Canadian Diabetes Association 2013 clinical practice guidelines - Do claims data align to the guidelines?
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When physicians assess and treat patients for diabetes, what tools are available to help them? The Canadian Diabetes clinical practice guidelines (CPGs) are widely recognized by the healthcare community as a reputable guide for diabetes diagnosis, treatment and management. The Canadian Diabetes Association (CDA) draws on the expertise of 120 professional volunteers, who review and assess all relevant evidence regarding the prevention and management of diabetes and then publish the findings as the diabetes CPGs.1

The guidelines are updated every five years; the most recent version was published in 2013: The Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. There are resources to support the dissemination of the information contained in the guidelines to both healthcare professionals and patient resources that can be accessed at: http://guidelines.diabetes.ca/PatientResources.aspx

The purpose of this article is to highlight select sections from the most recent 2013 CDA guidelines, including diagnosis and treatment, and to note any changes between the 2008 and 2013 versions of the CPGs. In addition, based on the recommendations found in the guidelines, we assess whether the diabetes prescription drug claims patterns we see in the TELUS Health book of business suggest that claimants’ diabetes prescription drug claims patterns are aligned with the guidelines and describe the cost implications of the prescription claims patterns. The focus of the analysis is newly treated, or what we define and refer to as treatment naive type II diabetes (caused by varying degrees of insulin resistance and/or insulin deficiency).

We also report how metformin, the guideline-recommended first-line drug therapy, is used and compare our actual claims to the Statistics Canada forecast to determine whether our prevalence rates match.

**Diagnosis**

The most reiterated message of the 2013 CPGs (see Figure 1) is that early diagnosis of diabetes and aggressive treatment translates into optimal delivery of patient care. Diagnosis requires one of four types of blood tests:

- fasting (fasting = no caloric intake for at least eight hours) plasma glucose (FPG) ≥7.0 mmol/L
- or
- glycated hemoglobin (A1C) value of ≥6.5% (in adults)
- or
- a two-hour plasma glucose (PG) value in a 75 g oral glucose tolerance test (OGTT) of ≥11.1 mmol/L
- or
- random (random = any time of day, without regard to the interval since the last meal) plasma glucose PG ≥11.1 mmol/L
Figure 1: CDA Guidelines on Treatment of Type 2 Diabetes

At diagnosis of type 2 diabetes
- Start lifestyle intervention (nutrition therapy and physical activity) +/- Metformin

<table>
<thead>
<tr>
<th>A1C &lt; 8.5%</th>
<th>A1C ≥8.5%</th>
<th>Symptomatic hyperglycemia with metabolic decompensation</th>
</tr>
</thead>
<tbody>
<tr>
<td>If not at target (2-3 mos)</td>
<td>Start metformin immediately Consider initial combination with another antihyperglycemic agent</td>
<td>Initiate insulin +/- metformin</td>
</tr>
</tbody>
</table>

Start/Increase metformin
- If not at glycemic target

Add an agent best suited to the individual:

**Patient Characteristics**
- Degree of hyperglycemia
- Risk of hypoglycemia
- Overweight or obese
- Comorbidities (renal, cardiac, hepatic)
- Preferences and access to treatment
- Other

**Agent Characteristics**
- BG lowering efficacy and durability
- Risk of inducing hypoglycemia
- Effect on weight
- Contraindications and side effects
- Cost and coverage
- Other

Add an agent best suited to the individual (agents listed in alphabetical order):

<table>
<thead>
<tr>
<th>Class</th>
<th>Relative A1C lowering</th>
<th>Hypoglycemia</th>
<th>Weight</th>
<th>Other therapeutic considerations</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-glucosidase inhibitor (acarbose)</td>
<td></td>
<td>Rare</td>
<td>neutral to</td>
<td>Improved postprandial control, GI side effects</td>
<td>$</td>
</tr>
<tr>
<td>Incretin agents:</td>
<td></td>
<td>Rare to</td>
<td>neutral to</td>
<td></td>
<td>$$</td>
</tr>
<tr>
<td>DPP-4 Inhibitors GLP-1 receptor agonists</td>
<td></td>
<td>Rare</td>
<td></td>
<td></td>
<td>$$$</td>
</tr>
<tr>
<td>Insulin</td>
<td></td>
<td>Yes</td>
<td></td>
<td>No dose ceiling, flexible regimens</td>
<td>$-$$$$</td>
</tr>
<tr>
<td>Insulin secretagogue:</td>
<td></td>
<td>Yes</td>
<td></td>
<td>Less hypoglycemia in context of missed meals but usually requires TID to QID dosing</td>
<td>$$</td>
</tr>
<tr>
<td>Meglitinide</td>
<td></td>
<td>Yes</td>
<td></td>
<td>Gliclazide and glimepiride associated with less hypoglycemia than glyburide</td>
<td>$</td>
</tr>
<tr>
<td>Sulfonylurea</td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TZD</td>
<td></td>
<td>Rare</td>
<td></td>
<td>CHF, edema, fractures, rare bladder cancer (pioglitazone), cardiovascular controversy (rosiglitazone), 6-12 weeks required for maximal effect</td>
<td>$$</td>
</tr>
<tr>
<td>Weight loss agent (orlistat)</td>
<td></td>
<td>None</td>
<td></td>
<td>GI side effects</td>
<td>$$</td>
</tr>
</tbody>
</table>

If not at glycemic target
- Add another agent from a different class
- Add/Intensify insulin regimen

Make timely adjustments to attain target A1C within 3 to 6 months
Treatment
Earlier treatment with pharmacotherapy is now recommended, along with lifestyle intervention on nutrition and physical activity (see Figure 1). Compared with the 2008 CPGs, which suggested prescription drug treatment at HbA1C thresholds above 9%, the 2013 CPGs recommend that patients qualify for drug therapy sooner, i.e., drug treatment is now recommended for those with HbA1C cut-offs > 8.5%. The recommended initial drug therapy, metformin, has remained consistent between the 2008 and 2013 versions of the guidelines. For those with an HbA1C of > 8.5% at diagnosis, combination therapy of metformin and another antihyperglycemic (AG) agent based on a number of patient and agent considerations is recommended (Figure 1).

Cost
A Cost Consideration Working Group was put together for the 2013 CPGs to determine how cost can be incorporated into the guidelines. It was decided that exact or specific costs would not be included, to ensure optimal clinical evidence for the patient; however, it was recognized that cost should be part of the decision-making process. Drug costs are now incorporated as an indication of the magnitude of the cost, e.g., $, $$, $$$. (Figure 1) and approximate wholesale cost in appendix 5 of the guidelines (http://guidelines.diabetes.ca/Browse/Appendices/Appendix5).

Methodology
The consistent recommendation of metformin as the initial prescription drug therapy for newly diagnosed type II diabetics between the 2008 and 2013 CPGs provides a concrete benchmark against which to assess and report claims patterns according to a Guideline YES or Guideline NO outcome.

The methodology we employed to segment the claimants is schematically represented in Figure 2. We first start with all claimants for all diabetes drugs from January 2013 to June 2013, excluding insulin, and then segment into new claimants and existing claimants (Figure 2, Boxes 1, 2 and 3). We are interested in the new claimants (Box 2). Next, we segment the new claimants based on their claim history into one of five mutually exclusive groups. The claimants of interest are new claimants with no AG claim in the previous 180 days. We consider these claimants to be newly treated patients and define and refer to them as treatment naive (Figure 2, Box 9). To determine whether claims patterns for these treatment naive patients were according to guidelines, we further segment the treatment naive claimants into one of two mutually exclusive groups: Guideline YES, defined as having claimed metformin +/- another AG, or Guideline NO, defined as not having claimed metformin (Figure 2, Boxes 9 and 10).

Results
Claims analysis
Based on a sample of claimants (N=64,744) across the TELUS Health book of business from January 2013 to June 2013 claiming an AG drug, excluding insulin, 35% (N= 22,464) of patients were treatment naive (Figure 2, Box 4).

Of the treatment naive claimants, between 85% and 87% were Guideline YES, with the remaining classified as Guideline NO (Figure 3). This claims analysis suggests that of those who have their prescriptions filled, the majority of the treatment-naive claimants are started with the first-line drug option as recommended by the CPGs.

Cost analysis
When we consider the cost of the treatment-naive segment, and the proportion contributed by claimants who are Guideline YES and Guideline NO, half of the cost of this category can be attributed to the minority of Guideline NO claimants (~13%) who are not started on the guideline-recommended drug (metformin) (Figure 3). This is not surprising, as the cost of other AGs is roughly more than five times the cost of metformin (Figure 4). These substantial price differences highlight that compliance with treatment guidelines is important not only from a clinical standpoint, but also from the perspective of maximizing cost effectiveness to ensure that drug plans remain economically sustainable for government, employers and patients.
Figure 2: Methodology
Segmentation of AG drug claimants

N=64,744
Box 1: All AG drug claimants
Time Period: Jan 2013 - June 2013
At least 1 AG drug claim
(excluding insulin)

Box 2: New claimants
No claim for the AG drug in previous 180 days.

Box 3: Existing claimants
Claim history for the AG drug in previous 180 days.

Box 4: Treatment naive
Claim AG drug for the first time.

N= 22,464
Box 5: Switch
Claim history for a different AG drug in previous 180 days (previous drug is stopped).

N= 4,937
Box 6: Add on
Claim history for a different AG drug in previous 180 days (and previous drug is not stopped).

N=22,327
Box 7: Restart
(same)
Claim history for same AG drug; but interrupted therapy for more than 180 days.

N= 1,009
Box 8: Restart
(switch)
Used to claim another AG drug but interrupted therapy for more than 180 days.

Box 9: Guideline YES
Treatment naive started on metformin +/- another AG

Box 10: Guideline NO
Treatment naive started on non-metformin AG

Figure 3: Treatment-naive claimants

Guideline YES & NO: Percent Claims & Cost

- Guideline YES: claims
- Guideline YES: cost
- Guideline NO: claims
- Guideline NO: cost
Metformin Use

According to the CPGs, a combination of metformin and another AG may be an appropriate starting therapy depending on the HbA1c level, as noted above, and also if patients are not reaching their glycemic target after a trial of metformin. The guideline suggests considering individual patient and agent characteristics when selecting the agent most suited to the individual.

To determine how metformin is used in combination with other AGs, we took a snapshot of all metformin use for the month of June 2013. When all metformin use is considered, 66% of claims are monotherapy, 27% are in combination with another AG and 7% are in combination with two or more AGs (Figure 5).

Figure 5: All metformin users: June 2013
Of the 27% of claimants who used metformin in combination with another AG, 62% were using metformin with another class of AGs called sulfonylureas (e.g., Gliclazide, Glimepiride and Glyburide). This class of medication has been on the market for a long time (since the early 1990s) and is genericized and therefore relatively inexpensive, and physicians have gained experience with prescribing these drugs. The next most common AG category used in combination with metformin is the dipeptidyl peptidase -4 inhibitors (DPP-4s) at 22%.

Of the 7% of metformin claimants who use metformin in combination with two other AGs, the same trend applies with sulfonylureas as the most common combination therapy, followed by DPP-4s.

Prevalence of diabetes

We determined whether the number of treated plan members in the TELUS Health book of business based on 2012 claims aligns with the projected number of individuals affected by diabetes based on Health Canada’s epidemiological data by calculating the difference between these two groups in Figure 6.

Based on the TELUS Health drug claim data for 2012, the projection suggests that the percentage of actual number of diabetics is lower than the predicted prevalence (Figure 6). This suggests that there are fewer plan members undergoing treatment than there should be. This under treatment could represent as much as 3% of plan members in the older age groups (see Figure 6).

Reasons for the difference between actual and predicted prevalence could include coordination of benefit claims not captured, paper-based claims not reported and plan member reluctance to get prescriptions filled. However, there is also the possibility that people with diabetes are not aware of it or not yet treated. Since there is a significant health burden associated with diabetes due to complications such as heart disease, stroke, kidney disease, blindness, amputation, erectile dysfunction and depression, to name a few, programs to raise awareness of diabetes and the need for screening should be considered by plan sponsors. The introduction of health and wellness awareness programs in the workplace can assist in closing this gap and, with earlier diagnosis and treatment, essentially delay the development and treatment of possible complications.

Figure 6:
Discussion

The TELUS Health book of business represents drug claims data from private employer or union-sponsored drug plans, covering mainly a working-age population under 65 and their spouse and dependents. From the standpoint of analyzing an age-related condition like diabetes (i.e., type 2), these plan members represent a younger population than the diabetes patient population at large, which is skewed toward ages 65 years and over. Therefore, treatment patterns will tend to reflect earlier disease stages with fewer complications, comorbidities and combination therapies.

The analysis represents the claim filing behaviour of the claimants and does not necessarily reflect prescribing behaviour, as we can only report on claims that have been submitted or paid using our network. Follow-up articles are planned to report on compliance (i.e., is the medication taken regularly as prescribed?) with diabetes medications and the comorbidities of diabetic claimants.

While the majority of claimants in this analysis appear to be treated according to guidelines, the costs attributed to the Guideline NO claimants suggest that programs to ensure metformin is used as the first-line agent are warranted. Programs such as step therapy help determine which products are used as the first-line agents. If AG drugs are subject to step therapy, claimants would be eligible for coverage after trying an alternative first-line drug that is more cost effective. In addition, the use of managed care plans (e.g., the National Formulary) can ensure that coverage is granted for first-line medications and effectively reduce costs.

Plotting our claims data against Canadian surveillance data suggests that diabetes may be undertreated in the TELUS Health claimant population. The under treatment gap grows rapidly after age 40. Plan sponsor programs as basic as providing plan members with a link to the resources available through the Canadian CPGs are warranted. Increased awareness of diabetes and its many significant comorbidities, treatment (nutrition, exercise and drug therapy) and prevention is needed.

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Data: design, analysis and extraction:
Richard Lavoie, Senior economist
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References
3. http://guidelines.diabetes.ca/CDACPG_resources/Appendices/A5_Cost_Reference_List_for_Antihyperglycaemic_Agents_1.jpg
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