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## Patterns, Policy and Appropriateness: A 12-Year Utilization Review of Blood Glucose Test Strip Use in Insulin Users

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### ABSTRACT

**Objectives:** Considerable attention has been paid to the rising costs of the use of blood glucose test strips (BGTS). Insulin users have generally been treated as a single homogeneous group, resulting in policies that cap usage (8.2 strips/day) in provincial drug insurance programs. The objective of this study was to conduct a utilization review of BGTS by insulin users and to evaluate use patterns against current insulin use patterns and BGTS policy.

**Methods:** BGTS usage was examined in a cohort of insulin users with type 1 and type 2 diabetes over a 12-year period (2001 to 2013) using the population-based administrative data in Manitoba, Canada.

**Results:** Total BGTS strip use increased by 121%, from \$4.3 to \$9.5 million. However, the number of insulin users also increased by 115%. Use has been stable at 1.5 strips per day per person since 2004 by insulin users with type 2 diabetes but has risen from 1.9 to 3.0 strips per day per person in those with type 1 diabetes. Mean daily test strip use was below the number of daily tests recommended for patients using insulin as per the current Canadian guidelines, with 11% and 15% of insulin users with type 1 and type 2 diabetes not claiming any BGTS use and a further 15% (type 1) and 28% (type 2) using fewer than 1 strip per day.

**Conclusions:** BGTS use per insulin user has been stable for most of the past decade, and the vast majority of use falls well below provincial insurance caps. The amount of low-level testing (0 to <1 strip/day) suggests that greater attention should be directed to ensuring a safe level of testing by all insulin users.

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### R É S U M É

**Objectifs :** Les coûts croissants de l'utilisation des bandelettes de mesure de la glycémie ont fortement retenu l'attention. Les patients sous insuline ont en général été considérés comme un seul groupe homogène, d'où des politiques de plafonnement de l'utilisation (8,2 bandelettes par jour) par les programmes provinciaux d'assurance médicaments. L'objectif de cette étude était d'effectuer un examen de l'utilisation des bandelettes de mesure de la glycémie par les patients sous insuline et d'évaluer les profils d'utilisation par rapport aux schémas d'insulinothérapie courants et aux politiques actuelles relatives à ces bandelettes.

**Méthodes :** L'utilisation des bandelettes de mesure de la glycémie a été évaluée pendant une période de 12 ans (2001 à 2013) au sein d'une cohorte de personnes sous insuline atteintes de diabète de type 1 ou de type 2, à partir des données administratives populationnelles du Manitoba (Canada).

**Résultats :** Le coût total de l'utilisation des bandelettes de mesure de la glycémie s'est accru de 121 %, passant de 4,3 à 9,5 millions de dollars. Toutefois, le nombre d'utilisateurs d'insuline a aussi augmenté de 115 %. L'utilisation est demeurée stable à 1,5 bandelette par jour par personne depuis 2004 chez les patients sous insuline atteints de diabète de type 2, mais est passée de 1,9 à 3,0 bandelettes par jour par personne chez les patients atteints de diabète de type 1. Une utilisation en deçà des recommandations énoncées dans les lignes directrices a été mise en évidence, puisque 11 % et 15 % des patients sous insuline atteints de diabète de type 1 et de diabète de type 2, respectivement, n'ont utilisé aucune bandelette et que 15 % (type 1) et 28 % (type 2) des autres ont utilisé moins de 1 bandelette par jour.

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**Conclusions :** L'utilisation de bandelettes de mesure de la glycémie par patient sous insuline est demeurée généralement stable au cours des dix dernières années, et était en majeure partie bien inférieure aux plafonds imposés par les régimes provinciaux d'assurance médicaments. La proportion de patients qui vérifient peu leur glycémie (0 à <1 bandelette par jour) donne à penser que plus d'efforts devraient être consentis pour garantir que tous les patients sous insuline vérifient leur glycémie à une fréquence qui garantisse leur sécurité.

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## Introduction

Self-monitoring of blood glucose (SMBG) in diabetes can play an important role in the prevention of hypoglycemia and in improved glycemic control (1–3). In publicly funded drug programs, a great deal of attention has been paid to the cost of blood glucose test strips (BGTS). In the province of Ontario, BGTS were found to be the third largest “drug” expenditure (4). The value of this expenditure has been questioned. The efficacy of SMBG in people with type 2 diabetes not using insulin is limited, producing only modest reductions in glycated hemoglobin (A1C) levels (0.3%, 95% CI 0.1 to 0.4) at 6 months and no statistically significant change at 12 months (2,5,6). Furthermore, there are indications that the results are not used and may cause distress (7,8). In response, a number of Canadian provinces (British Columbia, Saskatchewan and Ontario) and Health Canada's Non-Insured Health Benefits Program have implemented caps on the number of BGTS they will cover: 3000 strips per year for insulin users, 400 strips per year for users of oral medications that may cause hypoglycemia, 200 strips per year for all others (9). Ontario is expected to save more than \$100 million over the next 5 years by implementing these caps, with the vast majority of savings coming from people with diabetes who are not using insulin (10).

The evidence supporting the efficacy of SMBG is stronger for people with diabetes using insulin (11–14). SMBG can guide individuals in behaviour modification and insulin adjustment and can help to identify episodes of hypoglycemia and hyperglycemia (1,13,15). The *Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada* endorse individualized SMBG based on patient-specific characteristics, with a recommended frequency of at least 3 times per day (including pre- and postprandial measurements) for individuals using insulin more than once a day and at least once a day for those with type 2 diabetes on once-daily insulin (1). The guidelines also suggest that more frequent testing may be required to reduce risk for hypoglycemia (1). Clearly, a great deal of variety exists in the intensity of management of insulin users; however, a single current cap of 3000 strips per year (approximately 8 strips/day) applies to all insulin users. The majority of use and the majority of growth in BGTS use has been with those who use insulin, while the expenditures on BGTS in people who do not use insulin has stabilized since 2010 (10). Past analysis in Canada has considered insulin users primarily as a homogeneous group, evaluating them against the single 3000-strip cap (9,16). Given the level of use, the increase of BGTS expenditure for insulin users and the heterogeneity of SMBG needs of these people, greater evaluation of the utilization of BGTS in this group is needed. The objective of this study was to identify and evaluate trends in test-strip utilization in relation to treatment intensity in people with diabetes using insulin in Manitoba.

## Methods

A retrospective, longitudinal study using a population-based cohort of people with diabetes using insulin was conducted to examine BGTS use between January 1, 2001, and December 31, 2013,

in the province of Manitoba, Canada. Data were obtained through the Manitoba Centre for Health Policy's Population Research Data Repository, which contains administrative healthcare databases. The repository contains linked, deidentified records of virtually every contact between Manitoba residents and the province's universal healthcare system (17,18). The sources used included the hospital discharge abstracts database, which contains summary records of all hospital stays; and data from the provincial Drug Program Information Network (DPIN), an online, point-of-service prescription database system that connects all community pharmacies to the provincial Pharmacare program and other third-party payers. The Pharmacare program provides full prescription coverage after an annual, income-based deductible has been fulfilled. This program covers BGTS for all users up to a maximum of 4000 strips per year.

Approval for this study was granted by the University of Manitoba Health Research Ethics board and the provincial Health Information Privacy Committee.

BGTS use was evaluated within a cohort of insulin users with type 1 and 2 diabetes. Prescription records for hypoglycemia drugs or insulin, and medical claims or hospital discharge abstracts with International Classification of Disease-9 (ICD-9) or ICD-10 codes for diabetes mellitus were used to assess cohort entry. Persons were categorized as having diabetes, provided they met at least 1 of 3 criteria: 1) 1 or more hospitalizations with a diabetes code, 2) 2 or more medical claims with diabetes codes within a 3-year window, or 3) 1 diabetes medical claim plus a prescription for a diabetes drug. The definition of diabetes has been validated previously and has shown 88.4% sensitivity and 98.8% specificity (19). This cohort was further restricted to those who had received 2 or more prescriptions for insulin within the study period. Individuals were classified as having type 2 diabetes if they had had 1 or more prescriptions for a noninsulin hypoglycemic drug.

Individuals were further classified by the type of insulin regimen, defined by the combination of insulin types they were prescribed within each study year. This was done by first creating 5 categories of insulin preparations based on their pharmacokinetic profiles and identified by their Anatomical Therapeutic Chemical (ATC) classification system code. These groups were 1) rapid-acting insulins: insulin lispro, insulin aspart, insulin glulisine (ATC codes A10AB04, 05, 06); 2) regular (Toronto) insulin (A10AB01); 3) intermediate-acting NPH and Lente insulins (A10AC); 4) pre-mixed insulin combinations containing regular or rapid-acting insulin with a longer-acting insulin (A10AD) and 5) long-acting insulins: ultralente insulin, insulin glargine and insulin detemir (A10AE).

Regimens were then defined using various combinations of these classes and were rank ordered in terms of level of intensity (increasing number of variable dose injections per day) of that regimen (Table 1). This grouping of regimens is adapted from the clinical practice guidelines approaches to treatment and testing (20–22). Similar groupings have been used in a previous study of BGTS and insulin use (23). Individuals' regimens were determined by the most intensive treatment regimen they used in each year.

The quantity of BGTS dispensed for each person within each study year in which they were treated with insulin was then tabulated, and the number of strips per day was calculated by dividing by the days in the year. In cases in which an individual was hospitalized

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