

# Clinical inertia in patients with T2DM requiring insulin in family practice

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## ABSTRACT

**OBJECTIVE** To describe the clinical status of patients with type 2 diabetes mellitus (T2DM) in the primary care setting at insulin initiation and during follow-up, and to assess the efficacy of insulin initiation and intensification.

**DESIGN** Ontario FPs from the IMS Health database who had prescribed insulin at least once in the 12 months before November 2006 were randomly selected to receive an invitation to participate. Eligible and consenting FPs completed a questionnaire for each of up to 10 consecutive eligible patients. Patient data were recorded from 3 time points.

**SETTING** Family practices in Ontario, Canada.

**PARTICIPANTS** One hundred and nine FPs and 379 of their T2DM patients taking insulin (with or without oral agents).

**MAIN OUTCOME MEASURES** Glycated hemoglobin (HbA<sub>1c</sub>) levels, daily insulin dose, and use of concomitant oral agents at insulin initiation and 2 subsequent visits.

**RESULTS** Data from each patient were obtained on insulin initiation and intensification, glycemic control, further pharmacologic therapy, and related complications. Mean time from diagnosis of T2DM to insulin initiation was 9.2 years. Mean HbA<sub>1c</sub> values were 9.5% before insulin initiation, 8.1% at visit 2 (median 1.2 years later), and 7.9% at visit 3 (median 3.9 years after initiation). Mean insulin dose was 24 units at initiation, 48 units at visit 2, and 65 units at visit 3. At visit 3, 20% of patients continued to have very poor glycemic control (HbA<sub>1c</sub> >9.0%). With the exception of a decrease in sulfonylurea use, concomitant use of oral antihyperglycemic agents remained static over time.

**CONCLUSION** Even in patients identified as being sufficiently high risk to warrant insulin therapy, a clinical care gap exists in physician efforts to achieve and sustain recommended HbA<sub>1c</sub> target levels. Family physicians need strategies to facilitate earlier initiation and ongoing intensification of insulin therapy.

## EDITOR'S KEY POINTS

- Insulin is underused by FPs in patients with type 2 diabetes mellitus (T2DM), despite the fact that early addition of insulin is an efficient way to quickly and safely achieve glycemic targets and that its use is recommended by national and international guidelines. Recognition of a clinical problem but failure to act on it has been termed *clinical inertia*.
- This study demonstrated that FPs waited an average of 9.2 years before initiating insulin in patients with T2DM, at which point glycated hemoglobin (HbA<sub>1c</sub>) levels were well above target and resultant diabetes-related complications had begun to develop.
- Once insulin was initiated and intensified, patients experienced an average drop in HbA<sub>1c</sub> levels from 9.5% to 7.9%; however, after more than 3 years of insulin therapy, 20% of patients still had poor glycemic control (HbA<sub>1c</sub> >9.0%) and 68% of patients were above the target HbA<sub>1c</sub> level of 7.0%. Furthermore, the prevalence of comorbidities and complications rose from 74% to 94%.
- Most FPs identified barriers to initiation and intensification of insulin therapy (as evidenced by the late introduction of insulin), which negatively impacts the potential to achieve glycemic control and reduce the risk of complications. Barriers to insulin initiation and intensification need to be addressed.



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# Inertie clinique en médecine familiale à l'égard des diabétiques de type 2 requérant de l'insuline

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## RÉSUMÉ

**OBJECTIF** Décrire l'état clinique des patients souffrant de diabète de type 2 (DT2) dans un contexte de soins primaires au moment de l'introduction de l'insuline et durant le suivi, et évaluer l'efficacité de l'introduction et de l'intensification de l'insuline.

**TYPE D'ÉTUDE** Choisis au hasard à partir de la base de données IMS Health, des MF ontariens qui avaient prescrit de l'insuline au moins une fois durant l'année précédant novembre 2006 ont été invités à participer. Les MF admissibles et consentants ont complété un questionnaire individuel concernant jusqu'à 10 patients admissibles consécutifs. Les données des patients ont été enregistrées à 3 étapes dans le temps.

**CONTEXTE** Cliniques de médecine familiale d'Ontario, Canada.

**PARTICIPANTS** Cent neuf MF et 379 de leurs patients diabétiques de type 2 recevant de l'insuline (avec ou sans hypoglycémifiants oraux).

**PRINCIPAUX PARAMÈTRES À L'ÉTUDE** Niveaux d'hémoglobine glycosylée (HbA<sub>1c</sub>), dose quotidienne d'insuline et utilisation concomitante d'hypoglycémifiants oraux au moment du début de l'insuline et à 2 visites subséquentes.

**RÉSULTATS** Pour chacun des patients, on a obtenu les données concernant l'introduction et l'intensification de l'insuline, le contrôle de la glycémie, les autres médicaments utilisés et les complications connexes. L'intervalle moyen séparant le diagnostic de DT2 et le début de l'insuline était de 9,2 ans. Les valeurs moyennes de l'HbA<sub>1c</sub> étaient de 9,5% avant le début de l'insuline, de 8,1% à la visite 2 (médiane = 1,2 an plus tard) et de 7,9% à la visite 3 (médiane = 3,9 ans après le début de l'insuline). Les doses moyennes d'insuline étaient de 24 unités au début, 48 unités à la visite 2 et 65 unités à la visite 3. À cette dernière visite, 20% des patients avaient toujours un contrôle inadéquat de leur glycémie. (HbA<sub>1c</sub> > 9,0%). Sauf pour une diminution des sulfonurées, l'utilisation concomitante d'hypoglycémifiants oraux n'a pas changé avec le temps.

**CONCLUSION** Même pour des patients qui présentent des risques suffisamment élevés pour justifier une insulinothérapie, les efforts des médecins pour atteindre et maintenir les niveaux cibles recommandés d'HbA<sub>1c</sub> demeurent insuffisants. Les MF ont besoin de stratégies favorisant l'introduction plus précoce et l'intensification subséquente de l'insulinothérapie.

## POINTS DE REPÈRE DU RÉDACTEUR

- Les MF n'utilisent pas suffisamment l'insuline chez les diabétiques de type 2 (DT2), malgré le fait que l'addition précoce de cette hormone est efficace pour atteindre de façon rapide et sécuritaire les glycémies cibles, et malgré les directives nationales et internationales qui en recommandent l'utilisation. On utilise le terme *inertie clinique* lorsqu'on observe un problème clinique sans agir en conséquence.
- Cette étude a montré que les MF attendaient en moyenne 9,2 ans avant de débiter l'insuline chez des DT2, lorsque les niveaux d'hémoglobine glycosylée (HbA<sub>1c</sub>) étaient bien supérieurs aux niveaux cibles et que les complications avaient commencé à apparaître.
- À partir du moment où l'insulinothérapie a été introduite et intensifiée, les niveaux d'HbA<sub>1c</sub> sont passés de 9,5% à 7,9% en moyenne; toutefois, après plus de 3 ans d'insulinothérapie, 20% des patients avaient toujours un contrôle inadéquat de leur glycémie (HbA<sub>1c</sub> > 9,0%) et 68% d'entre eux avaient des niveaux d'HbA<sub>1c</sub> supérieurs à 7,0%. En outre, la prévalence de la comorbidité et des complications avait augmenté de 74% à 94%.
- La plupart des MF ont identifié des obstacles à l'introduction et à l'intensification de l'insulinothérapie (comme en témoigne l'introduction tardive de l'insuline), qui peuvent nuire à la possibilité de contrôler la glycémie et de réduire les risques de complication. Il est nécessaire de s'attaquer à ces obstacles.

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In Canada, primary care physicians provide the bulk of care for patients with diabetes.<sup>1</sup> They see their patients with diabetes frequently (on average 9 times per year), and 60% of these visits are specifically for diabetes management.<sup>2</sup> Yet despite numerous opportunities for optimal treatment, approximately half of people with type 2 diabetes mellitus (T2DM) are not achieving the recommended glycated hemoglobin (HbA<sub>1c</sub>) target of less than 7.0%.<sup>3-7</sup> Process measures of diabetes care have improved,<sup>4,8-10</sup> so inadequate glycemic control might reflect the failure of physicians to adequately intensify antihyperglycemic therapies.<sup>11</sup> The phenomenon of recognition of a clinical problem but failure to act on it has been coined *clinical inertia*.<sup>12</sup>

As glycemic control erodes over time,<sup>3,13,14</sup> most people with T2DM will require progressively intensified pharmacologic therapy to achieve recommended glycemic targets.<sup>14</sup> Although early addition of insulin is an efficient way to quickly and safely achieve targets<sup>15-17</sup> and its use has been recommended by national and international guidelines,<sup>18-20</sup> chart audit studies have consistently shown that insulin has been and continues to be underused.<sup>3,21-23</sup> For example, in the Diabetes in Canada Evaluation study, only 12% of patients with T2DM were taking insulin (with or without oral agents).

This study sought to describe the clinical status of patients with T2DM in the primary care setting at the time of insulin initiation as well as during follow-up, and to assess the effectiveness of insulin initiation and intensification on HbA<sub>1c</sub> levels.

## METHODS

### Recruitment

Using the IMS Health database, a list was generated of all FPs in the province of Ontario who had prescribed insulin at least once in the 12 months preceding November 2006. From this list, physicians were randomly selected to receive an invitation to participate and were asked to complete a form to determine whether they were eligible and interested in participating. Physicians were considered eligible if they had been practising for at least 2 years, were practising at least 3 days a week, were treating at least 100 patients per week, and were seeing at least 5 patients with T2DM per month. Invitation letters continued to be generated until the predetermined sample size of eligible and consenting physicians was achieved. Charts of patients with T2DM were eligible for inclusion if HbA<sub>1c</sub> levels were documented, the patient had been taking insulin for at least 12 uninterrupted months before the most recent visit, and if the patient's insulin therapy was initiated between January 1, 1999, and March 31, 2006.

### Physician data

Each FP completed a questionnaire providing the following information: sex, year of medical school graduation, medical specialty, practice setting (ie, urban or rural), knowledge of the Canadian Diabetes Association's recommended HbA<sub>1c</sub> target levels, and perceived barriers to insulin initiation and intensification.

### Patient data

Family physicians completed a questionnaire for each of up to 10 consecutive eligible patients whose visits occurred on or after July 1, 2007. Patient data were recorded at 3 time points. Visit 1 was the initial appointment, at which the patient was first prescribed insulin; visit 2 occurred between 12 and 15 months after the initial appointment; and visit 3 was the most recent visit to the practitioner's office (ie, the present-day status of the patient).

In addition to standard demographic data and dates of visits, the following were retrospectively collected from the patients' charts:

- Visit 1: weight at insulin initiation, date of T2DM diagnosis, date of insulin initiation, date and value of the last HbA<sub>1c</sub> level recorded before insulin initiation, diabetes-related complications and comorbidities, and details of the insulin regimen (with or without oral antidiabetic drugs [OADs]).
- Visit 2: date and value of last recorded HbA<sub>1c</sub> measurement closest to visit 2 (within 3 months) and changes to insulin regimen from visit 1 (including the addition or cessation of OADs).
- Visit 3: weight, date and value of last recorded HbA<sub>1c</sub> measurement, diabetes-related complications and comorbidities, and changes to insulin regimen from visit 2 (including the addition or cessation of OADs).

### Analysis

For recruitment purposes, the following assumptions were made in determining the sample size of FPs: A typical FP has approximately 50 patients with T2DM, with 12% or approximately 6 patients taking insulin.<sup>3</sup> Therefore, a target of at least 4 charts per FP was set. In order to minimize practice bias, the maximum number of charts allowed per FP was 10. Analysis was adjusted for clustering (ie, an intracluster correlation coefficient of approximately 0.075 based on the measures of HbA<sub>1c</sub> values, diabetes-related comorbidity, and body weight). Based on these assumptions, at least 91 FPs were required for the study, providing approximately 384 charts for review. In order to compensate for incomplete or incorrectly completed questionnaires, an FP oversampling of 15% was used.

Data were entered into a Microsoft SQL Server 2005 database.

Descriptive statistics were used to report and summarize the findings. A logistic regression model was

employed to determine whether or not there were statistically significant relationships between visit 1 variables and a patient's HbA<sub>1c</sub> values exceeding 9.0% at visit 3. A random intercept for practice was included to account for the cluster sampling.

The study protocol was approved by the University of Western Ontario Research Ethics Board for the Review of Health Sciences Research Involving Human Subjects.

## RESULTS

Of the 200 eligible FPs who initially responded to the invitation to participate, 109 completed the physician questionnaire, providing data on 379 patients.

The FPs had been in practice for a mean of 27 years, were predominantly men (85%), and predominately practised in urban settings (75%). A full 99% of respondents correctly identified the guideline-recommended HbA<sub>1c</sub> target of 7.0% or less. Most physicians reported that they perceived barriers to insulin initiation (87%) and intensification (65%).

Patient characteristics are shown in **Table 1**. Insulin was initiated by the FP in 55% of patients, by specialists in 35% of patients, and at diabetes centres in 8% of patients. With respect to glycemic control at the time of insulin initiation, 6.8% of patients had HbA<sub>1c</sub> values of 7.0% or less, 36% had HbA<sub>1c</sub> values between 7.1% and 9.0%, and 57.2% had HbA<sub>1c</sub> values of greater than 9.0%. The primary reason for insulin initiation was poor glycemic control. Seventy-four percent of patients had a diabetes-related complication at the time of insulin initiation.

The median time intervals between visits 1 and 2 and between visits 1 and 3 were 1.2 years and 3.9 years, respectively. **Table 2** summarizes changes in HbA<sub>1c</sub> values, insulin dosage, and weight over the 3 visits. Mean HbA<sub>1c</sub> values decreased from 9.5% to 7.9%. Insulin therapy was intensified over the 3 visits with respect to mean total daily dose, mean units per kilogram, and proportion of patients taking multiple injections. Mean patient weight increased by 3.45 kg, with 2.08 kg (60%) of this weight gain occurring by visit 2. The prevalence of diabetes-related complications rose from 74% at visit 1 to 94% at visit 3.

**Table 1. Patient characteristics: N = 379.**

CHARACTERISTIC	N	MEAN (SD)
Age, y	379	63.5 (12.8)
Age at T2DM diagnosis, y	370*	50.7 (12.6)
Weight at time of insulin initiation, kg	361*	87.3 (22.6)
Time from diagnosis to insulin initiation, y	365*	9.2 (6.5)
HbA <sub>1c</sub> level before insulin initiation, %	369*	9.51 (1.89)

HbA<sub>1c</sub>—glycated hemoglobin, SD—standard deviation, T2DM—type 2 diabetes mellitus.

\*Not all patients are included owing to missing data.

**Table 2. Clinical parameters over time**

PARAMETER	VISIT 1	VISIT 2	VISIT 3	DIFFERENCE BETWEEN VISIT 1 AND VISIT 3*
Median interval, y	Initiation	1.2	2.7	3.9
Mean HbA <sub>1c</sub> , % <sup>†</sup> (mean change since last visit <sup>†</sup> )	9.5	8.1 (-1.50)	7.9 (-0.13)	-1.63
Mean weight, kg <sup>†</sup> (mean change since last visit <sup>†</sup> )	87.3	90 (+2.08)	91.4 (+1.25)	+3.45
Mean daily insulin dose, U <sup>†</sup> (mean change since last visit <sup>†</sup> )	24	48 (+24)	65.4 (+16.4)	+41.0
Mean insulin dose per kilogram, U <sup>†</sup> (mean change since last visit <sup>†</sup> )	0.28	0.54 (+0.26)	0.72 (+0.18)	+0.43
No. of injections per day (% of patients)	1 (48.5)	1 (20.9)	1 (13.0)	1 (-35.5)
	2 (39.5)	2 (54.4)	2 (45.4)	2 (+5.9)
	3+ (12.1)	3+ (24.8)	3+ (41.6)	3+ (+29.5)

HbA<sub>1c</sub>—glycated hemoglobin, U—units.

\*The difference between the 2 time points is based on only those patients who had recorded values at both time points.

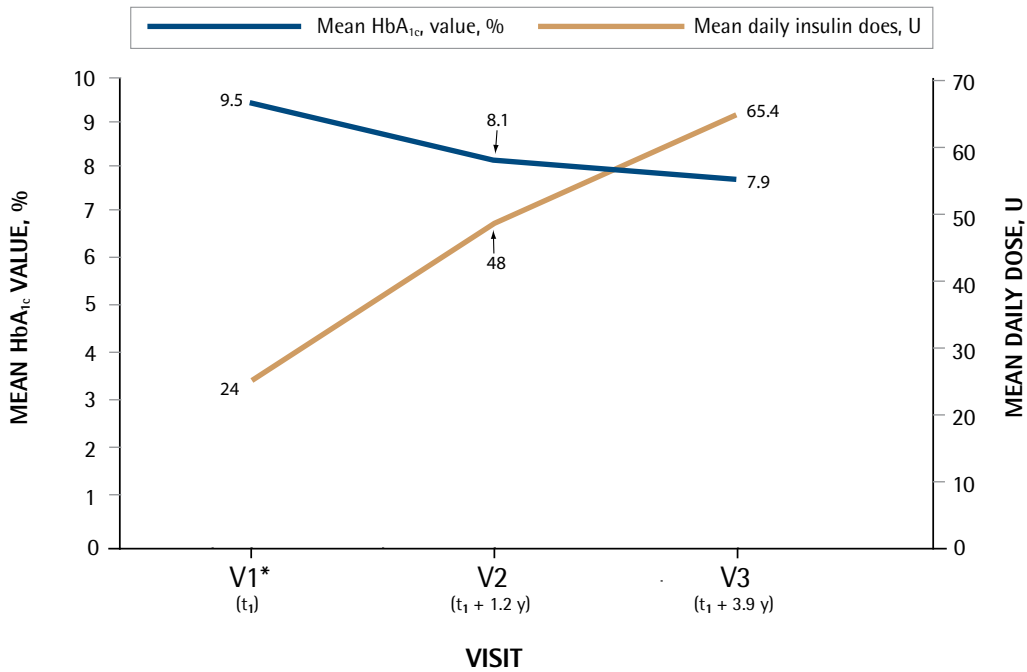
<sup>†</sup>Means at each time point are based only on patients who had recorded values for that particular time point.

## Therapeutic strategies

**Figure 1** shows mean insulin dose over time (ie, 24 units at initiation, 48 units at visit 2, and 65 units at visit 3) and corresponding mean HbA<sub>1c</sub> values (ie, 9.5% before insulin initiation, 8.1% at visit 2, and 7.9% at visit 3). **Figure 2** shows the proportions of patients at and above the glycemic target over time. Substantial proportions of patients saw improvements in glycemic control, with the proportion of patients with HbA<sub>1c</sub> values of greater than 9.0% falling from 57% to 19% from visit 1 to 3. The proportion of patients who achieved the target HbA<sub>1c</sub> of 7.0% or less increased from 7% to 33% during the same period. At visits 2 and 3, 19% of patients had HbA<sub>1c</sub> levels greater than 9.0%, and at visit 3, 68% were above the target HbA<sub>1c</sub> value of 7.0%.

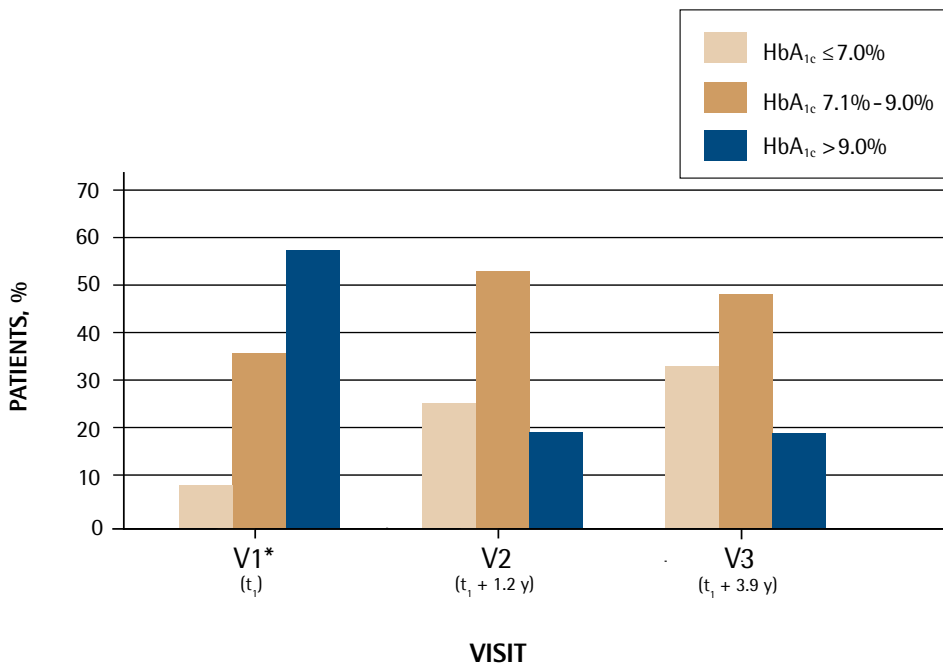
The only visit 1 variables that were significantly associated with an HbA<sub>1c</sub> of greater than 9.0% at visit 3 were an initial HbA<sub>1c</sub> value of greater than 9.0% (odds ratio 2.9, *P* = .0006) and initial weight (odds ratio 1.13 per 10 kg, *P* = .0310).

Figure 1. Mean insulin dose and mean HbA<sub>1c</sub> value, by visit: N=379.



HbA<sub>1c</sub>—glycated hemoglobin, U—unit, V—visit.  
\*Insulin initiation.

Figure 2. Patients' HbA<sub>1c</sub> values, by visit: N=379



HbA<sub>1c</sub>—glycated hemoglobin, V—visit.  
\*Insulin initiation.



**Table 3** shows the use of concomitant oral agents. For the most part, concomitant use of oral antihyperglycemic agents did not change substantially (with most patients continuing to take metformin), except for a decrease over time in sulfonylurea use.

**Table 3. Percentage of patients taking concomitant oral agents, by visit: N = 379.**

CLASS	PROPORTION OF PATIENTS		
	VISIT 1	VISIT 2	VISIT 3
Metformin	63.5	56.7	52.8
Thiazolidinediones	10.5	10.0	7.9
Sulfonylureas	26.3	17.1	11.3
Meglitinides	5.0	2.9	2.6
$\alpha$ -Glucosidase inhibitors	1.6	0.5	0.8
Orlistat	0.8	1.0	0.8
Combination formulations	1.3	0.3	1.0

## DISCUSSION

This study provides insight into the realities of insulin use in patients with T2DM in family practice and reinforces the role of clinical inertia in the failure of many patients to achieve and sustain glycemic control. This patient cohort, with a high mean HbA<sub>1c</sub> level (9.5%) and high prevalence of complications (74%), had an average delay to insulin initiation of 9 years. The degree to which factors such as failure of oral agents, insufficient lifestyle modifications,  $\beta$ -cell decline, or physician clinical inertia contributed to the high HbA<sub>1c</sub> levels at the time of insulin initiation is unknown. However, the fact that the mean HbA<sub>1c</sub> value was 9.5% at the time of insulin initiation suggests a period (of unknown duration) of HbA<sub>1c</sub> values well above target. Unlike oral agents, there is no upper limit to insulin doses, so insulin theoretically has the greatest potential for lowering HbA<sub>1c</sub> of all available therapies. The UK Prospective Diabetes Study found that for every 1.0% decrease in HbA<sub>1c</sub> levels, there was a corresponding 37% decrease in the prevalence of microvascular complications.<sup>13</sup> Earlier use of insulin, therefore, could lead to a substantial decrease in patients' long-term risk of developing complications.

Once insulin was initiated, FPs showed an understanding of the need to intensify therapy, as evidenced by progressive and substantial increases in daily insulin doses, increases in the proportions of patients on multiple daily injections, and attendant reductions in mean HbA<sub>1c</sub> levels. However, these efforts appeared to be most intensive and have the greatest effect during the first year after insulin initiation (ie, between visit 1 and visit 2), with signs of a plateau effect after visit 2. After 3.9 years, the

mean HbA<sub>1c</sub> value remained above target at 7.9%, despite a mean insulin dosage increase of 41 units daily (from 24.0 units to 65.4 units). While the proportion of patients with an HbA<sub>1c</sub> level of 7.0% or less increased from 7% to 33%, two-thirds of patients remained above target with a mean HbA<sub>1c</sub> level of 7.9%. Furthermore, at visit 3, 1 out of 5 patients still had marked hyperglycemia (HbA<sub>1c</sub> >9.0%). The effect of inadequate control was further evidenced by an increase in the proportion of patients with complications during the same time period.

These results are consistent with those of an American study,<sup>24</sup> in which many of the subjects had high levels of glycemia—60% had HbA<sub>1c</sub> levels of 8.0% or higher and 35% had levels of 9.0% or higher after taking insulin for 2 years. Insulin therapy was also shown to be particularly effective in those with HbA<sub>1c</sub> levels of greater than 10.0%; insulin therapy was 3 times more effective in reducing HbA<sub>1c</sub> levels in a patient with a baseline HbA<sub>1c</sub> level of 13.0% than in a patient with a baseline HbA<sub>1c</sub> level of 9.0%.<sup>24</sup> In a large multinational European study, there were considerable increases in the use of insulin with and without oral agents over a period of approximately 5 years (1.3% to 29.6%), but the proportion of patients with HbA<sub>1c</sub> levels of less than 7.0% only declined from 45.8% to 39.8%.<sup>25</sup> Failure to achieve targets, even once insulin was initiated, was also found in a study of insulin-treated T2DM patients in the United Kingdom (with a mean duration of diabetes of approximately 10 years). After a mean of 2 years of insulin therapy, 81% of subjects had HbA<sub>1c</sub> values of greater than 7.0%, and 27.5% had HbA<sub>1c</sub> levels of greater than 9.0%.<sup>26</sup>

Most FPs in our study identified barriers to initiation and intensification of insulin therapy. Physician discomfort with aggressive insulin therapy has been reported in other studies.<sup>27-32</sup> In a large survey of patient and provider attitudes toward insulin, most nurses and GPs (50% to 55%) reported that they delayed insulin therapy until absolutely necessary.<sup>33</sup> In the Diabetes in Canada Evaluation study undertaken with a similar cohort of patients with T2DM (mean age 62.7 years, mean duration of diabetes 7.8 years, and baseline HbA<sub>1c</sub> level 7.3% [with 49% of patients above the HbA<sub>1c</sub> target of 7.0%]), only 6% of FPs planned to add insulin and only 10% of physicians planned to increase insulin dose.<sup>3</sup> Plans to increase or add insulin increased with duration of diabetes.

In our study, weight at the time of insulin initiation was a predictor of poor glycemic control at visit 3. As by far most people with T2DM are overweight or obese,<sup>34</sup> physicians are sometimes reluctant to induce weight gain in this population. However, weight gain due to insulin treatment typically occurs during the first 2 to 3 years of insulin treatment then stabilizes.<sup>35</sup> During the first year of insulin treatment, people with T2DM have been reported to gain approximately 2 kg per percentage-point decrease in HbA<sub>1c</sub> value.<sup>36</sup>

## Limitations

That physicians consented to participate in this study presents a participation bias, potentially resulting in a sample of physicians with a special interest in diabetes; furthermore, we cannot exclude the possibility of patient selection bias. However, in the event of such bias, one would anticipate that the findings would be considered conservative. It is unknown whether any patient factors (eg, nonadherence with therapy) might have affected glycemic control. Compared with FPs who responded to the 2007 National Physician Survey,<sup>37</sup> there were more male physicians (85% vs 61%) and more urban-based physicians (75% vs 63%) in our cohort. In addition, more of our physicians graduated in the 1970s (40% vs 24%).

## Conclusion

Insulin is underused in patients with type 2 diabetes. Despite knowledge of glycemic targets, FPs in this study added insulin late in the course of disease. Although there was some initial intensification, it was often inadequate to achieve good control. These results highlight the need for novel education and strategies as well as systemic supports to help FPs initiate insulin and intensify therapy in the face of inevitable disease progression. ✱

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### Contributors

All authors approved the final manuscript; made substantial contributions to the intellectual content of the paper in terms of concept and study design; and participated in the interpretation of the data, drafting of the manuscript, and critical revision of the manuscript. **Dr Willan** participated in the analysis of data; **Dr Kapor**, **Ms Houston**, and **Ms Lank** provided administrative, technical, and material support; and **Dr Harris** supervised the study.

### Competing interests

**Dr Harris** has received funding from Novo Nordisk Canada, Eli Lilly, and Sanofi-Aventis. **Dr Kapor** and **Ms Houston** are employees of Novo Nordisk Canada. **Ms Lank** was funded by Novo Nordisk Canada to assist with protocol and manuscript development. **Dr Willan** was funded by Novo Nordisk Canada to assist with protocol development and to complete statistical analysis. Participating physicians were compensated for their time to complete physician and patient questionnaires.

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