	0.52–0.88	0.003
Female	1.00		
Level of education			
High school or less	1.42	1.11–1.83	0.006
More than high school	1.00		
Marital status			
Not married	1.46	1.13–1.88	0.003
Married/partner	1.00		
Smoking status			
Current smoker	1.62	1.22–2.17	<0.001
Non-smoker	1.00		
Physical activity level			
Not active	2.20	1.69–2.85	<0.001
Active	1.00		
Daily BG testing			
<1x/day	0.71	0.53–0.92	0.015
≥1x/day	1.00		
Physician visit for diabetes treatment during past year			
No	1.36	0.97–1.90	0.077
Yes	1.00		
Perception of diabetes control			
Fair/poor	2.22	1.70–2.89	<0.001
Excellent/very good/good	1.00		
Perception of ability to control amount of food eaten			
Not at all/a little	1.41	1.07–1.87	0.016
Moderately/very much	1.00		

BG = blood glucose

fostering healthy eating behaviours) rather than focusing on any one of these behaviours.

Depression was associated with more frequent blood glucose testing. It may be that individuals with major depression had poorer blood glucose control and subsequently took action to test their blood glucose levels more frequently (glycated hemoglobin or glycemic values are not available in this data set). Interestingly, Franciosi and colleagues (34) found an association between more frequent monitoring of blood glucose levels and higher levels of frustration, worries and depression. Gallichan (35) suggests that the association between frequent monitoring of blood glucose levels and poorer psychological well-being could be related to the feeling of powerlessness caused by unsatisfactory results when patients are not able to improve blood glucose control. It was also of interest to observe that there was no association between blood glucose testing and depression in the subsample of subjects with type 1 diabetes. This may be due to the small sample size, but because blood glucose testing in type 1 diabetes is required, in most cases, for insulin dose

adjustment, the reasons for blood glucose testing may weigh differently in type 1 and type 2 diabetes.

As a whole, our results suggest that depression among individuals with diabetes is not only related to poorer lifestyle and care indicators, but also to patients' perceptions of these indicators. However, it could not be determined whether lifestyle indicators were due to depression or whether depression was partly caused by lifestyle indicators, and whether the negative perceptions of control were due to depression. The mechanisms that underlie these observations require longitudinal investigations. Furthermore, it is not clear whether to target depression intervention, thereby improving lifestyle/care outcomes, or to target lifestyle/care interventions, thereby improving depression status (36–38).

A limitation of this large, community-based study of individuals with diabetes was the self-reported method of data collection and the use of cross-sectional data. Another limitation was that we did not address family history or past history of depression, which may have affected current lifestyle/care indicators. Nevertheless, the results of this study reinforce the importance of adequate follow-up and management of individuals with diabetes and depression to improve their overall health and well-being.

## AUTHOR DISCLOSURES

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## AUTHOR CONTRIBUTIONS

LM, BE and IS wrote the manuscript, which was critically revised by NS, GG, AM, AL, RB and JLW. All authors contributed to the conception and design of the study. NS collected the data. LM and BE conducted the analyses with substantial contributions by NS and IS. All authors approved the final version to be published.

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## ORIGINAL RESEARCH

# Self-Monitoring of Blood Glucose: What Are Healthcare Professionals Recommending?

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## ABSTRACT

**OBJECTIVE:** The clinical benefit and cost-effectiveness of self-monitoring of blood glucose (SMBG) in adults with type 2 diabetes not using insulin has been questioned. The objective of this study was to gain insight into healthcare professionals' recommendations, practices and beliefs with respect to SMBG in well-controlled adults (glycated hemoglobin  $\leq 7.0\%$ ) with type 2 diabetes not using insulin.

**METHODS:** Interviews were conducted with diabetes educators, pharmacists and family physicians in 3 district health authorities in Nova Scotia, Canada. Audiotaped interviews were transcribed and analyzed using a thematic analysis approach.

**RESULTS:** All participants recommended SMBG for persons in this population. Recommendations varied both within and between professional groups and were noted to be highly individual. SMBG results were perceived to be valuable for both patients and healthcare professionals. Participants identified clinical practice guidelines as a trustworthy source of information about SMBG in this population.

**CONCLUSION:** Guidelines cite a lack of substantial evidence for SMBG in this population. Customized SMBG practices are important, but so are clarity and consistency in guideline recommendations. Reducing the use of SMBG in patient populations where it is unlikely to be beneficial will allow reallocation of resources to interventions with proven benefit.

**KEYWORDS:** blood glucose control, self-monitoring of blood glucose, type 2 diabetes

## RÉSUMÉ

**OBJECTIF:** Les avantages cliniques et le rapport coût-efficacité de l'autosurveillance de la glycémie chez les adultes atteints

de diabète de type 2 non insulinotraités ont été remis en question. L'objectif de cette étude était de déterminer quelles étaient les recommandations, pratiques et croyances des professionnels de la santé en matière d'autosurveillance de la glycémie chez les adultes dont le diabète de type 2 est bien maîtrisé (taux d'hémoglobine glycosylée  $\leq 7,0\%$ ) et qui ne sont pas insulinotraités.

**MÉTHODES :** Des éducateurs spécialisés en diabète, des pharmaciens et des médecins de famille de trois autorités sanitaires de district de la Nouvelle-Écosse, au Canada, ont été interviewés. Les entrevues enregistrées ont été transcrites et analysées selon une démarche thématique.

**RÉSULTATS :** Tous les participants recommandaient l'autosurveillance de la glycémie dans cette population. Les recommandations variaient au sein des groupes professionnels et d'un groupe à l'autre, et on a remarqué qu'elles étaient très individuelles. Les résultats de l'autosurveillance de la glycémie étaient considérés comme utiles tant pour les patients que pour les professionnels de la santé. Les participants ont mentionné que les lignes directrices de pratique clinique étaient une source de renseignements fiable sur l'autosurveillance de la glycémie dans cette population.

**CONCLUSION :** Selon les lignes directrices, on manque de données substantielles sur l'autosurveillance de la glycémie dans cette population. L'individualisation des pratiques d'autosurveillance de la glycémie est importante, mais la clarté et l'uniformité des recommandations des lignes directrices le sont aussi. En réduisant le recours à l'autosurveillance de la glycémie dans les populations pour lesquelles elle est peu susceptible d'être utile, on pourrait affecter les ressources à des interventions dont les avantages sont démontrés.

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**MOTS CLÉS :** contrôle de la glycémie, autosurveillance de la glycémie, diabète de type 2

## INTRODUCTION

Self-monitoring of blood glucose (SMBG) is a common practice, regardless of diabetes type (type 1, type 2 or gestational diabetes), treatment (insulin, oral antihyperglycemic agent [OAA] or lifestyle only) or severity. It is assumed that performing SMBG will result in improved health outcomes. However, in an environment of fiscal restraint and evidenced-informed healthcare policy decisions, practices that have not been rigorously assessed require justification.

SMBG has become a foundational aspect of initial and ongoing diabetes education and monitoring. Most clinical practice guidelines endorse SMBG as part of diabetes self-management, enabling patients to adjust their lifestyle and/or treatments to improve glycemic control, while avoiding hypoglycemia (1-3). However, the results of recent clinical trials and evidence-based reviews have questioned the clinical benefits of routine SMBG in individuals with type 2 diabetes who are not using insulin (4-6). In addition to the uncertain benefit of SMBG with respect to health-related outcomes, decreased quality of life and questionable cost-effectiveness have also been cited as reasons to review SMBG recommendations (4,6-9). Diabetes test strips are insured benefits under the Nova Scotia Pharmacare Programs, which provide publicly funded coverage to Nova Scotia residents. Although all residents can enroll in the Pharmacare Program, it is the payer of last resort and therefore provides coverage only after private or other insurer coverage. In the Pharmacare Program, claims for diabetes test strips exceeded \$8 million in 2008 (10), with widespread usage in beneficiaries not using insulin (7). Similar studies from the United Kingdom and United States report high SMBG utilization and have demonstrated cost savings following implementation of policies that restrict SMBG testing to specific patient groups (11-14).

Healthcare professionals often refer to clinical practice guidelines as a basis for their recommendations to patients. When the present study was conducted in 2007 and early 2008, the 2003 Canadian Diabetes Association (CDA) clinical practice guidelines were current; they noted that for individuals with type 2 diabetes treated with OAAs or lifestyle modification alone, the optimal frequency of SMBG remained unclear, but suggested there was evidence to support benefit, especially when the information was used to make appropriate, timely treatment adjustments (2). Since general statements are open to interpretation, it is not unreasonable to assume that discrepancies in recommendations for SMBG exist between and among healthcare professionals. As a result, people with type 2 diabetes may not test when appropriate, overreact to results, take unnecessary precau-

tions and fail to benefit from the intended testing regimen.

The goal of our research was to interview a sample of Nova Scotia healthcare professionals (including physicians, pharmacists and diabetes educators) to gain insight into a) the recommendations for SMBG they provided to well-controlled adults with type 2 diabetes who were not using insulin (glycated hemoglobin [A1C]  $\leq 7.0\%$ ) and why and how they made these recommendations; b) if and in what ways they used the results of SMBG in this population, including what they did with abnormal results; and c) the perceived value of SMBG for this subset of people with diabetes. We also inquired about trusted sources of information regarding SMBG in this population. This study is intended to inform educational and/or policy interventions aimed at more consistent SMBG recommendations among healthcare professionals.

## METHODS

Healthcare professionals most likely to be providing SMBG recommendations to persons with type 2 diabetes were approached for participation: diabetes educators (nurses and dietitians), community-based pharmacists, family physicians and nurse practitioners. An interview guide, containing a core set of questions customized for use with each healthcare professional group, was developed by the project investigators, whose backgrounds include diabetes education, family medicine and pharmacy. Interviewees were asked about their SMBG recommendations to patients managing their diabetes with either diet alone or diet plus OAAs (including differences in approach for persons taking insulin secretagogues vs. non-secretagogues). Interviewees were also asked about how they used patient SMBG records, the advice they give to patients and their trusted sources of information regarding SMBG. Each interview guide was piloted with a member of the appropriate professional group, and refinements were made. A copy of the full interview guide is available on request; a synopsis is provided in Table 1.

Ethics approval was obtained to recruit participants in 3 District Health Authorities in Nova Scotia, Canada. A letter of invitation to participate, signed by the principal investigator, was mailed to family physicians using addresses obtained via the publicly available website of the College of Physicians and Surgeons of Nova Scotia. Physicians who were hospitalists, had a limited or defined practice (e.g. emergency) or were known retirees were excluded. Signed letters of invitation were sent to diabetes educators, community-based pharmacists and nurse practitioners via email from the Diabetes Care Program of Nova Scotia; the Division of Continuing Pharmacy Education, Dalhousie University; and the College of Registered Nurses of Nova Scotia, respectively. The first 7 physicians to respond to the letter were interviewed. The first 7 diabetes educators and

**Table 1. Interview guide synopsis**

<b>Beliefs, recommendations and practices</b>	<ul style="list-style-type: none"> <li>Let's start by considering clients/patients who are attempting to control their diabetes with diet alone. Do you recommend that those clients/patients perform SMBG?</li> <li>Next, let's consider clients/patients who are also taking oral agents. Do you recommend that those clients/patients SMBG?</li> <li>Do you take a different approach to clients/patients taking non-secretagogues such as metformin (Glucophage) in contrast to those taking secretagogues such as glyburide (Diabeta) or gliclazide (Diamicon)?</li> <li>Thinking specifically again of all clients/patients with type 2 diabetes not taking insulin and having A1C <math>\leq 7.0\%</math>, do you think that SMBG is useful in special circumstances?</li> </ul>
<b>Use of results</b>	<ul style="list-style-type: none"> <li>What do you advise clients/patients to do regarding abnormal results?</li> <li>Do you review your clients'/patients' SMBG records? <i>If yes:</i> <ul style="list-style-type: none"> <li>Can you tell me how you go about doing that?</li> <li>How do you use this information?</li> </ul> </li> </ul>
<b>Factors influencing recommendations</b>	<ul style="list-style-type: none"> <li>On what do you rely when formulating your SMBG recommendations for clients/patients in this group of people with diabetes?</li> </ul>
<b>Sources of information</b>	<ul style="list-style-type: none"> <li>If you needed to seek information about SMBG for this group of clients/patients, where would you turn for trusted information?</li> </ul>

A1C = glycated hemoglobin

SMBG = self-monitoring of blood glucose

pharmacists to self-select in response to the email invitations were also interviewed, ensuring regional representation. No nurse practitioners responded to the recruitment invitation.

One-on-one interviews, approximately 15 minutes each, were conducted in person or on the telephone by a single project investigator who had experience in qualitative methods but was not a healthcare professional. Interviews occurred at sites up to 2 hours' driving distance from Halifax, Nova Scotia, Canada, enabling a mix of participants from both urban and rural areas. In keeping with the plan to sample to saturation or to a maximum of 6 to 8 per professional group, a total of 21 interviews were conducted with 7 each of diabetes educators, family physicians and pharmacists. An honorarium of \$25 was offered to all self-employed individuals and salaried individuals interviewed during non-work hours.

Interviews were taped with participants' permission and transcribed. Transcripts were reviewed against the tapes by the interviewer for accuracy. Participants were given the opportunity to review their individual transcript for clarity and accuracy. Clarifications submitted by the participants were added to the transcripts and included in the analysis. All project investigators read the transcripts and contributed to the identification of key findings. Responses of healthcare

professionals were collated by question. A thematic analysis approach was used to identify, analyze and report patterns and themes in the data (15).

## RESULTS

### Recommendations for control of diabetes through diet or diet plus OAAs

All participants recommended some form of monitoring for people whose diabetes was managed with diet alone or diet plus OAAs. There was an apparent reluctance to rely solely on A1C values. However, specific recommendations varied both within and between healthcare professional groups.

#### Diabetes educators

Most participants recommended that the "diet control only" population test once per day. Alternating times (before meals and bedtime on different days) were preferred. A few participants noted that the frequency of testing could be reduced to every second day or less if the individual's SMBG results were consistently within acceptable limits. Other recommendations included testing a few times a week before and/or 2 hours after meals.

For individuals using OAAs, the majority of participants indicated that their recommendations were the same or similar to those for the "diet control only" population. For those taking insulin secretagogues, hypoglycemia was the greatest concern. More frequent testing was recommended for changes in physical activity, new medication starts and symptoms of hypoglycemia.

Reasons for recommending SMBG included obtaining a picture of blood glucose control throughout the day, enabling the person with diabetes to see the impact of various foods and activity on blood glucose, and helping to inform diabetes management.

#### Pharmacists

Recommendations for the "diet control only" population ranged from occasional testing to 4 times daily, at least at the beginning of treatment. There was a sense that testing did not need to be intensive in this group, and a few participants spoke of reducing the frequency of SMBG if the individual's results were consistently within acceptable limits. Most respondents favoured alternating times (before meals and bedtime); other recommendations included postprandial readings, a fasting reading followed by a random test and pre-/postprandial testing.

For individuals using OAAs, most participants indicated that their recommendations were generally the same or similar to those for the "diet control only" population. A couple of participants noted that they might recommend more frequent testing on a temporary basis, with the introduction of certain medications. Overall, a similar approach

to testing was recommended whether the medication was an insulin secretagogue or not, but individuals on insulin secretagogues were counselled to be more cautious, especially if they experienced symptoms of hypoglycemia, and to be aware of the effects when starting on these agents or changing the dose.

Reasons for recommending SMBG included providing the patient with feedback on the effects of diet, activity and drugs on blood glucose levels; obtaining a picture of blood glucose control throughout the day, and a source of feedback about overall diabetes management.

### Physicians

Recommendations for individuals in the “diet control only” population ranged from once or twice a week to twice daily, with most participants favouring that readings be taken a few times a week. Several participants noted that testing frequency could be reduced if the individual’s SMBG results were consistently within acceptable limits. The majority of participants favoured fasting and postprandial readings. One participant recommended testing to those in the “diet control only” population only if they already owned or had access to a meter.

For individuals using OAs, the majority of participants indicated that their recommendations were the same or similar to those for the “diet control only” population, but they would be watchful for any signs of hypoglycemia. Some participants indicated that they might recommend more frequent testing for those taking insulin secretagogues (particularly seniors or those with hypoglycemia).

Reasons for recommending SMBG included obtaining a picture of blood glucose control throughout the day, ensuring patients were meeting targets, monitoring for hypoglycemic episodes and fostering self-management skills in case of disease progression.

### Factors influencing recommendations

Participants were asked to list other circumstances in which they would ask individuals to perform SMBG, or to increase the frequency of monitoring. The most commonly cited circumstances included medication-related issues (e.g. medication changes, new medication starts, taking over-the-counter medications or antibiotics); times of illness; starting or increasing physical activity; curiosity about the effects of different foods; and periods of stress.

Several potential influencers of SMBG recommendations were identified, including clinical practice guidelines. Members of all professional groups spoke clearly about the individuality of each situation and the need to account for a variety of circumstances and issues. The person with diabetes was a critical variable, as succinctly noted by one physician, who stated that recommendations were influenced by “...who’s sitting across from me.” The financial status of the

person with type 2 diabetes was the most common consideration when making recommendations:

Usually strips are anywhere from \$0.75 to \$1.00 apiece ... it’s very expensive ... When you have a patient that doesn’t need to be testing every day or twice a day, then it’s foolish to have them spending \$14 a week. That could be milk or bread for the family or one other medication that they’re not taking because they can’t afford it because they have to test their blood sugars. [Diabetes educator 2]

A list of patient factors influencing recommendations (responses to the question “On what do you rely when formulating your SMBG recommendations?”) is provided in Table 2.

**Table 2. Patient factors influencing recommendations**

- Financial circumstances
- Interest in, or compliance with, testing
- Ability to monitor (manual dexterity, cognition, access to family supports, if necessary)
- Potential to increase stress or anxiety (by testing or not testing)
- Variability in SMBG results
- Closeness to glycemic target (A1C  $\leq$ 7.0%)
- Age
- Medications
- Understanding of, and intent to use, the information
- Presence of comorbid conditions
- Duration of diabetes

A1C = glycated hemoglobin

SMBG = self-monitoring of blood glucose

### Use of results

All diabetes educators and physicians indicated that they reviewed the SMBG records of their patients and encouraged them to bring their logbooks and/or meters to their appointments for review. Because patients may not typically bring their logbooks or meters to their pharmacists, this group was less likely to be able to review SMBG results, but they generally indicated a willingness to review results, if available.

The review processes described by participants focused predominantly on examining the numbers and scanning for trends and outliers. However, some participants also spoke of checking to ensure that meters were properly set up, ensuring outdated test strips were not being used, and looking at the frequency and timing of testing:

I just look at their logbooks in terms of how often they’re testing, what their readings are, hoping that they’ll have an A1C record there as well, too ... And then we look at when they’re testing to make sure that they’re getting sort of a good reflective 24-hour period ... they’re not always testing at the same time every day. And then we look at when you’re taking medications vs. when you’re testing, when you’re eating when you’re testing. [Pharmacist 2]

None of the participants indicated that isolated abnormal readings were a concern. Participants spoke of looking for “trends” or “patterns,” or readings “consistently” or “persistently” out of range. Abnormal results represented an opportunity

**Table 3. Trusted sources of information cited by health professional groups**

Source of information	Specific sources cited*		
	Pharmacists	Physicians	Diabetes educators
Guidelines (online/written)	• CDA	• CDA	• CDA
Online information	• CDA • MD Consult • Pharmacists Letter • Pharmacy Practice • PubMed • ADA	• CDA • Doctors NS • UpToDate • MD Consult • CMA	• CDA
Government publications and organizations	• DEANS • DCPNS	—	• DCPNS
Educational materials	• Textbooks ( <i>CPS, Pharmacotherapy, Therapeutic Choices</i> ) • Newsletters provided by pharmacy employer • In-store course offered to patients	• Continuing medical education	• Journals (no specific source cited)
Other healthcare professionals	• Local diabetes education centre	• Other colleagues in diabetes care (e.g. endocrinologists) • Local diabetes education centres and staff • Pharmacists	• Diabetes educators • Other colleagues in diabetes care
Industry	• Meter companies	—	• Meter companies

\*Source information:

#### Websites

- Canadian Pharmacist's Letter: [www.canadianpharmacistsletter.com](http://www.canadianpharmacistsletter.com)
- DCPNS: <http://www.diabetescareprogram.ns.ca>
- Doctors NS: <http://www.doctorsns.com>
- DEANS: <http://www.gov.ns.ca/health/Pharmacare/committees/deans.asp>
- MD Consult: <http://www.mdconsult.com>
- Pharmacy Practice: <http://www.pharmacypractice.org>
- PubMed/Medline: <http://www.ncbi.nlm.nih.gov>
- UpToDate: <http://www.uptodate.com>

Accessed January 25, 2011.

#### Textbooks

- Dipiro JT, Talbert RL, Yee GC, et al. *Pharmacotherapy: A Pathophysiologic Approach*, 7th ed. New York, NY: McGraw-Hill Medical; 2008.
- Gray J, ed. *Therapeutic Choices*, 5th ed. Ottawa, ON: Canadian Pharmacists Association; 2007.
- Repchinsky C, ed. *CPS 2010: Compendium of Pharmaceuticals and Specialties*. Ottawa, ON: Canadian Pharmacists Association; 2010.

ADA = American Diabetes Association

CDA = Canadian Diabetes Association

CMA = Canadian Medical Association

CPS = Compendium of Pharmaceuticals and Specialties

DCPNS = Diabetes Care Program of Nova Scotia

DEANS = Drug Evaluation Alliance of Nova Scotia

to dialogue with and educate the person with type 2 diabetes about the impact of food and activity. Thus, the primary recommendation was for the patient to highlight abnormal results and document possible reasons. The majority of participants noted that patterns or trends (up or down) may indicate a need to re-evaluate some aspect of management.

I encourage them to look for patterns, to see where they think the problem is ... and to notice if something particular has happened to see what we can do to find the cause, and if not, then we need to take it further and go back to the physician. [Pharmacist 5]

Isolated numbers I don't get too concerned about, but if they're persistent, the same—if they're high every morning or high every evening, or after meals 2 hours, then I'd say I'd have to adjust my management of those individuals. [Physician 2]

If they have a reason for a low or a high or change in general blood sugars, they just make a note and they learn from that ... If you have no reason, you make a note: "no reason." And if this starts happening again, then you may need to see the family doctor. [Diabetes educator 7]

In discussing SMBG results, participants indicated that their usefulness was not limited to the identification of potential problem areas. Other uses, congruent with the reasons participants provided for recommending testing, were identified for both people with diabetes and healthcare professionals.

For people with diabetes, benefits included providing insight into their diabetes (e.g. feedback about blood glucose control, enhancing or maintaining awareness of the need to eat properly and exercise), a means of fostering self-management skills and a basis for positive reinforcement:

Even though this person would already be in fairly good control, it gives them a good tool. "Oh, I went out for Chinese food at lunch and yeah, that wasn't the best thing for my blood sugar because I'm checking before supper and I can see I'm still carrying a lot of sugar from that meal." Those types of things. So we teach them to try to get good information for themselves from that data that they collect. [Diabetes educator 4]

When they go to the doctor they know what they're supposed to be looking for and what they're doing. It gives them a little bit more responsibility to look after themselves, that they're not just relying on the doctor to do the blood work. [Diabetes educator 3]

I think patients, when they have someone else give them objective feedback that they've done well, they appreciate

that and that keeps them motivated to continue doing what they're doing. [Physician 2]

Participants indicated that SMBG results can be useful to the healthcare professional in managing diabetes:

I think people have poor memories ... and it gives us a good record of what's going on. You can pick up patterns better, you can see it in black and white. [Physician 3]

It makes it a whole lot easier for us to be able to make recommendations or address any issues. [Diabetes educator 2]

Testing is something that I use to decide if my treatment is working. [Physician 5]

### Sources of information

Participants were asked where they would turn for trusted information about SMBG for this group of people with type 2 diabetes. The CDA clinical practice guidelines were the most frequently cited source. The CDA guidelines, the CDA website and diabetes education centres were common to all professional groups. Table 3 lists the sources cited by each healthcare professional group.

## DISCUSSION

All of the healthcare professionals who participated in our study recommended some form of SMBG for people with type 2 diabetes in good control. The most striking finding was the variation within and between healthcare professional groups with respect to the recommended frequency of testing. This variability was consistent for each of the patient groups considered, since most participants provided the same or similar recommendations for those controlled with diet alone or diet plus OAs. There was consensus that treatment with insulin secretagogues required a more cautious approach because of the increased risk of hypoglycemia. Participants identified several factors influencing their recommendations and stressed the individuality of each situation. A commonly noted influencing factor was the patient's ability to pay for test strips. It was frequently suggested that the amount of testing could be reduced if blood glucose levels were stable.

The reasons for recommending SMBG and the perceived value of the results were similar among participants. Primary themes included the belief that SMBG gives patients an understanding of the effects of food and exercise, and that SMBG is a key empowerment tool in diabetes self-management.

Participants indicated that SMBG results provide valuable information for both patients and healthcare professionals. Physicians and diabetes educators stated that they reviewed SMBG records and encouraged patients to bring meters and/or logbooks to appointments. This finding is not consistent with

the "practice gap" cited in the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) Gap Analysis and Key Messages for the Prescribing and Use of Blood Glucose Test Strips for the Self-Monitoring of Blood Glucose, which noted that there was "limited use of SMBG results in therapeutic decisions by physicians" (16). The apparent reluctance of our participants to rely solely on A1C levels to evaluate blood glucose control suggests SMBG results provide important supplemental information. However, all participants noted that they were looking primarily for trends and patterns rather than for singular highs or lows in blood glucose results. Additional research is required to explore whether treatment decisions that incorporate SMBG results are different from those that use A1C alone in this population.

Given the variability in the frequency of testing recommended by the participants, the sources of information that may be used to guide recommendations are highly relevant. Several participants noted that they considered clinical practice guidelines when making recommendations, and many cited guidelines as a source of information they would turn to for information on SMBG in this population. Interestingly, the guidelines cite a lack of substantial evidence with respect to SMBG in this population and do not clearly support the behaviours reported in this study relating to the recommended frequency of SMBG. The 2003 guidelines state in the supporting text that the optimal frequency of SMBG remains unclear in patients with type 2 diabetes who are treated with lifestyle modifications alone or in combination with oral antihyperglycemic agents (2). The explicit recommendation for SMBG was given a Level C (Consensus) grade of evidence (2):

For most people with type 2 diabetes treated with insulin or oral antihyperglycemic agents, BG measurement at least once daily is recommended [Grade C, Level 3].

Since our survey, the CDA guidelines have been updated (2008) with the following recommendation (1):

For individuals treated with oral antihyperglycemic agents or lifestyle alone, the frequency of SMBG should be individualized depending on glycemic control and type of therapy and should include both pre- and postprandial measurements [Grade D, Consensus].

The CDA recommendations are open to broad interpretation. Healthcare professionals need to critically review their trusted sources of information and be aware of areas of uncertainty and consensus-based recommendations. As well, guidance bodies need to be cognizant of the importance of clarity in their recommendations. Nova Scotia healthcare professionals generally see patients separately rather than in an integrated team setting, so there is limited opportunity to develop a common approach toward SMBG recommendations. A potential consequence of the variation in recommendations seen in this

study is the confusion created for patients seeking guidance. For example, a patient visiting the healthcare professionals in our survey could have been advised to test once a week or up to 4 times per day. While general guidance would be very helpful, the number of factors influencing testing recommendations necessitates flexibility. Clarity in recommendations and a consensus on approach will help healthcare professionals provide patients with consistent advice.

Recommendations articulated by COMPUS in 2009 provide clearer guidance and may, as they are adopted, lead to more consistency (17). Specifically, the COMPUS recommendations state the following:

Most adults with type 2 diabetes managed on oral antidiabetes drugs do not require routine SMBG. Periodic testing in selected patients (e.g. those with unstable glucose levels, acute illness, pharmacotherapy changes, risk of hypoglycemia with insulin secretagogues like glyburide) should be linked to specific patient actions (e.g. prevention or management of hypoglycemia, self-directed dosage adjustment).

Most adults with type 2 diabetes controlled by diet alone should not require routine SMBG.

Prevalent in our study was the commonly held belief that SMBG empowers patients to take control of their disease, which in turn directs healthcare professional behaviour. This belief has been central to the treatment and follow-up of patients with diabetes and is promoted by clinical practice guidelines, although most acknowledge that the clinical utility of SMBG is limited and the cost-effectiveness of routine testing in non-insulin-treated patients is unfavourable (3,17,18). Any change to patient or healthcare professional behaviour based on beliefs and routine will take time to implement and require a multidisciplinary approach to get the correct messages and approaches into play. All aspects of patient care (primary care, inpatient care, continuing care, etc.) will be affected if the approach to SMBG is changed.

Options to address the variability in recommendations should be considered. We believe interdisciplinary continuing education programs could lessen the variability demonstrated in our study.

The economic burden of SMBG to patients and healthcare professionals is of global interest (8,11-14,17). Clinical practice guidelines often recognize cost issues but do not generally consider formal cost-effectiveness or budget impact analyses in their recommendations (3). Third-party payers are often required to place restrictions on drugs or devices, especially those that lack evidence of benefit or have questionable cost-effectiveness. Currently, the Nova Scotia Pharmacare Program provides unlimited coverage for SMBG test strips, at a yearly cost of \$8 million (10). COMPUS identified \$188 million in

spending on SMBG test strips in diabetes patients not using insulin within publicly and privately funded drug plans in Canada. Two recent Canadian studies (9,19) reported that for most patients with type 2 diabetes not using insulin, SMBG is unlikely to represent efficient use of finite healthcare resources (9), and the implementation of policies that focus SMBG test strip use on patients likely to benefit could yield substantial cost reductions (19). Cameron and colleagues reported that testing at lower frequencies of 1 to 2 tests per week in these populations may be cost-effective (9). The high and predicted increase in diabetes prevalence necessitates careful consideration of opportunity costs to ensure that scarce resources are spent in the most cost-effective ways.

Our study is one of the first to provide a Canadian perspective on healthcare professionals' recommendations for SMBG specifically in well-controlled patients with type 2 diabetes not using insulin. In 2009, COMPUS posted a practice analysis of healthcare professionals, which considered a larger group of diabetes patients, including those using insulin (20). In the COMPUS study, most healthcare professionals recommended SMBG but acknowledged that testing may be less beneficial in patients controlled with lifestyle or OAAAs alone (20). A United Kingdom study found similar results to our study, with respondents recommending SMBG for most patients and showing variation in the recommended frequency of testing (21). These and other studies provide insight into the lack of consensus on approaches to SMBG that exist not only in Canada, but around the world (20-23).

### Limitations

The results of this study are specific to the participants who responded to the invitation to participate in the study. It is acknowledged that those who agreed to participate may have represented a segment of healthcare professionals particularly interested in, or in favour of, SMBG. It is unknown to what extent the views expressed by participants in this study are reflective of other healthcare professionals in the province. Similarly, it is not known if results would vary in different practice settings or with medical specialists.

The purpose of this study was to talk with a sample of Nova Scotia healthcare professionals to gain insight into their recommendations, practices and beliefs with respect to SMBG in well-controlled adults ( $A1C \leq 7.0\%$ ) with type 2 diabetes who were not using insulin. It is recognized that the natural complement to this research would be the patient perspective of SMBG, including information about their SMBG practices and beliefs.

### Conclusion

Among the healthcare professionals interviewed for this study, we identified a lack of consensus in the recommendations for SMBG in well-controlled individuals with diabetes

not using insulin. These findings have important implications for healthcare professionals, guideline developers, continuing education providers, policy-makers and patients. The debate on the benefits, risks and costs of SMBG needs to be informed by current evidence. Dissemination of the evidence to healthcare professionals and changes to SMBG recommendations will take time to implement and require a multidisciplinary approach. Interdisciplinary education could be used to improve the consistency of recommendations. While it is important to customize SMBG practices to individual patients, clarity in guideline recommendations and consensus on the incorporation of a broader approach to patient care are also required to improve consistency. Attempts to reduce the use of SMBG in patient populations where it is unlikely to be beneficial will allow reallocation of resources to interventions with proven benefit.

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## AUTHOR DISCLOSURES

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## AUTHOR CONTRIBUTIONS

All authors participated in the conception and design of this study, analysis and interpretation of findings, review of drafts for intellectual contribution and approved the final draft. CL also acquired data and drafted a substantial part of the paper. PMV participated in drafting the letter.

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## ORIGINAL RESEARCH

# Dietary Self-Care in Adolescents with Type 1 Diabetes: Report from the Juvenile Diabetes and Dietary Study

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## ABSTRACT

**OBJECTIVE:** This study had 3 aims: a) to examine the relationships between metabolic control, self-perceptions of dietary self-care, types of motivation and parental autonomy support toward dietary self-care in adolescents with type 1 diabetes; b) to explore gender differences in the above variables; and c) to verify the extent to which types of motivation and autonomy support from parents predict metabolic control and dietary self-care.

**METHODS:** A consecutive series of 289 adolescent patients with type 1 diabetes, aged 11 to 17 years, was recruited from 2 pediatric diabetes outpatient clinics in the province of Québec between January and December 2003.

**RESULTS:** Metabolic control was found to be suboptimal, with mean glycosylated hemoglobin levels of 8.5% (SD 1.6). Dietary recommendations were generally carried out for autonomous reasons: that is, for the satisfaction and pleasure of eating healthfully (mean 3.62, SD 1.0, range 1–5) or because these activities were valued or considered important (mean 4.35, SD 0.8, range 1–5). Results also showed that the more adolescents performed these activities because they felt controlled or were amotivated, the more they presented poor dietary self-care and metabolic control. Similarly, regression analysis revealed that controlled regulation ( $\beta$  0.13,  $p < 0.05$ ) and amotivation ( $\beta$  0.13,  $p < 0.05$ ) toward dietary self-care predicted poor metabolic control. Analyses revealed no gender differences.

**CONCLUSION:** Minimizing sources of pressure to pursue dietary self-care could be a promising avenue for improving dietary self-care in adolescents with type 1 diabetes.

**KEYWORDS:** adolescents, dietary self-care, metabolic control, motivation, type 1 diabetes

## RÉSUMÉ

**OBJECTIFS :** Cette étude avait trois objectifs : a) examiner les liens entre le contrôle métabolique, les perceptions d'autogestion alimentaire, les types de motivation et le soutien à l'autonomie de la part des parents en matière d'observance du plan alimentaire chez les adolescents atteints de diabète de type 1; b) examiner les différences entre les sexes pour ce qui est des variables ci-dessus; et c) déterminer dans quelle mesure les types de motivation et le soutien à l'autonomie de la part des parents permettent de prédire le contrôle métabolique et l'observance du plan alimentaire.

**MÉTHODES :** Une série consécutive de 289 adolescents de 11 à 17 ans a été recrutée au Québec dans deux services de soins externes pour enfants atteints de diabète de type 1 entre janvier et décembre 2003.

**RÉSULTATS :** Les résultats ont montré que le contrôle métabolique était sous-optimal, le taux moyen d'hémoglobine glycosylée étant évalué à 8,5 % (écart type [ET] : 1,6). Les recommandations alimentaires étaient en général suivies pour des raisons autonomes, c'est-à-dire pour la satisfaction et le plaisir de manger sainement (moyenne de 3,62, ET de 1,0, écart de 1 à 5), ou parce que ces recommandations étaient considérées importantes (moyenne de 4,35, ET de 0,8, écart de 1 à 5). Les résultats ont aussi montré que plus les adolescents suivaient les recommandations parce qu'ils se sentaient contrôlés ou amotivés, plus leur observance et leur contrôle métabolique étaient médiocres. De la même façon, l'analyse de régression a indiqué que la régulation contrôlée ( $\beta$  0,13,  $p < 0,05$ ) et l'amotivation ( $\beta$  0,13,  $p < 0,05$ ) en matière d'autogestion alimentaire étaient des prédicteurs de contrôle métabolique médiocre. Les analyses n'ont pas révélé de différences entre les sexes.

**CONCLUSION :** Réduire au minimum les sources de pression en ce qui a trait aux comportements alimentaires pour-r

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être prometteur pour l'amélioration de l'autogestion alimentaire chez les adolescents atteints de diabète de type 1.

**MOTS CLÉS :** adolescents, autogestion du plan alimentaire, contrôle métabolique, motivation, diabète de type 1

## INTRODUCTION

To keep blood glucose levels within a normal range, young patients with type 1 diabetes must perform a complex set of self-care activities, including insulin replacement and following a healthy diet as recommended in Health Canada's *Eating Well with Canada's Food Guide* (1). Specifically, this involves consuming a wide variety of foods from each of the 4 food groups that suit young patients' nutritional needs, eating habits, lifestyle, ability and interest, and matching food consumption with adequate insulin administration (2). However, data suggest that dietary self-care in adolescence is difficult for many young patients, with adherence levels as low as 20 to 50% (3). Moreover, the literature shows that metabolic control in adolescents is often unsatisfactory, with most having blood glucose levels higher than the optimal range (4-6). Given that early diabetes control reduces the onset and progression of complications (5), it is important to know the extent to which adolescents with type 1 diabetes follow their dietary plan and succeed in controlling their glycemic levels. Specifically, examining the reasons why some adolescents do or do not follow their recommended dietary plan is important to our understanding of poor metabolic control in adolescence.

According to self-determination theory (SDT) (7), developing a sense of autonomy, where action comes from the self, is critical to the initiation, direction and maintenance of human behaviour. Within SDT, the concept of autonomy relates to a sense of volition, as opposed to one of being controlled. SDT proposes that the extent to which a social milieu allows one to experience feelings of autonomy will determine one's quality of motivation. As such, a large body of research based on SDT focuses on how external behaviours (such as prescribed dietary self-care activities) can be integrated into one's value sets with the help of significant others (such as parents) and how this integration can translate into optimal motivation and well-being. While no SDT studies have yet been carried out on dietary self-care in adolescents living with type 1 diabetes, research in adults suggests that patients who perceive to be supported in their dietary self-care efforts ultimately present the highest quality of motivation, as well as better dietary self-care and metabolic control (8,9).

The primary goals of this study were as follows: a) to document and examine the relationships between metabolic control, self-perceptions of dietary self-care, types of motivation (intrinsic, identified, controlled, amotivation) and parental autonomy support toward dietary self-care in

adolescents with type 1 diabetes; b) to explore gender differences in the above variables; and c) to verify the extent to which types of motivation and autonomy support from parents contribute to the explanation of dietary self-care and metabolic control. Before addressing these goals, we portrayed the demographic and lifestyle attributes of adolescents with type 1 diabetes, as well as their recall of other important diabetes self-care recommendations and practices, such as for insulin injections and blood glucose readings. This study is the first to pursue these goals among a sample of Canadian adolescents with type 1 diabetes.

## METHODS

### Procedure and participants

Data were obtained from the first wave of the Juvenile Diabetes and Dietary Study, a 3-year longitudinal study of dietary self-care in families of adolescents with type 1 diabetes (10). Participants were recruited at the outpatient clinics of 2 major pediatric diabetes centres in the province of Quebec. Rather than relying on a convenience sample of patients, efforts were invested in the identification of all patients with type 1 diabetes aged 11 to 17 years and who attended the 2 outpatient clinics from January to December 2003. Consecutive series of participants were recruited using 2 methods: either an interviewer initially contacted the adolescents and their parents to invite them to complete a questionnaire at the child's next scheduled appointment, or adolescents and parents were approached by the treating physician during consultation and then referred to a trained research assistant, who was present in the clinic's waiting room. Informed consent was obtained from all participants. Adolescents completed a self-report questionnaire on dietary self-care and motivation for dietary self-care, while the accompanying parent answered a background questionnaire that included demographic data (age, family structure). Both questionnaires were completed individually. Adolescents also agreed to participate in a 10-minute phone interview 7 days later to answer additional questions about their diabetes history (year of diagnosis, complications and general diabetes self-care recommendations and practices). Adolescents received \$10 each for their participation. The study protocol received ethical approval from the research ethics committees at Université Laval and the Mother and Child University Hospital Centres of Sainte-Justine and Université Laval.

### Measures

The medical charts of participating adolescents were consulted by the treating physician to retrieve data on metabolic control prior to the beginning of the study. These data were abstracted using a pen-and-paper system. Metabolic control was assessed using glycated hemoglobin (A1C) level. Higher

A1C levels reflect poor blood glucose control. The current recommended goal for A1C in adolescents with type 1 diabetes is <7.0%, which is considered to be good metabolic control (1).

Dietary self-care over the previous 7 days was assessed by a single item of the diet subscale of the Summary of Diabetes Self-Care Activities scale from Toobert and Glasgow (11), a scale developed for use with adults, but adapted and used with adolescents with type 1 diabetes in previous studies (12-14). This item asked adolescents to evaluate how often they had followed their recommended dietary program over the last 7 days. It was scored on a 5-level descriptor scale ranging from 1 (never) to 5 (always). Higher scores indicate better dietary self-care.

Motivations for managing dietary self-care activities was assessed using the Dietary Self-Care Motivation Scale for Adolescents with Diabetes (DSMS-AD) (15). The DSMS-AD consists of 12 items representing 4 motivational constructs that reflect different types of motivation, which can be situated along a continuum of autonomy. Each item represents a possible answer to the question "Why do you follow your dietary self-care activities?" and was scored on a 5-point scale ranging from 1 (do not agree at all) to 5 (completely agree). Based on SDT (7), the DSMS-AD assesses intrinsic regulation (3 items), the most autonomous form of motivated behaviour; in this case, managing dietary self-care for the satisfaction and pleasure of eating healthfully (e.g. "Because I found it fun to prepare meals and snacks that are good for my health"; Cronbach value of 0.75). Next is identified regulation (3 items), a relatively autonomous motivational construct because it relates to activities that are accepted by oneself, judged important and valuable for one's health, but not interesting in themselves (e.g. "Because I want to remain healthy as long as possible"; Cronbach value of 0.83). Further along the continuum is controlled regulation (3 items), which underlies dietary self-care behaviours that are performed to avoid feelings of guilt or shame, or due to the demands, treats or rewards of an external agent (e.g. "Because my doctor asks me to"; Cronbach value of 0.72). Finally, at the lower end of the continuum lies amotivation, which represents the least autonomous form of motivated behaviour (3 items) and involves a lack of intention or motivation (e.g. "I don't know what I'm getting out of dieting"; Cronbach value of 0.79).

Perceived autonomy support from parents was assessed by a modified version of the Perception of Parents Scale (16). The original scale comprised 21 items for mothers and 21 for fathers. To obtain a measure assessing the interpersonal style of both parents, mothers' and fathers' items were merged into a single scale. Three items were then judged redundant and removed (e.g. "My parents try to tell me how to run my life"; "My parents aren't very sensitive to many of my needs";

"My parents are often disapproving and unaccepting of me"). The remaining 18 items were adapted to diabetes-related situations. The subscale included supportiveness items such as "My parents seem to know how I feel about my diabetes"; involvement items such as "My parents find time to talk with me about my diabetes"; and warmth items such as "My parents accept me and like me as I am." Items were scored on a 7-point scale ranging from 1 (not at all true) to 7 (absolutely true). Cronbach's alpha for this sample was 0.90.

### Statistical analyses

Means and standard deviations were used for continuous variables, and categorical variables were described using frequency statistics. Unpaired Student's t-tests were used to compare adolescent boys and girls on some demographic variables, health characteristics, age, diabetes duration, A1C and number of medical conditions related to diabetes. Pearson's correlation coefficients were calculated to determine the degree of association among types of motivations (intrinsic, identified, controlled and amotivation), dietary self-care, parental support and A1C. Linear regression analyses using stepwise variable selection were conducted to verify the contribution of intrinsic regulation, identified regulation, controlled regulation and amotivation in the prediction of both dietary self-care (first regression analysis) and A1C (second regression analysis). SPSS version 11.5 (SPSS Inc. Chicago, Illinois) was used for all analyses. Two-tailed p values of <0.05 were considered statistically significant.

## RESULTS

### Preliminary analysis

The demographic and lifestyle characteristics of participants are presented in Table 1. In total, 289 consecutive series of adolescents participated in this study (133 girls, 46%). There were no significant differences between boys and girls with respect to the number of medical complications related to diabetes, diabetes duration or age. Factors related to adolescents' general self-care recommendations and practices are presented in Table 2. The mean number of glucose readings per day was 3.6 (SD 0.7), significantly lower than the mean number of recommended glucose readings per day ( $3.9 \pm 0.4$ ;  $t [260] = -7.224$ ,  $p < 0.001$ ). As for insulin injections, almost all adolescents reported that they followed medical recommendations. Of the total sample, 61% injected insulin 3 times a day, 38% injected 4 or more times a day and 1% injected twice a day.

### Main analyses

Mean A1C was 8.5% (SD 1.6), with no significant differences between boys and girls. Target A1C (<7%) was achieved in only 46 (16%) adolescents (24 boys, 52%); 151 (52%) had A1C levels between 7.0 and 9.0% (84 boys, 56%); and

**Table 1. Characteristics of participants (N=289)**

Characteristic	Value
Mean age of adolescent, y±SD (range)	13.9±1.5 (11–17)
Mean age at diabetes diagnosis, y±SD (range)	8.2±3.7 (1–16)
Mean duration of diabetes, y±SD (range)	5.6±3.8 (0–15.5)
Complications from diabetes	
Yes	26 (10)
No	232 (90)
Sex of parent	
Female	221 (78)
Male	53 (19)
Guardian other than parent	11 (3)
Mean age of parent, y±SD (range)	42.7±4.9 (32–57)
Family structure	
2-parent family (married or not)	214 (75)
Single-parent family	71 (25)
Number of siblings	
None	35 (12)
1 or 2	217 (75)
≥3	37 (13)
Smoking status of adolescent	
Yes	21 (7)
No	266 (93)
Alcohol consumption status of adolescent	
Yes	88 (31)
No	198 (69)
Education of parent	
High school	101 (37)
College or professional degree	91 (33)
Graduate studies	84 (30)
Employment of parent	
Full-time job	42 (15)
Part-time job	190 (69)
Unemployed	45 (16)
Net annual income of parent	
≤\$29 999	120 (46)
\$30 000–\$39 999	50 (19)
\$40 000–\$49 999	32 (12)
\$50 000–\$59 999	22 (9)
≥\$60 000	35 (14)

Numbers are n (%) unless otherwise indicated. Numerical discrepancies reflect missing values.

92 (32%) had A1C levels >9% (48 boys, 52%). In terms of adolescents' perceptions of dietary self-care, 51% reported they had followed their dietary program *sometimes* or *never* during the previous week. In contrast, 49% reported they had followed their dietary recommendations *usually* or *always*. No gender differences were found in reports of dietary self-care ( $t [286]=0.10, p=0.92$ ).

For dietary self-care motivation, mean scores were higher on the more autonomous forms of motivation, namely identified and intrinsic regulations. Mean identified regulation in adolescents was 4.35 (SD 0.8), whereas mean intrinsic regulation for dietary self-care was 3.62 (SD 1.0). For lower autonomous motivation, the mean score for

**Table 2. Treatment recommendations and self-care behaviours of adolescents with type 1 diabetes (N=289)**

Characteristic	Value
Mean A1C, %±SD (range)	8.5±1.6 (5.3–14.2)
Number of hypoglycemic episodes in previous month, mean±SD (range)	8.9±7.7 (0–40)
Insulin pump therapy	
Yes	7 (2)
No	280 (98)
Number of insulin injections per day, mean±SD (range)	3.4±0.5 (2–6)
2	3 (1)
3	162 (61)
≥4	100 (38)
Adolescents' report of adherence to insulin recommendations	
Yes	279 (98)
No	5 (2)
Number of blood glucose tests per day, mean±SD (range)	3.6±0.7 (1–5)
1–2	17 (6)
3	75 (29)
≥4	169 (65)
Number of recommended blood glucose tests per day, mean±SD (range)	3.9±0.4 (2–4)
2	5 (2)
3	27 (10)
≥4	244 (88)
Physical activity counselling by healthcare practitioners during the course of diabetes	
Yes	32 (11)
No	255 (89)
Practicing a sport or exercising on a regular basis	
Yes	182 (64)
No	103 (36)
Dietary counselling at diagnosis	
Yes	180 (65)
No	7 (3)
Too young to remember	87 (32)
Number of appointments with a dietitian in the previous year, mean±SD (range)	2.9±1.4 (1–6)
1	33 (12)
2	106 (39)
≥3	131 (49)
Person mostly responsible for meal preparation at home	
Both parents, equally	49 (19)
Mother	193 (73)
Father	22 (8)

Numbers are n (%) unless otherwise indicated. A1C = glycated hemoglobin

controlled regulation was 2.86 (SD 1.0) and for amotivation was 1.88 (SD 1.0). Independent t-tests revealed no gender differences in type of motivation, indicating that girls and boys reported similar levels of intrinsic regulation, identified

regulation, controlled regulation and amotivation toward dietary self-care.

Correlation coefficients between type of motivation and dietary self-care followed an ordered pattern, where positive correlations were observed between dietary self-care and intrinsic regulation ( $r=0.17$ ,  $p\leq 0.01$ ) and identified regulation ( $r=0.13$ ,  $p\leq 0.05$ ), and negative correlations with controlled regulation ( $r=-0.21$ ,  $p\leq 0.01$ ) and amotivation ( $r=-0.22$ ,  $p\leq 0.01$ ). As for the relationships between dietary self-care motivation and parental autonomy support, results revealed that the more adolescents perceived that their parents were autonomy supportive of their dietary self-care initiatives, the more they regulated self-care recommendations for identified reasons ( $r=0.46$ ,  $p\leq 0.01$ ) and the more they engaged in these activities for intrinsic reasons ( $r=0.43$ ,  $p\leq 0.01$ ). In contrast, perceptions of parental support were related negatively to motivations that were non-autonomous in nature, such as controlled regulation ( $r=-0.15$ ,  $p\leq 0.05$ ) and amotivation ( $r=-0.36$ ,  $p\leq 0.01$ ). Interestingly, A1C levels were associated positively with controlled motivation ( $r=0.16$ ,  $p\leq 0.01$ ) and amotivation ( $r=0.16$ ,  $p\leq 0.01$ ), meaning that metabolic control was worst with non-autonomous types of motivation. As for the relationship between metabolic control and dietary self-care, results indicated that better dietary self-care was associated with better metabolic control ( $r=-0.18$ ,  $p\leq 0.01$ ).

Regression analysis revealed that intrinsic regulation ( $\beta=0.36$ ;  $p<0.001$ ), controlled regulation ( $\beta=-0.15$ ;  $p<0.01$ ) and amotivation ( $\beta=-0.17$ ;  $p<0.01$ ) were significant predictors of dietary self-care, accounting for 23% of variance. As for metabolic control, controlled regulation ( $\beta=0.13$ ;  $p<0.05$ ) and amotivation ( $\beta=0.13$ ;  $p<0.05$ ) were the only significant predictors, accounting for 4% of variance.

## DISCUSSION

The present study aimed to document dietary self-care and motivation in adolescents with type 1 diabetes. Along with demographic and lifestyle information, diabetes self-care recommendations, practices and metabolic control were documented in a consecutive series of adolescents with type 1 diabetes. Results showed that adolescents performed up to 3 or more glycemic readings and insulin injections per day. Few had received physical activity counselling at diagnosis, but the majority were physically active on a regular basis. Dietary counselling was given to most adolescents at diagnosis and was a continuing priority, as a good proportion of adolescents consulted with a dietitian several times a year. Nonetheless, overall metabolic control was suboptimal in this sample, with mean A1C values of 8.5% (SD 1.6). More precisely, only 16% of the adolescents in this sample had A1C values  $<7.0\%$ , the threshold above which the risk of diabetes complica-

tions is known to rise steeply (5). In line with the results of other studies in pediatric populations (6,17), our findings correspond with the well-documented phenomenon of deterioration in metabolic control during the teenage years (18). Given the importance of dietary self-care to metabolic control (19), this study also aimed to document the extent to which adolescents succeeded in following their recommended dietary program. Results showed that, on average, adolescents perceived they had *sometimes* succeeded in following their dietary self-care program in the previous 7 days. This result concurs with the current diabetes adherence literature, which reports dietary adherence rates of approximately 40% in pediatric and adult populations (3).

Our findings have practical implications for the management of type 1 diabetes in adolescents. More efforts should be devoted to educating adolescents and their families about the importance of effectively managing dietary self-care activities. In contrast to insulin and glycemic recommendations, dietary self-care recommendations are more subjective. Thus, some adolescents may think they follow their dietary recommendations, when in fact they are under- or overestimating the carbohydrate contents of foods, resulting in poor metabolic control (20). However, growing evidence suggests knowledge alone does not translate into dietary improvement (21) and addressing patients' own perceptions about self-care is necessary to improve diabetes outcomes and quality of life (22).

Based on SDT (7), the reasons for engaging in dietary self-care activities were also investigated. Motives for dietary self-care were evaluated as autonomous, with higher mean scores on intrinsic and identified regulations. This means that dietary self-care recommendations were perceived as being performed largely in congruence with adolescents' personal values and goals (identified regulation) or out of pleasure (intrinsic regulation). Levels of controlled regulation were also noted, meaning that pressure from oneself ("Because I would feel ashamed if I didn't") or others ("Because my doctor asks me to") were relatively important motives for dietary self-care practices.

SDT suggests that, compared to less autonomous forms of regulation (controlled regulation and amotivation), the more autonomous regulations (intrinsic and identified regulations) are linked to more beneficial outcomes such as effective care, healthy eating and metabolic control (8,9,23). Although adolescents in this study reported higher autonomous motivations toward dietary self-care, this did not translate into adequate metabolic control. That is, regression analyses show that the only significant predictors of metabolic control were the less autonomous forms of motivation, namely controlled regulation and amotivation. It is, however, known that deterioration in diabetes control at adolescence

is also based on biological factors (i.e. pubertal insensitivity to insulin). Therefore, promoting autonomous motivation in adolescents with diabetes could be a continuing priority so that adolescents can remain engaged in their dietary self-care program and not become discouraged when A1C results do not match their self-care efforts. Further supporting this idea is the finding that intrinsic regulation, the most autonomous form of motivation, was found to be a significant predictor of dietary self-care in this study. Nonetheless, additional studies are required to replicate the present findings so as to confirm the relationship among types of motivation, metabolic control and dietary self-care.

According to SDT, when contextual agents are autonomy-supportive, patients tend to become more autonomous, and consequently experience greater choice and volition in their self-care behaviours (7). Autonomy-supportive practices involve acknowledging patients' perspectives and providing them with meaningful information and choices while supporting their self-care initiatives. Equally important for autonomy support would be minimizing coercive measures that pressure patients to behave involuntarily, such as being forced to adopt recommended dietary self-care practices. Because type 1 diabetes is a life-threatening condition, it is probable that parents use both autonomy-supportive and controlling actions to motivate their children to eat properly. For instance, Anderson and Coyne (24) outlined a process called "miscarried helping," which occurs when parents' well-intentioned efforts to help and motivate their children can thwart diabetes self-care because these actions are perceived as intrusive, excessive or inappropriate rather than supportive. Important here is the way adolescents perceive the actions of parents toward their dietary self-care efforts. Parents may believe that they adequately support their adolescents' choices and values about dietary self-care, but adolescents may, in fact, perceive their parents as being nagging and controlling. Such discrepancy in perceptions suggests that parents and adolescents should openly discuss their feelings and needs relating to dietary self-care. By addressing these issues, parents could adjust the way they support their adolescents' behaviours and in reaction to this, adolescents could potentially express better motivation (higher intrinsic regulation and lower controlled regulation and amotivation) as well as better dietary self-care.

In the self-determination theory literature, a growing number of studies conducted in adults with diabetes indicate that patients who perceive greater autonomy support have greater autonomous motivation and ultimately present better dietary self-care and metabolic control than patients who feel pressured to comply with dietary recommendations (9,25). In light of our study findings, which suggest that the more adolescents perceived their parents to be supportive, the more autonomous and the less controlled they were

about their dietary self-care, interventions should aim to encourage parents to be less controlling. Ultimately, such interventions could diminish levels of less autonomous forms of motivation (controlled regulation and amotivation), which was associated with poorer dietary self-care and metabolic control in this study.

### Strengths and limitations

This study has several limitations, each with implications for future research. Although the aim of this study was to document diabetes control and self-care in adolescents with type 1 diabetes, our sample may not be representative of the current general population. Adolescents were recruited in 2003 from 2 pediatric diabetes clinics in the province of Quebec, and very few were treated with insulin pump therapy (2%), a technology that closely mimics physiological insulin secretion upon carbohydrate load and consequently reduces the variability of patients' blood glucose levels. Because insulin pump therapy is now more widespread in Canada, future studies should examine dietary self-care in adolescent pump users. Moreover, in response to the growing costs of diabetes care and its complications in Canada, efforts should be made to gather more information about diabetes self-care in other provinces and territories. Nonetheless, because data from this study came from a consecutive series of patients, we believe that our results are representative of the adolescents served by our pediatric diabetes clinics. Another limitation is that we relied largely on self-reported measures, which can produce common method variance. We tried to minimize this problem by selecting self-reported measures that were formulated in different terms and by using different scale ranges. Future research could use information from other sources, such as motivations for dietary self-care as reported by parents and healthcare professionals. Finally, an additional study limitation is the lack of anthropometric data. Other studies should investigate whether adolescents' motivation and dietary self-care differ according to body mass index.

Notwithstanding these concerns, our findings contribute to the existing research on adolescents with type 1 diabetes. This study documents diabetes care in a consecutive series of adolescents with type 1 diabetes. Given the actual need to improve national diabetes surveillance systems in cohorts of patients with type 1 diabetes, our results have provided valuable information about the general self-care recommendations, practices and difficulties that adolescents face every day. Most importantly, our results have brought to light the importance of studying types of motivation and parental support for improving young patients' dietary self-care and metabolic control at adolescence. Finally, the finding of poor metabolic control in this study, as well as its association with poor dietary self-care, strongly supports

the relevance of improving nutritional education in order to promote healthy eating in adolescents with diabetes and minimize the risks of diabetes morbidity and mortality in this population.

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## AUTHOR DISCLOSURES

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## AUTHOR CONTRIBUTIONS

SA participated in the data collection, data analysis and interpretation, and in drafting the manuscript. CS participated in the study design, supervision of the data collection, and the critical revision of the manuscript. FG participated in the review of the data and the manuscript. AN participated in the review of the manuscript. Funding was secured by CS, FG, and AN.

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## ORIGINAL RESEARCH

# The Efficacy of Diabetes Patient Education and Self-Management Education in Type 2 Diabetes

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## ABSTRACT

**OBJECTIVE:** The goal of this randomized, controlled trial was to compare the 6-month efficacy of didactic diabetes patient education to a model that augmented this education with a self-management program.

**METHODS:** Adults with type 2 diabetes were randomly assigned to a group that received diabetes patient education or to a group that received this education augmented by a community self-management program. Outcome measures were taken at baseline and 6 months. Analysis included pre- and 6-month-post-program paired comparison for each group; a comparison of change between groups; and an intent-to-treat comparison of change between groups.

**RESULTS:** At baseline, there were no between-condition differences with respect to behavioural or biological outcomes or healthcare utilization. The pre- and 6-month-post-program comparison found statistically significant improvements in both groups in terms of glycated hemoglobin (A1C) and weight, and the experimental group had statistically significant improvements in 4 additional outcomes. A 12-month analysis found that baseline scores were statistically lower for both A1C and weight in the experimental group and statistically higher than baseline A1C in the control group.

**CONCLUSION:** Augmenting diabetes patient education with a low-cost community self-management education program brought about additional improvements. Study limitations included self-selection of participants, short-term study duration and lack of comparison studies.

**KEYWORDS:** diabetes patient education, randomized controlled trial, self-management education

## RÉSUMÉ

**OBJECTIF :** Cet essai contrôlé avec répartition aléatoire avait pour objet de comparer l'efficacité, après six mois, d'un programme d'éducation sur le diabète à un modèle associant ce programme à un programme d'autogestion.

**MÉTHODES :** Des adultes atteints de diabète de type 2 ont été répartis au hasard pour participer au programme d'éducation sur le diabète seulement ou à ce programme et à un programme communautaire d'autogestion. Des mesures ont été effectuées au départ et six mois plus tard. Trois analyses ont été effectuées : une comparaison par paires des valeurs obtenues avant le programme et après six mois dans chaque groupe, une comparaison du changement entre les groupes et une comparaison en intention de traiter du changement entre les groupes.

**RÉSULTATS :** Au départ, il n'y avait pas de différences entre les groupes pour ce qui est des comportements, des valeurs biologiques ou de l'utilisation des services de santé. La comparaison entre les mesures effectuées avant le programme et six mois plus tard a montré qu'il y avait eu des améliorations statistiquement significatives dans les deux groupes de l'hémoglobine glycosylée (HbA<sub>1c</sub>) et du poids. Dans le groupe expérimental, il y a eu des améliorations statistiquement significatives de quatre autres mesures. Une analyse effectuée douze mois plus tard a montré que les scores de base étaient statistiquement plus bas tant pour le taux d'HbA<sub>1c</sub> que pour le poids dans le groupe expérimental et statistiquement plus hauts pour le taux d'HbA<sub>1c</sub> dans le groupe témoin.

**CONCLUSION :** L'association d'un programme communautaire d'autogestion peu coûteux à un programme d'éducation sur le diabète a produit d'autres améliorations. Les limites de l'étude étaient l'auto-sélection des participants, la courte durée de l'étude et le manque d'études de comparaison.

**MOTS CLÉS :** éducation des patients diabétiques, essai contrôlé avec répartition aléatoire, éducation sur l'autogestion

## INTRODUCTION

The United States (US) national standards for diabetes self-management education (1) and the Canadian Diabetes Association 2008 clinical practice guidelines (2) provide a comprehensive description of the evidence-based education that is effective for improving clinical outcomes and quality

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of life for people with diabetes. Education that couples diabetes disease management with behavioural strategies—namely the use of action plans and problem solving—has been shown to bring about improved outcomes (3). Therefore, the standards and guidelines strongly specify that education should be interactive and presented in behavioural terms to exemplify the importance of action-oriented behavioural goals and objectives, and that goal setting, action planning/ follow-up and problem-solving skills are effective strategies. The International Diabetes Federation has formulated a strong position statement on diabetes self-management, advocating that people with diabetes need to understand the nature of their illness; identify emerging health problems at early, reversible stages; adhere to self-care practices; and make needed changes to their health habits (4).

The standards and guidelines are consistent with the literature advocating the involvement of registered nurses, dietitians and pharmacists as key primary educators, but they also cite literature supporting the involvement of lay health and community workers and peers in providing information and behavioural support (5). The goal of this randomized, controlled trial was to compare the 6-month efficacy of didactic diabetes patient education that focused on disease management to the same program augmented by participation in a community peer-led self-management program that taught and reinforced the use of action planning, follow-up and problem solving.

## METHODS

The standard protocol for diabetes care in British Columbia, Canada, is that adults diagnosed with type 2 diabetes are referred to a diabetes education centre. Between April 2004 and December 2006, all persons referred to the diabetes education centre at Richmond Hospital, Richmond, British Columbia (approximately 1400 in total) were informed about this study. Diabetes education centre staff explained the purpose and process of the study, and inquired about patients' interest in participating. The majority of adults (n=1079) indicated they were too busy to participate in a study that involved additional diabetes education. Those who were interested (n=321) were given a copy of the study consent form, which they reviewed with a staff member, and provided their signature. Ethical approval for this project was obtained from the University of Victoria Human Research Ethics Committee and Richmond Health Services Delivery Area Research Advisory Committee.

Diabetes education staff made arrangements with the laboratory to obtain metabolic data (glycated hemoglobin [A1C], high-density lipoprotein cholesterol [HDL-C] and low-density lipoprotein cholesterol [LDL-C]) and recorded patients' self-reported weights. Patients then completed 2 self-administered questionnaires. The first questionnaire

inquired about the following:

- a) Self-management behaviours (i.e. communication with physician, amount of time doing aerobic exercise, amount of time doing stretching/strengthening exercise and number of times in the last week a relaxation technique was practiced) (6).
- b) Self-efficacy to manage symptoms and emotional distress (6).
- c) Health status (i.e. self-rated health) (7), social/role activities limitations (6), health distress (7), fatigue, shortness of breath and pain severity (6).
- d) Medical care utilization in the last 6 months (number of doctor appointments, visits to hospital emergency room, times hospitalized and nights in hospital).

The second questionnaire was the Diabetes Empowerment Scale (8). This scale contains 28 questions comprising 3 subscales: managing the psychosocial aspects of diabetes (9 items); assessing dissatisfaction and readiness to change (9 items); and setting and achieving diabetes goals (10 items). This scale is a valid and reliable measure of diabetes-related psychosocial self-efficacy.

Completed questionnaires were sent to the project coordinator at the University of Victoria, who randomly assigned each subject to a group that would receive regular diabetes patient education (control group) or a group that would receive the same education and also participate in a local Stanford Chronic Disease Self-Management Program (CDSMP) (experimental group). Randomization involved summing the last 3 numbers of patients' provincial health number and assigning those with even numbers to one group and odd numbers to the other. Subjects in both groups received diabetes patient education delivered in group format by a certified diabetes educator nurse and dietitian over a 2-day period. The education delivered at the centre was consistent with the 2003 Canadian Diabetes Association *Standards for Diabetes Education in Canada* (9).

After attending diabetes patient education, subjects in the experimental group were mailed a schedule of self-management programs taking place in their community to select the program they wished to attend. The coordinator contacted subjects who had not responded within 2 weeks to assist them with their selection. A maximum of 2 contacts were initiated, the first being the mailed course schedule, and the second the telephone call to subjects who had not responded. The Stanford CDSMP (10) involves participants with a variety of chronic health conditions. Each CDSMP is delivered by 2 program leaders, who successfully complete a 4-day training workshop and demonstrate they can deliver the program following a scripted leader manual (11). Leaders are trained by pairs of master trainers who have completed an additional 4½-day training workshop, during which they learn to use a master trainer manual to train new program leaders. Pairs of trained leaders deliver

the CDSMP to groups of 10 to 12 people for 2½ hours once per week for 6 consecutive weeks. Participants are considered to have completed the CDSMP if they attend at least 4 of the 6 sessions. A review of CDSMP attendance records of an earlier sample of 4000 participants in British Columbia showed mean attendance was 4.3 sessions (unpublished data). In this study, all 82 participants attended at least 4 of the 6 sessions.

The program teaches general skills for living with and managing chronic health condition(s), including the following: a) problem-solving skills, which involve problem definition, generation of possible solutions, solution implementation and evaluation of results; b) decision-making (making day-to-day decisions in response to their disease conditions); c) seeking out and using resources; d) building a partnership with healthcare providers by reporting the trends and tempo of their disease, making informed decisions about treatment and discussing these with their healthcare provider; and e) taking action by making short-term action plans and carrying them out.

In the CDSMP, participants obtain new information, learn new skills and abilities, and develop higher levels of self-confidence to manage and cope with chronic health conditions. The sessions are highly interactive, with emphasis on strategies to help individuals manage more effectively. It includes skills mastery (accomplished through weekly contracting to do specific behaviours and through feedback) and modelling (accomplished by leaders with chronic conditions). As well, there are frequent group problem-solving sessions. The 82 experimental group subjects participated in 1 of 15 CDSMPs being offered in their local area during the study period, led by 15 different pairs of program leaders.

In total, 321 people registered in the study; 169 were randomly assigned to the experimental group, and 152 to the control group. These target sample sizes were determined by referring to multiple sources for previous results. This author's pilot study [12] showed a standard deviation of 0.008 in pre- to six-month post program A1C scores. A review of the literature determined that a clinically relevant mean pre- to post-program change in A1C was 0.005. Allowing for a small placebo effect of 0.001 in the control group, and to achieve 80% power and a 5% 2-tailed significance level, a sample size of 64 per group was required. The sample sizes were increased to approximately 165 per group to allow for detection of smaller changes in A1C (0.0035 to 0.001). The final sample size (82 subjects in the experimental group and 152 in the control group) was therefore considered adequate for this study.

Six months after attending the diabetes education program, subjects were contacted by diabetes education centre staff to obtain A1C, HDL-C and LDL-C lab results. The project coordinator also mailed questionnaires to subjects.

The study was designed as an efficacy study; that is, the main research question was whether outcomes of subjects who attended the community CDSMP were different from outcomes of subjects in the control group. For an efficacy study, the question is whether the intervention can work if subjects do indeed receive the intervention. Hence, the analysis plan involved comparisons of the control group with that subset of the experimental group who took the CDSMP (i.e. a protocol-compliant experimental group). For completeness, a secondary, intent-to-treat analysis compared the control group to the full experimental group (i.e. those who took the CDSMP and those who did not).

Five sets of analysis were undertaken. To begin, baseline outcome measures within the assigned experimental group were done to compare the 82 subjects who attended the CDSMP with the 87 subjects who did not attend. As well, baseline comparisons were made between the experimental group subjects and control group subjects. Two-sample t-tests were used for quantitative variables and chi-square tests of independence for categorical variables.

Next, matched comparisons of pre- and 6-month-post-program findings were done with paired t-tests and Wilcoxon rank tests for quantitative outcomes. A comparison of change (calculated by subtracting Time 2 minus Time 1 between the experimental and control groups) was carried out using 2-sample t-tests and Mann-Whitney rank tests, and analysis of covariance (ANCOVA) to adjust for baseline differences.

An intent-to-treat analysis of change scores between groups was carried out using all subjects originally assigned to the experimental group—not just those who attended the CDSMP. Finally, an exploratory comparison of groups with respect to 12-month changes was carried out on a subset of cases for whom 12-month data were available, using the same tests as were used for the 6-month comparisons.

Mann-Whitney tests were used to compare group changes for the number of visits to the doctor, visits to a hospital emergency room, times hospitalized for 1 night or longer and total number of nights spent in hospital in the last 6 months.

## RESULTS

In total, 321 people registered in the study; 169 were randomly assigned to the experimental group, and 152 to the control group. Of the 169 subjects randomly assigned to the experimental group, only 82 (49%) agreed to take the community CDSMP after receiving diabetes patient education, even though they had all agreed to so when they registered in the study. The main reasons provided for not wanting to take the community CDSMP were as follows: not able to take time off work (n=19), not having transportation to travel to the program location (n=6), not feeling comfortable with the English language (n=12) and not being

interested in taking more patient education (n=50). Five subjects in the experimental group and 15 subjects in the control group did not complete the 6-month-post-program questionnaire. The reasons for not completing the 6-month follow-up for subjects in the experimental group were as follows: moved and could not be located (n=3) and illness (n=2). Reasons for the control group were as follows: moved and could not be located (n=1), illness (n=1), out of the country (n=1) and refused to complete the questionnaire (n=12). Therefore, the analysis was based on 77 subjects in the experimental group and 137 in the control group.

### Baseline comparisons

Table 1 shows demographics and key baseline measures for subjects in the control group and 2 subgroups of the assigned experimental group (attendees and non-attendees). Subjects in the control and experimental groups (attendees) were similar with respect to age, sex, education, ethnic origin, marital status, time since diagnosis, height, lipid profile and presence of other health conditions. Subjects in the control group were heavier (83 vs. 80 kg) and had higher A1C levels (7.1 vs. 6.8%) than those in the experimental group (attendees).

### Pre- to 6-month-post-program and comparison of groups

Paired t-tests and Wilcoxon rank tests showed statistically significant ( $p < 0.0125$  using the Bonferroni method for multiple testing) reductions in weight and A1C in both groups at 6 months post-program of ~3% weight loss and ~6%, respectively. The experimental group also had statistically significant improvements in self-rated health; health distress; communication with doctors; number of times a relaxation technique was practiced in the previous week; and in the 3 subscales of the Diabetes Empowerment Scale (setting and achieving goals, managing psychosocial aspects and assessing readiness to change). The experimental group had statistically significantly greater changes than the control group in self-rated health, communication with doctor and 2 subscales of the Diabetes Empowerment Scale. An analysis of covariance using baseline weight and A1C levels did not find a significant effect of the covariates on the level of change in the 2 groups. Table 2 shows the pre- and 6-month-post-program means and significance, as well as 6-month change means and significance for outcome measures.

Table 3 shows that while there was no change in the mean number of times subjects were hospitalized for 1 night

**Table 1. Baseline characteristics of subjects in the experimental, control and no course groups**

	<i>Experimental group (n=82)</i>	<i>Control group (n=152)</i>	<i>No-course group (assigned to experimental group) (n=87)</i>
Age, y	55 (12)	59 (12)	55 (11)
Sex, %			
Female	54	55	40
Male	46	45	60
Education, y	14 (4)	14 (3)	14 (3)
Ethnic origin, %			
English	51	54	36
Chinese	15	9	12
Filipino	7	9	12
Married/partner, %	71	72	77
Time since diagnosis, y	2.8 (4.6)	2.8 (5.2)	3.4 (4.9)
Height, cm	168 (10)	170 (20)	170 (13)
Weight, kg	80 (15)	83 (19)	85 (22)
A1C, %	6.8 (1.2)	7.1 (1.5)	7.5 (1.5)
HDL-C, mmol/L	1.19 (0.74)	1.15 (0.35)	1.01 (0.34)
LDL-C, mmol/L	2.81 (1.11)	2.79 (0.81)	2.79 (0.79)
Other conditions, %			
Heart	9	11	9
Hypertension	55	49	40
Lung	5	5	3

A1C = glycated hemoglobin

HDL-C = high-density lipoprotein cholesterol

LDL-C = low-density lipoprotein cholesterol

Data are mean (SD) unless otherwise indicated

Table 2. Pre- and 6-month-post-program means and significance, and 6-month change means and significance

Outcome measure*	Experimental (n=82)			Control (n=152)			Experimental	Control	p value <sup>‡</sup>
	Pre-program, mean (SD)	Post-program, mean (SD)	p value <sup>†</sup>	Pre-program, mean (SD)	Post-program, mean (SD)	p value <sup>†</sup>	6-month change, mean (SD)	6-month change, mean (SD)	
<b>Health status</b>									
Self-rated health (1–5) ↓	2.82 (0.81)	2.50 (0.89)	<0.01 <sup>§</sup>	2.85 (0.92)	3.01 (0.89)	0.07	−0.32 (0.82)	0.17 (0.85)	<0.01 <sup>§</sup>
Health distress (0–5) ↓	1.69 (1.29)	1.35 (1.0)	<0.01 <sup>§</sup>	1.51 (1.24)	1.46 (1.23)	0.66	−0.34 (0.99)	−0.05 (0.99)	0.05
Social/role activity limitations (0–4) ↓	0.70 (1.03)	0.62 (0.86)	0.44	0.68 (0.97)	0.80 (1.05)	0.17	−0.08 (0.95)	0.13 (0.88)	0.13
Fatigue (0–10) ↓	4.09 (2.79)	3.50 (2.50)	0.02	4.15 (2.45)	4.16 (2.50)	0.97	−0.59 (0.23)	0.01 (2.3)	0.09
Shortness of breath (0–10) ↓	1.57 (2.19)	1.17 (1.81)	0.04	2.11 (2.57)	2.06 (2.37)	0.86	−0.40 (1.68)	−0.04 (2.37)	0.26
Pain (0–10) ↓	2.82 (2.94)	2.58 (2.46)	0.39	3.17 (2.92)	3.38 (2.83)	0.43	−0.23 (2.37)	0.21 (2.58)	0.24
<b>Self-management behaviours</b>									
Communication with doctor (0–5) ↑	2.62 (1.12)	2.96 (1.07)	<0.01 <sup>§</sup>	2.40 (1.02)	2.26 (1.12)	0.27	0.34 (1.05)	−0.14 (1.16)	0.01 <sup>§</sup>
Time doing stretching/strengthening exercise (0–4) ↑	0.99 (1.20)	1.12 (1.04)	0.35	0.96 (1.17)	1.04 (1.18)	0.61	0.14 (1.25)	0.07 (1.27)	0.75
Time doing physical exercise (0–4) ↑	0.50 (1.18)	0.72 (0.41)	0.14	0.75 (0.61)	0.74 (0.58)	0.91	0.22 (0.58)	−0.01 (0.66)	0.91
Times practiced relaxation in last week ↑	0.40 (1.23)	1.08 (2.32)	0.01 <sup>§</sup>	0.98 (2.40)	0.94 (2.18)	0.91	0.68 (2.35)	−0.03 (2.68)	0.07
<b>Self-efficacy</b>									
Self-efficacy to manage symptoms (1–10) ↑	7.12 (2.51)	7.66 (2.39)	0.03	6.95 (2.86)	7.04 (2.73)	0.78	0.54 (2.12)	0.09 (3.00)	0.03
Self-efficacy to manage disease in general (1–10) ↑	7.11 (2.87)	7.54 (2.79)	0.11	7.03 (2.79)	7.21 (2.78)	0.55	0.43 (2.33)	0.18 (2.89)	0.54
<b>Laboratory tests</b>									
A1C, % ↓	6.8 (1.2)	6.4 (0.6)	<0.01 <sup>§</sup>	7.1 (1.5)	6.7 (1.0)	0.01 <sup>§</sup>	−0.50 (0.80)	−0.40 (1.30)	0.93
HDL-C, mmol/L ↑	1.24 (0.83)	1.20 (0.35)	0.70	1.15 (0.35)	1.18 (0.37)	0.21	−0.04 (0.81)	0.03 (0.19)	0.48
LDL-C, mmol/L ↓	2.66 (0.99)	2.74 (0.88)	0.38	2.76 (0.71)	2.58 (0.81)	0.62	0.08 (0.64)	−0.18 (0.79)	0.35
Weight, kg ↓	80.5 (15.3)	78.1 (15.1)	<0.01 <sup>§</sup>	83.0 (18.0)	80.0 (17.4)	<0.01 <sup>§</sup>	−2.40 (5.13)	−3.00 (4.8)	0.50
<b>Diabetes empowerment</b>									
Setting and achieving goals (1–5) ↑	3.94 (0.55)	4.14 (0.47)	<0.01 <sup>§</sup>	3.96 (0.56)	3.88 (0.68)	0.24	0.20 (0.49)	−0.08 (0.64)	<0.01 <sup>§</sup>
Managing psychosocial aspects (1–5) ↑	3.78 (0.67)	4.02 (0.57)	<0.01 <sup>§</sup>	3.85 (0.61)	3.82 (0.69)	0.73	0.24 (0.61)	−0.03 (0.73)	0.02
Assessing readiness to change (1–5) ↑	3.77 (0.46)	4.05 (0.49)	<0.01 <sup>§</sup>	3.81 (0.53)	3.76 (0.53)	0.48	0.30 (0.53)	−0.05 (0.61)	<0.01 <sup>§</sup>

A1C = glycated hemoglobin

HDL-C = high-density lipoprotein cholesterol

LDL-C = low-density lipoprotein cholesterol

\*Numbers in parentheses give range of the scales. Arrows (↓↑) indicate direction of improvement

†Paired t-tests were used to compare pre-program vs. post-program in each group

‡2-sample t-tests were used to compare the 2 groups with respect to 6-month change

§Statistical significance &lt;0.0125 level (adjusted for multiple testing)

**Table 3. Pre- and 6-month-post-program means and significance, and 6-month change means and significance for healthcare utilization**

Healthcare utilization in last 6 months	Experimental (n=75)			Control (n=90)			Experi- mental	Control	p value <sup>†</sup>	p value <sup>‡</sup>
	Pre-program, mean (SD)	Post-program, mean (SD)	p value*	Pre-program, mean (SD)	Post-program, mean (SD)	p value*	6-month change, mean (SD)	6-month change, mean (SD)		
Number of doctor visits	3.20 (2.09)	2.35 (2.30)	0.002	3.34 (2.37)	2.62 (2.31)	0.007	0.85 (2.25)	0.72 (2.52)	0.74	0.63
Number of visits to emergency room	0.15 (0.49)	0.07 (0.38)	0.28	0.17 (0.48)	0.18 (0.61)	0.88	0.08 (0.63)	-0.01 (0.70)	0.38	0.48
Number of times hospitalized for 1 night or longer	0.05 (0.28)	0.01 (0.12)	0.26	0.04 (0.21)	0.10 (0.34)	0.13	0.04 (0.31)	-0.06 (0.35)	0.065	0.09
Total number of nights spent in hospital	0.40 (1.99)	0.17 (1.39)	0.32	0.10 (0.50)	0.48 (2.17)	0.08	0.23 (1.94)	-0.38 (2.03)	0.054	0.083

\*Based on paired t-tests of dependent means

†Based on 2-sample t-tests of independent means

‡Based on Mann-Whitney rank test of 2 distributions

or longer in either group, there was a trend that subjects in the experimental group spent fewer nights in hospital (0.40 to 0.17), while subjects in the control group spent more nights in hospital (0.10 to 0.48). Nights patients spend in hospital is a significant healthcare expenditure, and certainly any intervention that suggests effectiveness in reducing hospital nights needs to be further investigated.

#### Intent-to-treat analysis

A similar set of analyses (2-sample t-tests, Mann-Whitney, ANCOVA) was carried out to compare the intent-to-treat experimental and control groups. There was a statistically significant change ( $p=0.008$ ) with respect to assessing readiness to change subscale of the Diabetes Empowerment Scale; mean change in the experimental group was 0.183 (SD 0.61) and in the control group was -0.045 (SD 0.61).

#### Comparison of 12-month changes

An attempt was made to follow subjects beyond the 6-month-post-program period, but diabetes education centre staff were able to convince only a subset of subjects in both groups to return for repeated tests. In total, 12-month post-program A1C measures and weights were obtained for 40 and 51 subjects of the experimental group (attendees), and 55 and 88 subjects of the control group, respectively. At 12 months, experimental group subjects' scores were statistically lower than at baseline for both A1C (6.4 vs. 6.8%) and weight (79.2 vs. 80.0 kg), respectively. Mean weight in the control group was still lower than at baseline (78.5 vs. 83.0 kg), while mean A1C had risen from 7.1% at baseline to 10.6% at 12 months. However, because the samples were not random and sizes were small, one cannot

draw inferences. A longer-term (i.e. 12 to 36 month) randomized, controlled trial would provide stronger evidence regarding the sustainability of changes.

## DISCUSSION

This study compared the efficacy of a didactic model of diabetes patient education provided at a diabetes education centre in British Columbia, Canada, to that of a model that combined diabetes patient education with a community self-management program. Results showed that at 6 months post-program, subjects in both the experimental and control groups had made improvements in key diabetes measures, namely A1C level and weight. Adjustment for baseline A1C levels and weight did not account for the differences between experimental and control groups. The analysis found that for 4 outcome measures, the experimental group had statistically greater pre/post changes at 6 months than the control group. The intent-to-treat analysis found 1 statistically significant change between the groups. This was to be expected, since only about half of the experimental group subjects actually received the intervention; including these subjects in the analysis resulted in a diluting of the effect of the "add on" CDSMP.

The major significance of this study is that a non-disease-specific self-management intervention that taught subjects to use action plans and the problem-solving process was effective in bringing about improvements in a few outcome measures, over and above the effectiveness of didactic diabetes education that focused on disease management. While new Canadian, US and international guidelines encourage diabetes educators to incorporate self-management support strategies into patient education

(1,2,4), referring patients to community self-management programs is a cost-effective option.

The study also found that the group that participated in the self-management program showed improvements in 4 additional areas, in contrast to subjects in the control group, who had statistically worse scores in 2 areas. The study demonstrated that additional positive changes could be brought about by attending an “add-on” community self-management program. In recent years, self-management skills have been integrated into best practice diabetes education by the Canadian Diabetes Association (2) and the US national standards for diabetes self-management education (1) and are used by diabetes educators. Self-management programs have become widely available in most communities and are usually available at either no cost or a minimal fee. Two principles of effective patient education are to have programs and services available where they can be easily accessed and taken when people are ready and motivated. As A1C levels generally start increasing after 6 months following diabetes patient education, participation in a self-management program following diabetes patient education can provide a maintenance function, especially as the self-management programs focus on strategies that address lifestyles factors such as exercise and eating habits. Future studies need to investigate the optimal timing and “dose” of self-management programs following patient education. In addition, diabetes educators should encourage patients to take a community self-management program, as research has demonstrated that if people are encouraged to take the program by a health professional, they are 18 times more likely to do so (13). Community self-management programs should therefore be considered an extension and reinforcement to the diabetes patient education provided at diabetes education centres.

The study uses self-report data on weight and healthcare utilization. While self-report data is frequently used because of its accessibility and cost-effectiveness, there are problems with social desirability and recall bias (14). However, studies have indicated that self-reported and actual weights reached are reported with acceptable accuracy (15). A number of studies have reported fairly high concordance between self-reports and medical records of hospital care among the general population (16-19).

There were several limitations to this research. The first is that the results cannot be extrapolated to the larger population of adults with type 2 diabetes referred to a diabetes education centre, because only a portion of this population agreed to participate in the study. A second limitation is that longer-term follow-up could not be accomplished, as subjects were reluctant to return to the diabetes education centre for retesting, and only a small number of subjects were retested at 12 months. A third limitation is that it was

not possible to compare the results of this study to similar studies, because the study team could not find published studies examining the efficacy of an intervention comprised of didactic diabetes patient education augmented by completion of the CDSMP, and could not find publications that examined the efficacy of diabetes patient education in British Columbia, Canada. This lack of efficacy evaluations was highlighted in the British Columbia Auditor General Report (20), which noted that diabetes education centres in British Columbia collected little performance information, and the norm was to focus on input measures of services provided (visits, attendance in a class, hours of class time) rather than on more patient-specific outcome information. While this type of information is necessary for ongoing budgeting and planning, major centres should be encouraged and supported to participate in efficacy studies by both provincial and federal funding as well as professional and legislative bodies.

## CONCLUSION

A subset of patients receiving diabetes patient education agreed to also participate in a 6-week community self-management program. By examining pre- and post-program changes in self-report and biometric disease measures the findings suggest incorporating a low-cost community self-management program into routine diabetes care can bring about additional patient improvements. The community lay-led self-management program provided support for the clinical services delivered by diabetes health professionals and should be considered an adjunct to usual care.

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## AUTHOR DISCLOSURES

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## ORIGINAL RESEARCH

# Evaluation of a Nova Scotia Diabetes Assistance Program for People with Type 2 Diabetes

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## ABSTRACT

**OBJECTIVE:** This study was intended to evaluate the impact of a province-wide Diabetes Assistance Program (financial and self-management support) in a representative sample of individuals with diabetes and unmet financial needs. The impact of the program was evaluated on individuals managed with insulin or oral antihyperglycemic agents alone and also on individuals with good, suboptimal or poor diabetes control.

**METHODS:** Participants were recruited from the entire population of individuals approved for the Nova Scotia Diabetes Assistance Program into this pre/post cohort study of people with type 1 or 2 diabetes. Participants were recruited by letter, and data were obtained via phone interview. Participants were assessed with regard to glycemic control, self-care and quality of life.

**RESULTS:** The Diabetes Assistance Program was unable to show a strong net benefit for the entire study sample, but there were significant findings when initial degree of glycemic control was considered, and to a lesser extent, method of control. The strongest positive impact was for those patients with poor control (glycated hemoglobin [A1C] >8.5%), who had significant improvements in glycemic control (absolute reduction in A1C of 0.9%), self-care and quality of life were observed. Minor positive effects were also demonstrated for those with suboptimal control. Those with good control demonstrated an increase in A1C.

**CONCLUSION:** This study demonstrates the value of providing support for those with poor glycemic control. Interestingly, those with good control did not benefit from support. These data suggest that efforts to support individuals with diabetes should be directed at those most likely to benefit.

**KEYWORDS:** diabetes support, financial assistance, self-management support

## RÉSUMÉ

**OBJECTIF :** L'objet de l'étude était d'évaluer les effets d'un programme provincial d'aide aux personnes diabétiques (soutien financier et de l'autogestion) dans un échantillon représentatif composé de personnes diabétiques ayant des besoins financiers non satisfaits. Les effets du programme ont été évalués chez des personnes qui prenaient de l'insuline ou des antihyperglycémiants oraux seulement et chez qui la maîtrise du diabète était bonne, sous-optimale ou médiocre.

**MÉTHODES :** Les sujets de cette étude de cohortes pré/post sur des personnes atteintes de diabète de type 1 ou 2 ont été recrutés parmi toutes les personnes inscrites au programme d'aide aux personnes diabétiques de la Nouvelle-Écosse. On a procédé par envoi d'une lettre pour le recrutement et par entrevue téléphonique pour la collecte des données. Les facteurs évalués ont été le contrôle de la glycémie, les soins auto-administrés et la qualité de vie.

**RÉSULTATS :** On a constaté que le programme d'aide aux personnes diabétiques n'avait pas d'avantage net très marqué dans l'ensemble de l'échantillon étudié, mais les résultats étaient significatifs quand on tenait compte du degré initial de contrôle de la glycémie et, dans une moindre mesure, de la méthode de contrôle. Les effets positifs les plus marqués ont été observés chez les patients dont le contrôle de la glycémie était médiocre (taux d'hémoglobine glycosylée [HbA<sub>1c</sub>] > 8,5 %) : chez elles, il y a eu des améliorations significatives du contrôle de la glycémie (réduction absolue de 0,9 % du taux d'HbA<sub>1c</sub>), des soins auto-administrés et de la qualité de vie. Il y a aussi eu de légers effets positifs chez les personnes dont le contrôle de la glycémie était sous-optimal. Chez les personnes dont le contrôle de la glycémie était bon, le taux d'HbA<sub>1c</sub> a augmenté.

**CONCLUSION :** Cette étude démontre l'utilité du soutien chez les personnes dont le contrôle de la glycémie est médiocre.

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Fait intéressant, le soutien n'a pas été utile quand le contrôle de la glycémie était bon. Ces données laissent entendre que le soutien des personnes diabétiques devrait s'adresser à celles qui sont les plus susceptibles d'en profiter.

**MOTS CLÉS :** soutien des personnes diabétiques, aide financière, soutien de l'autogestion

## INTRODUCTION

Diabetes is a chronic disease that requires ongoing medical management (oral antihyperglycemic agents [OAs] and/or insulin) and behavioural modification (healthy eating, physical activity and self-monitoring of blood glucose [SMBG]) for optimal glycemic control, but there are significant self-management and financial challenges associated with optimal management. For example, the Canadian Diabetes Association (CDA) estimates that medical costs for people with diabetes are 2 to 3 times higher than for people without diabetes (from \$1 000 to \$15 000 per year), primarily for medication and testing supplies (1). Those with financial limitations and unmet needs, as well as those who lack private insurance, are disadvantaged compared to those who are able to cover these extra costs. There is very little empirical research into the impact of providing diabetes supplies on patients' glycemic control, self-care and quality of life. A few studies have suggested that assistance programs might improve glycemic control, prevent worsening of control or improve self-care behaviour (2-6), but most of these studies examined a highly selective sample, such as those attending an academic medical clinic. Firmer conclusions could be drawn from a more representative sample of individuals needing financial support. As well, the impact of financial and self-management support in those differing in diabetes treatment method or degree of glycemic control is relevant to understand.

In recognition of the financial and self-management challenges that might mediate poor diabetes outcomes, the Nova Scotia Department of Health initiated the Diabetes Assistance Program for eligible Nova Scotians. In addition to financial assistance, the Diabetes Care Program of Nova Scotia (DCPNS) self-management committee created written materials for distribution to program participants. This study is a non-experimental pre/post evaluation of the impact of the Diabetes Assistance Program in a representative sample of program participants. The impact of the program on glycemic control, self-care and quality of life over the program's first year was evaluated.

The Diabetes Assistance Program provided diabetes supplies and self-management tools to facilitate diabetes self-care. Supplies consisted of insulin, OAs, blood glucose testing strips, syringes, needles and lancets. Self-management tools were brochures focused on encouraging

a healthy lifestyle by targeting healthy lifestyle choices, using SMBG results to support improved diabetes management, linking with healthcare resources as appropriate and taking medication/insulin as prescribed. Recent research has supported the value of providing self-management education via nontraditional media, such as the computer, telephone or mail-outs (7-9).

In recognition of the fact that different types of diabetes treatment make varying demands on people with diabetes, the impact of the Diabetes Assistance Program on people managed with lifestyle alone, OAs only and insulin (with or without OAs) was examined (10), as was the program's impact on individuals with poor glycemic control. It was hypothesized that participants would demonstrate improvements over time with respect to glycemic control, self-care behaviours and quality of life.

## METHODS

### Participants

The main inclusion criterion for this year-long evaluation study was that participants be approved to receive benefits from the Diabetes Assistance Program. Exclusion criteria included minimum Grade 8 education, age <65 years (those age ≥65 years and older were covered by a Seniors' Pharmacare Program), and ability to understand English.

### Sample size determination

Sample size for measures of metabolic control (glycated hemoglobin [A1C]), SMBG frequency and quality of life was determined using data collected in previous research by the principal author (unpublished) involving approximately 330 individuals with type 1 or type 2 diabetes from across the province. Sample size for self-report measures of diabetes self-care was determined using a second data set derived from a program evaluation study of approximately 150 individuals at the principal author's centre (11,12). Standard deviations for the total samples were used as estimates of population variance; sensitivity was set to 0.3 for A1C and 0.25 for other measures, resulting in a range of estimated required sample sizes (95% CI) of 20 to 120, depending on the measure. Sample size was based on the higher estimate, adding approximately 20% to account for attrition. As the intent was to study 3 groups separately (i.e. those managed with lifestyle alone, OAs alone and insulin with or without OAs) recruitment was planned to obtain sufficient participants to apply the power analyses to the subsamples (i.e. 150 individuals per subsample, for a total of 450).

### Self-management support materials

A multidisciplinary committee (2 individuals living with diabetes, Nova Scotia CDA representative, physician, diabetes educators (nurses and dietitians), pharmacists, psycholo-

gist, social worker) directed by the DCPNS provided content expertise for 4 self-management brochures (see Table 1). Materials were developed using a self-management focus. The materials were designed to encourage action and were reviewed by the primary investigator (a health psychologist) to ensure that principles of motivational enhancement were incorporated. Two community-based focus groups of individuals living with diabetes provided detailed feedback on the draft content of the brochures.

### Procedure

When participants applied for the Diabetes Assistance Program, they received a permission-to-contact form as part of their application materials (see flow diagram, Figure 1). This form explained the study and requested contact information and permission to be contacted for enrolment. Enrolment and consent occurred via telephone with written consent being obtained after the fact by mail. Pre-scheduled telephone interviews lasted an average of 20 to 30 minutes, during which basic demographic information was obtained on sex, age, duration of diabetes, method of treatment and study variables. One year following enrolment, the same individuals were contacted again by phone to obtain follow-up data. This protocol was approved by the Research Ethics Board of the Capital District Health Authority, Halifax.

### Data analysis

Data were analyzed using repeated-measures analyses of variance. For each dependent variable, a split-plot analysis of variance was calculated, with 2 between-subject factors (treatment type: OAAs alone vs. insulin with or without OAAs; and degree of glycemic control: good, suboptimal or poor) and 1 within-subject factor (time: entry and one year follow up).

### Outcome measures

#### Glycemic control

The impact of the program on glycemic control was evaluated by obtaining participants' permission to contact their family doctor to obtain their most recent A1C value.

#### Self-care

Participants completed a series of self-report instruments regarding regimen adherence and healthy eating. Specifically, participants reported the number of days they performed SMBG; average frequency of testing per day on the days they test; familiarity with diabetes management and medication principles; frequency of missing medication/insulin; frequency of raising diabetes as a topic during medical visits; frequency of eating 3 meals per day; and extent to which participants considered themselves to have a "sweet tooth." These self-report measures were developed and validated by the study group.

#### Quality of life

Quality of life was assessed using the short form of the Diabetes Care and Complications Trial Quality of Life Scale (DQOL-SF) (13), the short form of the SF-36 (SF-12) (14) and the short form of the Mental Health Inventory (MHI-5) (15).

## RESULTS

### Sample recruited

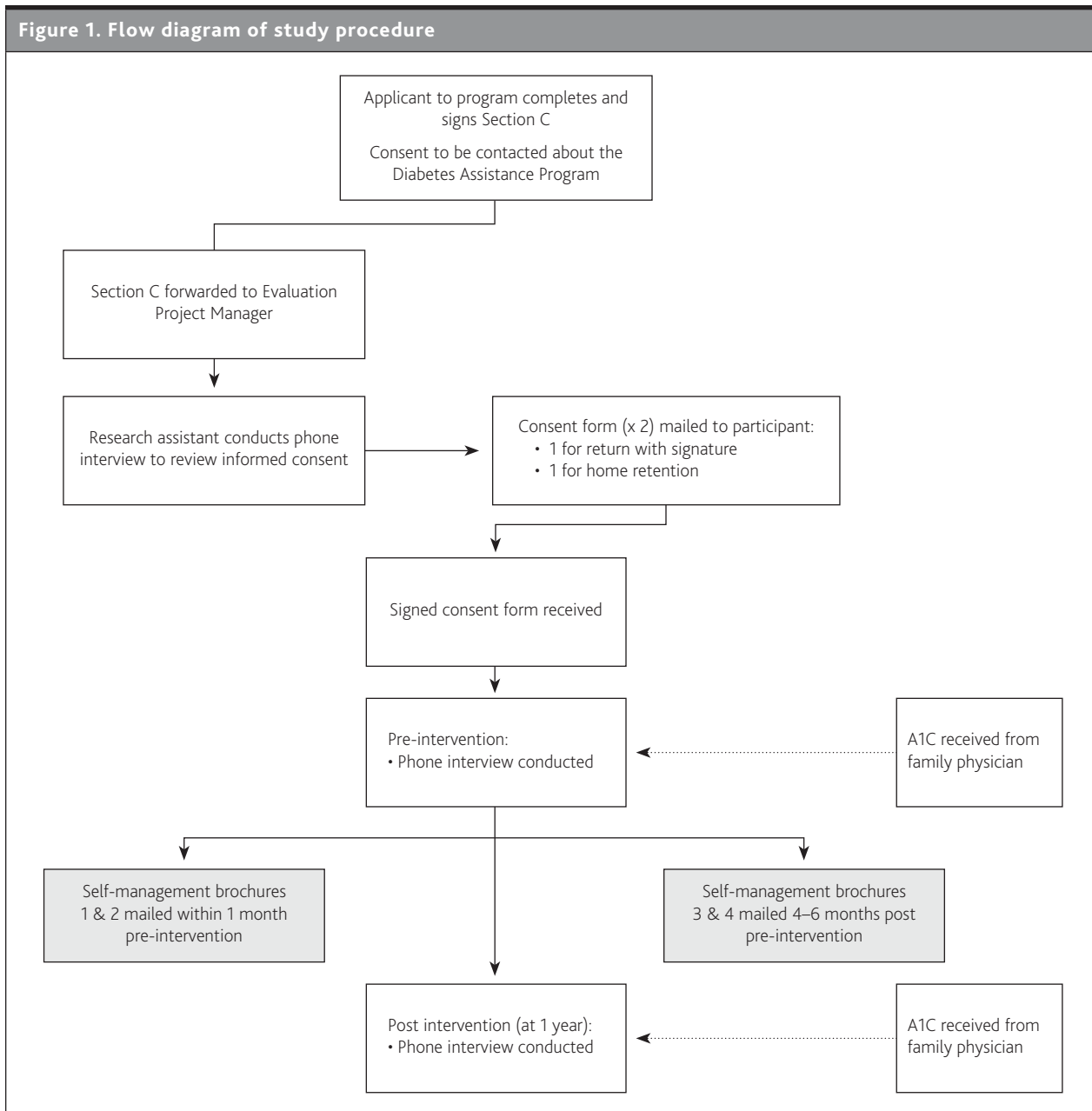
The initial intent was to enrol 150 individuals from each of 3 groups: insulin use (with or without OAAs), OAAs use alone and those managed with lifestyle alone. However, this strategy was altered for 2 reasons. First, it proved impossible to recruit an adequate sample of individuals managed with lifestyle alone; of the first 250 eligible participants, only 6 fell into this category. Second, the Nova Scotia government announced a new Family Pharmacare program that would render the Diabetes Assistance Program obsolete shortly after its launch. Given these factors, it was decided to recruit as many participants as possible within the time frame allowable (June 2006 to June 2007). At the end of the recruitment period, only 15 participants managed their diabetes by lifestyle alone; as a result, the lifestyle only group was eliminated from the analyses.

The sample recruited is described in Table 2. More females were recruited than males, but the proportion of females and males was the same for both treatment groups.

**Table 1. Self-management brochures provided to Diabetes Financial and Self Management Support Program participants**

Brochure 1	<i>Healthy Living and Self-Care: Living with Diabetes</i> contained tips for healthy living, including eating well, engaging in physical activity, managing stress and self-care (e.g. how often to see the doctor; what tests to have and how often; diabetes management; and where to go to learn more about diabetes).
Brochure 2	<i>You and Your Blood Sugars: Testing for Better Health</i> discussed why persons with diabetes should test their blood glucose; when to test; causes of highs and lows; usual target blood glucose values; and tips for appropriate use of meter, lancets and strips.
Brochure 3	<i>Staying Well with Diabetes: Using Health and Community Supports</i> contained information on the diabetes healthcare team and how best to interact with team members and healthcare providers. There are tips on preparing for appointments and descriptions of diabetes tests and their usual target values. There was also important information regarding family/friends and community supports and how to access them.
Brochure 4	<i>Making the Most of Your Medications</i> discussed the importance of diabetes medications (why take them); the way medication use may change over time for a person with diabetes; and how physicians decide when and if to change a person's medications. There were also tips for using medications and working with a pharmacist.

Figure 1. Flow diagram of study procedure



Participants were, on average, in their 50s, although those using insulin were younger. Those using insulin had also had diabetes for significantly longer than those managed with medication only, were more likely to have type 1 diabetes and had poorer glycaemic control. The majority of participants from both groups had less than high school education; there was no difference between the groups in distribution of education level.

To evaluate the impact of the Diabetes Assistance Program on participants with varying levels of glycaemic control, the overall sample was divided into three control-related categories: good (A1C <7.0%), suboptimal (A1C 7.0 to 8.5%) and poor (A1C >8.5%). Data on A1C levels reported by a family physician were available for 93.7%

of the sample. There was an even distribution of degree of control across the sample at enrolment: 34.0% good, 33.7% suboptimal and 32.3% with poor control.

## Outcomes

### Glycaemic control

Analysis of A1C yielded significant effects for insulin/OAAs ( $F=6.432$ ,  $p=0.013$ ) and degree of pre-program control ( $F=148.142$ ,  $p<0.0001$ ), as well as a pre-program control by time interaction ( $F=23.776$ ,  $p<0.001$ ). Overall, those using insulin had poorer control (7.96% vs. 7.67% for those on OAAs only) and, by definition, those with good control had lower A1C (6.67%) than those with suboptimal or poor control (7.6 and 9.18%, respectively). The degree

Table 2. Study sample			
	Insulin (alone or with OAA) (n=176)	OAA (n=175)	Group difference (p)
Sex			
Male	34.7	35.4	NS
Female	65.3	64.6	
Age, years (SD)	53.7 (10.3)	56.9 (7.2)	0.001
Duration of diabetes, years (SD)	16.4 (10.9)	8.6 (7.5)	<0.001
Education			
< High school	60.0	54.5	NS
High school	31.0	30.1	
College or greater	9.0	15.4	
Diabetes type			
Type 1	30.2	—	<0.001
Type 2	58.7	91.9	
Unknown	11.0	8.1	
Glycemic control at enrolment			
<7.0%	23.2	45.3	<0.001
7.0–8.4%	33.9	33.5	
>8.5%	42.9	21.1	

All values are %, unless otherwise indicated

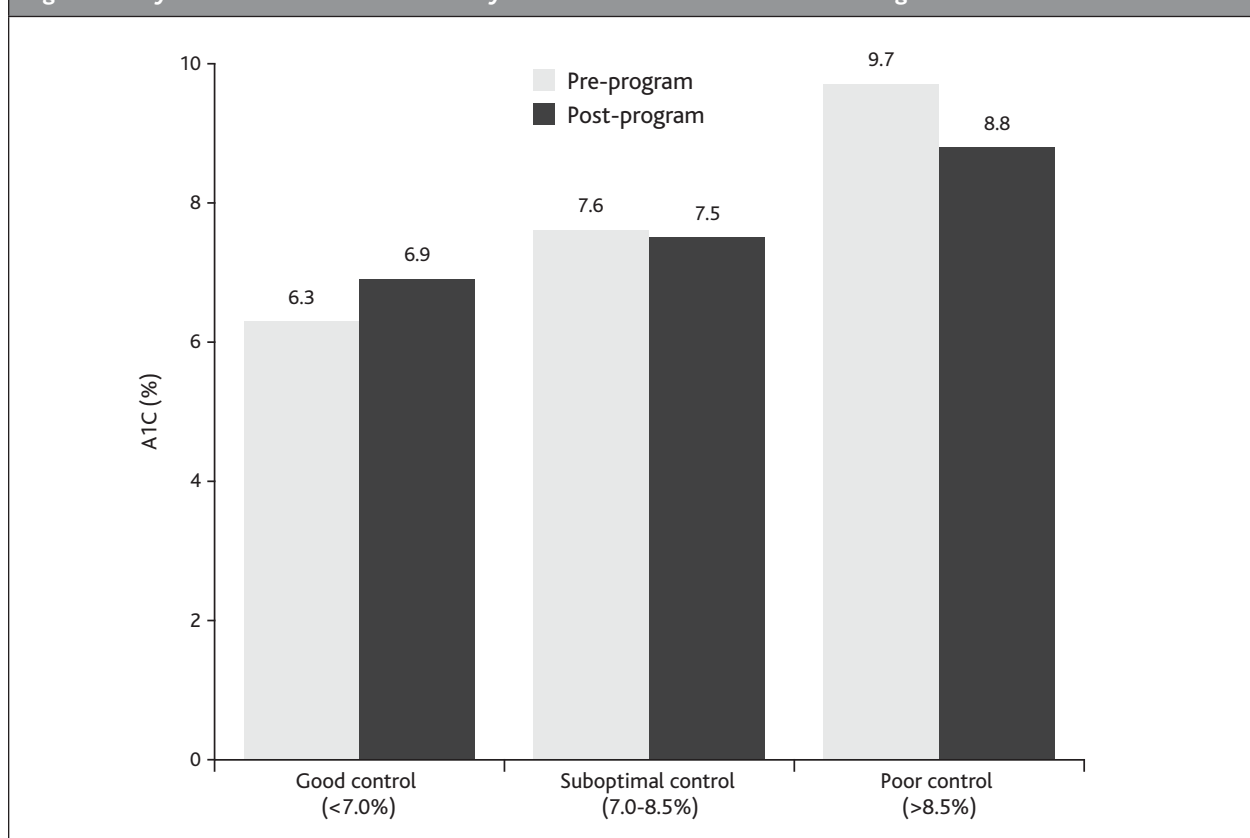
OAA = oral antihyperglycemic agent

of pre-program control by time interaction is shown in Figure 2. Over the year of the study, A1C became significantly worse for those with good control at entry (increased by 0.73% for those taking insulin and 0.61% for those on OAs only); did not change for those with suboptimal control (increased by 0.06% for those on insulin, decreased by 0.06% for those on OAs only); and significantly improved for those with poor control (decreased by 0.68% for those on insulin and 1.12% for those on OAs only).

### Self-care outcomes

Frequency of SMBG was assessed by self-report of the number of days per week testing was done (coded 1 for 1 to 2 days per week; 2 for 3 to 4 days per week; 3 for 5 to 6 days per week and 4 for daily) and by self-report of the average number of times testing on the days testing occurred (from 1 to 4). Overall, those on insulin tested more days than those on OAs only (3.70 vs 2.93, respectively;  $F=51.45$ ,  $p<0.001$ ). Frequency of days tested increased from enrolment to 1 year, but differentially based on level of control and method of management. Frequency of SMBG increased for those on OAs only (2.83 to 3.03), but not for those on insulin (3.74 to 3.66;  $F=3.99$ ,  $p=0.047$ ). As well, only those with poor control at entry demonstrated an increase in SMBG (3.07 to 3.37) relative to those with

Figure 2. Glycemic control over the first year of the Diabetes Assistance Program



A1C = glycated hemoglobin

suboptimal control (3.36 to 3.39) or good control (3.42 to 3.27) ( $F=3.35$ ,  $p=0.037$ ). The number of tests per day did not change over time for any group (all  $F$ s NS) and did not differ by degree of control (NS). Those on insulin tested more times per day (2.65) than those on OAAs only (1.85;  $F=50.55$ ,  $p<0.001$ ).

On ratings of the degree to which participants understood the medications they were taking, analyses indicated that level of understanding increased from enrolment (5.62) to 1 year (5.89), a change that was not affected by initial degree of control or medication type ( $F=6.94$ ,  $p=0.009$ ). Overall, however, those on insulin reported a greater understanding of their medication compared to those on OAAs alone (6.04 vs. 5.47;  $F=10.93$ ,  $p<0.001$ ). When asked about the frequency with which medications were missed, ratings were generally low (1.8 at entry, 1.7 at 1 year) and did not change over time ( $F=0.78$ , NS). However, those in poor control reported missing medication more often (2.01) relative to those with suboptimal or good control (1.60 and 1.67, respectively;  $F=3.74$ ,  $p=0.025$ ).

Participants were asked to rate their understanding of the principles of diabetes management using a 7-point scale, specifically in regards to diabetes itself; medication; use of SMBG; preventing highs, lows and complications; and the benefits of improving glucose control and self-care. Ratings were averaged to yield a measure of overall understanding of the principles of diabetes self-management. In general, there was an increase in understanding from enrolment to 1 year (5.72 to 5.95,  $F=23.21$ ,  $p<0.001$ ); those on insulin reported higher levels of understanding than those on OAAs only (6.0 vs. 5.67;  $F=9.85$ ,  $p=0.002$ ). The increase in understanding over the year of the program was not influenced by initial degree of control ( $F=2.28$ , NS) or type of management ( $F=0.90$ , NS).

Participants also used 7-point scales to rate the extent to which they agreed that the best possible self-care would delay or prevent complications (5 questions). Average ratings were high both at entry and 1 year. There were no differences in average ratings over time or between those with different levels of control or type of treatment (all  $F$ s NS).

Participants also responded to 6 questions about the frequency with which they discussed various aspects of diabetes care with their family physician. The average frequency rating increased from entry to the 1 year assessment (4.28 to 4.61;  $F=18.53$ ,  $p<0.001$ ). Frequency of discussing diabetes with the family physician was not influenced by degree of control ( $F=0.56$ , NS), but it was higher for those on insulin than those taking OAAs only (4.67 vs. 4.22;  $F=7.24$ ,  $p=0.008$ ).

The frequency of self-report of eating 3 meals per day did not change over time ( $F=0.088$ , NS), but was greater for those on insulin than for those on OAAs alone (6.35 vs. 5.78;  $F=8.46$ ,  $p=0.004$ ); it was also greater for those with

good (6.24) or suboptimal control (6.31) than those with poor control (5.65;  $F=4.21$ ,  $p=0.016$ ).

Participants were also asked to rate the extent to which they were an emotional eater or had a "sweet tooth." This data was collected because cravings have been shown to be important factors influencing self-care and control. There were no differences in the extent to which participants considered themselves to be emotional eaters (average rating 3.60), either over time or between groups (all  $F$ s NS). The only difference was that those on insulin rated the extent to which they had a "sweet tooth" lower than those on OAAs alone (4.01 vs. 4.68;  $F=5.12$ ,  $p=0.024$ ).

### Quality of life outcomes

On the SF-12 physical health subscale, there were no changes in physical functioning over time ( $F=2.59$ ,  $p=0.109$ ), and no differences based on degree of control ( $F=0.04$ , NS) or treatment type ( $F=0.09$ , NS). As well, there were no interactions between treatment type, degree of control and time (all  $F$ s NS). On the SF-12 mental health subscale, scores increased from enrolment to 1 year (29.90 to 32.54,  $F=9.17$ ,  $p=0.003$ ). Overall, mental health scores did not differ based on degree of control ( $F=0.2$ , NS) or treatment type ( $F=0.31$ , NS), but the interaction between degree of initial control and change over time was just at significance level ( $F=2.94$ ,  $p=0.055$ ). Those with poor control showed the greatest improvement in mental health scores (28.44 to 33.79) compared to those with suboptimal (30.44 to 33.05) or good control (30.83 to 30.79).

There were no changes in diabetes-specific quality of life (DQOL-SF) from enrolment to 1 year (3.13 vs. 3.14;  $F=0.27$ , NS), and no difference between those on insulin and those on OAAs only (3.15 vs. 3.13;  $F=0.24$ , NS). However, there was a difference based on degree of control, those with poor control reported a lower quality of life (3.09) relative to those with suboptimal or good control (3.11 and 3.22, respectively;  $F=3.68$ ,  $p=0.026$ ). None of the interactions in this analysis were significant.

Finally, there were no significant differences over time with respect to general psychological well-being (the MHI-5), or related to degree of control or type of treatment, and there were no interactions between these factors (all  $F$ s NS).

### Post-hoc analyses

Although not part of the main hypotheses, data were collected concerning participants' evaluation of the self-management materials. At the 1 year evaluation, participants were asked 3 open-ended questions; verbatim responses were recorded and coded. For the first question (What did you think of the self-management materials?), responses were coded as *negative*, *don't recall*, *neutral*, *positive* and *did not receive*. For the second question (Did you learn anything new from the

self-management materials?), responses were coded as *no*, *not really*, *yes (but unspecified)* or *yes (specified)*. For the third question (Did the self-management materials help you with diabetes management?), responses were coded as *did not help in management* or *positive, helpful*.

Almost all participants (96.8%) answered the first question, but only 49.2% answered the second and 45.4% answered the third. In terms of overall judgment of the self-management materials, only 0.6% reported a negative reaction, but 33.7% reported they either did not receive or could not recall the material. Few (6%) reported a neutral response to the self-management material, and 48.3% reported a positive response. Of those who responded to the second and third questions, most (60.7%) stated they did not learn anything new, but nonetheless found the materials helpful (86.4%). The distribution of these responses was not influenced by method of treatment (all  $\chi^2$  NS). As well, there was no relationship between response to self-management materials, type of treatment and change in glycemic control (all Fs NS).

One other issue was addressed in a post-hoc manner. Specifically, we were interested in understanding the role of sex in the program. Sex was not associated with glycemic control, either in terms of overall differences between men and women, or in response to financial and self-management support (all Fs ns).

There was no sex-specific impact of financial and self-management support on any measure of quality of life (SF-12, DQOL or MHI); that is, sex was not associated with change in quality of life over time. However, women reported lower quality of life than men overall on the SF-12 mental health subscale ( $F=14.52$ ,  $p<0.001$ ) and the MHI ( $F=14.87$ ,  $p<0.001$ ). No sex differences were found on the SF-12 physical health subscale or the diabetes-specific quality of life measure (Fs NS).

Regarding self-care, there were sex differences with respect to SMBG. First, there was an interaction between degree of control and sex regarding the number of days per week SMBG was performed ( $F=3.64$ ,  $p=0.033$ ). The frequency of SMBG did not change over time or differ between sexes for those with good or suboptimal control. However, for those with poor control, men but not women reported increasing SMBG frequency over time. With respect to the frequency of testing on days when tests were completed, women reported testing more often than men overall ( $F=4.22$ ,  $p=0.05$ ).

Sex was also associated with a change in understanding of medications: men but not women reported an improved understanding of their medication over time ( $F=9.91$ ,  $p=0.005$ ; women reported higher levels of understanding at entry and stayed at the same level). Finally, women reported higher levels of emotional eating than men ( $F=17.23$ ,  $p<0.001$ ). No other sex differences were found.

## DISCUSSION

Type 2 diabetes is taking an enormous toll on the lives of those living in industrialized societies and methods to improve glycemic control have the potential to greatly reduce this toll, both for the individual, the healthcare system and society in general (16). Efforts to improve glycemic control have been assisted by the development of new medications and self-management tools, but these cost money, and financial barriers can severely limit the ability of an individual to engage in and sustain self-care behaviours (1).

In recognition of these financial and self-management challenges, the Nova Scotia government decided to provide support to those with diabetes and unmet financial needs. Although this program has since been transformed so that it now covers more than just diabetes supplies (Family Pharmacare), the Diabetes Assistance Program was operating long enough for us to conduct an evaluation of its impact.

In light of the fact that the provincial department of health was not prepared to support a randomized evaluation of the Diabetes Assistance Program, a systematic evaluation of the impact of the program was worthwhile, even if causality could not be addressed. As it turned out, the Diabetes Assistance Program was a finite project, eventually replaced by another system. Therefore, the overall population of individuals who received Diabetes Assistance Program benefits can be described. A total of 2579 Nova Scotians were approved for benefits totalling \$7 034 829, of which \$5 141 833 were claimed. Recipients were, on average, 52.8 years of age and 55.6% were female. Given the sample recruited, it appears that females were more likely to volunteer for our study, as our female population was approximately 65%.

In terms of our overall hypotheses, collapsing across groups based on initial degree of control, few significant findings resulted. Overall, A1C did not change from enrolment to 1 year. In terms of self-care, there was an overall increase in self-reported understanding of the principles of diabetes management; understanding of medications for glycemic control; and frequency with which individuals discussed diabetes with their physician. There was no change in self-reported SMBG frequency or medication adherence. There were no changes in quality of life for the group as a whole.

This overall negative finding is somewhat deceptive, however, because the Diabetes Assessment Program interacted significantly with degree of glycemic control and, to a lesser extent, type of treatment. The program was found to have a significant positive impact on those with poor initial control (>8.5%), who demonstrated an absolute A1C reduction of 0.9% over 1 year—a reduction that was both clinically and statistically significant. Further, these individuals reported an increased understanding of the principles of diabetes management and their medications, a greater frequency of discussing diabetes with their physician and a significant

increase in number of days per week they performed SMBG. These individuals also reported an increase in non-disease-specific quality of life (SF-12 mental health score). Finally, men with poor control reported an increase in SMBG frequency over the evaluation period.

In contrast to those with poor control, the program had little impact on those with suboptimal control at enrolment. These participants demonstrated only an increase in understanding of diabetes and medications, increased frequency of discussing diabetes with their physician and a trend toward improved non-disease-specific quality of life (SF-12 mental health score).

Finally, the program did not appear to have an impact on those with good control at enrolment. The only positive change for these participants was a nonspecific increase in understanding of diabetes management and medication, as well as an increased frequency of discussing diabetes with their physician. Surprisingly, this group demonstrated a significant increase in A1C of 0.58% over the duration of the program.

These data suggest that degree of glycemic control is an important moderating factor for support programs such as the Diabetes Assistance Program, and that those with poor control are the most likely to benefit. Apart from response to the program, these individuals distinguished themselves from those with suboptimal or good control in a number of ways: they reported missing their medication/insulin more often and were less likely to eat 3 meals per day. They also reported lower disease-specific quality of life. Those with poor control appear to be a specific group who are compromised not only in their glycemic control, but also in their self-care and quality of life. These data support the notion that resources should be devoted to those most in need of help. This study also adds data to suggest that providing financial support to this vulnerable group will improve glycemic control, self-care and quality of life.

This study also found some interesting differences based on type of treatment. First, those on OAAs only reported an increase in frequency of SMBG over the evaluation period. This finding is qualified by the fact that those on insulin performed SMBG more often overall. The increase in testing frequency for those on OAAs was significant, but by the end of the study those on OAAs only were not testing as frequently as those on insulin. Further, those on OAAs only had better glycemic control overall than those on insulin (7.67 vs. 7.97%), but those on insulin reported higher levels of understanding of diabetes management and medication principles, greater frequency of discussing diabetes with their physician, greater frequency of eating 3 meals per day and lower ratings of having a “sweet tooth.”

A post-hoc analysis revealed few differences between men and women. Women appeared to be more chal-

lenged regarding quality of life and emotional eating. Men appeared to have benefited more with respect to increased SMBG for those in poor control and increased understanding of the role of medications. This study was not designed to assess sex differences, but the observations uncovered justify a more detailed examination into the role of sex in self-management support.

This study contributes to our understanding of how to help individuals with type 2 diabetes manage their disease. Other studies have also suggested that providing financial support is beneficial; however, this is the first to examine the impact based on degree of glycemic control. Strum and colleagues (3) studied a medical assistance program on a relatively small sample of individuals in a specific diabetes practice; our study sampled from all Nova Scotians who enrolled in the Diabetes Assistance Program. As this turned out to be a finite program, we were able to calculate the proportion of participants who enrolled in our study. While we oversampled female participants, our sample represents 13.61% of the entire population of Nova Scotians enrolled in the Diabetes Assistance Program. Nyomba and colleagues (4) randomized a small group of insulin-requiring people with type 1 and 2 diabetes to receive free blood glucose test strips or none. Over the short term, they found an increase in frequency of SMBG in those given free strips and a stabilization in A1C across the 1 year evaluation period, in contrast to an increase in A1C in the control group. Our study demonstrated, for those with poor glycemic control, that A1C actually decreased over the 1 year evaluation period. Interestingly, those with good control, who did not benefit from the Diabetes Assistance Program, showed a significant rise in A1C levels. Horswell and colleagues (17) was able to tie the degree of benefit of medication assistance programs to adherence, as measured by prescription refills. They reported a linear association between increased adherence and lower A1C values. This study, like ours, took the approach of identifying patient subgroups rather than analyzing all patients as a single group.

Lack of a control group, particularly a randomized control, is a limitation of this study and raises the possibility that findings might reflect regression to the mean. While this threat to internal validity cannot be neutralized by the study design, a number of facts suggest regression to the mean is not in play. First, A1C is seen as a stable, gold-standard measure of glycemic control. A reduction of 0.9% is clinically significant and reflects substantial improvement in glucose metabolism. Regression to the mean would imply that the change from pre- to post-program is only a statistical phenomenon, but this is not consistent with how A1C is seen in the field. Second, the improvements noted in the poor-control group was reflected not only in A1C but also in self-care and quality of life measures, despite

the fact that group categorization was based solely on A1C. If the results were simply due to a statistical artifact, then improvements in self-care and psychological functioning would not be expected.

In conclusion, this study suggests there is an important role of providing financial and accessible self-management support to those with diabetes and poor control. It appears as though supporting these individuals has benefits in regard to glycemic control, self-care and quality of life.

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## AUTHOR DISCLOSURES

This study was funded by the Nova Scotia Department of Health, with funds administered by the Diabetes Care Program of Nova Scotia.

## AUTHOR CONTRIBUTIONS

All authors were involved in the study design, running the study, and data interpretation. MV took responsibility for design, analysis and writing, with the assistance of PD. LT and AN took primary responsibility for collecting data and managing the database.

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# Author Guidelines

Canadian Journal of Diabetes

Guidelines revised March 2009

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The following criteria should be met:

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- Reference list should not exceed 50 citations.
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