Provider beliefs about diabetes treatment have little impact on glycemic control of their patients with diabetes

Erin S LeBlanc,1 A Gabriela Rosales,1 Sumesh Kachroo,2 Jayanti Mukherjee,2 Kristine L Funk,1 Jennifer L Schneider,1 Gregory A Nichols1

ABSTRACT

Objective: To improve the health of people with diabetes, it is essential to identify why patients experience extended periods of poor glycemic control before therapeutic intensification.

Research design and methods: We surveyed 252 primary care providers at Kaiser Permanente Northwest to determine their beliefs about the glycemic goals of their patients, treatment intensification behavior, and barriers to achieving optimal glycemic control. We linked the responses of 149 providers to the health records of their 18,346 patients with diabetes.

Results: Patient glycemic levels were not related to either individualized glycemic goals or provider intensification behavior. Providers’ beliefs about diabetic treatment and glycated hemoglobin (HbA1c) goals were poorly associated with patient HbA1c levels. Providers identified patients’ resistance to lifestyle behaviors and taking insulin, lack of medication adherence, and psychosocial issues as the main barriers to optimal glycemic control. Lack of time to care for complex patients was also a barrier. Providers who agreed that “current research did not support A1C levels <7%” were less likely to have patients with HbA1c levels <7% (OR=0.87, 95% CI 0.78 to 0.97) and patients of providers who disagreed that “some patients will have an A1C >9% no matter what I do” were 16% more likely to have patients with HbA1c <7% (1.16, 1.03 to 1.30) compared with providers who were neutral about those statements.

Conclusions: Given the consistency of HbA1c levels across providers despite differences in beliefs and intensification behaviors, these barriers may be best addressed by instituting changes at the system level (ie, instituting institutional glycemic targets or outreach for dysglycemia) rather than targeting practice patterns of individual providers.

Key messages

- Patients’ glycated hemoglobin levels are consistent across providers despite differences in providers’ beliefs and treatment intensification behaviors.
- From the providers’ perspectives, lack of time with patients as well as patients’ resistance to healthy lifestyle behaviors and insulin use, poor compliance, and psychosocial issues contribute most to poor glycemic control.
- Addressing barriers to optimal glycemic control may be best done at the health system level rather than through intervention at the individual provider level.

INTRODUCTION

Type 2 diabetes is a progressive disease that requires ongoing treatment intensification to achieve and maintain glycemic control.1 Only 55% of people with diabetes in the USA between 2007 and 2010 had the American Diabetes Association’s recommended glycated hemoglobin (HbA1c) levels of less than 7%.2–3 Studies suggest that approximately 50–60% of patients with HbA1c levels above goal are not being prescribed a change in therapy or are actually having their therapy decreased,1–5 despite several therapeutic guidelines for managing hyperglycemia.6–8 One factor that has been cited for driving this lack of therapy intensification is “clinical inertia”, defined as a clinician recognizing a problem but failing to act.9–10

Delays in treatment intensification lead not only to long (>12 months) periods of hyperglycemia, but also to a lower likelihood of therapeutic success once therapy is intensified.11–16 However, analyses of administrative data that identify clinical inertia when the HbA1c exceeds a guideline-level recommendation may not adequately account for mitigating factors that affect clinician decision-making. Indeed, current guidelines suggest that patient characteristics such as older age, frailty, or multiple comorbidities may be legitimate reasons for delaying therapy intensification.3–18 In addition, clinician beliefs about the importance of glycemic control, especially in the context of these patient characteristics, may help explain why apparent clinical inertia is, in fact, clinical decisiveness. Therefore, to better understand the reasons why providers do and...
do not take action when their patients are not at glycemic
goal, we conducted a study that taps into an often over-
looked source of information—the providers themselves —and linked their responses to actual patient data
extracted from electronic medical records.

METHODS
Setting
Kaiser Permanente Northwest (KPNW) is a not-for-profit,
group-model health maintenance organization that pro-
vides integrated, comprehensive medical care to about
490,000 individuals in a 75-mile radius around Portland,
Oregon. Primary care providers (PCPs) include physicians,
nurse practitioners, and physician assistants of Internal
Medicine and Family Practice departments. Patients select
a personal PCP, although they are also free to visit other
clinicians for short-notice appointments or when their
PCP is not available. All patients with a selected PCP are
called that PCP’s ‘panel’.

Overall study design
The study was executed in three phases. In the first
phase, we conducted 45 min qualitative interviews with
12 PCPs. Guided by the interview findings, we developed
a questionnaire that was fielded to all KPNW PCPs
(phase 2). In phase 3, we linked the electronic medical
records of patients with diabetes to the panels of PCPs
who responded to the questionnaire to ascertain individ-
ual patient and overall panel glycemic control.

Phase 1: Qualitative interviews
We created lists of PCPs who had ‘high’, ‘medium’, and
‘low’ performance based on the proportion of patients
with diabetes with HbA1c levels <7%, proportion of
patients with diabetes with HbA1c levels >7% who were
on diabetes medications, and the mean time to diabetes
medication initiation after an HbA1c level >7%. We ran-
domly approached by email PCPs from each of the
three groups on the list, inviting them to participate in
the structured, open-ended interview about their
approach to diabetes therapy and glycemic control.
Recruitment continued until we met our goal of 12
interviews, 4 from each group. A trained qualitative
interviewer (JLS) conducted the interviews using a
guide developed by the research team. Interview data
were analyzed by JLS using a content analysis
approach. During recruitment, conducting, and ana-
lysis, both the interviewer and the participant remained
unaware as to the group from which the PCP was drawn.

On the basis of data from the qualitative interviews
(online supplementary table S1), we developed a short
survey that could be completed in 5–10 min. Survey
questions focused on glycemic goals, barriers to achiev-
ing those goals, triggers for intensification of pharma-
co logical therapy, and opinions about goal HbA1c levels
and diabetes therapy.

Phase 2: Survey of providers
We sent email invitations to 252 KPNW primary care
clinicians to participate in the survey (online supple-
mentary figure S1) and received 124 responses. After no
response to three email reminders, we sent paper copies
of the survey via interoffice mail and obtained 57 addi-
tional responses, an overall response rate of 72%
(n=181). Of the 181 respondents, 14 returned blank
surveys and 18 did not provide their clinician identifi-
cers (necessary for linking purposes) or had fewer than 20
general patients and/or 3 patients with diabetes on their
panel, leaving 149 analyzable and linkable respondents
(59% of the total survey sample).

Phase 3: Linkage to patient-level data
We identified all patients who were on PCP panels and
were known to have diabetes at the time of the survey
distribution (August 2013). We collected the patient
HbA1c value closest to this date.

Statistical analyses
Descriptive statistics were summarized by mean and SD
values and by numbers and percentages. We categorized
patients’ mean HbA1c values according to commonly
used cut-points (<7%, 7–7.9%, ≥8%). We calculated the
percentage of each PCP’s panel of patients with diabetes
that was within these cut-points. We also averaged
together the HbA1c values of the PCP’s panel of
patients with diabetes. For specific questions, we first
identified the number of PCPs who answered those
questions in a particular way; then, among those PCPs
who answered in that way, we reported the mean HbA1c
values of their patients and/or the mean percentage of
their patients who had HbA1c values within the follow-
ing cut-points: <7%, 7–7.9%, or ≥8%. We used hierarch-
calized generalized linear models to assess providers’ beliefs
about diabetic treatment and HbA1c goals as predictors
of their patient’s HbA1c levels. All models were adjusted
by their panel’s age and gender characteristics and were
the level-1 variables in the models (online supplemen-
tary material: Summary of an HGLM model). The PCP’s
responses to the survey questions were used as level-2
variables in the models. Analyses were conducted using
SAS V.9.2 (SAS institute, Cary, North Carolina, USA)
and HLM 7 for Windows (Scientific Software

RESULTS
Baseline characteristics
In phase 1, 12 PCPs were interviewed; 252 were sent
surveys during phase 2, and 149 were analyzed in phase
3 (table 1). The PCPs in each phase had generally
similar demographics: the average age was 44 in phase 1
and 47 in phases 2 and 3, and 42%, 46%, and 50% were
male, respectively. There was a higher percentage of
internal medicine physicians among those surveyed in
phase 1 and a lower number of patients with diabetes

Epidemiology/health services research
Phase 1: Qualitative interviews of 12 providers
From the qualitative interviews, we identified several themes related to diabetes treatment: patient-level barriers to optimal control, care-setting barriers to optimal control, patient factors that influence glycemic goals, facilitators to optimal control, and follow-up and outreach approach with patients at different HbA1c levels (online supplementary table S1).

Phase 2: Survey of providers
The complete survey and response frequencies are shown in online supplementary table S2. The three primary domains captured in the survey are described below.

Barriers to optimal glycemic control: The most common identified patient-related barriers (the majority of PCPs stated that the factor contributed ≥50% of the time) were psychosocial issues, resistance to lifestyle change, and non-compliance; the most common care-setting issue was lack of provider time to care for complex patients. The moderately common factors (>1/3 providers stated that the factor contributed ≥50% of the time) were unwillingness to use insulin and competing organizational demands on providers. The least common factors (<1/3 providers stated that the factor contributed ≥50% of the time) included costs of treatment, cultural issues, other medical issues that took precedence, and a limited formulary.

Issues that delay pharmacological intensification: The most common factors (≥25% of the time) were resistance to lifestyle change and non-compliance. Unwillingness to consider insulin and psychosocial issues were less common factors (>15 to <25% of the time), as were older age and other medical problems that took precedence (>10 to <15% of the time). Side effects of medicines, costs of medicines, cultural issues, and a lack of established patient-provider relationship contributed only a small amount of the time (≥5 to <10% of the time).

Opinions about diabetes treatment: 80% of PCPs stated that they allowed patients who were above their individualized glycemic goal to work on lifestyle changes for 3–6 months before prescribing a pharmacological change; only 4% stated that they waited >6 months before making a pharmacological change. Eighty percent of PCPs agreed that older patients need less stringent HbA1c goals. Almost all PCPs agreed that weight loss was a critical component of diabetes care, but only 40% agreed that the manner in which a diabetes medication affects weight influenced their therapy decisions.

Phase 3: linking PCP responses to patient level data
Glycemic goals: Table 2 shows the number and percentage of responding PCPs who reported that none or very few (<10%), some (10–40%), about half (41–60%), most (61–90%), or nearly all (>90%) of their patients had HbA1c goals of <7% or 7–7.9%. Also displayed is the percentage of PCPs’ panels with actual HbA1c levels of <7% and 7–7.9%. For example, 61 (42%) providers reported that most of their patients had an HbA1c goal <7%. Among those 61 providers, a mean of 56% (±0.07%) of their panel had HbA1c levels <7%. The percentage of providers’ patients who were <7% or 7–7.9% was similar among providers despite different individualized glycemic goals in their respective panels of patients.

HbA1c triggers for intensification: For their patients who were already on one oral hypoglycemic agent, 45 (33%) providers reported that their trigger for a medication change was one HbA1c test result at least 0.5% above goal (table 3). The mean HbA1c of the patients of these 45 PCPs was 7.2% (±0.2%), and on average 55.6% (±0.07%) of their panels had HbA1c values <7%. Based on the results of the hierarchical linear models, there was no statistically significant association between the HbA1c trigger and the odds of patients achieving glycemic goals. As an illustration, 13 (9%) providers reported that they would make a medication change when two HbA1c values were at least 1% above goal. The glycemia of the patients of these 13 PCPs (mean HbA1c 7.3% (±0.3%) with a mean of 53.7% (±0.06%) having HbA1c values <7%) was similar to the 45 PCPs whose medication trigger was more stringent.

Opinions about diabetes treatment: Table 4 shows the proportion of respondents who agreed or strongly agreed with four statements about HbA1c levels, and the proportion that disagreed or strongly disagreed with a fifth statement. Also shown is the mean HbA1c of the per provider in the entire survey population (phase 2) compared with the phase 1 or phase 3 providers.

Table 1 Baseline characteristics of PCPs

<table>
<thead>
<tr>
<th></th>
<th>Interviewed</th>
<th>Surveyed</th>
<th>Analyzed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PCPs</td>
<td>12</td>
<td>252</td>
<td>149</td>
</tr>
<tr>
<td>Age (mean±SD)</td>
<td>44±5</td>
<td>47±9</td>
<td>47±9</td>
</tr>
<tr>
<td>Male (%)</td>
<td>41.70</td>
<td>46.00</td>
<td>50.3</td>
</tr>
<tr>
<td>Internal medicine (vs family practice) (%)</td>
<td>75</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>MD (vs physician assistant/nurse practitioner) (%)</td>
<td>91.7</td>
<td>96.4</td>
<td>97.3</td>
</tr>
<tr>
<td>Number of diabetes patients per PCP (mean±SD)</td>
<td>130±91</td>
<td>96±68</td>
<td>131±71</td>
</tr>
<tr>
<td>Total number of patients with diabetes for all PCPs combined</td>
<td>1562</td>
<td>21 919</td>
<td>19 527</td>
</tr>
<tr>
<td>Age of patients (mean±SD)</td>
<td>64±2</td>
<td>64±4</td>
<td>62±4</td>
</tr>
<tr>
<td>HbA1c of patients (mean±SD)</td>
<td>7.2±0.1</td>
<td>7.3±0.5</td>
<td>7.2±0.3</td>
</tr>
</tbody>
</table>

HbA1c, glycated hemoglobin; MD, medical doctor; PCP, primary care providers.
Table 2  PCPs’ reports on how many of their patients have certain glycemic goals compared with how many of their patients actually achieve those goals

<table>
<thead>
<tr>
<th>PCPs’ reports of how many of their patients have an HbA1c goal of &lt;7%*</th>
<th>Percentage of PCPs’ patients who have an HbA1c goal of &lt;7% Mean±SD</th>
<th>PCPs’ reports of how many of their patients have an HbA1c goal of 7–7.9%*</th>
<th>Percentage of PCPs’ patients who have an HbA1c goal of 7–7.9% Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>None or very few (&lt;10%) of their patients have this HbA1c goal</td>
<td>12 (8)</td>
<td>56.3±0.08</td>
<td>12 (9)</td>
</tr>
<tr>
<td>Some (10–40%) of their patients have this HbA1c goal</td>
<td>21 (15)</td>
<td>54.0±0.05</td>
<td>85 (63)</td>
</tr>
<tr>
<td>About half (41–60%) of their patients have this HbA1c goal</td>
<td>29 (20)</td>
<td>54.9±0.08</td>
<td>21 (15)</td>
</tr>
<tr>
<td>Most (61–90%) of their patients have this HbA1c goal</td>
<td>61 (42)</td>
<td>56.0±0.07</td>
<td>17 (13)</td>
</tr>
<tr>
<td>Nearly all (&gt;90%) of their patients have this HbA1c goal</td>
<td>21 (15)</td>
<td>52.4±0.05</td>
<td>1 (&lt;1)</td>
</tr>
</tbody>
</table>

*Rows are not mutually exclusive.
HbA1c, glycated hemoglobin; PCP, primary care providers.

Table 3  PCPs’ reports of what HbA1c elevation triggers them to intensify pharmacological therapy compared with how many of their patients have various HbA1c levels

<table>
<thead>
<tr>
<th>Reported trigger for intensification</th>
<th>Proportion of PCPs reporting this HbA1c trigger n (%)</th>
<th>Mean HbA1c of patients whose PCPs report this trigger Mean±SD</th>
<th>Percentage of patients with HbA1c &lt;7% Mean±SD</th>
<th>Percentage of patients with HbA1c 7–7.9% Mean±SD</th>
<th>Percentage of patients with HbA1c ≥8% Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 HbA1c ≥0.5% above goal</td>
<td>45 (33)</td>
<td>7.2±0.2</td>
<td>55.6±0.07</td>
<td>23.0±0.05</td>
<td>21.4±0.05</td>
</tr>
<tr>
<td>2 HbA1c ≥0.5% above goal</td>
<td>46 (33)</td>
<td>7.3±0.3</td>
<td>54.3±0.07</td>
<td>23.6±0.04</td>
<td>22.1±0.06</td>
</tr>
<tr>
<td>1 HbA1c ≥1.0% above goal</td>
<td>35 (25)</td>
<td>7.2±0.2</td>
<td>54.9±0.07</td>
<td>23.5±0.06</td>
<td>21.6±0.05</td>
</tr>
<tr>
<td>2 HbA1c ≥1.0% above goal</td>
<td>13 (9)</td>
<td>7.3±0.3</td>
<td>53.7±0.06</td>
<td>22.8±0.04</td>
<td>23.5±0.07</td>
</tr>
</tbody>
</table>

HbA1c, glycated hemoglobin; PCP, primary care providers.
patients of these PCPs, the percentage of their patients with different HbA1c levels, and the age-adjusted and sex-adjusted probability of their patients attaining HbA1c <7% compared with patients of PCPs neutral for that statement. For example, 77% of providers agreed or strongly agreed that most patients should strive for HbA1c <7%. The mean HbA1c of their patients was 7.3% (±0.3%), and on average 55.3% (±0.07%) had HbA1c values <7%. However, the probability of patients of these PCPs attaining an HbA1c of <7% was not statistically different from patients of PCPs who were neutral about this statement (OR 0.94, 95% CI 0.80 to 1.11).

Two statements were associated with the probability of patients attaining an HbA1c <7%. The 21% of PCPs who agreed that “current research did not support A1C levels <7%” were less likely to have patients with HbA1c levels <7% compared with PCPs who were neutral about that statement (0.87, 0.78 to 0.97; p=0.02). Second, 21% of providers disagreed that “some patients will have an A1C >9% no matter what I do.” The odds of these providers’ patients having an HbA1c <7% were 1.16 times (1.03 to 1.30; p=0.01) greater than the odds of patients whose providers were neutral about that statement. No other associations were statistically significant (table 4).

**DISCUSSION**

This novel study examined clinician-reported attitudes and beliefs about glycemic control, barriers to achieving it, and antihyperglycemic treatment intensification practices. Importantly, it also examined the association between these beliefs and actual HbA1c results of the patients with diabetes on the responding PCPs’ panels. The Diabetes Attitudes, Wishes and Needs Study (DAWN) as well as DAWN2 simultaneously collected survey data from patients with diabetes and from providers.22 23 Although patients and providers gave parallel responses to many study topics, the studies did not attempt to link patient responses directly to their own providers. To the best of our knowledge, no previous research has linked what clinicians identify as patient and care setting barriers to the documented glycemic control of their patients.

We did not find an association between patient glycemic levels and provider-reported glycemic goals or intensification behavior. Even providers’ beliefs about diabetic treatment and HbA1c goals had limited associations with the HbA1c levels of their patients. These data suggest that patient and system barriers play a larger role than clinician beliefs and behaviors in prolonged poor control and delayed treatment intensification. HbA1c levels were consistent across patients despite differences in their providers’ treatment behaviors, HbA1c goals, and diabetic treatment opinions.

Our interviews and surveys revealed that providers identified patient resistance to lifestyle behaviors and taking insulin, lack of medication adherence, and psychosocial issues as barriers to optimal glycemic control, Table 4 Glycemic level of patients according to their PCP’s opinions about diabetes management

<table>
<thead>
<tr>
<th>Proportion of PCPs with this opinion</th>
<th>Percentage of patients with HbA1c &lt;7%</th>
<th>Percentage of patients with HbA1c 7–7.9%</th>
<th>Percentage of patients with HbA1c ≥8%</th>
<th>Odds of patients having HbA1c &lt;7% compared to patients of PCPs neutral to statement</th>
<th>Adjusted OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td>Mean±SD</td>
<td>Mean±SD</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------------------------</td>
<td>--------------------------------------</td>
<td>--------------------------------------</td>
<td>--------------------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td>Most patients should strive for HbA1c &lt;7%</td>
<td>143 (110 (77)</td>
<td>7.3±0.3</td>
<td>7.3±0.2</td>
<td>7.3±0.4</td>
<td>0.94 (0.80 to 1.11)</td>
</tr>
<tr>
<td>For most patients, an HbA1c of 7–7.9% is acceptable</td>
<td>143 (56 (39)</td>
<td>7.3±0.2</td>
<td>7.3±0.2</td>
<td>7.3±0.4</td>
<td>0.99 (0.90 to 1.09)</td>
</tr>
<tr>
<td>No patient should have an HbA1c &gt;9%</td>
<td>141 (90 (64)</td>
<td>7.3±0.2</td>
<td>7.3±0.2</td>
<td>7.4±0.4</td>
<td>1.02 (0.89 to 1.18)</td>
</tr>
<tr>
<td>Current research does not support HbA1c &lt;7%</td>
<td>141 (51 (36)</td>
<td>7.3±0.2</td>
<td>7.3±0.2</td>
<td>7.4±0.4</td>
<td>0.87 (0.78 to 0.97)</td>
</tr>
<tr>
<td>Some patients will have HbA1c &gt;9% no matter what I do</td>
<td>143 (30 (21)</td>
<td>7.2±0.3</td>
<td>7.3±0.3</td>
<td>7.2±0.3</td>
<td>1.16 (1.03 to 1.30)</td>
</tr>
</tbody>
</table>

*PCPs who agree/strongly agree with this statement.†PCPs who disagree/strongly disagree with this statement. HbA1c, glycated hemoglobin; PCP, primary care providers. Copyright BMJ Publishing Group Ltd. on behalf of the British Diabetic Association.
as well as lack of time to care for complex patients. These findings are consistent with concepts revealed by the DAWN study and with the notion that patients with diabetes may need greater encounter frequency or appointment length to deal with competing healthcare needs.\textsuperscript{24–26} Also, although most providers believed weight loss to be a critical component of diabetes management, most did not take into account how diabetes medications impacted patients’ weight, which may contribute to the effectiveness of pharmacological therapy.\textsuperscript{27}

This finding may have resulted from our health system’s limited formulary. Alternatively, the development of new classes of medications that have more favorable effects on weight may be too recent to have changed the providers’ approach to diabetes management. Regardless, despite differences in beliefs and intensification behaviors, HbA1c levels were consistent across providers. Taken together, it seems that intervention to reduce barriers to glycemic control directed at providers would not produce much benefit, and that addressing these barriers may be most fruitful at the health system level.

A unique strength of our study was the ability to assess clinician beliefs and then to link those beliefs to their patients’ glycemic control. We achieved a relatively high response rate given the busy schedules of PCPs.

Our study had several limitations. Our analyses were hindered by a lack of variation in provider attitudes. This may be the result of conducting the study within a single organization that is highly structured and has a culture of conformity among the clinicians. Regardless of the setting, however, there may be little variation in attitudes and beliefs about glycemic control among PCPs in general. Our patient population lacked cultural diversity (>85% were Caucasian, non-Hispanic), which may have falsely lowered the importance of cultural issues. Indeed, in the qualitative interviews, cultural issues were often mentioned among PCPs with more diverse panels. We studied an insured population that may not represent uninsured patients or clinicians who treat them. Importantly, our restricted formulary discourages the use of newer medications that are typically more expensive than long-existing agents. This could affect the relative importance of cost issues in prescribing and intensification practices, and may also constrain our ability to assess the value of more therapeutic options. Lastly, we did not assess patient beliefs about glycemic control or attitudes about treatment intensification. Since treatment decisions are often jointly made by clinicians and their patients, our data cannot fully capture that interaction. Future work should also survey patients as patient beliefs could inform decisions about what system level programs can best improve diabetes management.

**CONCLUSION**

Clinicians’ beliefs about glycemic goals and intensification behavior were not clearly associated with their patients’ glycemia levels. Nevertheless, our findings highlighted several key factors that providers identified as driving suboptimal glycemic control including patients’ resistance to lifestyle change and starting insulin, non-compliance, and psychosocial issues. It is not surprising, therefore, that providers also identified that lack of time to deal with these complex patients and their multiple issues were key reasons for prolonged suboptimal control. In the seminal paper defining clinical inertia, the authors concluded that modifying medical education to better prepare clinicians to improve management of patients with problems such as diabetes is necessary to reduce clinical inertia.\textsuperscript{28} Given the lack of association of patients’ glycemia with their providers’ beliefs or behaviors, our results suggest that tackling these barriers may be best done at the system level.

**Contributors** ESL contributed to the study conception, design, and interpretation of results, and developed the first draft of the manuscript. AGR contributed to the study conception and design, researched and analyzed the data, contributed to interpretation of results, and reviewed/editied the manuscript. SK and JM contributed to the study conception and design and reviewed/editied the manuscript. KLF and JLS contributed to the study conception and design and the discussion, and reviewed/editied the manuscript. GAN contributed to the study conception, design, and interpretation of results, and reviewed/editied the manuscript. The final draft for submission was approved by all authors. ESL is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

**Funding** This study was funded by Bristol-Myers Squibb and AstraZeneca. This study was presented at the 74th Scientific Sessions of the American Diabetes Association, San Francisco, California, 13–17 June 2014.

**Competing interests** ESL has received additional research funding from Amgen, and GAN currently receives additional research funding from Novartis and Merck for other unrelated projects. SK and JM are employees of Bristol-Myers Squibb.

**Ethics approval** The study was reviewed and approved by the institutional review board of Kaiser Permanente NW.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data sharing statement** No additional data are available.

**Open Access** This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/


